

**Strategically Natural:
Nature, social trust and risk regulation of genetically modified foods
and natural health products in Canada**

A thesis submitted in partial fulfillment of the requirements for the
degree of Doctor of Philosophy

Department of Graduate Studies and Research, Carleton University

Anne Wiles ©

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Abstract

This thesis investigates the way concepts of nature shape attitudes to genetically modified (GM) foods and natural health products (NHPs) in Canada, and authorize the regulatory regimes of those products. GM foods are opposed by many as unnatural, but asserted as natural by advocates, while NHPs are accepted by consumers. The main research focus is the strategic use of a categorical understanding of nature in the naturalization of contentious technologies in society, by regulatory regimes seeking social trust in the products. The thesis takes a contextual approach, supported by research on social nature, hybridity, and regulation theory, and draws on literature in several social science fields.

Part 1 builds an analytical framework that describes an alignment among different concepts of nature, society, technology, risk, and trust. A critical distinction between nature and society is nature's freedom from social intentional modification, and, for ecocentrists, the autonomous agency of nature that gives it inherent value. The social relations of a technology that transforms nature into a social product are often contentious, complicating the implementation of the technology. Regulatory institutions attempt to avoid public scrutiny of the technology and gain social trust by naturalizing it.

The case studies, in part 2, draw on government documents and other literature, and interviews with individuals involved in the regulation of GM foods and NHPs. The risk assessment of GM foods under the Novel Foods Regulations stresses health protection, but minimizes the regulatory burden on the industry, and relies on narrow

definitions of nature and risk to naturalize the products and exclude contextual issues.

The Natural Health Products Regulations respect the products' naturalness and minimal social intervention on which the industry depends, and are less strategic in their use of the definitions of nature and society.

The final chapter considers the key concepts of risk and technology, trust, nature narratives, and strategic regulation of controversial technology as they are manifested in the case studies. It concludes that the nature-society duality that is central to modern economic dynamism retains strategic utility for naturalizing contentious transformations of nature, as well as for critics to discern and challenge such naturalizations.

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Abbreviations and Acronyms

| | |
|-------|---|
| AAFC | Agriculture and Agri-Food Canada |
| AFIC | Asia Food Information Centre |
| ASD | Alternative service delivery |
| B.t. | Bacillus thuringiensis |
| CAM | complementary and alternative medicine |
| CARC | Canadian Agri-Food Research Council |
| CBAC | Canadian Biotechnology Advisory Committee |
| CCMD | Canadian Council for Management Development |
| CELA | Canadian Environmental Law Association |
| CEPA | Canadian Environmental Protection Act |
| CFIA | Canadian Food Inspection Agency |
| CSA | Canadian Standards Association |
| DSHEA | Dietary Supplements Health and Education Act (U.S.) |
| DIN | Drug Identification Number |
| EACSR | External Advisory Committee on Smart Regulation |
| EU | European Union |
| FAO | Food and Agriculture Organization |
| FDA | Food and Drug Administration (U.S.) |
| FFN | functional foods and nutraceuticals |
| GE | genetic engineering. Used as equivalent to genetic modification |

| | |
|-------|--|
| GM | genetically modified; used in this thesis to refer to products of recombinant-DNA technology. Also described as genetic engineering. |
| GMO | genetically modified organism |
| GMP | good manufacturing practices |
| GM-R | GM regulator (research interview participant) |
| GM-S | GM stakeholder (research interview participant) |
| HLF | Higher life form |
| ISAAA | International Service for the Acquisition of Agri-biotech Applications |
| IP | intellectual property |
| NBAC | National Biotechnology Advisory Committee |
| NBS | National Biotechnology Strategy |
| NGO | Non-Governmental Organization |
| NHP | Natural Health Product |
| NHPD | Natural Health Products Directorate |
| NHP-R | Natural health products regulator (research interview participant) |
| NHP-S | Natural health products stakeholder (research interview participant) |
| NPM | New Public Management |
| NPN | Natural Product Number |
| OECD | Organisation for Economic Co-operation and Development |
| ONHP | Office of Natural Health Products |
| QRA | quantitative risk assessment |
| rDNA | recombinant DNA |

| | |
|-------|--|
| RSC | Royal Society of Canada |
| SARF | Social Amplification of Risk Framework |
| SE | substantially equivalent |
| SME | small and medium-sized enterprises |
| TCM | Traditional Chinese Medicine |
| TRIPS | Trade-Related Aspects of International Property Rights |
| WHO | World Health Organization |

Chapter 1

Introduction

This dissertation investigates the way concepts of nature and of society shape public attitudes and regulatory approaches to genetically modified (GM) foods and natural health products (NHPs) in Canada, and the way these ideas are employed strategically to authorize and defend those attitudes and approaches. It provides a multi-disciplinary perspective on the cultural meanings of the normative categories of nature and society, in themselves and in relation to each other. It also offers insight into the strategic naturalization of controversial technologies within a dynamic social environment, and the ways in which such naturalization is accomplished. In complex modern society, social trust and risk regulation play pivotal roles in framing GM foods and NHPs as natural or social products.

The thesis asks broadly about a pervasive, yet largely unstudied, pattern in perceptions of risk, attitudes to certain technologies, and ideas and ideals of nature. The elevated ‘public risk perception’ of technologies is commonly acknowledged, but it is less often asked what is the quality attributed to nature that leads many individuals to tolerate threats from nature. Why do many “risk” controversies turn on competing claims that a risk is technological or natural, and what makes that debate often so politically contentious? Indeed, how is it that different individuals in a society can have such contrasting opinions on what is natural? Why is nature often claimed as the category in which a contentious activity should be judged; and how is regulation used to press this claim?

The thesis takes a contextual research approach as used in research on the social construction of nature, hybridity, and regulation theory. These fields extend their research approaches to include, respectively, social and political values embedded into nature ideas, an acknowledgment of the material agency of nature as a factor in its incorporation into social systems, and the institutional and normative structures and assumptions that make up a broad mode of regulation for an economic program or other social initiative within an overarching ideological framework. The thesis proceeds by first describing an analytical framework that integrates literature from a range of disciplines on social constructions of nature in modern society, risk assessment and risk perception, risk society, trust and regulation in Canada. The second half of the thesis presents case studies of GM foods and NHPs in Canadian society in the terms set out in Part I, in which literature on the products and their regulation is augmented by results from a series of in-depth interviews of individuals involved in the regulation and use of the products.

Genetically modified foods have emerged in the early twenty-first century as a controversial issue in modern society, opposed as unnatural and an emblem of industrialism's inexorable creep into nature's domain and an additional technological risk to human health, the food supply and the environment. No clear impacts on human health have been documented from GM foods, yet members of the public are widely suspicious of them and interest groups have launched campaigns against them. The result has been a controversy over the presence and the control of GM foods in Canadian society that has given the products a media profile as 'Frankenfoods'.

In contrast with GM foods has been the quiet introduction of natural health products (NHPs) as a newly defined category of health products meant for consumer self care, controlled under their own new health protection regulations. Despite much-publicized health warnings and questions about the efficacy of some of these products, NHPs continue to be valued for their naturalness, and are used by many in the public with little concern.

These two products exist in two different dynamics in society, in the context of the relationship of different sectors of society to the products and, more specifically, the approach to their regulation. In the regulatory regime of a product we can see government, industry and public interpretations of the social value of the product and the benefits and risks it presents to different groups within society; these assessments lead to a determination of the kinds of public sector controls that these groups think ought to be imposed on it.

Regulation is understood in two ways, permitting a multi-dimensional understanding of the way it is used to shape, channel and control the integration of technologies into a society that is not always receptive to them. First, it is an institutional means of controlling behaviour in society, usually considered as managing the social impacts of private economic activity (Prince, 1999). In these terms, GM foods and NHPs are managed by, respectively, the Novel Foods Regulations and the Natural Health Products Regulations, by Health Canada under the Food and Drugs Act.

Secondly, regulation is discussed by geographers and political economists in the field of Regulation Theory as a broad and fluid set of activities and processes, including

formal regulation, that balance a regime of accumulation in order to sustain a capitalist system. Under this use of the term we can also include other institutions such as intellectual property law, research and development and other financial incentives to technology development, the scientific practice of risk assessment, and the policy framework that shapes the mandates of regulatory institutions. In addition, a set of normative assumptions and values emerges as clearly central to the attitudes that shape positions on GM foods and NHPs and drive strategic approaches to their institutionalization and management. The interplay between contested discourses is the process by which regulation and the products it manages proceeds (Whitehead, 2003). This view of regulation alerts us to the alignment of multiple activities, processes and attitudes with an overarching societal value system, and of the relationship with challenging approaches, that underlie the regulatory regimes in place for different products.

A normative assumption that is critically formative in the patterns of reception, management and challenge of GM foods and NHPs is the complex concept of nature in modern society. GM foods are often opposed as being ‘unnatural’, while NHPs are valued for their natural properties even though they are clearly processed, and in some cases even synthesized. I argue that different understandings of, and values for, nature are deeply intertwined with the motivations for the use of these different products, the character and extent of their control, and the social response to their regulation, considered in both the formal and the broader senses of the term.

An understanding of the complex multi-dimensionality of modern concepts of

nature, and of its web of interconnections with the social world, shows that nature is an enormously powerful concept that is both central and pervasive. The concept of nature in modern society incorporates the definition of the character of the physical universe and of human society, and hence of the proper purpose of society in the world and its proper relationship with the natural world.

Research approaches to social constructions of nature

Before any discussion on interpretations of nature can begin, we must locate ourselves in the debate on research on nature as a socially constructed concept. Recent research on nature and society has been complicated by the recognition that ideas of nature, along with most other social phenomena, are socially constructed as part of, and to serve, larger social and political systems. They are thus inseparable from the cultural perspective in which they are embedded. Interest in nature as inevitably 'social' has led to a questioning of what can be said about nature that is definitive, and to a subsequent proliferation of research orientations.

The social construction of nature is not peculiar to modern, Western society: all societies organize their perceptions of the environment into a model of the cosmos that integrates their image of society into nature and the way society fits into and interacts with nature (Tuan, 1971). Nature is constructed, or 'social', in several straightforward and more subtle ways. Most straightforward is that nature as the environment is physically shaped by current and historic human action. A more subtle aspect of nature constructivism is that we project our cultural constructions of the concept of nature onto

the landscape, to perceive landscapes with no visible evidence of humans, for example, as natural wilderness, or as natural resources for human use. That is, our culture shapes our ideas of what physical nature is, which in turn shapes and supports our actions in it; these actions then make nature physically conform to and express those cultural ideas. Finally, nature used as a 'normative principle' has underlain cultural concepts of a coherent 'order' of nature that is manifested in ecosystem nature, as well as in norms of human nature, race, gender, and social organization (Castree, 2001; Cronon, 1995).

The stress in current critical thinking on nature in the modern Western tradition is that in defining nature and society as separate categories, modern thought has been able to use the conceptual category of nature to authorize social power relations (Whatmore, 2002;). As prior and all-encompassing, external, untouched nature becomes a moral imperative for human and social behaviour, an external authority for a moral precept deemed present in nature. Its separateness from human agency places nature in primary and essential opposition to the universal sense of nature, as everything in existence and as obeying fundamental laws of biology and physics.

From this understanding, a primary interest in constructivist scholarship has been in the modern appeal to nature to, as Soper (1995: 32) describes it, "legitimate and preserve a status quo, whether of class relations, patriarchy, sexual oppression or ethnic and racial discrimination." Revealing the constructedness of the concepts of nature that have been employed to 'naturalize' such social arrangements has led to the challenging of such conventional definitions, and to an attentiveness to claims about nature as being used strategically. As Soper (*ibid*) says,

What is put in question through such challenges is precisely the extent to which what is claimed to be 'natural' is indeed a determination of 'nature', and hence a necessity to which we must accommodate, as opposed to a set of conventional arrangements, which are in principle transformable.

The social constructivist approach to nature as discourse or philosophical critique (Demeritt, 2001a) is a critique of modern society's heritage of Enlightenment rationalist assumptions of knowledge and existence, particularly the notion that nature and society are separate realms and that humans have broken free from the limits of nature. Constructivism focusses on the social context in which knowledge is formed and sustained, asserting that knowledge is contextual and thus partial, and is relative and plural rather than objectively real and universal. This implies that we can never know what nature is in itself, or what it means to other cultures.

A foundational issue in this body of research is that untouched nature, or wilderness, is a construction within a very strongly North American, modern cultural heritage and with a distinctly political edge. Critical geographers and environmental historians have strongly criticized the ecocentric valorization of wilderness and 'pristine' nature. Critics argue that not only is wilderness not a real physical quality of the North American landscape, (Demeritt, 2001a) but it is also not an intrinsic human need, as wilderness became the ideal of the natural only in the nineteenth century when it eclipsed the rural pastoral ideal (Olwig, 1995: 399). Wilderness is an idea of the elite that constitutes a flight from civilization into a romanticized retreat (Cronon, 1995).

Knowledge about risk to the environment is increasingly seen as contingent and value-based, as one of many possible knowledge claims. Understanding of

environmental damage caused by human activity is increasingly uncertain as science loses its credibility in creating universal and objective knowledge, and claims of environmental crisis are suspect as grounded in cultural assumptions and social agendas (Demeritt, 2001b; Bakker, 2005; Hewitt, 1983).

Other constructivist approaches, referred to as construction as refutation (Demeritt, 2001a) and the 'production of nature' approach (Castree, 2001b; Smith, 1996; Smith, 1998), take the form of a Marxist critique of capitalism. Capitalism 'metabolizes' nature to turn it into commodities, and becomes an 'accumulation strategy for capital' (Katz, 1998). These approaches focus on the naturalization of a mode of production and social relations characterized by social inequality and the exploitation of nature, and seek to undermine its 'given' appearance and reveal it as socially made and thus open to revision.

Constructivist approaches have been criticized (for example, Soulé and Lease, 1995) for an excessive relativism and a denial of physical realism. However, most constructivism is more moderate than the extreme expressions that have been strongly criticized. Whatmore (2002: 2) has responded to critics that "only the most vulgar of 'constructionist' accounts suggest that the world is . . . the product of an immaculate linguistic conception. Equally, only the crudest of 'realist' accounts refuse to recognize the contingency of knowledge claims about 'real world' entities and processes." While the call for academics and researchers to 'transcend' the now obsolete and discredited dualism of modernity persists as a major theme, constructivist approaches have progressed from a preoccupation with noting that nature is constructed to a consideration

of how particular constructions develop, in the context of which physical, social relational, and political potentials and constraints.

Constructivism has turned more recently to new ways of conceiving of and understanding the products of the combined action of nature and society. Many writers have employed the concept of hybridity, addressing the ‘rupturing’ of culturally normative boundaries, such as that between nature and society, which produces “something ontologically new” (Rose, 2000). Products like genetically modified foods, and phenomena like acid rain or the ozone hole, are hybrids constituted by both nature and technology that are ontologically ambiguous.

Hybridity research challenges the tendency of modern culture to separate phenomena into independent dualities, centrally of society and nature, one of which is often an active subject and the other a relatively one-dimensional, inert object (Rose, 2000). Hybridity research on nature and society argues the thorough integration of the social and the natural, pointing to society’s deep dependence on using nature to create social phenomena and products, and the active agency of nature in constituting, shaping and constraining social creations. Some hybridity research traces the way hybrids are created and sustained in networks involving both human and nonhuman actors, in some cases under the rubric of actor-network theory (Fitzsimmons and Goodman, 1998). Whatmore (2002: 4) undertakes to “de-couple . . . the subject-object binary such that the material and the social intertwine and interact in all manner of promiscuous combinations,” while also “de-centring social agency, apprehending it as a ‘precarious achievement spun between social actors rather than a manifestation of unitary intent.’”

Other research stresses the agency of nature, which is embedded in hybrid constructions but conventionally overlooked. Bakker and Bridge (2006), for example, call for “a research agenda that addresses the analytical significance of concrete differences in the material world and the way these enable and constrain the social relations necessary for resource production. . . . teasing out the analytical significance of concrete differences in terms of the biophysical properties of the material world” (ibid: 21).

As an analytical approach, constructivism ‘opens the fabrication of nature to interrogation’ (Castree and Braun 1998:34), to reveal the political bias and power structures that have been naturalized, or to trace the complex networks and interactions thorough which a social-natural object becomes defined and established in a culture and a polity. Seeing nature as both socially constructed and politically employed alerts us to the use of a separate category of nature for very social purposes. This can be physical or idealist and political, or both simultaneously. Whatmore (2002), for example, describes the insertion of proprietary genes into a traditional agricultural crop plant as turning the plant itself into a vector of corporate interest, an intrinsically and intensely political use of nature. The resulting products are ambiguously both natural and social; however, they are often described as natural in order to disguise the social relations implicit in the social alteration.

As used in this research, constructivism provides a conceptual framework for tracing the way a concept of nature is embedded in a cultural order, and the way a social reality is produced through the interactions - both normative and material - between

nature and a particular society. Constructivist and hybridity research approaches converge in considering GM foods and NHPs as constituted of natural substances and processes, technological interventions and designed functions, social values and economic priorities and political agendas. Regulation theory supports this detailed and contextual approach in its attention to the whole network of institutional functions that integrate a technology into society in alignment with a particular political ideology.

This perspective is brought to bear on the way that sometimes conflicting cultural concepts of nature shape positions on the use of GM foods and NHPs in Canadian society, and are tailored and employed to rationalize and defend those positions. The interplay between these nature ideas and social priorities is evidenced in the set of definitions and institutions that are brought together in the regulation of each of these products, and in the embedding of the relevant definition of nature directly into the terms of the regulation itself.

Nature, society, risk and trust: principles of the analytical framework

The analytical framework maps out a contextual perspective on risk regulation disputes that has the scope to incorporate the important factors that shape the two regulatory situations considered. This perspective attends to normative concepts of nature and society, social values and the material properties and uses of nature, and institutional arrangements and politics. What emerges is a constellation of concepts of nature, technology, risk and society, trust and regulation that are intrinsically and deeply inter-related.

The social controversy over the implementation of technology and its formal regulation begins in different variants of modern views of what nature is, and the way that humans and society ought to engage with and use it. In contemporary industrial society, conventional modernity is the politically and economically dominant cultural paradigm (Castree, 2001b; Delaney, 2003; Smith, 2002). However a large proportion of contemporary society holds a set of values that coalesce around an ecocentric philosophy that places more emphasis on respecting nature than controlling it, and on social values than on economic performance (Dunlap et al. 2000; Kempton et al. 1995).

Both sets of values share the basic modern concept of nature as separate from and external to society. Nature is, at the most fundamental level, what exists prior and external to society - the non-social and inevitable, beyond the reach of human or social (Delaney, 2003). Society is the domain of social relations and mutual accountabilities; it is that which is purposefully designed and made by humans to function in a particular social context (Lee, 2005; Simon, 1981). Accordingly, things made by humans, artefacts, include purposeful social transformations of nature (Rolston, 1998).

The two broadly modern perspectives differ, however, on their characterization of the two categories and on the distinction between them. To conventional moderns, nature is inert object, rightly used and controlled by humans and society to create wealth and advance social progress. The social category is primary and dominant: nature is material resources, raw stuff suited for transformation by human ingenuity, scientific knowledge and technology into valuable social commodities (Brown, 2004; Cohen, 2006; Lee, 1999; Plumwood, 2005).

To many in the public, on the other hand, nature has intrinsic value, agency, and an autonomous integrity that stands as a constraint on the social use of nature. Society is not privileged over nature, at least to the degree that it is in conventional modernity, and transformations and instrumental uses of nature that enrich individuals or groups in society are often opposed for those impacts (Soper, 1995; Deckers, 2005).

Technology, designed and managed through calculating risk rationality, is the emblematic artefact, and a core function that drives modern society economically and increases social differentiation and complexity (Starr, 1990; Canada, 2002a). Despite the high priority given by governments and industry to technological innovation and economic growth, the social complexity that is subtly but fundamentally intrinsic to technology is itself a central concern to many in society. This conflict between the modern drive to implement technology for its economic dynamism, and the opposition to the social implications of those technologies and the risk rationality that justifies them, is a crucial point of contention that is at the heart of the engagement of nature in many technology regulation disputes.

As a reflection of public concern, trust in many technologies, and their ultimate social value, is low, posing a serious concern for industry and government (Conference Board of Canada, 2005; Canada, 2003b). A key role in the building of social trust in technology is played by government risk regulation, which has a formal mandate to control and monitor the consequences of technologies (Conference Board of Canada, 2005). Its public interest responsibilities gain trust in the regulated activity by sanctioning the activity, and by imposing expert control of its risks; regulation balances

public interests against private economic activity, legitimacy against innovation (Purcell, 2002). This public interest function relieves individuals in the public of having to monitor the activity; it also attracts public scrutiny to itself and its processes, reducing or displacing the scrutiny that is possible of the activity and the industry (Bradbury et al. 1999; Taylor-Gooby, 2007).

The ability of regulation to build trust has been complicated, however, by the recent policy requirement that regulatory regimes support innovative technologies, aligning with other arrangements such as administrative infrastructure, financial support, and intellectual property law that collectively support a neoliberal economic policy agenda (Canada, 1999; Prince, 2000; Benevides, 2004). This strengthened economic focus requires greater public trust, in order to facilitate the dedication of public resources to innovation while also retaining legitimacy; in this context social trust has become both scarce and urgently desired (Canada, 2003b). Regulators thus turn to strategic measures in order to gain trust, naturalizing the technology in order to minimize the appearance of social relations associated with it.

The scientific concept of risk is instrumental here, as it is linked directly to the fundamental properties of external nature through the credible objectivity of science (Levidow, 2001). Based in a scientific definition of nature that can construe a technology as natural, and a narrow interpretation of risk assessment as free from social values, risk regulation excludes the social factors of a technology as irrelevant, or as not present at all (Jasanoff, 1998). This use of nature and risk definitions is fundamental to the construction of a public framing of the technology risk issue, which establishes the

essential terms in which the issue may be discussed, regulated, and challenged (Jasanoff, 1995).

It is self-evident that many products and activities in modern society are clearly hybrids of nature and social action, and that this hybridity is commonly, though often only tacitly, acknowledged and accepted (Whatmore, 2002). Despite the normative separation of nature and society, it is not the fact of this hybridity that is at issue in the social debates on GM foods and NHPs, but rather the kind of human or social intervention that is at issue, its social context, purpose, beneficiaries and social impacts (Whatmore, 2002; Verhoog et al. 2003; Myskja, 2006). The large-scale technological transformations of nature that impose further social differentiation and inequality, private ownership and power that are urgently advocated by government and industry are equally urgently opposed by many in the public (Kneen, 1999). Sensitivity to the transformation of nature appears to be calibrated to social purpose and impacts rather than simply to impacts on natural or environmental systems. Challenges to significant technologies are mounted in terms of nature as an ideal backdrop against which social interventions are delineated, and transformations of nature are highlighted as social in order to force attention to the inequitable benefits and impacts they imply.

Chapter outline

The framework of analysis is presented in Part 1, chapters 2 through 5. The meanings and distinctions it describes are used by people in society in elaborating and defending their positions on technology and nature; they reflect the structure of the

perceptions and values that are active in the debate on GM foods and are closely allied to concepts of risk in society.

Chapter 2, Nature and Artefact, describes the terms in which philosophers, scientists and members of the public describe nature as a category distinct from the social. The modern concept of nature establishes the social power of modern dualistic nature. This concept is deeply integrated into the legal and social fabric of society and undergirds modern social institutions such as science, economics and political priorities. Alternative, more ecocentric concepts held by a majority in society often pose a challenge to such dominant institutions.

Chapter 3, Nature and Risk, addresses the different concepts of risk that define the controversy over many technologies and regulatory approaches, including that of GM foods. The scientific concept of risk is based in the modern model of nature as mechanical, elemental, and morally empty, but is employed to help achieve the explicitly political objectives of risk management activities. In contrast, the popular, non-scientific concept of risk is frankly contextual, value-based, and concerned with the legitimacy and benefits of an activity in society in addition to health and environmental risks, revealing a persistent identification of risk with large-scale technological activities, and that is a direct challenge to the dominant policy orientation.

Chapter 4, Trust in Modern Society, looks at complex society, which emerges from risk perception research as the domain of risk and as antithetical to nature. Social trust has been identified as a requirement for the smooth functioning of complex society and an essential component in perceptions of lower technological risk. Regulation is an

institutional guarantor of social trust, controlling and sanctioning private activities in society in the public interest. Trust is employed by members of the public as maintained through critical monitoring of social activities, but is sought by government and industry as a faith in experts and authorities that permits a desired reduction of public scrutiny.

Chapter 5 discusses regulation in modern society as an active process that is shaped by the interactions between dominant and challenging discourses. It includes formal risk regulation and intellectual property laws, and the larger policy framework that aligns all elements towards neoliberal economic and political objectives. Risk regulation uses the terms of risk assessment to achieve economic objectives established by federal regulatory policy, as well as to protect human health. These two sets of obligations can place regulatory institutions in a conflict of interest, both promoting and regulating the same products, that challenges the legitimacy of the regulatory regime and the institution.

In Part 2, I explore the ways that normative concepts of the categories of nature and society, and of the relationship between them, shape different attitudes to GM foods and NHPs, and the dynamic that has developed around the regulatory regimes for those products. as expressed by people engaged at different locations in the regulation of GM foods and NHPs. Different and often conflicting perspectives are expressed from different social positions: the dominant group rationalizes its perspective to protect its position, while the other mounts a challenge to that rationality and dominance. In addition, GM foods and NHPs themselves are positioned differently in society, and the particular social dynamic of each is reflected in its regulation.

Part 2 is prefaced by a brief description, in Chapter 6, of the methodologies used in the case studies, and a review of the Food and Drugs Act under which both GM foods and NHPs are regulated.

Chapter 7 reviews the character of genetically modified foods and the development of the food and agriculture biotechnology industry, then looks at the emergence in international arenas of regulatory terms and approaches. The case study of GM foods in Canada is presented in Chapter 8. A set of regulatory objectives, approaches, and terms embedded in a strictly scientific risk assessment regime provides an authoritative basis for the public presentation of GM foods as indistinguishable from natural and traditional foods. While these terms are ambiguous and inconsistent with the terms of other institutional arrangements for GM foods, they serve the purpose of losing the social relations of GM foods in imposed definitions of the foods as natural.

Chapter 9 considers the use of natural health products under different institutional arrangements in different countries, and the rationales for their use in modern industrial countries. In Chapter 10, I examine the regulation of NHPs in Canada, which expresses a sensibility of respect for nature and for the autonomy of individual consumers to select NHPs for their own health, within their own cultural or philosophical framework. The concept of nature that underlies the NHP industry has a social orientation of its own, asserting and facilitating a less complex pattern of social relations.

Finally, in Chapter 11, I outline the insights and conclusions that can be drawn from this research.

Chapter 2

Nature and Artefact

If nature is socially constructed as a cultural norm and physically shaped by human actions, it must be asked why we in modern society continue to speak of nature as a distinct category of phenomena beyond the scope of social influence, and of society as an equally distinct realm of human affairs that has pulled away from the influence of nature. A first step in building an understanding of modern concepts of nature is to look at philosophers' arguments for a logical basis for distinguishing between nature and society and the ways that nature ideas are employed normatively.

A number of philosophers (Lee, 2005; Heyd, 2005; Stephens, 2004) argue that there is such a thing as an independent or autonomous nature that is "more than a social construct" and that is categorically distinct from human artefacts. Nature has an intrinsic/immanent teleology, with species behaving according to their own teleology, "independently of human agency and its manipulations, [with] nothing to do with humankind." Stephens (2004) concludes that "we can distinguish the natural from the humanized [and] it can still make perfectly good sense to talk about nature and naturalness as a force independent of human control" (ibid). Lee (2005: 67) further argues that we can speak of a nature that is not laden with a partisan human perspective. While all accounts of nature are of necessity anthropogenic, mediated through human consciousness and language, it does not follow that all accounts must therefore be anthropocentric, or that championing nature's autonomy or non-anthropocentric concerns "is a mere disguise for advancing the interests (sectional or nonsectional) of its

advocates.”

Lee (1999: 118) distinguishes the fundamental difference between nature, or natural kinds, and artefactual kinds. Saying that nature is autonomous means

What has come into existence, continues to exist, and finally, disintegrates/decays, thereby going out of existence, in principle, entirely independent of human volition or intentionality, of human control, manipulation, or intervention. . . Nature, both biotic and abiotic, is autonomous both negatively, as “what exists and continues to exist independently of human intentionality, control, manipulation, or intervention,” and positively “in terms of being self-generating and self-sustaining”(Lee, 2005: 59, 54).

Artefactual kinds, in contrast, are entities whose existence and maintenance are the intended outcome of human volition and agency. They come into, or go out of, existence entirely at human bidding. Technological products are artefacts, and artefacts are the material embodiment of human intentional structure (Lee, 1999: 188).

It is possible, these philosophers argue, to talk of nature in itself, and important to conceptualize the social as distinct from nature. As Soper (1995: 39) cautions, simply to note that the distinction between the natural and the human “remains a presupposition of all [Western] philosophical, scientific, moral and aesthetic discourse. . . “ is still “not to say very much”: “what is at issue in the humanity-nature division is not the positing of the distinction in itself, but the way in which it is to be drawn, and importantly whether it is conceptualized as one of kind or of degree” (Soper, 1995: 41).

Indeed, it is in the ways that the distinctions between nature and society are drawn that the cultural and political dynamics occur. The first thing that can be noted about the distinctions that are made between nature and society is that discussions of nature as autonomous are conducted in almost purely social terms: the character of the intervention is of greater consequence to the autonomy of nature than any physical

change that it renders in nature.

Economist Herbert Simon (1981) offers valuable insight into the essential features of technology as an intervention in the natural world that distinguish it from nature. Simon begins by asserting that “the world we live in today is much more a man-made, or artificial, world than it is a natural world “(Simon, 1981: 5). He defines ‘artificial’ as man-made, an artifact, rather than natural, but stresses that artefacts are not “apart from nature” and “have no dispensations to ignore or violate natural law’ (Simon, p.6). Artefacts are thus part of nature at a physical level, but their essential identity is that “they are adapted to man’s goals and purposes” (Simon, p. 6).

Simon lists four features that “distinguish the artificial from the natural” and “set the boundaries for sciences of the artificial”:

- Artificial things are synthesized (though not always or usually with full forethought) by man.
- Artificial things may imitate appearances in natural things while lacking, in one or many respects, the reality of the latter.
- Artificial things can be characterized in terms of functions, goals, adaptation.
- Artificial things are often discussed, particularly when they are being designed, in terms of imperatives as well as descriptives (Simon, 1981: 8).

An important aspect of artifacts is that they form an interface between the “inner environment” - “the substance and organization of the artifact itself” and an “outer environment” - “the surroundings in which it operates” (Simon, 1981: 9). Artifacts are like a natural organism in the need to adapt the inner and outer environments if they are to function and survive. However the outer environment of an artifact need not be natural physical conditions or processes, but, crucially, may be a social environment in

which it was designed to function.

The key aspect of artifacts is thus their design, the function they are intended to have within a given system or outer environment.

A second observation to be made from debates on the ontological status of nature is that while human interventions into nature are seen by some as categorical and total, to others they are a matter of degree. According to Rolston (1991) any intervention cancels naturalness, due simply to its being an intentional process. “On the meaning of ‘natural’ at issue here, that of nature proceeding by evolutionary and ecological processes, any deliberate human agency, however well intended, is intention nonetheless and interrupts these spontaneous processes and is inevitably artificial, unnatural”(Rolston 1991: 370).

Stephens (1992), however, draws a distinction between an extreme “dangerous purity” in ideas of nature that justifies an extreme and categorical purity of a dominant social group, and the more flexible notion of ontologically autonomous nature. He (Stephens, 2004: 92) concludes that “the ontology of the natural is relative, given along a spectrum that includes wilderness at one end and the wholly designed products of deep technologies at the other, and the extent of an item’s naturalness is in direct inverse proportion to the amount of abstract instrumentalisation that the item has undergone.”

The degree of abstract instrumentalism is a reflection of different modes of social intervention. In the “cultus” mode, nature is a guiding principle to action, as practised by artisans with a respect for the natural material they work with. The “policy” mode, on the other hand, “begins through a background assumption of separation and a motivation

of instrumentalism in which felt qualities of relationship are ruled out of court as ‘sentimental’ and . . . focusses on objectified items as abstracted from context” (Stephens, 1992: 296). These different human orientations towards their interactions with nature determine the ontological status of the product on the spectrum from natural to wholly artificial.

Lee (1999: 52- 53) maintains that there are gradations in artefacticity that depend on the material that is used - whether it is found in nature, such as stone or wood; derived from a natural material, like plastic from oil; or constructed “de novo” from natural building blocks like atoms and molecules. The highest degree of artefacticity is found when humans design an artefact from atoms, which is then “the total product of human design and technology.”

In the context of artefacticity as inhering in intentional design and in the degree to which that design imposes an external, human purpose on the entity, all of agriculture is artefactual to some degree. Pre-agricultural, hunter-gatherer societies had in common a relationship with the natural world that was based on knowing about the environment, showing respect for other forms of life on which survival depends, in order to ensure the continued availability of food: “the central preoccupation of hunter-gatherer economic and spiritual systems is the maintenance of the natural world as it is” (Brody, 2000: 117). Hunter-gatherer societies were small and egalitarian communities in which resources were shared (Brody, p.118).

Agricultural societies, on the other hand, select seeds and animals for domestication, concentrating effort on producing food from the crops planted in newly

made fields. Agriculture consists essentially in changing nature, improving it by adapting it to human needs (Brody, 2000: 118). Traditional farmers have nevertheless been constrained by the natural reproductive and adaptive capacities and limits of the plants they grew, and were able to develop new varieties by selecting and cultivating the strains with the characteristics they preferred.

Organic nature, including such factors as the land-base of rural activities, the length of plant germination and growing cycles and diurnal and seasonal cycles, has been a constraint on the development of capitalist industrial agriculture (Goodman et al. 1987). Developments in agricultural technologies over the last century have enhanced the ability of farmers, or increasingly of scientists and seed companies, to adapt crop plants more precisely to the demands of the agricultural industry. Plant breeding has become “more goal-directed and goal-oriented, and less haphazard. . . . an activity which could be planned and controlled’ (Fowler, 1994: 33).

It has required successive inventions and innovations to remove those “barriers to accumulation” incrementally (Goodman et al., 1987). Goodman et al. make the argument that the capitalist transformation of agriculture since the industrial revolution has proceeded piecemeal as new innovations in machinery, chemicals and now biotechnology have permitted the replacement of natural growing processes and human labour with industrial processes, and natural food products are replaced with chemical and synthetic processed food ingredients. They define this incremental transformation of agricultural processes into industrial activities to take advantage of opportunities for capital accumulation as “appropriationism,” and “substitutionism” as the process by

which industrial activities and products, such as chemical and synthetic ingredients in processed foods, replace agricultural outputs (Goodman et al.: 2).

In its fullest sense, appropriationism is constituted by the action of industrial capital to reduce the importance of nature in rural production, and specifically as a force beyond their direction and control. This was achieved initially by relaxing the constraint of land as space via mechanization, and subsequently by the continuing struggle to transform the secrets of biological production into scientific knowledge and industrial property. In effect, the process of natural reproduction of plants and animals is being internalized via science in the reproduction of industrial capitals. (Goodman et al., p.3).

“Appropriationism and substitutionism converge in the development of new crop varieties deliberately designed to incorporate properties which facilitate machine handling and meet the special requirements of food processors” (Goodman et al., 1987: 85). These processes result in agricultural products that, though grown as plant crops, have been biologically designed to meet the needs of their industrial outer environment. Such plants have included monogerm sugar beet varieties that eliminated the need for manual thinning of plants and enabled the complete mechanization of sugar beet production; a tomato variety on which all fruit ripened at the same time and was able to withstand machine handling and harvesting; and cotton plants on which the bolls set higher on the stalk and ripened within a short time frame, to facilitate efficient machine harvesting (Goodman et al.: 36).

A third message to be taken from the philosophical debate on nature is that, as the intrinsic value of nature as autonomous is largely negative - that is, it consists in the absence of certain human interventions and the quality of human interaction - it is not clear what is at the heart of the human valuation of such a normative concept of nature.

If a physically untouched nature does not really exist - and if many social interventions have no material effect on physical nature - what is the basis of the persistent human need to acknowledge and preserve a nature that appears to be free of human intervention?

Kellert (2005) takes a straightforward approach to an innate, “presumably biologically based” (p. 131) human valuation of nature. In his typology of nine ‘biophilia’ values he includes the naturalistic, aesthetic, humanistic, and moralistic, which have the potential evolutionary advantages of providing humans with, respectively, curiosity, inspiration, group bonding, and order and meaning in life. He argues that these aspects of human dependence on the natural world provide material benefits, but “far more significantly, the increased likelihood of fulfilling a variety of emotional, cognitive and spiritual needs in the human animal” (Keller, p. 131).

Somerville (2006) believes that through contact with nature we can “appreciate that as humans we are part of a much larger order of being, which can be an antidote to . . . despair and nihilism” (p.112; 110). She warns of the spiritual impoverishment that results from our distancing from nature. Loss of contact with nature causes the social individual to “lose contact with non-rational knowledge - ways of knowing other than reason” (Somerville, p. 113).

Lee (1999) argues that it is a matter of moral principle that humans respect the integrity of nature:

It is morally wrong of us humans to eliminate nature (by rendering it redundant, making it over in our image to serve our purpose), not simply because it diminishes ourselves as moral beings, but because the diminishment lies

precisely in our moral blindness to something other than ourselves which deserve moral consideration, or could be said to be the bearer of intrinsic value (p.119).

Other writers link the importance to humans of an autonomous nature to relations within society. Ridder (2007: 209) argues that the source of the value of wild nature is “that it symbolizes autonomy from the abstract, instrumental interventions characteristic of contemporary society.” Humans, he argues, desire this autonomy from “the abstractions of contemporary society,” a strong feature underlying Romanticism and similarly ecocentric concepts. Autonomous nature represents something ‘above and beyond the human realm, something more ancient and more enduring’ (ibid: 207); it is valued as a symbol of human freedom, a ‘refuge from totalitarianism’ (ibid: 209).

Abstract instrumentalism, introduced by influential actors within society, plays a significant role in undermining the autonomy of the individual. The influence of abstract instrumentalism on contemporary life is ubiquitous, through such features of society as centralized decision-making, corporate dominance, ease of information processing, the mass media, and so on. By undermining the autonomy of the individual, these processes will appear highly unnatural (ibid: 201).

Stephens (2004: 93-94) takes a more explicitly political position, arguing that “nature is precisely the manifestation of that which is not already predefined by human purpose, that which has yet to be allocated into an instrumental order. . . . Nature thus experientially supports liberty as a counterpoint to the arbitrariness of human will, providing the vital context of spontaneous independence for loosening narrow dogmatism, enabling human faculties and prospects to be broadened beyond mere power hunger.”

The notion that a separate, non-human nature is needed by people as a

‘counterpoint’ to an instrumental social has a historical correlative. Dahlberg gives a historical perspective on the intrinsic relation between the increased institutionalization of societies with the growing complexity of agricultural societies, and a feeling of the loss of nature, which associates the incursion of a social order per se with a sense that nature has been diminished:

This has been accompanied with increasing divisions of labor and specialization - something speeding up the gradual physical and cultural separation of individuals and societies from nature. . . . The combined growth of the built environment and the dividing up of the natural world and social worlds as well as the built environment into specialized components has resulted in radical shifts in the relative proportion of the biosphere that is ‘natural’ and that which is built and formally institutionalized (Dahlberg, p.139).

Stephens (2004: 94) concludes that “Nature is intimately connected to liberty . . . partly because it functions to protect liberty by curbing the Orwellian excesses of authoritarian definition Only nature, precisely because it operates outside the domain of arbitrary will, can provide such a grounding context of coherence upon which culture may build and in doing so provide a bedrock within which value judgements may be made and freedom exercised in a fulfilling manner.” The assertion of a separate, autonomous nature, then, may be motivated by a thoroughly social impulse to constrain members of society from aggressively dominating behaviour within society, placing a limit of respect for the ‘other’ that protects everyone from the excesses of such behaviour. As Heyd (2005) notes, recognizing nature’s autonomy means that it counts “in a manner similar to ourselves, namely *for its self*, thereby implying that there may be legitimate, morally relevant limits to our own acting” (Heyd, p. 6, original emphasis).

Smith (2002) refers to the importance of retaining and asserting a sense of an

ideal pure nature as a way to continue to think about alternatives to modernity's commodification and exploitation of nature, and to critique the ways modern society inevitably, and intrinsically, pollutes and contaminates nature and enforces inequitable social relations. Stressing that it is a mistake to reify such an ideal non-human nature, Smith (ibid: 422) argues that:

The state of nature may be a myth but it is not simply fictional, it is a sacred (ethical) ontology. It is an ethical expression of the desire and wonder we can still experience in relation to human and non-human Others. . . . Nature still survives and re-emerges on modernity's margins and innocence, . . . continues to critically survey the results of modernity's storm . . . [and] stands as an unanswerable indictment of the destruction wreaked in progress' name.

The order of nature

Humans have always organized their perceptions of the environment into an order of nature (Tuan, 1971). Delaney (2003: 12) argues that we must give meaning to the world or it is "literally unintelligible": and it is "not just the *idea* of such a world that would be unintelligible, but the world itself. Ground would be indistinguishable from sky, hand from rock." Humans must integrate our understanding of the physical environment into concepts of our cultural purpose and identity: we cannot live in "a space-time continuum," and have always ordered the physical environment to reflect our need for "privileged location and boundaries" (Tuan, 1971: 18). Human cultures have tended to define the space they live in from the centre, where they are situated. That centre is a sacred space: it is "a reified order, a two-dimensional cosmos. Beyond it is profane space, chaos or wilderness" (Tuan, 1971:18). Wilderness is 'pervasive and boundless; out of the wilderness humans create the garden, "the humanized order close

to the earth”; and the city, “the heavenly cosmos transposed to earth” (Ibid: 24). By taking possession of the land and cultivating it, humans ‘cosmicize’ the land and make it habitable (Glacken, 1967: 301). Dangers and disasters, in the form of ‘militant nomads or natural disasters that destroy crops are “scourges out of the wilderness” (Tuan, 1971: 25)

Such structured cosmologies derive from lived experiences and at the same time give them meaning and direction (Tuan, 1971: 24). Nature has appeared to many religions, literatures and to ordinary experience as “eating and being eaten, growth and decay, womb and tomb. . . . Civilization may be understood as a supreme human effort at replacing such ambivalence and inchoateness in experience and image with something simpler, firmer, cleaner and brighter” (Tuan 2004).

Models of nature are not just organized descriptions of all that is observed within the physical environment and social behaviour, but constitute a structured order that integrates a more normative ideal of nature with a social organization into a single coherent system (Douglas, 1992). Many cultures have divided the cosmos into natural and social categories. “People as different as the Gimi of New Guinea and the Lele of Kasai in Africa at one end of economic development to Chinese urban sophisticates at the other end have either special words for nature and culture, or have taken the trouble to describe and contrast them at some length” (Tuan, 2004: 733). Social classification systems define the boundaries of nature, society and the body (Lupton, 1999a). The concept of nature is the fundamental order that defines society in the world, and allocates properties, values, and risks to nature and to society.

A recent anthropologically based perspective on the integration of concepts of nature into society is that of cultural theory, which assumes that each culture has its own cultural bias of social organization and an associated myth of nature. It was first articulated in *Risk and Culture* (Douglas and Wildavsky, 1982), and described risk perceptions as functioning within structures of power and authority. Cultural theory was articulated as a more general theory in 1990 (Thompson, et al, 1990), and has been tested empirically with conflicting results (Sjöberg, 1998; 1999; Palmer, 1996; Grenstad and Selle, 2000; Brenot et al. 1998).

“Cultural theory starts by assuming that a culture is a system of persons holding one another mutually accountable” (Douglas, 1992; 31); all of nature, the universe - indeed, all cognition - are moralized and politicized (p. 5, 8). Cultural theory assumes there are only five main ways in which humans can perceive the world; these are the ‘cultural biases’ - hierarchy, egalitarianism, individualism, fatalism, and, in some cases, the hermit. A myth of nature is characteristic of each cultural orientation.

Nature Benign, the myth of the individualist, is forgiving and resilient, permitting a laissez-faire attitude and encouraging trial and error. Nature Ephemeral, the myth of the egalitarian, is fragile and unforgiving, requiring people to live in balance with nature and make only appropriately modest demands on it. Nature Perverse/Tolerant is the myth of the hierarchist: forgiving within certain limits, it is vulnerable to behaviour that exceeds set limits. Nature Capricious is the myth of the fatalist. It is a random world in which one cannot predict what may happen, in which one merely copes, rather than learning and managing.

Nature in the social order

The ordering of nature occurs as a cognitive process (Korpela et al., 2001); a cultural process of developing shared meaning of the world (Kempton et al., 1995); and a political process of justifying and maintaining social behaviour and power within social organizations (Douglas, 1966; Douglas, 1992). Justifications and defences of many social and political relations rest on a particular definition of nature, and challenges and modifications to them need to reach back to adjust the foundational ideas of nature. This implies that any challenge to or replacement of a dominant model of nature is itself a social construction, which requires cultural and political defences of its own to assert a viable alternative. We use nature “to make the world meaningful one way rather than another,” with all-important consequences for the material ways we interact with and use the environment (Delaney 2003: 18). The politics of nature “concern the sorts of conceptual-ideological work we want “nature” to do, the sorts of meanings we want to project onto the world and onto ourselves” (ibid).

We want nature to ‘do work’ for us because it has a ‘moral authority’ (Daston and Vidal, 2004) that cannot be derived from internal human or social sources: as Daston and Vidal note, “cases rest when they reach nature” (ibid: 9). They distinguish three sources of nature’s authority: “as a source of values and value in itself; as a means of thinking about necessity and freedom; and as a permeable and moving boundary that demarcates individuals and categories” (ibid: 5). “The most inexorable authority [of nature] is that of necessity, against which human will strives in vain” (ibid).

Perhaps the first task that nature is asked to do in modern society is to “provide a

background against which “the human” can emerge as a meaningful figure’. Nature and society are different and separate, with nature being a ‘negativity’ that provides a conceptual space ‘against which figures of humanness are contrastively drawn and made legible’(Delaney 2003: 36). Nature is, that is, simply defined as the non-human in order to differentiate the human: it “works the ontological boundary of humanness” which can otherwise be difficult to conceptualize as other than a ‘slab of matter’ (Delaney 2003:15).

If “nature” is used to make aspects of physical reality meaningful in complex but particular ways, it is also, and simultaneously, used to make us meaningful as other than ‘mere’ nature or “brute physicality.” The difference that it makes makes (sic) us other and more than animals, other and more than simply a collection of bodies. The significance of this cannot be overestimated. Perhaps we need “nature” and we need to “naturalize” the way a stream “needs” its banks or a figure “needs” a background. (Ibid: 12).

Despite the hybridity of many of the phenomena of modern life, the separate categories of nature and society remain culturally active, largely because of the normative power of nature. Because it is so normatively separate from society, nature naturalizes or “shore[s] up a social convention . . . or political arrangement by asserting that it is either irrevocable or optimal or both” (Daston and Vidal, 2004: 2). “[N]ature appears as an external authority, even if its imperatives are lodged deep in the body or psyche; it is the ‘permanent, inevitable, essential’ - what simply is, in contrast to the human, which is artificial, intentional, and revisable (Delaney, 2003: 15). Nature’s authority can also be internalized, made ‘natural’ in the sense of seeming inevitable or effortless’ (Daston and Vidal, 2004: 9). As such nature is ‘called into existence’ as ‘an allegedly neutral judge’, along with experts - “at first physicians and natural

philosophers in the early modern period, and later scientists - as allegedly disinterested interpreters of nature's verdicts" (Daston and Vidal, p.7).

Science is the modern means of knowing nature, and as science itself claims to be value-neutral and objective, its descriptions of nature, natural phenomena and human nature are conventionally taken to represent objective reality. This makes science an especially robust guarantor of social constructions in modernity, having apparently direct recourse to objective physical nature without the intermediary of an explicitly social interpreter.

Attributing an event or activity that may have adverse consequences or unequal benefits to nature makes it appear beyond human planning, intervention, and interest. Risk activities and technologies that are deeply controversial often involve disputes over their placement in nature or in society in efforts to assert or to deny their inevitability and the degree of social responsibility for them. Exposing this "covert conflation of the natural and the social," thus becomes a prime task of those who would challenge the dominant regime:

... The trick consists in smuggling certain items ... back and forth across the boundary that separates the natural and the social. Critics, like customs inspectors, return items to their rightful categories, extraditing the natural from the social, and especially, the social from the natural. Naturalization in this form assumes the existence of distinct categories of nature and society, of well-drawn boundaries between them, and of a certain asymmetric advantage in dwelling in one territory over another, nature being the land of choice for immigration. Naturalization imparts universality, firmness, even necessity - in short, authority - to the social. (Daston and Vidal, 2004: 3).

Plumwood (2005: 38 -9) elaborates on the process of naturalization by delineating three types of naturalizing and denaturalizing strategies. Naturalizing 1 -

deceptive naturalness - involves counting as purely natural something that has had human intervention or contribution, hiding the “social relations that have gone into that construction, often in the interests of making it seem unchangeable.” Overhumanizing, or deceptive humanness, is “counting something as purely human when it involves the labor of nature jointly with human labor [and that] can hide or deny the ecological dependency relations in that construction” (Plumwood, p. 39). Finally, deceptive naturalness 2 is the counting of human groups involved as nature, to hide social relations by not acknowledging their contribution.

Nature that has come under social influence shifts to the social category. The categorical separateness of nature from society “describes the reach of human powers to effect physical transformations” (Delaney 2003: 51), marking the limits of causal or moral responsibility just as it keeps nature free of social influence. “Nature rendered known yet still beyond the powers of human control is . . . semi-domesticated - captive if not tamed. . . Nature known and controlled is nature annexed to the realm of human intentionality” (Delaney, p. 51).

Modern Western culture is associated strongly with the desire to control nature: science in particular has held a heroic view of new possibilities of control over nature, of society mastering and managing nature to its greatest advantage. However, “man” does not control nature “so much as differentially empowered social actors do” (Delaney, 2003: 44). Those few who own parts of nature have control over the use of that property, which also gives them control over people. Property gives rights of exclusion, use, and disposition (Brown, 2004: 12), and thereby becomes a powerful means of social

differentiation and control. The “politics of nature often revolve around struggles to maintain or change the social division and distribution of control over segments of the physical world” (Delaney 2003: 45), just as they also involve efforts to contain actions to the natural sphere to limit the appearance of private interest.

Latour (1993) has proposed a set of principles that structure the modern relationship with nature, and from which proceed many of the approaches to understanding the combinations of nature and society. He distinguishes two set of practices that characterize modern culture. The first is that of translation, which “creates mixtures between entirely new types of beings, hybrids of nature and culture,” linked together in networks consisting of, for example, elements of nature, scientific expertise, and institutional policies. The second is the practice of purification, which “creates two entirely distinct ontological zones: that of humans beings on the one hand; that of nonhumans on the other.” The practice of purification Latour calls the “modern critical stance” (Latour, p. 10-11); essentially that “there shall exist a complete separation between the natural world (constructed, nevertheless, by man) and the social world (sustained, nevertheless, by things) . . . There shall exist a total separation between the work of hybrids and the work of purification” (Latour, p. 31). The practice of purification permits moderns to “bracket off entirely the work of hybridization, . . . of not thinking at all about the consequences of their innovations for the social order” (Latour, p. 41). Without purification, the practice of translation “would be slowed down, limited, or even ruled out” (Latour, p.11).

Through the practices of translation and purification, moderns are able to

“innovate on a large scale in the production of hybrids” and create an unprecedentedly dynamic society.

They are going to be able to make Nature intervene at every point in the fabrication of their societies while they go right on attributing to Nature its radical transcendence; they are going to be able to become the only actors in their own political destiny, while they go right on making their society hold together by mobilizing Nature. . . . this makes it possible to do everything without being limited by anything (Latour, p. 32).

This modern ‘constitution’ has proved exceptionally dynamic, as Latour has pointed out; and it also proved to be exceptionally destructive of the environment. Thus the emphasis in drawing attention to the social constructedness of nature is to point out the social injustices and the environmental damage that are perpetuated by the continuation of modern dualistic thinking. First, it is materially inaccurate and thus confounds our ability to recognize what may be a social or a natural substance or process or, more usually, a thorough combination. Second, it disguises social action and intent, whether in the form of technical interventions in processes that require diagnosis and remediation, or of more routine shaping and production that are motivated by political ideologies. Third, it overlooks the agency of nature and natural processes, attributing to human action and ingenuity alone the material production of society.

Nature and social institutions: law and regulation

Ideas of nature are deeply implicated in social institutions and hence in regulation, understood both broadly and legally. Key social norms are institutionalized around historically specific cultural assumptions about nature, human nature, and the

relation of humans and society to nature, just as certain ideas of nature are selectively employed to authorize a particular institutional perspective. Nature and society are fundamental categories used by the law to delineate boundaries of social jurisdiction, responsibility and accountability. The detailed content and political objectives of laws and regulations may also be grounded in and authorized by a definition of nature.

In the Western context a traditional concept of nature and human nature gave form to social norms and law from the ancient Greeks through to medieval times in the philosophy of natural law. The basis of this philosophy was that nature as a system was normative and thus provided a model for proper human behaviour. This was derived from the notion that both nature and human society had a shared teleological purpose given by God and expressed by nature, and that humans should behave in alignment with that purpose. This philosophy was most fully articulated by Thomas Aquinas in his scholastic philosophy in which he melded Aristotelean and Christian ideas.

(Illathuparampil, 2003; Forte, 1998; Delaney, 2003).

Though natural law ceased being the formal authority shaping social behaviour and law with the Protestant Reformation and the development of scientific inquiry by individuals, the principle that social norms required a grounding in a notion of fundamental nature persisted in various ways (Forte, 1998).

Early modern philosophers, most prominently Hobbes, Locke and Rousseau, derived their social theories and formulation of the political state from an understanding of the prior 'state of nature'. Locke's hypothetical state of nature manifested the principles and values that are normative - that is, the laws of nature that we take to be

normative were actually active in the state of nature, though this prior condition lacked a strong means for solving conflicts and wars. It is Locke's political principles, derived from his hypothetical state of nature, that have been particularly influential in modern political norms and institutions. The notions of the equality of all men, the rights of the individual to his person and property, and the notion of property as deriving from labour added to nature, the protection of which is a primary rationale for the existence and power of the state, are all fundamental values of liberalism that are derived from the state of nature. The American constitution included natural law norms in its complex statement of the American political values and system (Forte, 1998: 4). Contemporary intellectual property and patent law remains founded on basic principles articulated by Locke that distinguish the private ownership of an invention or product from common nature (Hesse, 2002).

Illathuparampil (2003) asks whether the normative status of nature that gave natural law its authority through classical and medieval times is weakened in a technological world. He concludes that the modern framework in which nature is "predominantly viewed as an instrument of human use" (Illathuparampil, p 232) does diminish the foundations of natural law. For one thing, the rule of nature is no longer the measure of human happiness: technological advancements have greatly changed the non-technological attitude toward nature as an inviolable principle. Second,

The modern idea of nature has radically relocated the traditional distinction (or even opposition) between nature and the artificial which seems to have been presupposed by the natural law theorists in their adoption of a teleology for nature. But according to modern scientific knowledge, all natural things are constructs of some basic elements, called atoms, if you will. Such constructs are

not different from one another, whether they were constructed with human intervention or not. . . . This provides us with a radically expanded view of artefacts and, conversely, a shrunken view of nature (Illathuparampil, p. 232).

Illathuparampil's view describes the shift in attitudes that comes of the dominance of the scientific perspective on nature and the economic perspective on social uses of it. However there is significant resistance to this shift in values, articulated in large part in direct response to the new levels of incursions into nature by biotechnology. Somerville (2006) argues for a "presumption in favour of the natural" as a guide for ethical human behaviour. She takes a position that is similar to that of natural law, in arguing that "nature in itself is an inherent good" (Somerville, p.114) and that "some elements that constitute the natural in human nature are intrinsic to it, and, therefore, non-negotiable. Even if we have the power to change them, we should not do so. They should be regarded as the secular sacred" (Somerville, p. 99).

Even in this age of scientific rationalism and economic instrumentalism, or perhaps because of it, the normative value of nature is reasserted, and may be the more common belief, although it is not politically dominant. Somerville (2006: 114) states that "a profound respect and awe for the natural is already interwoven into most of the cultures and religions that give shape to humanity. In fact, the current challenge to our presumption in favour of the natural and respect for nature and the natural is posed by a relatively small group of secular fundamentalists, who hold what I call a 'pure science' worldview."

Law also uses the categories of nature and society to do its work (Delaney, 2003). Nature is, by definition, not the province of law: it is the non-social, the 'other'

that is external to society. In addition to the essential distinction between nature and a human artifact that may be treated as private property, law also relies on a culturally determined boundary in order to delineate responsibility, accountability and liability. This is of interest in relation to damage from so-called natural events.

Delaney (2003:141-161) notes that in the past, the attribution of actions and events to nature has limited liability in some cases of complex events that resulted in damages. Steinberg (2000) has recounted the use by U.S. institutions of natural events caused by “acts of God”, a morally neutral category for placing damages from damaging events that appears to distance authorities from the event and thus absolve them of responsibility for consequences. More recently, however, courts have held those involved in technological interventions in natural systems responsible for damages caused by adverse consequences on the grounds of their disruption of those systems and the obligation to anticipate such consequences. A key shift in this move to assign liability in damages from events that are no longer seen as “purely” natural has been an acknowledgement of the impacts of human interventions in nature and social accountability for them.

Because the land was owned - even if it was not “developed” - it was better seen as situated within the domain of human agency or intentionality. Because ownership and possession entail “the right to control,” then “nature” cannot be used to sever this right from a correlative *duty* to control. . . . If someone, call him “man,” enters the landscape in order to work his will on it and to profit from that, then he already *is* within the nomic web of right *and* duties. (Delaney, 2003: 160 original emphasis).

Property gives rights to use, exclusion and disposition, but it also assigns responsibility and accountability; attempts to separate these sets of social relations, to

take advantage of the first set without the burden of the second, underlie much debate on the essence of an object or activity as natural or social.

Cultural construction of modern Western ideas of nature

Nature ideas are cultural interpretations of the physical world and of humans' and society's place and role within it. But they are also more than that; ideas of nature are structured to support a particular model of human nature and society, and the way society should relate to and treat the rest of nature. Changes in ideas of society, and in the way society should relate to and use nature, require reaching back to change the fundamental ideas of nature. The tightly integrated changes and definitions offer the potential to do certain things in and with nature, and create as well the complex and subtle strategic opportunities that the normative categories of nature and society offer within social relations.

It is conventionally understood that the rationalist outlook that led to discoveries about the physical world 'pushed' the development of the modern worldview through what we now call the scientific revolution. However, the emergence of modernity is more accurately seen as an evolution of a new conception of humans and their purposeful actions in the physical world. This involved revolutionary shifts in concepts of the physical world and humans within the cosmos, which, through a long period of negotiation, converged in what we now refer to as modernity. Two definitive aspects of modern thought about nature and society are that humans and nature are more categorically separate than they had been in earlier traditions; and that humans have

rights to own and use the rest of nature to their profit and advantage (Brown, 2004). This concept of nature is a synthesis of several traditions, including the Judeo-Christian biblical tradition, Greek rationalism; and liberalism, science, and the market economy (Brown, 2004; Coleman, 1996).

Contemporary Western concepts of nature and the relationship of humans and society to nature are derived from classical Greek thought, and from there through European Christian philosophy. Christian thought and the Judaic tradition from which it is derived were agricultural cultures in which the state of mankind is to labour to wrest a livelihood from an often reluctant soil; changing and controlling nature are already assumed by the cosmology at the heart of Christian thought (Brody, 2000).

Medieval teachers and clergy taught a model of nature based on an interpretation of Aristotelian philosophy modified with scholasticism. They used Aristotle's doctrine of immaterial forms to "enshrine the basic Christian division between body and soul" (Jacob, 1997:17). Aristotle taught that "form imparted meaning to nature; the motion of a body was directed by a purposefulness; heavy bodies fall to earth, for example, because it is in the nature of heaviness, imparted through form, to seek that which is heavier. . . . Armed with Aristotle, it was relatively easy for Christian theologians to argue that God endowed nature with its teleology, its purpose" (Jacob, p. 17).

In the pre-modern Judeo-Christian tradition, "nature" did not really exist as a separate physical entity or a "natural process independent of God's agency. . . . all forms of material, cultural and political creation originate with God" (Coleman, 1996: 27). In the early middle ages, nature was a symbolic landscape infused with the spirit of God:

there was a “universal belief in analogy . . . the medieval world was a cryptogram full of hidden meanings for man, awaiting decipherment” (Thomas, 1983: 64). The world was a hierarchy with lower beings created to serve the needs of those above them, with humans at the top (Lee, 1999: 40). Events in nature were directed by God as moral lessons to humans; natural disasters and social calamities were interpreted as God’s revenge for human pride and sin.

Nature domesticated by humans expressed the perfect form intended by God, and was clearly separated from ‘wild’ nature, which was still a chaotic waste in a state of original sin. The boundaries of this natural order had to be maintained: there was a strict duality between the human and the animal, and between the wild and the tame; the encroachment of wild creatures into human domains was alarming, as was any event that appeared to “defy the regularity of nature” (Thomas, 1983: 77-8; Glacken, 1967).

Aspects of the environment that did not bear the imprint of the divine order were not, properly speaking, nature until they had been cultivated or domesticated by humans.

Untouched nature - wilderness - was disorder, chaos and danger, an obstacle to human progress; human cultivation imposed order in progress towards the divine plan (Coates, 1998). All of nature was created by God - in Aristotle’s terms, plants and animals had their own tele - and existed only secondarily for humans. This facilitated a “passive anthropocentrism and instrumentalism” (Lee, 1999: 40) in which human exploitation of nature was constrained by respect for divine creation.

Conceptions of nature and society in European culture shifted between roughly the twelfth and seventeenth centuries. Scientists and social philosophers alike recognized

the foundational role of the definition of nature, and much debate focussed on the implications of the description of the physical operations of nature and on the hypothesized state of nature necessary to formulate a changed social order. Through the interaction of developing science and shifts in theology, the divine spirit that had infused all aspects of the universe was extracted out of material nature, leaving it inert, morally void matter, operating on a set of physical laws that were essentially “mathematically expressible motions of matter” (Burt, 1952 [1932]: 101). The divine was placed distantly over the entire structure (Coates, 1998), where it still oversaw the movement of matter and authorized the divine plan of human progress towards the domination of nature. Nature became the inert object subservient to the agency of the human subject.

These abstract changes in ideas of nature evolved over centuries as part of changing social and economic expectations, and in a historical context. This larger context reveals the related movements in science and theology as changing values became articulated and established as liberalism, the political system that emerged to define and protect individual rights within a public order, necessary to sustain a market economy (Coleman, 1996). Brown (2004) describes liberalism as grounded in Judeo-Christian tradition, formally articulated by John Locke in the late seventeenth century; Coleman (1996) attributes the foundation of liberalism to Hobbes, but likewise stresses its inspiration in biblical precepts. Locke reasserted the biblical tradition that God had given the earth and its contents to humans to use, and derived from that the assertion that human labour made private property out of formerly common nature.

Science as a uniquely human achievement was the means to understanding

nature and to achieving the domination of nature that God had intended for humans: “the whole purpose of studying the natural world was ‘that, Nature being known, it may be master’d, managed, and used in the services of human life (Thomas, 1983: 27). Thomas (p. 25) observes that “a reader who came fresh to the moral and theological writings of the sixteenth and seventeenth centuries could be forgiven for inferring that their main purpose was to define the special status of man and to justify his rule over other creatures.” Science likewise envisioned this objective. Seventeenth-century scientist Robert Boyle observed that the old ‘veneration’ of nature was “a discouraging impediment to the “lords and possessors of nature” (Thomas, p.34).

There were also more political objectives that required the adjustment, through science, of the definition of nature. The helio-centric universe of Copernicus and later, Galileo, which led the shift in the concept of the physical universe, came at a time of political and religious upheaval in Europe. Many of the figures now noted for their contribution to the establishment of early science were also driven by an overriding concern to establish a particular scientific definition of nature to authorize their preferred social order. In England, Francis Bacon’s experimental method and practical orientation promised to facilitate the human domination of nature, with science firmly in the hands of the social elite under a “strong central administration led by an intelligent king and a unified [Protestant] church” (Jacob, 1997: 30). In France, Descartes’ more theoretical, mathematical philosophy was aimed at secular elites, in “the service of strong central government” (Jacob, p. 41). Descartes similarly believed “that science in the right hands promised order and progress in the material realm without threatening to unleash

the disorder that early modern states dreaded above all else” (Jacob, p. 46).

Many, particularly in England, considered Descartes’ philosophy to be dangerous for its suggestions of individualism and human equality (Jacob, 1997: 46-47), and for the implication that as matter moved itself, there was no need for a God to maintain the system. In England, after the execution of the king in 1649, nothing was more important than social order and the protection of property; the populist and egalitarian philosophies of many of the radical Protestant sects left the “early modern elite focussed on the danger of popular unrest” (Jacob, p. 53). Many members of radical sects preached philosophies of pantheism or of animism, turning to naturalism and magic, and advocated a science that could justify democracy in church and state. “What must be grasped in the crisis of the 1650s is the important role played by philosophies of nature in giving expression to human goals and aspirations” (Jacob, p.56). A group of moderates who later founded the Royal Society aimed to “promote the organized pursuit of experimental science, but to detach it from any attempt at the radical reform of church, state, the economy, or society. . . . Scientific progress should occur without altering the existing social arrangements in the direction of greater levelling or redistribution of property” (Jacob, p.55).

In the service of this objective Robert Boyle proposed an atomic philosophy that could be tested experimentally, and which implied that “only a providential God, not random chance, was responsible for all motion in the universe. . . and hence maintained the order of the universe” (Jacob, 1997: 58): “The idea that matter is moved mechanically by the will and according to the intelligence of a supernatural God upheld

the orthodox Christian dualism of matter and spirit.” Newton subsequently provided the theoretical basis for this assertion, describing “the power of divine will to move ‘brute and stupid’ matter; the independent, absolute existence of space and time; and, most essential to the concept of universal gravitation, the notion that ‘force is the causal principle of motion and rest’ which operates on bodies in a vacuum” (Jacob, p. 65).

Science was also oriented away from any association with mystical experiences or divine revelation to uneducated people: “knowledge would come to men of merit not through visions or divine illumination but rather through a searching and sustained inquiry into nature” (Jacob, 1997: 59). The intellectual capacities and cultural achievements of some men were also meant to distinguish them from the lower orders of mankind. The ‘common people’ were often dehumanized, likened to beasts and denied full moral consideration, and thus full rights to the ownership of and mastery over nature. This justified their use as labourers and as beasts of burden, and their exclusion from, for example, rights to hunt in enclosed parks (Thomas, 1983).

Re-defined nature enabled these wholesale changes in social purpose, activity and structure because it was stripped of its previous intrinsic teleology and separated categorically from rational humans, being reduced to non-sentient, mechanistic matter to be used and controlled in the service of social progress. This shift from religious to economic priorities required the changed view of nature and its relation to society. Glacken (1967: 382) writes of “the need to believe in the constancy of nature and the regular operation of its laws if any forward-looking attitude toward nature, science, and civilization was to be achieved.” This nature appears completely independent of and

disinterested in human affairs - it is rendered “the permanent, inevitable, essential” (Delaney, 2003: 15) that has social authority in its separation from the artificial, intentional and revisable human - and the culturally laden metaphysical God. Modern social and political theory developed “only when society was given a naturalistic instead of a religious explanation’ (Tawney, 1937: 21).

Social progress through the mastery of nature was achieved through the rise of capitalism: the domination of nature and modern science are linked “both logically and historically with capitalist or bourgeois society” (Leiss, 1972: 178). Tawney (1937) observed that the definitive feature of modern thought is the predominance of economic rationality. “While in medieval thought economic expediency was subordinated to a higher moral authority, the hallmark of modern thought is that economic expediency became the justification for “any particular action, policy or system of organization” (Tawney, p.52).

An economic approach to nature began to spread to the appreciation of the natural world, including consideration of plants as botanical economic resources. In the early modern period when Europeans were exploring parts of the world that were unknown to them, a concerted effort took shape to collect and classify new plant species and put them to economic use. From the sixteenth century, botanic gardens were established for research and commercialization of newly discovered plants (Fowler, 1994). This required a rational and systematic approach to the collection, reproduction and distribution of economically valuable plant material. As Fowler (p.5) argues,

The importance of the discovery of new plants in the New World was not their

discovery, per se, but the fact that the plants could be *used*. . . . The importance lay in the facilitation of exploitation of these new botanical resources, and in the creations of social conditions (including the imposition of slavery) which would make this exploitation profitable.

By the nineteenth century, the development of hybrid seed varieties emerged as a professional occupation and a commercial enterprise. This gave ownership and control over plant materials to commercial interests and began to undermine "the farmer-as-plant breeder and the farmer-as-seed saver" (Folwer, 1994:33).

Such an economic orientation on social interactions with the world entailed a further refinement of human nature; 'homo economicus' became the scientifically articulated natural, universal essence of humanity. Adam Smith's seminal conception of the free market was based on his "'system of natural liberty' [which] . . . explained how the natural desire for self-improvement and the range of natural human capacities could cohere to produce a prosperous economic system . . ." (Cohen, 2006: 14). In this Enlightenment view, culture allows humans to transcend earlier hierarchical models of nature, and to see human nature also as being 'improvable' and thus able to progress towards such social ideals as equality and justice (Soper, 1995: 30). Humans achieved this new purpose in practice by becoming "homo faber":

humans realize themselves through fabrication, that is, through imposing their ends and values on nature, via their labor and their tools/technology; nature itself is bereft of being, of value, until humans work upon such a blank canvas to endow it with being and with value. (Lee, 1999: 128).

The historical process that saw the emergence and establishment of the scientific and economic model of society was essentially the naturalization of the modern vision of the world, a long and negotiated process in which a particular set of social values was

attributed to and fixed in external nature. Nature changed from a symbolic manifestation of a divine creation to an entirely material resource with no spiritual content, moral significance, or agency (Plumwood, 2005: 43). This justified the exploitation of nature with none of the constraints due to an entity with a rational mind or moved directly and purposefully by God. Humans, however, retained their participation in God's design, and gained divine sanction to own and use nature to their own ends. None of these traditions has any empirical foundation or scientific authority (Brown, 2004), yet the anthropocentrism they assert remains dominant in today's "casual moralizing, clinical ethics, legal reasoning, and - most fatefully of all - microeconomics" (p. 14). The combination of the denial of any intrinsic teleology of nature, which "made room for an ontology of materialism and mechanism" and a divinely sanctioned progressive teleology of humanity led to an "aggressive anthropocentrism and instrumentalism, . . . underpinned by modern science, its method and its ideological goal of controlling nature through its technology" (Lee, 1999: 40).

Jacob (1997) presents science as a method and a set of observations that have accumulated defensible knowledge of the physical universe, framed within an interpretive framework that reinforces and authorizes a particular material relationship with nature and relations within society itself. As Cohen (2006: 16) argues, "modern science . . . has long gone with the grain: seeking useful inventions, practical advantages, and the 'relief of man's estate' through a growing mastery of nature's laws and human biology."

Summarizing the core features of modernity as beginning with Locke's

establishment of key principles, Smith (2002) notes three points. The first is the “appropriation of nature transforming it from God’s common gift to humankind to personal property”. The second is “the beginning of the commodification of nature and the introduction of a hierarchical social organisation”. The third is the implicit adoption of the social contract, by which people agreed to “limit one’s inherent freedoms and control one’s inherent nature in the name of reason and social progress’ (Smith, p. 408-9). “These mutually supportive and interacting elements constitute the necessary conditions for the ongoing trajectory of progress, for leaving the state of nature further and further behind” (Smith, p. 410).

Modernity and nature

The modern model of nature provides a progressive purpose for humans against a background of a set of physical natural resources. The assumptions of science and economics have resolved into the fundamental assumptions of contemporary modernity, a ‘nature-transcending’ view (Soper, 1995) that is identified with human exceptionalism and scientific rationalism, a progressivist view of society, and an instrumentalist approach to nature in which social progress is measured in terms of domination of nature (Gregory, 2000; McNaghten and Urry, 1998). As described by environmental sociologists, the conventional modern worldview is the economically dominant Human Exemptionalist Paradigm (HEP): humans are unique on earth as they have culture; culture is variable and changes more rapidly than biological traits; human differences are socially induced and can thus be altered; and cultural accumulation means progress can

continue without limit as social problems are solvable (Catton and Dunlap, 1978: 43). Rushbrook's (2002) cultural theory perspective overlaps here, as she similarly found that the individualist viewpoint, in which humans have to struggle to survive in nature and need to implement technology in order to create social progress, was a minority viewpoint that was expressed by those in industry, and overlapped with government outlooks.

The modern view of nature involves a now secularized mechanistic nature made up of chemicals and particles that obey consistent and universal laws of physics and are thus stable, knowable and predictable. With the emergence of the concept of random, mechanistic nature, the primary qualities of the universe were also quantitative: "number, figure, magnitude, position, and motion . . . qualities which can be wholly expressed mathematically. The reality of the universe is geometrical" (Burt, 1932: 84). The qualities of nature that are available to the senses are secondary, and these are "confused and untrustworthy" (Burt, p. 84).

The scientific revolution provided the cosmological necessities and a morally neutral and mechanical universe that operates on stable physical laws and is separate from the human realm. We cannot directly perceive these laws but, through systematic observation and calculation, we can quantify and predict them. This is the foundation of the fundamental identity of the essence of the universe as uncertain, and of the rationale for mathematical probability as a means of understanding and predicting events in it. Science is explicitly a learned, if not explicitly expert, method of perceiving the world, as the physical laws of nature are not apparent to the casual or the untrained observer.

Although science emphatically “rejects authority [as] anyone can play, including ‘outsiders’” (Park, 2006: 49), it asserts the authority of judgements based on credible scientific knowledge. Collins (2006: 48) defends the exclusion of non-experts from decision making, criticizing the

... romantic value today placed on the instincts of the general public: the folk are said to be as wise, or wiser than, experts. It is a political necessity and responsibility in a democratic society to take account of the technological “preferences” of the people, but this should never be confused with technological or scientific ‘wisdom’. That roads leads to a society that none of us would want to inhabit. . . We must keep hold of the idea that judgement, though never perfect, is generally better done by those who know what they are talking about.

To science the definitive properties of nature are located at an elemental level; humans are at this level inevitably part of nature, yet they are also separate by virtue of their ability to understand these processes rationally and form society and culture. It is the rational mind, which is unique to humans, that is considered to produce credible knowledge, and ranks above emotion or other subjective ways of knowing that humans may share with animals.

Though they share a realist and rationalist approach to physical nature, scientists differ to some extent in their disciplinary emphases in defining nature. The dominant scientific view of nature takes a molecular-scale, physical and biochemical perspective (McAfee, 2003) in which nature is viewed as particles, forces, and electromagnetic fields that operate on and between fundamental particles, and constituent parts of things (Penrose, 1992). Biologists, despite their interest in communities of organisms, also focus on nature at the elemental level, taking advantage of the discovery of DNA to examine evolution at the molecular level (May, 1992). And theoretical ecologists, whose

field requires the 'synthesis' of individual components of an ecosystem, nonetheless study "components and their interactions individually" using "tools that are essentially reductionist" (Perry, 2003: 153-4). This "molecular-genetic reductionism" (McAfee, 2003: 207), assumes that 'the whole can be understood by analysis of its individual parts.' Genes are conceptualized as "unitary objects with stable, predictable properties"; "functional units of information which can be characterized precisely, counted, added or subtracted, altered, switched on and off . . ." (AcAfee, p.204).

Engineers have a more explicitly pragmatic approach to nature. Human and technological systems are seen as analogs to natural systems: "In a developed industrial society there exists a set of interrelationships that tie together energy use and a wide range of physical, economic, and social aspects of life. This is no different, in concept, from the web of interrelationships which form the ecology of natural systems" (Starr, 1990: 12). When technology is seen as natural mimicry, there is nothing distinctive about changes brought about by social intervention, and interventions that benefit society are actively pursued as improvements to society.

The important purpose in transforming nature with technology is economic growth, the engine of the improvement of affluence and health and a "measure of social success" (Starr, 1990: 13). In an economic perspective, nature is considered society's natural capital; using nature wisely to improve people's health and living conditions is a moral imperative. This natural capital consists of such resources as fossil fuels, minerals, agricultural soils, or recreational areas used by societies to create wealth. In a more specific sense, nature is a set of ecosystems and populations that combine to make up

natural and wildlife resources. These are defined in terms of their use by and value to humans and economies, and as such need to be managed by society, usually by governments to ensure sustainable catch, cuts, yields, or other such ‘harvests’ of the resource. This applies to forestry and fishery resources, for example, which are the basis of commercial industries, and to certain types of wildlife that are the basis of hunting and fishing industries. Governments monitor and control the number of bears, deer, moose and other game animals that are considered a resource managed by harvest each year, to sustain tourism and hunting industries (Ministry of Natural Resources, 2001). Likewise, excess populations of animals such as deer that damage agricultural crops are culled to maintain a more manageable population. Even policies to protect and preserve natural diversity are based on:

... an anthropocentric resource-use policy, not an ecological model. Consumptive demand measured against resource supply, not ecosystem function, determines the limit of sustainability. What is the maximum amount of mahogany, or tuna, or leopard pelts that can be harvested and still allow projected human demand for the product to be met for the foreseeable future? (Meyer, 2006: 54).

Price (2004) and Brown (2004) argue that the dominant method for determining the value of nature is the neoclassical economics contingent valuation method, which accepts “the utilitarian theory of value, with its hedonism, its monism and its formalism. Nature’s value is solely its capacity to produce pleasure in us, and that value can inherently be substituted for by other forms of pleasure (for example, monetary payoffs)” (Price, 2004: 198). Even more recent ecological economics approaches, which base their evaluations on measures of ecological energy, entropy, and distributions of matter (ibid:

193), retain the neoclassical focus on quantification and accounting: “*Neither* neoclassicism nor ecologism shows much interest in limiting the scope of economic reasoning” (ibid: 194, original emphasis).

Yet the basic anthropocentric assumptions of economics cannot be defended, let alone proven, by science; on the contrary, evolutionary biology may be more likely to demonstrate that humans are closer to many forms of non-human life than that they are distinct from them (Brown, 2004). *New Scientist* magazine (2007) has recently editorialized about “a long list of supposedly unique human behaviours and abilities that have been discovered in other animals:

Whales apparently have empathy, baboons and chimps can demonstrate abstract thought, chimps and elephants can recognize themselves, scrub jays have foresight and chimps a basic sense of morality, or justice. . . . Chimps and monkeys have an extensive ‘vocabulary’ of calls, and whale song has a grammar with hierarchical syntax.

Science and economics are, like their respective categories of nature and society, separate, and proceed on different terms. While the elemental focus of science does not corroborate the assumptions of economics it does not explicitly refute them - indeed, “there is no empirical evidence that the world was made for humanity, and no hypothesis that can be falsified” (Brown, 2004: 14). Economic positions are value-based, and thus less objectively and authoritatively grounded than are positions verified by science.

Romantic/ Ecocentric perspectives

By the late eighteenth century, a reaction was developing against rising urban industrialism and the rationalist attitude to nature. The city - and associated concepts of

the state and complex civilization - became identified with corruption and decay, while nature became identified as free of corruption and a place of retreat for city dwellers. In late eighteenth-century romanticism, the city is profane and nature is not wild but tamed by agriculture; the ideal landscape is a "middle region" between the chaos of the city and the chaos of wilderness. By the end of the nineteenth century "it is the city - the original paradigm of cosmic order - that is called 'wilderness' with something of the primitive meaning of that awesome word" (Tuan, 1971: 38).

This romantic 'rebellion' idealized nature, particularly the 'sublime' wild nature that resonated with people's creative imagination. Nature is "counterposed to the utilitarianism and instrumental rationality through which the Enlightenment ideals were practically realized and theoretically legitimated: the point is not to return to a past primitivity, but to discover in 'nature', both inner and outer, the source of redemption from the alienation and depredations of the "cash nexus" (Soper, 1995: 29).

While it originated in a response to industrialism, Romanticism was also continuous with the longer tradition of pastoralism which, beginning with Virgil in classical times and appearing through renaissance and eighteenth-century literature, idealized a simple, rustic livelihood in nature as a retreat from society. Indeed, as Ridder (2007) notes, "the cultural tendency to link nature to autonomy from society has a long history," going back to ancient China. The pastoral ideal is a "lament for a destruction of a more 'natural' way of life of the immediate past" (Soper, 1995: 188), in which the older order that is to be preserved from the corruption of modernity is imbued with the mythic qualities of the pre-historic 'unworked' nature" (Soper, p.190). It is characterized

by its lack of urban corruption; both romanticism and pastoralism “originate in a recoil from the pain and responsibility of life in a complex civilization” (Marx, 1964:22).

In the modern industrial West, concepts of nature derived from Romanticism remain among the most commonly held among non-scientists. They are represented by a cluster of more precisely articulated philosophies and looser outlooks, including ecology, deep ecology, ecocentrism - to which Soper (1995) refers collectively as ‘nature endorsing’ for their tendency to hold a realist model of the natural world that is intrinsically valuable as a separate domain, an “essentially innocent and benevolent power” (p. 31).

Many broadly ‘nature-endorsing’ perspectives begin with a conception of physical nature that differs from the strictly scientific model largely in being contextual and including a strong focus on process as well as composition. This view considers that “parts cannot be understood except in the context of the whole, living organism, developing and evolving in continuous, dynamic interaction with its environment, and altering that environment in the process’ (McAfee, 2003:207).

For the past several billion years evolution on Earth has been driven by small-scale incremental forces, such as sexual selection, punctuated by cosmic-scale disruptions - plate tectonics, planetary geochemistry, global climate shifts, and even extra-terrestrial asteroids (Meyer, 2006: 1).

Reproductive processes that occur in nature include sexual and asexual reproduction within species. Changes occur through natural selection, in which certain characteristics resulting from random mutations adapt in a local ecosystem (Kneen, 1999; Clark, 1999; Holdrege and Talbott, 2001). Essential to natural evolution is the

process of selective pressures that an ecosystem exerts on an organism as it adapts and survives, or dies out.

A large study of American environmental values (Kempton et al., 1995) found that most people hold one of three related models of nature: as a unique, fragile and closed system with which people should live in harmony for their own survival; as interdependent and fragile in the face of larger disturbances; and as balanced and unpredictable, with different elements and sub-systems of nature so interdependent that affecting one causes cascading effects through the others in a chain reaction that is so complex that it cannot be predicted.

Rushbrook (2002), working with the three 'active' biases in cultural theory - the individualist, egalitarian, and hierarchist - observes that the most of the public are aligned with the egalitarian viewpoint. In this perspective nature is vulnerable: humans should work in harmony with nature, and industrial interventions are considered likely to have catastrophic environmental consequences. This assumption leads to a proscription against human interference in nature because the limits of our own knowledge and understanding of ecosystem complexity prevent us from predicting the effects our intervention might have.

People tend to see physical environments as natural when they do not include people; nature is "other," untouched, lacking human access, vast, unnamed, and not privately owned. A landscape that shows visible signs of human impact, including designed and placed elements, appears to be less 'natural'. The 'consensus assumption' within environmental psychology is that, for evolutionary reasons, people generally

prefer natural scenes that do not include human influence (Van den Berg et al., 1998).

Natural environments are preferred for restorative purposes, while urban environments are preferred for socialization. 'Restoration' in this context is "mental rest and recovery from stress" or from attentional fatigue (Staats et al. 2003). The preference for natural landscapes for restoration may actually be due to "a decrease in preference for urban environments" (ibid: 155); restoration requires, most importantly, 'being away', a psychological distance from one's regular routine (Korpela et al., 2001; Herzog et al., 2003), and natural environments are seen as being free of social responsibilities and constraints (Mausner, 1996). Preferred restorative environments thus appear to be natural largely insofar as these offer a venue for withdrawal from society, solitude, and a supportive setting for personal relaxation and contemplation.

The romantic perspective sees untouched nature as the source of original innocence and as having intrinsic value, being a coherent order that embodies the principles that are of ultimate value to humans; it is degraded by organized civilization, the source of corruption and decay. Nature is 'other', and has "its own teleology and integrity. . . a wisdom that can be trusted" (Deckers, 2005: 466). It is "balanced, highly interdependent and complex" (Dunlap et al., 2000). As separate from society and having its own internal integrity, nature is outside of, and transcends, social systems. It is unplanned, and lives and grows by itself (Verhoog, 2002).

The new 'ecological' perspective that is emerging in Western nations (Catton and Dunlap, 1978; Schultz and Zelezny, 1999), the New Ecological Paradigm (NEP), is said to "reflect the degree to which people define self as part of nature" (Schultz and

Zelezny, 1999: 263; Hodgkinson and Innes, 2000). However, a central assumption, that “nature is balanced, highly interdependent and complex” which makes it “susceptible to human interference” (Dunlap et al., 2000: 429), suggests that nature is a system that is ‘meant’ to function without humans, with a separate, material coherence and integrity that it loses when humans modify it. Butler and Acott (2007) also found that a majority in their study held an ecocentric position, which centred on a belief that nature has intrinsic value, and that people also value and should respect nature. This led to a belief that there is a limit to the degree that society should modify nature, and that “we have a duty not to exceed that limit” (Butler and Acott: 166).

Ecocentrist philosophies centre on the notions that a separate, wild nature is inherently valuable, in itself for the life that exists in it and as a spiritual connection for humans, and that such wilderness is threatened, if not already eliminated, by human industrial activity. Ecocentrist approaches have both a spiritual focus, in stressing the need for humans to retreat periodically to wilderness, and often a strongly radical critical analysis of the intrinsically destructive tendency of modern industrial society. Somerville (2006: 111 - 114) laments that many people in modern society have lost a sense of “connection” with the natural world and its ‘fragility and preciousness’; we need to regain our respect for the natural and “revere nature”: “we are unique in that we have two roles with respect to nature: we are both an integral part of it and, because we alone have the power to destroy it, we must be its protector.” As Price (2004: 95) notes,

Ethicists claim that nature’s value is of an entirely different kind than is economic value; where the protection of wild nature is concerned, economic reasoning does not apply. This effective walling off of nature from economy is

accomplished by establishing a direct moral claim that nature exerts on us.

Nature is associated with an enduring stability that is interpreted as dependability in a spiritual relationship. "Life persists in the midst of its perpetual perishing. Mountains are reliably there generation after generation. The water cycles back, always moving. In wilderness, time mixes with eternity: that is one reason we value it so highly" (Rolston, 1991: 274).

The 'pristine' nature versus society distinction is the crux of some more radical ecocentrists' argument. Nature truly exists only where there are no people or human alterations of the landscape; that is, wilderness. Human culture is "radically different from wild nature. . . . Information in wild nature travels intergenerationally on genes: information in culture travels neurally as persons are educated into transmissible cultures"(Rolston, 1991: 368). This renders human action in the environment qualitatively different from impacts made instinctually by animals, such as beaver dams or bird nests which are considered 'natural' while even minor human-made impacts are seen as artificial (Soper, 1995). Rolston (1991: 370) considers that nature affected by humans is degraded, saying that it is a "fallacy to think that a nature allegedly improved by humans is anymore real nature at all. The values intrinsic to wilderness cannot, on pain of both logical and empirical contradiction, be "improved" by deliberate human management, because deliberation is the antithesis of wildness. Nature is spontaneous and genetic, adapting through natural selection, while human adaptations to the world are a social artefact: "humans rebuild their world through artifact and heritage, agriculture and culture, political and religious decisions" (Rolston, p. 370).

In his ecocentric critique of modern society, Bill McKibben (1989) has famously proclaimed the 'end of nature'. There is no more nature to conserve; everything in our environment is artificial, as it has been affected by industrial processes and substances. Industrial pollution is globally destructive, in contrast to the "normal" destruction of nature that humans have traditionally engaged in, which was local and reversible. While McKibben makes a detailed case for the real, physical changes that industry has made to the global environment, he also argues that the 'actual' state of the environment is no longer the point. He describes a "new rupture with nature [that] is different not only in scope but also in kind from salmon tins in an English stream. We have changed the atmosphere, and thus we are changing the weather. By changing the weather, we make every spot on earth man-made and artificial. We have deprived nature of its independence, and that is fatal to its meaning. Nature's independence *is* its meaning" (McKibben, p. 58).

The significance of social intervention is that our awareness of it destroys our faith in nature. Whereas the 'old' nature was characterized by its "utter dependability," "the salient characteristic of this new nature is its unpredictability" (McKibben, p.96). We no longer have that faith, whether the nature we live in is affected or not. Nature is now a "man-made phenomenon" - or it might be; one can no longer be sure that phenomena are the result of laws of nature or "the laws of nature as they have been rewritten, blindly, crudely, but effectively, by man" (McKibben, p. 59).

Many ecocentrists believe that people should stay out of wilderness areas in order to protect them; yet nature is also held up as the true spiritual home of human

beings and its preservation is important for that reason. While people see themselves as being apart from nature, they also yearn for a reintegration into nature and a more spiritual experience of being in nature (Mausner, 1996). Ecocentrists feel a profound connection with nature - "when I am backpacking or canoeing, hunting or fishing in a Wilderness, I am home" (Foreman, 1998; 404). They trace this back to humans' cultural development as hunters and gatherers in a harmonious relationship with all of nature that was lost with the shift to an agricultural way of life (Rolston, 1991: 370; Oelschlaeger, 1991). The human intrusion of critical importance is civilization, or technology itself - specifically modern, noisy, visible technology (Marx, 1964; McKibben, 1989). We yearn to get back to nature, but can do so only as individuals making a spiritual connection, not as a society; and for only a brief period. There is a distinction made between the human and the social as the categorical opposite to nature: as individuals, humans retain an intuitive link to nature and can reconnect spiritually; society, however, as a rationalist, hierarchical and dominating entity, is mutually exclusive to nature and contaminates nature. Once nature is seen as whole and intact only when it is empty of humans, it cannot be a working landscape for society; such a thing may exist, but it is no longer nature (White, 1995).

McKibben has been roundly criticized for his naive idealization of a "virgin nature," (Soulé (1995; also Graber, 1995; Lee, 2005) that is extrapolated from the awareness that nature is everywhere modified by society. As Vogel (2005: 302), argues, McKibben "wanted to think of nature as Otherness, but he understood this so literally and flatfootedly that for him as soon as humans put their dirty fossil-fuel burning paws

anywhere near it, it immediately loses its otherness and meets its 'end'".

Others argue that the understanding of nature as a process allows some human activity in nature without stripping it of its integrity, depending on the type of intervention (Myskja, 2006; Verhoog et al., 2003). Some activities, such as organic farming, are considered to be conducted in a cooperative rather than a dominating spirit, and appear to be harmonious with nature. There are gradations of human actions in the environment, the ethics of which are guided by notions of the positions of both nature and society. When people use nature, as in agriculture, they should do so in accordance with natural principles and in an interactive context that recognizes ecosystem interdependencies (Verhoog et al., 2003). Human action in nature should show respect for the 'otherness of nature' by working as a partner with it rather than trying to control it or 'going against the grain' (Myskja, 2006:236). Interventions into the deep structures of nature or attempts to control nature (Myskja, 2006; Streiffer and Hedemann, 2005) exceed the proper relationship of humans to nature - "Attempts to change the natural order in radical ways . . . were perceived as failures to accept the natural order, and therefore, *prima facie*, wrong" (Deckers, 2005: 466).

Both the politically dominant modern view and the alternative ecocentric concept of nature define nature as separate from social law and relations; and indeed philosophers argue that this is a reasonable distinction that recognizes the important qualities of nature and makes explicit the definitive properties of the social realm. The conventional modern viewpoint privileges the social, as it developed historically to do, giving priority to generating social value through the use of nature. Nature's biophysical

and morally void character makes it a thoroughly appropriate raw material for the advancement of human progress. In the ecocentric perspective, nature has intrinsic value and agency, and this positive autonomy stands as a constraint on social intervention. When modified by social action, nature incorporates the social power relations and becomes an artefact.

The different views of the artefact raise the question of the moral status of social intervention into nature, and of social progressivism itself. While conventional moderns consider the progress of science and technology to be a heroic advance towards greater human understanding and control of nature to the benefit of society, ecocentrists see social interventions as being of ambiguous value, and weigh the social value and purpose of the intervention and its risks and benefits. Much debate among ecocentrists focusses on the limits to human intervention in nature that are implied by nature's intrinsic value, and on the degree and the kind of intervention that can be made without rendering nature artefactual.

The separateness of nature from social relations makes it a valuable strategic category to which to attribute social actions that appear to some to exceed the limits of proper human interventions into nature, and invite unwelcome public challenge about unequal benefits and risks. This attribution is often achieved with the use of the scientific concept of risk, which thus becomes a focus of controversy over technological interventions into nature.

Chapter 3

Nature and Risk

Attending to the definitive qualities of nature and society clarifies those interventions that are considered significant by those identifying with conventional modern beliefs and those with more ecocentric values. These distinctions are given further contour as nature and society are viewed within the context of risk, both scientific risk analysis and broader evaluations by the non-scientific public.

Debates about the use of technology in society, such as genetically modified foods, are commonly referred to as risk controversies, and the regulatory regime and institution are the focus of debate about whether the approvals of and controls on the technology are appropriate. The terms in which risk is assessed and managed are therefore central to the debate, and have been themselves the focus of controversy over technology implementation. Risk assessment and the definition of risk that is at its core are based in a scientific concept of nature, and are authorized by the scientific process and expertise that give science its structure and credibility. The cultural context that shapes risk assessment and the range of activities involved in risk management place formal risk management in the wider scope of regulation theory, as aspects that contribute to a higher level management of the economic system itself. Public views of risk, in contrast, are more contextual and value-based, and show a distinct relation to concepts of nature.

Technical approaches to risk, hazard and risk assessment

Risk and hazard are related terms that are often used interchangeably, but which have important differences. Risk is a complex term that incorporates the simpler concept of hazard. A hazard is defined as “a source of potential harm” (Canadian Standards Association, 1997); it is a fundamental characteristic that is inherent in a substance or activity itself. Risk incorporates hazard as well as exposure to the hazard and the likelihood of a resulting consequence, expressed quantitatively as a probability of occurrence within a given time period. Its most basic technical definition is ‘risk equals probability times consequence’; or ‘the likelihood of occurrence of an adverse effect within a specified time-frame’ (Thomas and Hrudey, 1997: 264). The consequence used in calculating risk is defined according to the field of application, conventionally death for health and safety risk, though more recently other measures of health effects are used.

While hazard is a feature of danger or harm inherent in a substance or activity, risk separates the possibility of harm from the hazard itself, and further distinguishes the degree of exposure to the hazard and the likelihood that the defined harm will occur in a given population. The risk is then expressed as a mathematical probability. Risk is abstract, precise in numerical calculation but imprecise as to when, where, or to which individual in a population the effect may occur.

The modern technical definition of risk shares science’s non-contextual, elemental vision of nature. It relies heavily on the concept of probability, assumed by conventional science as reflecting a property of the objective physical universe. However, underlying probability are deeper assumptions about the world in which the

events of concern occur. The essential element required for probability is the random physical universe, which emerged only with the scientific revolution (Hacking, 1975). Probability is defined as “a branch of mathematics concerned with the analysis of random phenomena. The outcome of a random event cannot be determined before it occurs, but it may be any one of several possible outcomes. The actual outcome is considered to be determined by chance” (Encyclopaedia Britannica, 2001).

There are two important aspects of probability: the first is that of relative frequencies, in which, over many instances, there is regularity in occurrence of particular outcomes, but the outcome of any specific trial cannot be predicted. The second type, subjective probability, is a personal measure of uncertainty. It states a degree of belief that an event will happen, based on our state of knowledge of contributing factors.

As applied in risk assessment, risk is “the chance of injury or loss as defined as a measure of the probability and severity of an adverse effect to health, property, the environment, or other things of value” (Canadian Standards Association, 1997: 3). Risk assessment as a quantitative technique “originated in the finance and insurance industries, and was adapted for use in hazardous industries during the expansion of nuclear power in the 1960s and 1970s. . . . In 1983 the influential U.S. National Research Council promoted [the shift to risk assessment in regulation] by defining risk assessment as a largely scientific component of regulatory decision making that should precede, and be separated from, value judgements that were considered appropriate only at the later stage of ‘risk management’” (Jasanoff, 2005: 256). The strength of risk assessment is its “scientific rigour” and “logical and consistent methods” by which it

arrives at “sound decisions” (Neram, 2000). Risks measured through this process are taken by risk assessors to be the ‘real’ risks that are most likely to do us harm.

Risk assessment usually consists of three steps: hazard identification, risk estimation, and risk evaluation. Hazard identification involves identifying a threat to health or safety, including a “preliminary assignment of frequency and consequence to the risk scenario” (Canadian Standards Association, 1997: 15). Risk estimation is the step at which a quantitative measure of the risk is generated. For toxicological risks, this is based on a dose-response assessment that estimates the probability of harmful effects from a specified exposure, exposure assessments of the types of exposure likely in the population, and a risk characterization that combines these assessments and “specifies the likelihood of harmful health effects for various levels of exposure within a range of likely exposure scenarios” (Neram, 2000:1-7 - 1-8). To estimate risk from technological systems, engineers “attempt to quantify the risk by a physical appreciation of possible failure mechanisms or modes and their analyses” (Crossland et al., 1992: 13). This may include use of records of the failure rate of components, fault-tree analysis and other modelling techniques (Crossland et al., 1992; Canadian Standards Association, 1997: 20).

The risk assessment professional is bound to serve the public interest, which is equated not with public preferences but with an improvement in health and life expectancy of the greatest number in society and the best use of public funds to achieve this goal. In Canada, the Joint Committee on Health & Safety of the Royal Society of Canada and the Canadian Academy of Engineering (1993: 5) argued that the present

approach to risk management is inconsistent and often driven by a desire of the public to reduce already low risks. “Sober scientific assessment of the level of actual harm involved in most of the dramatic and sensational cases (for example, PCBs, asbestos, alar, radiation, trichlorethylene, etc.) invariably confirm a low level of risk” (Lind et al, 1991: 153). Public perceptions are dominated by “misperceptions of hazards, sensationalism, vociferous interest groups and faulty indicators” ((Lind et al, 1991: 3); public perceptions should therefore be “recognized as an irrelevant factor” (Lind et al, 1991: 20). This rationalist model of risk probabilities and technology acceptance has generally assumed a ‘knowledge deficit’ model of non-scientists’ risk judgements.

Hansen et al. (2003) describe the rationalist model in terms of four key assumptions:

- that subject to acceptable levels of risk, the optimisation of productivity is a commonly shared value in modern societies;
- that the acceptable levels of risk associated with optimal productivity are universally, or at least widely, agreed;
- that scientific knowledge is the most effective, and hence desirable, basis on which to improve both the production of goods and risk control, and therefore, scientific evidence should be the primary guide in risk management;
- if the public does not comply with the advice and recommendations of scientific experts, this is because they have a poor understanding of the scientific reasoning informing that advice, i.e. a ‘knowledge deficit’ (p.112).

The objectivity of science and of risk assessment has been critiqued in recent years, leading to some reconsideration of the value of risk assessment and the appropriate applications of it. Critical examinations of risk assessment have contributed to the growing recognition of science as a social and subjective, rather than an objective and value-free, activity. Work by philosophers such as Shrader-Frechette (1991) shows many

persistent value biases embedded in the scientific practice of risk analysis and assessment itself.

The first criticism is that risk assessment does not have the scientific clarity or objectivity it claims, as any scientific methodology involves values and choices of inputs and processes. (Shrader-Frechette, 1991). Although frequency probability is optimum for health risk assessment (Hrudey, 1998), these assessments often include a large measure of inference, or subjective probability, since “there is rarely adequate and relevant frequency data to develop a strictly actuarial approach” (Jardine and Hrudey 1997: 492). Toxicology assessments increasingly use a distribution of risk estimates rather than a single estimate because of uncertainty resulting from incompleteness or unavailability of data, or from difficulties in determining appropriate mathematical models; these uncertainties often require that scientists “make inferences, assumptions, and judgements in order to characterize a risk” (Health Canada, 2000a: 34). With respect to risk estimates of technological systems, Crossland et al. (1992) note that since “it is not acceptable to wait for a body of disasters to occur so as to build up a body of case histories as a basis for policy decisions, an anticipatory approach based on judgement and experience is required” (p. 13). Furthermore, technical calculations and models used in risk assessments use simplifying assumptions that are often at variance with exposures of real people to risks, or that homogenize members of a population so that meaningful risk information for individuals cannot be provided (Jasanoff, 1998).

This situation means, first, that the precision and reliability that are expected of risk analysis are greater than it can deliver, given inevitable uncertainty and “unknown

unknowns” (Freudenburg, 1996: 49). Failures in technology that were not prevented by such analyses undermine the credibility of risk assessment and science. Secondly, it renders risk assessment much more entirely a matter of judgement, value, and social priority than of quantifiable risk estimates. Studies on risk judgements of experts have shown that while the clearest split in perception is between experts and non-experts, (Kraus et al., 1992), scientists are not a homogeneous group and bring disciplinary and personal biases to their professional judgements Barke and Jenkins-Smith, 1993; Mertz et al., 1998). A post-modern critique of science argues that science is a cultural activity and thus does not have a greater claim to credibility than any other type of knowledge. Societal decision making should thus not privilege one kind of knowledge (Pollak, 1996).

The second criticism is that scientific risk evaluation strategies are not appropriate for social risk management decisions. Shrader-Frechette (1991: 56) argues that using probabilistically assessed risk as the standard for risk management challenges the democratic control of technology by ignoring the full range of qualitative considerations about technology and reducing them to mathematical probabilities. Shrader-Frechette further argues that the utilitarian principle for evaluating the acceptability of a risk is not an appropriate decision-making framework on a societal scale, since decision-makers can never know the preferred utility that members of the public would maximize.

Risk assessment cannot resolve or transcend contentious issues through attempts to be objective (Graham and Rhomberg, 1996; Jasanoff, 1998), and conflicts over risk

management will remain to be resolved through other means. It is clear from risk perception and other risk research that the values embodied in risk judgements are the most important component for many in the public, and these need to be explicitly included and addressed. Citizens want to see these values reflected in risk management policy (Pollack, 1996). Shrader-Frechette (1991) argues that advocates of objective risk assessment are “naive positivists”; risk evaluation and management are “irreducibly political” and should be treated as such (p. 218)..

Researchers in many fields now often claim to incorporate an understanding of the importance of interactions between physical and social processes in the causation of risks and hazards. In response to these critiques many recent guides on risk assessment note the importance of social values in risk management decisions and differentiate between risk assessment and management (Canadian Standards Association, 1997). In other applications efforts are made to state assumptions, and note the different results achieved through the use of different assessment methods (Thomas and Hrudey, 1997). The CSA standard and the Health Canada (2000) risk management framework give high priority to communicating the assumptions and the progress of a risk assessment process to the stakeholders and the public.

Recent applications of risk assessment in Canada

In its risk assessment practices, Health Canada uses its own Decision-Making Framework for Identifying, Assessing and Managing Health Risks (Health Canada, 2000a). This consists of six inter-related steps, grouped broadly under the headings of

issue identification, risk assessment, and risk management.

In the first step, issue identification, officials “clearly define and describe the issue and its context. This is key to focussing risk assessment efforts, identifying risk management goals, selecting efficient and effective strategies, and appropriately allocating resources” (Health Canada 2000a: 14). This leads to a preliminary identification of hazard and exposure, for a preliminary risk characterization. Risk management goals are varied, and can be risk-related - reducing adverse health effects; related to public values - protecting vulnerable sub-populations; or economic - balancing health protection while avoiding loss of jobs. Goals will also be directed by legislative and policy requirements.

Risk assessment is a core activity, which “involves determining the likelihood that a specific adverse health effect will occur in an individual or population, following exposure to a hazardous agent” (Health Canada, 2000a: 27). The risk assessment uses “biological, chemical and physical data from scientific studies” in considering hazard, exposure, exposure pathways, and other risk factors. Health Canada (2000a) emphasizes that “risk assessment must be conducted distinctly from other activities. Appropriate mechanisms must be in place to ensure that there is no interference with the scientific assessment of risk” (p. 27). The final risk assessment consists of a quantitative estimate of the risk and a description of the uncertainty involved. Health Canada’s Framework includes procedures for a benefits assessment, but this is not usually undertaken in risk assessments (MacKenzie, 2000: 52), and its inclusion in the framework “is not intended to imply that benefits (known or potential) must be assessed in every situation

(MacKenzie, 2000: 37).

At the risk management stage, information provided by the scientific risk assessment is considered in the identification of options for risk management. Health Canada's (2000a) primary objective in risk management is "maintaining and improving health" (p. 44). A range of risk management options are available:

- **regulation:** direct regulation, self-regulation in compliance with legislated requirements; permits and approvals
- **national guidelines:** include voluntary standards and codes of practice
- **education/advice:** information to help risk producers reduce risk, help more informed decisions
- **voluntary compliance:** encouraging risk producers to take action
- **economic:** financial incentives and disincentives to reduce or limit risk
- **technological:** development or application of new risk-reducing methods
- **taking no action when none is required:** maintain current level of risk protection, when risk is negligible or current management is sufficient (Health Canada 2000a: 41)

Science and scientists are central at each stage: "scientists produce and collect the data relevant to the issue, assess the risks based on all available evidence, and identify possible courses of action. They are an essential voice during the decision-making process where all risk factors are considered and weighed against potential benefits. Once a course of action is determined and implemented, scientists will also monitor and evaluate effectiveness" (Health Canada 2005a). Stakeholders and members of the public can "play a key role in issue identification, risk assessment and risk management" (Health Canada 2000a: 11), providing information, knowledge and insights, and should be involved throughout.

Health Canada's decision-making framework exists within a government-wide strategy on risk assessment and management. The Treasury Board of Canada's Integrated

Risk Management Framework (Canada, 2001: 4) was developed as part of the federal government's "new management framework", that "supports a whole-of-government view grounded in rational policy setting and principles of responsible spending" (Canada, 2001).

In an increasingly complex public policy environment, it is important that Public Service employees are encouraged to approach their work with creativity and a desire to innovate. At the same time, however, we must recognize and respect their need to be prudent in protecting the public interest and maintaining public trust. Achieving this balance is what this *Integrated Risk Management Framework* is all about (p.1).

The Integrated Risk Management Framework defines risk as "the uncertainty that surrounds future events and outcomes. It is the expression of the likelihood and impact of an event with the potential to influence the achievement of an organization's objectives" (Canada, 2001: 4). This definition shifts the stress of the concept of risk from the likelihood of adverse effects to uncertainty, and includes benefits as well as risks among the possible outcomes.

Risk management is defined in the Integrated Risk Management Framework as "a systematic approach to setting the best course of action under uncertainty by identifying, assessing, understanding, acting on and communicating risk issues." Integrated risk management is "... about making strategic decisions that contribute to the achievement of an organization's overall corporate objectives" (Canada, 2001: 5).

In order to apply risk management effectively, it is vital that a risk management culture be developed. The risk management culture supports the overall vision, mission and objectives of an organization. Limits and boundaries are established and communicated concerning what are acceptable risk practices and outcomes (Canada, 2001: 4).

A key tool, shown in Table 3-1, increasingly used in risk management frameworks is the 'risk management model' that scores the significance of a risk and indicates the appropriate management strategy.

| Impact | Risk Management Actions | | |
|-------------|---|-------------------------------|--------------------------------|
| significant | considerable management required | must manage and monitor risks | extensive management essential |
| moderate | risks may be worth accepting and monitoring | management effort worthwhile | management effort required |
| minor | accept risks | accept, but monitor risks | manage and monitor risks |
| | <div style="display: flex; justify-content: space-around; align-items: center;"> Low Medium High </div> <p style="text-align: center;">Likelihood</p> | | |

Table 3-1: Risk Management Model, from *Integrated Risk Management Framework* (Canada, 2001: 14)

Risk, as the likelihood of an adverse outcome from exposure to a hazard, is the calculation of a hypothetical, but specific, event to help avoid adverse impacts. With recent shifts in the approach to risk as a concept, and in the application of risk assessment in risk management, risk has become something we take. Risk is a calculated aspect of a larger strategy of implementing societal and economic scale activities, a step in the active process of fine-tuning design and implementation to maximize benefits and minimize costs. "Modern scientifically based risk management rests on the idea that we can derive significant new human benefits by becoming increasingly cunning in shaving the margin of error in our manipulations of nature" (Leiss, 2000:64). "When assessed and managed properly, risk can lead to innovation and opportunity" (Canada, 2001: 4).

The Integrated Risk Management Framework is meant to apply to all corporate activities and types of risks they may entail, and as such is non-specific about the organizational objectives that may be in place. With respect to health risk management, an executive level perspective is expressed in the 1999 Report of the Commissioner of the Environment and Sustainable Development (OAG, 1999: 3-8 - 3-10). It summarizes the diverse activities involved in managing toxic substances, saying that

The ultimate aim of these activities is to permit the safe and productive use of chemical substances while safeguarding Canadians and their environment from unacceptable risks. . . . We are often faced with choices involving trade-offs between risks and benefits. Modern chemicals provide important economic, health and social benefits. Therefore, actions to reduce risks by eliminating exposure can have significant economic and social implications. For this reason, stakeholders often debate whether the costs of reducing the risks, including lost uses of the substance, are worth the benefits.

Laypersons' risk perception

Early risk perception studies within the 'psychometric paradigm' described a set of subjective risk characteristics that, in combination with decision-making heuristics and details of cognitive limitations, were used to describe the divergence between risks as perceived by non-scientists and 'real' risks as determined statistically. These were cognitive and social psychology laboratory studies in which participants ranked hazards and activities according to their risk.

The main finding was that unlike risk professionals' probabilistic approach, laypersons' approach to risk is qualitative and multidimensional. Laypersons include a number of considerations in composite risk judgements, including the familiarity, catastrophic potential, equity, and the level of knowledge of the risk to their ratings; and

often rely on heuristics, such as the amount of media coverage of a subject (Slovic, 1987). In distinction from the scientist, the non-scientist is uninterested in the key risk factors of statistical probability of occurrence, dose and exposure (McGregor, et al., 1999), and is primarily concerned with the social context and possible consequences of a risk.

Psychological research on risk management is often concerned with risk communication. These studies attempt to understand the factors that contribute to the credibility of risk information and messages, and find that people are aware of different information sources and regulatory roles and assign responsibility and trust accordingly. The Social Amplification of Risk Framework (SARF) adapts communication theory to describe a set of information sources and channels that influence the way an individual and community may respond to a risk (Kasperson, et al., 1988). This approach has contributed an awareness of the social and often fluid and dynamic character of risk issues and debates. It has been criticized, however, for suggesting, not always explicitly, that individuals are largely passive recipients of information and societal communication processes (Holick-Jones et al., 2003).

The SARF claims to account for the shifting character of risk perceptions, which it portrays as constantly re-evaluated in ongoing social processes of considering new risk information. Much risk communication literature has been based on this 'causal chain account' of risk perception (Eiser et al. 2002) in which trust in risk information drives risk perceptions. That is, trust in the information source is said to shape perception of the risk of a technology, which in turn shapes acceptance of the technology and the social

impacts and 'ripple effects' of such social attitudes. Distrust is linked to a sense that risk information is hidden or controlled by vested interests, so that greater transparency and participation will increase trust in official sources and reduce public susceptibility to media messages that amplify a risk (Frewer, 2003).

This general approach has recently been challenged, as research and perspectives on risk judgements broaden to acknowledge more mature social judgements on political aspects of risk. Frewer et al.(2003) contend that neither source credibility nor social trust drives risk perception, but that each is an independent reflection of "prior and more general attitudes towards the technology" which are not subject to change with new information but are relatively stable.

Within the psychometric approach, the concepts of risk and benefit have conventionally been understood as distinct: that is, the "nature of the gains attained from pursuit of a hazardous activity or technology is qualitatively different from the nature of the risks" (Finucane et al., 2000: 3). The tacit assumption has been that there is general agreement on benefits, and that assessments, decision making, and differences of opinion focus on risks (Gaskell et al., 2004).

Recent research has shown, however, that evaluations of the risks and the benefits of an activity are integrated together into a general 'affective' evaluation of the activity. 'Affect' is described as a general positive or negative feeling that is linked, through experience and learning, with an activity (Finucane et al., 2000; Poortinga and Pidgeon, 2005). The affect heuristic is the decision-making process by which "images, marked by positive or negative affective feelings, guide judgement and decision making" (Finucane

et al., 2000). The affect heuristic reverses the model that cognitions or beliefs build evaluations or general preferences, and suggests that it is these broader attitudes that guide the formation of more specific beliefs: these general affective images of an activity are prior to, and direct, judgements of risk and benefit (Finucane et al., 2000).

Psychologists now are considering that risk perceptions combine analysis and feelings in a 'risk-as-value' approach that "motivates individuals and groups to achieve a particular way of life" (Finucane and Holup, 2006:144).

This view of risk judgements suggests not only that perceptions of risk involve broader considerations such as benefits of the activity, but also that the overall judgement is shaped by underlying and more general attitudes (Poortinga and Pidgeon, 2005).

Gaskell et al. (2004) argue that consideration of risks and weighing risks against benefits comes into play only when benefits are actually apparent and relevant; otherwise, consideration of benefits may pre-empt consideration of risks. Other research (Grunert et al., 2003) argues that risk attitudes are 'embedded in a system of general attitudes and values' that guide the derivation of more specific attitudes in a way that preserves the evaluative tendency of the higher-order attitudes" (p. 439).

Risk and nature

Risk perception research has shown that risk perceptions are stable attitudes that are shaped by prior and more fundamental social values. One of the strongest of these shaping values is the value of nature. Sjöberg (2000) recently proposed a model of risk perception in which he claims that the dimension of "unnatural and immoral risk" has the

greatest power to explain risk perception. This dimension includes “interference with nature” and human arrogance, and points to the salience of nature as a normative principle in risk judgements.

A central finding in risk perception research has been that people rate a risk they undertake themselves, or are exposed to voluntarily, as being lower than one that is imposed on them. (Slovic et al.,1995; Starr, 1969). People ‘discount’ their vulnerability to lifestyle risks, including those that involve technology, over which they feel a sense of personal control (Sjoberg, 2000), but do not do so with so-called “societal”risks, which are imposed and cannot be avoided by any personal competence (Weinstein, 1989). Such ‘risk-dominated’ perspectives usually involve large-scale technologies, in which the benefits are counted in societal and economic terms and often appear remote to people. The downplaying of the benefits of these technologies is related to the ‘feeling of powerlessness’ in relation to them (Alhakami et al.,1994).

A more accurate statement might be that people perceive risks from technology as greater than those from nature and have elevated perceptions of the risks of chemicals and technology. Many studies have found that members of the lay public perceive higher risk from chemical or technological sources than from natural sources (Brun, 1992; Kraus et al., 1992; Williams and Hammit, 2001; Walsh-Daneshmani and MacLachlan, 2000). The word ‘chemical’ is interpreted as a synthetic substance, rather than as a fundamental component of nature, and associations with it are mostly negative, eliciting responses like ‘dangerous, poison, or toxic’.

Industrial chemicals and complex and large-scale technologies are seen to have

the potential for catastrophic accidents. When they occur, technological disasters result in a series of stresses that are not present when the agent is perceived to be natural (Kasperson and Pijawka (1985: 17). Technological disasters have been called “dissensus-based” disasters, “because they tend to be conflict-intensive situations where there are sharply contrasting views of the nature of the situation, what brought it about, who is to blame and what should be done about the situation” (Ploughman, 1997: 121). People affected by a technological disaster experience a prolonged sense of threat and mental stress, reporting feelings of loss of control and helplessness (Edelstein, 2000). Technological disasters are seen as avoidable and controllable and thus to carry an obligation to control them, and to violate ethical norms in a way that natural hazards do not (Axelrod et al., 1999). “Unnatural” hazards, or those for which “somebody can be held responsible,” are judged as more severe than natural hazards (Hansen et al., 2003: 114). Man-made or technological risks are seen to be actively imposed and in greatest need of public management and control (Brun, 1992).

The correlation between involuntary, or imposed, risks and technological risk was noted early in risk perception research (Starr, 1969). Kasperson and Kasperson (1982) noted that “most technological risks are not accepted; they are imposed, often without warning, information, or effective means of redress” (p. 137). This observation suggests an important shift from presuming public perceptions of risk to be individual experiences of collective, societal risk-taking decisions on technology, to one of the public bearing the risks imposed by a technology implemented by a social elite. These technologies are seen as promoted, implemented and operated by elites for economic

benefits that seem remote to the general public, or may appear not to benefit the public at all - but poses risks to which the public feels vulnerable (Leiss and Chociolko, 1994). Technology is described as a risk due to its societal implementation. Bauer (1995: 2) states that the resistance to technology “fights the process, not the product, of technological development.” The main ‘objects of resistance’ are “big business and state power” (Bauer, p.19).

In marked contrast, negative associations do not seem to apply to risks that appear to be natural. Thus naturally radioactive radon gas is frequently mentioned as a relatively high health risk that the public is not concerned about, despite the high concern about radiation in nuclear power (Slovic, 1996), and chemicals perceived to be natural are judged less risky than man-made chemicals (Kraus et al., 1992; Williams and Hammitt, 2001). Disasters perceived as natural are often considered “consensus disasters” - “where there is agreement on the meaning of the situation, the norms and values that are appropriate and the priorities to be followed” because they produce a “therapeutic community” in the aftermath that helps victims cope with immediate and longer term recovery, and because communities largely reestablish order after recovery. (Kroll-Smith et al. 2002). Natural hazards appear to be unavoidable and imply little societal obligation to control them (Axelrod et al., 1999), appearing relatively benign even when they pose a significant threat (McDaniels et al., 1995). This research suggests that risks from nature are perceived as lower because nature is external to the social relations attached to technological risks.

People’s beliefs about and values for nature influence the risks they will perceive

in technology. Those who hold “ecological” values are more likely to consider technology to be a risk (Axelrod, et al., 1999); when technology is seen to pose a risk to nature, the general perception of risk rises, sharpening the sense that society is accountable for controlling this risk.. A ‘morality index’, predicted by “threat to nature, moral blameworthiness and anthropogenic causation” (Böhm, 2003), is associated with major technological hazards like chemical dumps. The language used to describe technological interventions into nature is itself revealing of their perceived character as irresponsible actions that impair a coherent and functional system. Sjoberg (2000) talks of ‘interfering’ with nature, associated with human arrogance, while others speak of technological interventions as ‘tampering’ (Somerville, 2006:150) or ‘meddling’ (Hansen et al. 2003) with nature.

Perceptions of food risks

Until fairly recently risk perception research did not focus explicitly on perceptions of the risks of foods. Recent research on perceptions of food quality and risks suggests that perception of foods is particularly influenced by ideas of and attitudes towards nature and technology.

Like perceived risks in general, the perception of food risks is influenced by socio-economic factors. Those who have higher income and more education perceive lower risks, and those who are more conservative tend to perceive less risk in the world and in foods. As is found in risk perception in general, women perceive higher food risks (Dosman et al. 2001). With regard to food, women seem to have a more reflexive, that is,

more conscious and deliberate, relationship to food safety, perhaps due to a responsibility for the provision of food for a family (Berg, 2004); women who have more young children in the home perceive higher food risks, suggesting an influence of family responsibility in food risk perception (Dosman et al., 2001). In addition, women relate to food differently than men do; they are more concerned about food, and for them food is “a means of presenting oneself in different social environments” (Backstrom et al., 2003).

Hansen et al. (2003) challenge the prevalent knowledge deficit model that is often applied to the public with respect to food risk perceptions. Attitudes to foods and food risks are complex and related to a broad range of food concerns that relate to market and political considerations. These attitudes have been found to be based in fundamental values, rather than changeable reactions to information about health risk, and are stable over time (Hansen et al., 2003; Huotilainen and Tuorila, 2005; Frewer and Miles, 2003; Grunert et al., 2003). Once again, nature is associated with the inherent value of nature as separate and free of contamination, and with the absence of the inherent risks and uncertainties of purposeful technological intervention.

Many studies have found that perceptions of food risks are related to more, and broader, associations than health risk (Miles and Frewer, 2001; Holm and Kildevang, 1996; Fife-Shaw and Rowe, 1996). A number of social values have been associated with perceptions of food quality and risk, including humans being to blame for the hazard; hazardousness in large or small quantities; the adequacy of regulations, and immediate or delayed effects. The food hazards perceived to be the most serious are those that are risky

in small quantities and that have an immediate effect. A belief that humans are to blame for a hazard - the perception that it is not natural - shows a concern about unnatural foods, such as additives and technological processes. These foods are thought to be inadequately regulated. (Fife-Shaw and Rowe, 1996). Lay people are far more likely than experts to see high risk in these foods and to see less benefit in them, and to attribute adverse health effects like cancer and allergies to them.

'Mad cow disease', GM foods and pesticide residues were associated with a number of more general concerns such as animal welfare, environmental effects, and long-term and unknown effects. GM foods in particular were associated with negative characteristics like interfering with nature and not being under consumer control, due to the absence of product labelling (Gaskell et al. 2004; Grunert et al., 2003). Foods defined as technologies, such as those grown with pesticides and GM foods, were considered to have both risks and benefits - such as cheaper food and less waste.

Similarly, researchers noted that healthy eating is conceived of as avoiding additives and contaminants, and protection against 'known and unknown dangers perceived to be associated with modern foods. Many people's food ideas are 'pervaded by the idea that modern industrial production and processing methods carry unwanted consequences with them that existing safety systems cannot predict" (Holm, 2003:537). Trust in new foods was related to adherence to technology, and was negatively correlated with suspicion and adherence to nature. Huutilainen and Tuorila (2005) reason that

Technological themata do not fit everyday thinking of food, as they originate from a wider orientation to technology. . . . In everyday thinking, technology is seen as something that ought not to be related to food, as technology - especially

gene technology - as a means of producing food was considered unnatural, and technological or 'plastic' food was expected to be tasteless or to taste weird (p.569).

In a climate of increased wariness of conventionally produced foods and a strong preference for natural products, many consumers have turned to organic foods.

Purchasers of organic foods perceive relatively high risks from conventionally produced foods, largely from pesticide and fertilizer residues (Williams and Hammett, 2001).

These risks are perceived as high in relation to other non-food risks. The purchase of organic food is driven by health reasons, as organic foods are seen as reducing the risks of pesticides. Lay persons clearly distinguish pesticides from natural toxins and microbial hazards, though they may not distinguish between the latter two as they are both 'natural'. Organic foods have been described by study participants as having "no risks; and were seen as healthy, not being used for profit only, and as necessary and serving a good purpose" (Koivisto et al. 2003: 208). Ideas of natural foods and some medicines as being inherently better than manufactured alternatives persist despite the knowledge that a synthetic version may be more healthy. These preferences were based in moral or normative arguments that suggest a fundamental belief that 'nature is better' (Rozin et al., 2004).

Rozin (2001; Rozin et al., 2004) explains that a risk perception focus on food must recognize the special role of food in people's psychology. Food has 'symbolic meanings that attach to different types of food, the circumstances in which it is bought and consumed, and the wider societal context in which its production and consumption takes place" (Hansen et al. 2003: 120). "Food connects 'internal' and 'external' nature,

exposing the connections between individual and environmental risk, and modernity (Mol and Bulkeley, 2002: 185). New foods, in particular, appear to arouse a sense of suspicion, as food technologies “touch our lives in a personal and intimate way. What we eat literally becomes a part of us” (Backstrom et al., 2003: 299).

Discussing food risks as technological stigma, Rozin (2001) points out that stigma often involves ingestion and focusses on bodily harm, threatening health or personal welfare by entering the body. People tend to be very sensitive to “traffic with strange, foreign, potentially dangerous entities,” which most intimately occurs by mouth. Rozin et al. (2004) found a strong ‘preference for natural’ among Americans for foods and for medicine. This derived from both a respect for nature and opposition to human intervention. They describe four ‘instrumental’ beliefs about the preference for nature:

- human intervention damages nature
- natural entities are healthier, and nature is superior
- the sensory qualities of natural products are more pleasant
- nature is pure and safer.

Rozin (2005) claims that judgements of naturalness depend more strongly on the history of the process of a food than on its content. This may be expressed in the principle of contagion, in which properties of two substances that touch are permanently transferred to each other, and which is biased to the negative, in that contact with a negative substance is more contaminating than contact with a positive entity is purifying.

Rozin et al. (2004) suggest a distinction between ideational and instrumental reasons for the preference for nature, and conclude that for most people the preference for natural is ideational, that is, having a moral or aesthetic superiority, or a preference

for a normative natural order, whether or not it is considered to be prior to human intervention. They report that there is little evidence that natural products are instrumentally preferable, or have any actual nutritional or medical advantage over manufactured products; the authors suggest that “it may be that naturalness is perceived as desirable in itself, independent of any instrumental values” (Rozin et al. (2004). In general, they conclude that “the principal basis for natural preference is an ideational/moral belief in some type of superiority of nature” (Rozin et al.:153).

Despite the ideational basis of the preference for nature and the sense that human contact is a contaminant, contagion may involve what Rozin calls “medicalization”, in which a medical or scientific explanation for a contagion belief is preferred. That tendency leads people to express aversions to stigmatized foods in terms of physical symptoms or health complaints, and treat them as a health risk (Rozin, 2001). As both physical and spiritual danger can be sources of contagion, there can also be a strong fear of moral taint, which may “masquerade behind a presumed physical threat.” Health issues in particular are prone to taking on moral characteristics and becoming conflated with physical issues. If there are moral aspects to responses to stigma, assurance of health and safety will not shift attitudes towards acceptance.

Risk society and artefacts at the end of nature

Risk society theory takes a sociological approach in which the social relations of the production of, and concern about, risks and ideas of nature are inter-related phenomena that help define each other. Within the theoretical sociology tradition, Ulrich

Beck (1992, 1998, 2002) and Anthony Giddens (1990; 1991; 1998; 2002) have elaborated variants on a theory of 'risk society'. This theory identifies technological risk as a central societal concern in late modernity. The risks of concern are mostly catastrophic technological risks to the global environment, in explicit contrast to more benign, 'traditional' dangers from nature.

Beck's risk society thesis is that the risks of greatest concern are not the traditional risks from nature like diseases or floods, but 'new' risks produced by the very system that is put in place to identify and control them. Industrial risks, like radiation, that may have global and irreversible catastrophic consequences are the unintended outcomes of deliberate decisions to implement a technology, through a calculated risk process that is at once precise and entirely uncertain of what may happen or when. Beck (1992) argues that the risks faced by contemporary society are qualitatively different from those faced by previous societies: they are caused by deliberate decisions made by social elites; they have the potential to cause widespread, if not global, and irreversible ecological damage that is beyond our ability to calculate; and their consequences are beyond the capability of traditional insurance systems to compensate. Thus society is beginning to be characterized by the distribution of 'bads' that it produces incidentally, rather than, as in earlier industrial society, by the distribution of goods.

Beck (1999) states that "pre-industrial hazards, no matter how large and devastating, were 'strokes of fate' raining down on humankind from 'outside' and attributable to an 'other' - gods, demons or Nature. Here too there were countless accusations, but they were directed against the gods or God, 'religiously motivated', to

put it simply, and not - like industrial risks - politically charged". In contrast, the risks of concern in late modernity are based on "decisions that focus on techno-economic advantages and opportunities and accept hazards as simply the dark side of progress It is not the number of dead and wounded, but rather a social feature, their industrial self-generation, which makes the hazards of mega-technology a political issue" (p.50). Late modern society has become marked by an intensification of concern about risk, particularly from those large-scale technological risks that threaten entire ecosystems. These are unlike the dangers of pre-industrial society, which were largely natural disasters and diseases, and those of industrial society, which were calculable and compensable through insurance; today's environmental risks threaten global destruction and catastrophe and are beyond calculability, compensation and remediation. Major institutions in late modern society - government, industry and science - are "singled out as the main producers of risk" (Lupton, 1999b: 4).

Giddens (2002: 26) distinguishes two types of risk: external, which comes from outside or nature; and manufactured, "created by the very impact of our developing knowledge upon the world." He argues that in traditional societies, people worried about risks from external nature, such as droughts or floods. "At a certain point, however - very recently in historical terms - we started worrying less about what nature can do to us, and more about what we have done to nature. This marks the transition from the predominance of external risk to that of manufactured risk."

Risk society sociologists introduce an interpretation of risk that has a different emphasis than the scientific definition. They do not dispute that the scientific definition

achieves the purpose for which it is used by regulatory institutions in the developed world. However they focus on other aspects of the use of this risk approach that are overlooked by scientists, but are aligned with public interpretations of the concept: risk is a means of calculating, planning and implementing deliberate social activities. This leads to a focus on the interests behind technology implementation and accountability for the management of its risks, and the overall rationale of such planned activities and the distribution of their benefits. It stresses purposeful intervention and the planning process - risk society theory is vague on the specific products of risk planning - and includes primarily technological risk. Technological risk is perceived in a risk-bearing context, with benefits that are not valued by and do not accrue to the public. The risks are taken by, and benefit, social elites, who are distinguished from a diversity of other individuals within 'the public': "The industrial system profits from the abuses it produces, and very nicely, thank you" (Beck, 1992: 56).

Beck and Giddens describe risk as the calculated and purposeful implementation of technology in almost the same terms that philosophers use to describe artefacts: deliberately brought into being by humans, and designed in order to achieve a purpose in the environment or context in which they are to function (Lee, 1999; Lee, 2005; Heyd, 2005; Simon, 1981). They are typically organized by function (Simon, 1981), creating the expert systems of Giddens's theory. Also like artefacts, risk as organized social intervention is ontologically opposite to nature, being the operative principle in determining the identity of something as natural or as technological or artefactual. And like artefacts, Beck's and Giddens's risk, as institutionally calculated and implemented activities, encroaches on or reworks nature to

such an extent that the natural world has essentially been overtaken by social planning.

Like the proponents of second nature and the end of nature, Beck and Giddens take a categorical interpretation of nature and society. By the 'end of nature' Giddens (1998: 26) means that "there are now few if any aspects of the natural world untouched by human intervention." Nature comes to an end as it is ordered according to the "internally reflexive systems of modernity," in which people live in increasingly artificial environments (Giddens, 1991: 164). This causes the 'sequestration' of people from nature as most people live in a built environment physically separated from most of nature. "Nature literally ceases to exist as naturally occurring events become more and more pulled into systems determined by socialized influences" and nature loses its "very character as an extrinsic source of reference" (Giddens, 1991: 166).

For Beck (1998:10) "risk society begins where nature ends." Beck takes a realist position on this: "the loss of boundaries between these realms is not only brought about by the industrialization of nature and culture but also by the hazards that endanger humans, animals and plants alike" (Beck, 1999: 145). He also, however, (Beck, 1999: 21) considers nature as a multi-faceted, cultural concept, all of which are "no longer there. . . . What is there, and what creates such a political stir, are different forms of socialization and different symbolic mediations of nature (and the destruction of nature)." Beck (1998) argues that the "notion of risk society clarifies a world characterized by the loss of a clear distinction between nature and culture. Today, if we talk about nature we talk about culture and if we talk about culture we talk about nature. When we think of global warming, the hole in the ozone layer, pollution or food scares,

nature is inescapably contaminated by human activity” (p.10).

Risk, technology and society

The concept of risk is a complicated articulation point, having multiple dimensions that allow it to be described as an extrapolation from systematically observed natural functions, as well as an intrinsically social phenomenon. Not only do the conceptual approaches to the concept of risk itself differ, but when applied to practical risk situations they give further contour to the two major ideas of nature and society.

The scientific definition of risk is put forward as socially neutral, as it considers only the objectively measured, natural, effects of the substances and processes involved, regardless of their origin. Scientific risk and nature concepts justify the assertion that the fact and the type of social intervention are irrelevant for public interest risk assessment and management. Despite this assertion, risk policy - largely articulated in the Integrated Risk Management Framework (Canada, 2001) - incorporates a neoliberal economic orientation into the basic working definition of risk, in order to change managerial attitudes to risk.

Sociologists and the public, on the other hand, focus on the deliberate design and implementation aspects of risk, linking it directly to social relations. The social terms of risk converge with the definition of an artefact - “the material embodiment of human intentional structure” (Lee, 1999: 188). Risk is identified with technology, which it advances through the increased control of nature: risk is that calculated, abstract instrumentality that, as Stephens (2004) argues, is inversely proportional to nature.

The key to an activity's public characterization as a risk relates to its social relations - who is doing what, for whose benefit, and at whose cost? The equation of technology and risk with social action and decision points, as indeed risk society theorists do, to the crucial importance in risk controversies of the dynamic of social relations that characterizes the social sphere, and the political nature of the evaluation of technologies and risk management.

Chapter 4

Complexity and Trust in Modern Society

Society is the sphere of artefactuality, intention and action, technology and risk. Risk controversies and public opposition to major technologies are associated with a sense of social responsibility for deliberately implemented technologies, which leads to a desire for the accountability of those who plan, implement and manage them. The management of technology and risk begins to look like the management of these political relations.

Governments, policy makers and industry have recently focussed on social trust as a crucial element in the smooth functioning of decision making and risk management. Belanger et al. (2001) begin their discussion on risk management with the observation that

Increasingly, . . . the risk issues facing government defy the kind of scientific analysis that in the past have allowed the likelihood and severity of risks to be clearly determined (think of global warming, biogenetics and genetically modified foods). Even if perfect information were available, it is impossible for citizens - or public servants - to be involved in every aspect of every risk management process. Under such circumstances, citizens' trust and confidence in government's ability to protect and advance the public interest are fundamental underpinnings of Canada's democratic system (p.5).

Belanger et al. (2001) go on to explain that trust is "especially critical for risk management" because of the involvement of uncertainty, in terms of both the likelihood and the probability of a risk; the possibility of negative effects to a particular group; and the distribution of benefits and risks. It is useful to review a range of disciplinary views of the concept of trust as a key function in modern society, and in the management of

complex institutional and technological activities, in order to place the perspective on social trust in regulatory institutions in a broader context.

Risk and trust

Many studies have found that perceptions of the risk level of an activity are related to trust in the authorities who manage it. Slovic (1999) considers that “social relationships of all types, including risk management, rely heavily on trust,” and that much of risk conflict can be attributed to a lack of trust among the public, industry and risk managers (p.697). Risk perception psychologists note that the degree of trust in the institutions responsible for research or risk management strongly influences the perception of the technology itself: “confidence in laws controlling technology and trust in companies doing it are important determinants of people’s judgements” (Siegrist et al., 2000).

Cvetkovich and Lofstedt (1999) reviewed the important characteristics of trust as it applies to risk management:

- trust implies a difference in power and control: as individuals determine whom to trust, it involves trading behavior and decision control for cognitive control,
- trust involves risk, as one is never certain the trust will not be betrayed; trust trades a primary (perhaps physical) risk for a social risk
- trust involves an expectation about a relationship, either with an individual or a group or organization;
- with respect to risk management, social trust relates to individuals who are likely personally unknown to a person, but who have been assigned responsibilities of a formal organizational role (p.3).

Interest in social trust has grown over the last decade, as scholars and policy makers in industrialized countries have noted that trust in government, institutions and

conventional authority has declined. Trust is seen as important in the functioning of society, as it ‘facilitates social cooperation’ (Taylor-Gooby, 2006: 76). Its decline is considered a marker of larger, worrisome changes in society. It is noted, for example, that “just as demands on trust are increasing, the supply may be diminishing” (p. 77).

Research into trust has increased with observations of its decline, but has not produced a clear understanding of what trust is or what it does. As Cvetkovich and Nakayachi (2007) note, “social science trust literature . . . has been characterized as a theoretical quagmire and a verbal and conceptual morass marked by a confusing potpourri of definitions . . . [and] a notable failure to integrate proposed conceptualizations” (p.224). It is generally agreed, however, that the type of trust that is of interest in the risk management context is social trust - also referred to, in different perspectives, as institutional or system trust - rather than interpersonal trust.

The function of trust in society is often described as reducing complexity. It is “a risk judgement that assigns to other persons (agencies, etc.) the responsibility for working on some necessary task”; trust reduces complexity and contingency in modern society, and is important in fostering collaboration and generating cooperation in a complex society (Bradbury et al., 1999: 122). The crux of the importance of trust in society, and in risk regulation in particular, is that it acts as a ‘social lubricant’, permitting more economic development by facilitating “efficiency, productivity, and cohesion” (Earle and Cvetkovich, 1999: 2). Social trust reduces the cognitive demands on the individual by simplifying decision-making about specialized functions in society, through its key function of ‘reducing complexity’ (Lofstedt, 2003; Cvetkovich and

Lofstedt, 1999).

The context of social trust

The fundamental context in which social trust exists is complex, differentiated society. The division of labour in society creates new groups involved in production and distribution (Taylor-Gooby, 2007), and specialized functions proliferate as society grows more differentiated (Luhmann, 1979). Modern industrial societies are largely urban and functionally specialized: social institutions have grown into systems, particularly expert systems run by technological and intellectual elites who “claim semi-autonomy from social and political constraints” based on their access to specialized knowledge (Dahlberg, 2001).

Sociological research observes that the increase of differentiated functions, including technology, increases social complexity, or the expanding of future possibilities as a consequence of instrumental planning, which “gives rise to a new form of insecurity” (Luhmann, 1979:15). Complexity consists of the ability to plan events in the future and to conduct actions that go beyond very elementary interpersonal interactions; it is the differentiation of specialized functions and their delegation to specialized groups or systems, with the implication that this increases hierarchical social structure.

Because specialized groups or systems are defined functionally and arranged hierarchically (Simon, 1981), relations are between individual and system rather than between individuals. With system trust the reduction of complexity depends on the

processing of information by others, which the trusting individual must be able to assume corresponds to the truth. The existence of trust in society increases the tolerance of the uncertainty this complexity generates, and permits the increased potential for complexity in society (Luhmann, 1979).

Trust is often described as existing in situations of risk or uncertainty - it matters “only when something is at stake” (Taylor-Gooby, 2006: 81; Meijboom, 2007).

Luhmann uses risk much as it is used in risk society theory, as situations associated with decision and action, and the possibility of being disappointed by our own choices or the actions of others (Luhmann, 1988: 97). Risk society theory stresses that modernity depends on trust of the lay person in abstract systems - like money, or heating and lighting services, which they do not understand. (Giddens, 1991). “Trust in systems takes the form of a faceless commitment in which faith is sustained in the workings of knowledge of which the lay person is largely ignorant, it is only demanded where there is ignorance” (Giddens, p. 84).

A central principle in the function of trust in society is that although trusting individuals delegate specialized functions, they also monitor the performance of these functions. As social complexity escalates, trust becomes more important, both to manage the complexity and to monitor the competence of those entrusted to carry out the functions and ensure that they remain aligned with social values and expectations. Competence can be monitored, as long as it is “based on shared knowledge and expertise” (Barber 1983: 5). In this way “performance can be controlled by trust. A fiduciary obligation is placed on the holder and user of the special knowledge and skill

with regard to the other members of his social system. Trust of this kind, then, is a social mechanism that makes possible the effective and just use of the power that knowledge and position give and forestalls abuse of that power” (Barber, 1983: 5).

Different forms of social trust function in different contexts. Luhmann distinguishes among familiarity, confidence and trust. Familiarity is the self-evident knowledge of “the world as lived in, including nature and human relationships, which is constructed in generalized terms” (Luhmann 1979: 21); confidence implies an expectation of the continued functioning of external systems, like political or traffic systems, the disappointment of which is attributed to outside forces. Trust, on the other hand, is the choice of one action over another and exists in situations of risk (Luhmann, 1988: 97). With growing complexity, created as future events are more determined by social decisions, familiarity becomes less useful as a way to determine the future, making trust more important. Trust is required in social environments of high complexity, those involving relationships of dependence with expertise, authority and power.

What trust is

There are many definitions of the concept of trust itself - one study found 28 definitions of institutional trust (Taylor-Gooby, 2006). Cvetkovich and Nakayachi (2007) compared three prominent concepts of trust: the ‘dimensions of trust’, salient value, and encapsulated interest perspectives. The dimensions of trust perspective is a traditional social science approach that “posits one or more dimensions or basic

characteristics of the other person, a 'dimension' of trust that is assumed to engender trust" (p. 224). Dimensions that have been considered include expertise, reliability, competence and care, honesty and fairness (Cvetkovich and Nakayachi (2007; Taylor-Gooby, 2006). While the concept assumes these dimensions to be universal, "perceived by all observers" and thus generally considered 'trustworthy' (Cvetkovich and Nakayachi, 2007; 225), Cvetkovich and Nakayachi (2007) found that they were context-specific; that is, people judged as fair or competent those whom they judged to hold values that are similar to their own. Supporting the notion that trust is not made up of universal psychological characteristics in the person or group being trusted, but is part of the values of the individual placing trust, Taylor-Gooby (2006) stresses that trust varies in society with social class and education. There are thus divisions and diversity in patterns of trust as with social attitudes and values. Those who are opposed to a technology will see it as being a higher risk, and may be less likely to trust those who promote it, suggesting that recommending the portrayal of such characteristics as universal and normative is "not valid" (Cvetkovich and Nakayachi, 2007: 223).

Salient value similarity is a concept originally proposed by Earle and Cvetkovich, which argues that "social trust is based on value similarity, with the value basis varying across people, contexts and time" (Earle and Cvetkovich, 1999: 8). Social trust is conceived of as a psychological state of willingness to rely or cooperate based on two context-specific judgements" (Cvetkovich and Nakayachi, 2007; 225). The first judgement assesses the saliency of values that apply to the problem at hand; the second assesses the "perceived agreement or similarity between self and the other person about

what is important, that is, salient value similarity.” Studies have shown that people tend to trust risk managers with salient values similar to their own, and to distrust those with dissimilar values’ (Cvetkovich and Nakayachi, 2007: 225).

The encapsulated interest concept assumes that people are motivated by self interest, and trust those whom we perceive to be committed to acting in our best interest - that is, they “encapsulate our interests in their own” (Cvetkovich and Nakayachi, 2007: 227; Hardin, 1998). From the point of view of the trustor, trust is “relational: it is often focussed on specific agents and is indexed to certain situations or a certain object of trust. We do not trust everybody with everything” (Meijboom, 2007: 235). It is also context-specific: in a situation of high concern, perceived value similarity was the best predictor of trust, and judgements of salient value similarity appeared to ‘incorporate considerations of encapsulated trust’ (Cvetkovich and Nakayachi, 2007: 234).

This emphasis on individuals judging whom to trust based on their assessments of the values of the manager is consistent with research on political trust, which has found that

Growing numbers of citizens have become increasingly critical of the major institutions of representative government . . . But support for the community and for democratic principles remains overwhelming. . . . We have seen the growth of more critical citizens who value democracy as an ideal, yet remain dissatisfied with the performance of their political system and particularly the institutions of representative government (Norris, 1999: 27).

Nevitte (2002) argues that increasing affluence and education, and a related shift in workplace capabilities, have produced a more capable and confident citizenry that is increasingly critical and demanding of government (Nevitte, 2000; Kanji, 2002). Greater

education and competence give people a sense of empowerment, enhanced by the increased availability of information and its easy electronic accessibility. These factors increase people's 'internal efficacy', their sense that they are competent to participate in and influence political processes and outcomes. The lag behind this internal efficacy of 'external efficacy', or the apparent responsiveness of the political system to citizen demands, creates an 'efficacy gap' that underlies the increased sense that governments are not meeting expectations (Nevitte, 2002; Kanji, 2002).

Meeting citizen expectations is a crucial requirement of government legitimacy, a precondition for citizen trust, or collective citizen consent or acquiescence to be governed (Purcell (2002: 309). Such consent is secured as citizens perceive that the state is meeting their expectations of its performance, including the provision of material well being, the protection of political rights and articulation and preservation of a community of common interest, and the protection against physical harm. This is a political relationship, which varies with other political factors, between the state and its citizens that is essential if the state is to be able to regulate effectively; a sense that expectations are not being met may cause "citizen loyalty and state legitimacy to collapse" (Purcell, 2002: 310). A sense that political equality is contradicted by economic inequality, for example, will make "political equality (which the state is expected to ensure) increasingly to be a lie" (Purcell, 2002:312).

From a sociological perspective Giddens argues in a similar vein that increasing pressure for greater 'democratisation of democracy' accompanies the emergence of 'active trust', " in which self-confident and active citizens seek to interpret the views of

different experts with varying claims to authority” (Taylor-Gooby, 2006: 80).

What is emerging in the picture of social trust is an engaged citizen exercising critical trust in what Taylor-Gooby (2006) terms “the new scepticism.” Automatic deference to authority and expertise can no longer be assumed from citizens, and unthinking trust is considered to have ‘negative effects’ (p. 77). Social trust incorporates critical attention to, or monitoring of, activities and institutions as an essential counterpoint to the delegation of responsibility. Newton (1999:169), for example, notes that “trust is not blind,” but requires constant updating of experience and modification, using information and assessments provided by credible trust mediators (Conference Board of Canada, 2005). Roese (2002) likewise argues that ‘blind trust is not a positive’; trust may be seen as a ‘healthy scepticism that is intertwined with attention to, vigilance towards, and knowledge of institutions’. Indeed, Roese observes that decreased trust is associated with increased political engagement, suggesting that sceptical distrust can motivate citizens to press for change within the political system.

Several researchers discuss the existence and role of distrust, (Cvetkovich and Lofstedt, 1999; Luhmann, 1979) equating distrust with a public insistence on greater scrutiny of a function. This is distinguished from trust, or the delegation of responsibility to experts or authorities, and is not simply the absence of trust. As Barber (1983) argues, “Trust and distrust, law, auditing, monitoring and insurance against malfeasance all serve as functional complements to maintain social order, promote effective social control, and preserve solidarity and moral community” (p. 23). “Rational distrust” is as important in a democratic society as trust is, as it both “holds in check the powers of

economic elites and technical experts,” and encourages a realistic appraisal of the operations of elites and democratic shortcomings of institutions without fostering the withdrawal of the social mandate or radical movements aimed at regime-level change (Kasperson et al., 1999: 39). Both social trust and distrust contribute to the functioning of democratic institutions and processes, and, as Kasperson et al. (1999) note, the “pressing need is not to maximize trust but to concoct the appropriate mixture of trust and distrust within the political system” (p.39). Social trust is an active function that includes both the delegation of responsibility for a specialized task and critical monitoring of the performance of those tasks. The degree of each element present varies with the context, and both are important in achieving a kind of balance in society between pressure for continued expansion and for caution or restraint.

Using trust in society

Regulation plays a crucial social trust role as it assumes, in the public interest, the monitoring and control of specialized activities, many of them having important political implications. Regulatory institutions have authority and expertise to evaluate and monitor the performance of private activities in society. This allows them to act as a guarantor to the public of the competence of specialized private activities that might otherwise remain inadequately monitored, or fail to gain social support as a net social benefit; in effect, regulation serves to secure social trust in the activity, monitoring and exerting pressure for competent performance.

Another set of players in social trust, particularly as it applies to organizations, is

“trust intermediaries” (Conference Board of Canada, 2005). These are “institutions (such as audit and oversight bodies, boards of directors, non-profit organizations and the media) that provide us with information, formally or informally, on the doings of corporations and government departments. They can also include individuals . . . who, for whatever reason, we find both credible and knowledgeable” (Conference Board of Canada, 2005: 12). The motivation of trust intermediaries appears to be the provision of public information for the public good rather than financial profit. Because these institutions appear to be credible and trustworthy, they also lend trust to an organization or government by auditing their “social responsibility reports” (Conference Board of Canada, 2005: 13).

Trust guarantors such as regulatory institutions reduce the risk of social activities by establishing and enforcing rules of behaviour (Conference Board of Canada, 2005). In performing a technical function in controlling private activity in society, for which it acts as a trust guarantor, regulation is defined by a specific mandate legally delegated to a particular organization within a political system and policy context, and is expected to perform up to these standards. It is thus subject to monitoring of its performance of that role, by public interest groups or ‘trust intermediaries’ and by the public at large.

However, the function that regulation performs is not simply the assumption of technical control and monitoring on behalf of the public, thereby relieving individuals of those duties. As Jasanoff (1995: 311) has argued, regulation is “a kind of social contract that specifies the terms under which state and society agree to accept the costs, risks and benefits of a given technological enterprise.” Regulatory institutions are accountable to

the public to represent their interest, if not in fact to reflect their preferences, in establishing the conditions under which a technology is implemented in society. Particularly in light of social differences on the value of technology and the leeway for interpretation of the public interest, public scrutiny and critical comment are an integral aspect of social trust in technology regulation.

It is evident that there is an essential tension between the function of trust in situations of complexity and lack of knowledge, and its association with the monitoring of a system against informed expectations of performance. Conventional risk-focussed debates on trust in technology regulation identify public trust with a lack of knowledge and a need for trust in expert authorities, while more politically-oriented approaches assert the right, and the capability, of the citizen to participate in key social decision making. Central issues are, then, which issues are relevant in a risk issue, what individuals need to know in order to monitor its management, and what they do know. The description of the public as uninformed or as knowledgeable and capable depends on the type of knowledge that is seen to be required.

Unravelling the apparent conflict between trust as involving a lack of knowledge or as a framework of informed expectation can begin with the recognition that there is complexity - that is, delegated specialized functions that require trust judgements and monitoring, and which trust is said to reduce - involved at several levels of risk regulation. One is the technical complexity of advanced technologies, designed, operated and managed by experts. A second is the use of specific technologies in society, their perceived risks and benefits and the manner in which they are regulated on behalf of the

public. Third is a more general political level that includes the democratic legitimacy of the policy process, and the degree to which it is seen to meet political expectations. The aspect that is focussed on as essential to risk regulation shapes considerations of the type of knowledge required to offer a credible judgement. Is the essential nature of risk regulation the expert control of the risks of complex technology on behalf of a largely uninformed public who do not understand the technology? Or is it the institutional achievement of political goals of implementing a particular technology in society according to the expectations of a largely informed and competent citizenry; or the setting of higher level policy directions?

In the risk regulatory context, complexity is often used to signify the inability of people to evaluate claims of risk or safety, or to monitor performance of risk management, in the implementation and control of sophisticated technologies. This is the scale at which risk assessment operates. In such situations people are said to rely on experts they trust to make decisions and manage the technology on their behalf. Risk society theorists stress the generalized concern among the lay public that technology carries catastrophic risks on a scale unknown to previous societies, being incalculable, global in effect and uninsurable. Trust in expert systems and knowledge is ambivalent and stressful, as the lay person does not simply passively rely on experts but attempts to monitor the objects of trust and must be prepared to accept the risk of their placement of trust. (Giddens, 1991: 116).

Freudenburg (1996; 2000) likewise attributes the generalized concern for technological risk to the specialization of expertise on technology and risk control that

laypeople - indeed, experts in other fields - do not understand and thus cannot monitor. He describes the concern for technological risk that exceeds probabilistic risk in terms of trust. He describes a "risk crossover," in which the technologies that reduced the risks to which people were traditionally subject have increased in complexity; now the greater concern is the lack of social control over the technologies themselves. We now depend on specialists to control the risks of those technologies - specialists who may, or may not, carry out their responsibilities in this regard.

Empirical research on trust in risk management, however, has found that individuals are able to make reasonable judgements of risk issues and management, being both sufficiently informed and attentive. Recent research notes that people are not simply passive recipients of risk information who change their views about risk with each new piece of information, but are "cognitively engaged" (Priest et al. 2003) individuals who have the 'capacity and inclination to engage in active interrogation of risk-related information' (Horlick-Jones et al., 2003). People's "interrogation of knowledge" arrives at trust judgements that are specific to a particular institution and expectations and observations of its performance (Walls et al., 2004).

While they are competent to make some judgements on technology management, non-scientists are not only, or even primarily, concerned about the probabilities of specific adverse consequences of technology. The main concern has been shown to be the context of large-scale technologies in society, and the regulatory priorities of public interest and safety or of private advantage. Trust and risk perception are independent indicators of a broader attitude (Eiser et al., 2002), and of general orientations towards

technology. Risk issues are often complicated by a range of considerations that go beyond questions of probable rates of harm, often becoming involved in 'symbolic tangles' associated with broader social issues and agendas (Horlick-Jones et al., 2003). These broader social issues are not abstract but are integral to the risk issue itself, as people evaluate what matters in each particular situation and make risk and trust judgements according to their assessment of the values that are important in that case.

On these social concerns inherent in risk issues, members of the public are well informed and confident in their priorities. Members of the public expect that a risk regulatory institution will perform its duties according to clear political priorities (Mendelsohn, 2003; MacKinnon et al., 2003; Health Canada, 1999; Pidgeon et al., 2003). Walls et al. (2004) concluded from their study in the UK that "participants . . . were able to take a reasoned view on what they regarded as appropriate behaviour for each [regulatory institution], often framed as whether they were seen to promote 'the public interest'. These processes of sense-making appear to draw upon socially-held interpretive resources, also reflecting broader political cultural sentiments, concerning, for example, what is seen to be the proper role of risk regulators in society" (p.146).

Citizens do not trust companies to regulate themselves, as industry is seen to have a short-term perspective that is incompatible with longer-term health protection, and a central duty of a government regulator is that it act in the public interest, or be altruistic (Pidgeon et al, 2003) and independent. While they accept that markets are an increasingly dominant force in society, they feel that health and safety protection should be independent from such influence.

On a more general policy level, the top priority of citizens for risk regulation is that health and safety protection must be the most important consideration, taking precedence over other considerations such as economic performance (Mendelsohn, 2003; Pidgeon et al., 2003). Canadians distinguish between economic, or sectoral regulation, and social, or health and safety regulation, and are unwilling to permit a relaxation of health and safety regulation as they are with economic regulation (Mendelsohn, 2003). They want higher standards of health protection, and stricter enforcement of those standards by regulatory authorities (Mendelsohn, 2003; MacKinnon et al., 2003). They also believe that the government has the primary responsibility to protect public health and safety and that government, and regulatory departments and institutions, should be more accountable to the public for discharging that duty (Mendelsohn, 2003; MacKinnon et al., 2003; Health Canada, 1999).

Survey research indicates that Canadians are quite clear on their expectations from government (Graves, 1999; Nevitte, 2000). The Canadian public desires greater participation in government decisions; their sense of powerlessness is less an expression of their lack of ability to participate in government than a recognition that they are capable of much greater participation and 'can operate as equals to elites and leaders' (Graves, 1999: 4). In this perspective trust is more a considered evaluation of government than an intuitive faith. Nevitte (2000: S86) considers that trust is "a fundamental social and political orientation that has been theoretically and empirically linked to the effective performance of democratic systems," a positive healthy scepticism that comes of increased cognitive sophistication, and a shifting political

culture in which citizens' first priority for elected officials is that they keep in touch with constituents.

Walls et al. (2004) and Poortinga and Pidgeon (2003) argue that trust in risk regulators falls somewhere on a continuum between uncritical trust, or acceptance, and cynical rejection. In between is critical trust, a 'healthy type of distrust'; distrust in society is an important component in political accountability, which the public needs to be competent enough to use. "Critical trust . . . attempts to reconcile the actual reliance by the public on institutions whilst simultaneously possessing a critical attitude toward the effectiveness, 'motivations' or independence of the agency in question" (Walls et al., 2004: 147).

Risk regulation is characterized by a multiple complexity, each aspect of which may be met with its own balance of knowledge and monitoring, and lack of knowledge and ambivalent reliance. While most in the non-scientific public are undoubtedly not knowledgeable enough about many technologies to evaluate their technical management, many are knowledgeable enough to form reasonable expectations of performance. They are also informed on important social aspects of technology, such as its benefits, larger impacts and ultimate social value, and on broader political expectations of democratic process and representativeness. The aspect of regulation that is identified as essential will shape the perspective of the balance of dependent trust and informed monitoring that is involved in the trust relationship.

Similarly, the kind of assurance that is required to satisfy trust will depend on the nature of the issue and the levels of concern involved. While political expectations are

often seen as concerned with procedure and democratic participation, concerns about a technology are more specific to the situation and demand a local or contextual understanding and response. As Cvetkovich and Nakayachi (2007) note,

With high concern issues, outcomes are personally important, and people are motivated to protect their values. When the issue is of low concern, outcomes are not personally important and there is low motivation for value protection. Values of procedural fairness have been found to be more important for low concern issues. This would suggest that the characteristics suggested by the dimensions of trust approach would be most important for low concern issues. (p. 226).

Trust is necessary in complex society when specialized groups carry out societal-scale activities that may create adverse consequences, social inequities or other relational implications. Members of the public monitor the larger value system within which a technology is implemented, and the understanding of the public interest which the technology and its management are to advance. They are concerned with the groups that design and implement, and generally profit from, technology, and state that they do not trust these groups to regulate themselves, but wish them to be regulated by an entity that represents the general public interest. They then consider the acceptability of the government regulation, referring to information available from a range of sources, as well as assessments and judgements made by non-profit organizations and other trust intermediaries.

In many cases the different levels of concern interact to create a systemic perspective on a risk or technology situation, in which elements of the technology itself become inseparable from political aspects of its implementation and broader social values. Bauer (1995) argues, for example, that a set of conditions in post-Second-World

War Western societies has led to a widespread resistance to large-scale technologies, notably nuclear power, information technology and biotechnology. These include a decline in faith in the notion of progress, and 'disenchantment' with expertise, often related to secret state-sponsored military programs during the Cold War, and also to a growing aversion to technocratic tendencies in large-scale technological projects. These factors converge in an opposition to big business and technocracy, much as risk perception and risk society findings note, with objections in particular to "public deceit and lies, manipulation and exclusion, pollution and exploitation, and the unequal distribution of risks" (Bauer, 1995: 13). Bauer (1995:19) notes that "New technologies are financed, developed and implemented by large corporate sectors or state bureaucracies under expert guidance, often in the context of defence and warfare." Expert and abstract system control of technology can be perceived as technocratic, which itself raises problems of trust: technocracy "seeks to abolish politics, and, by implication, to exclude the citizen and the public" (Bauer, 1995: 19). Lack of access to information and decision making of specialized functions like technology can in themselves generate lack of trust among an increasingly competent citizenry, reflecting a disapproval of political priorities and process.

What is described as a decline of public trust in risk regulation is not simply an expression of anxiety about complicated technology and the inability to verify its control by experts. It is at least in part an increase in the critical attention of an informed and competent public to regulatory institutions' performance of both the political and the technical aspects of regulation. This evaluation is informed by expectations for the

management of technology in the public interest, and an assessment of the degree to which those expectations are met. Social trust is an active function, in which both delegation and scrutiny are used to ensure the fulfillment of expectations and to put pressure on suspected instances of the betrayal of that trust.

It is risks, the activities and artefacts that are designed to achieve a specific goal within a particular social or economic environment, and the specialist groups or systems that implement and manage them, that are the domain of social or system trust. As ‘the social’, in categorical contrast to the natural, they are in the territory of complexity, the network of scrutiny and critical trust in the performance of specialist systems and public institutions. The concepts of the social, the artefactual, complexity, science and technology, and risk are aligned with each other, and as a constellation of social orientations they are subject to the onerous and demanding social trust that such complexity requires. The associated critical monitoring of technology can lead to demands that the public regulator establish and enforce stricter levels of control of a technology, and can indeed be seen to limit, slow down, and otherwise complicate the process of further transformations of nature.

Government, industry and other entrepreneurial groups interpret a public desire to maintain scrutiny of specialized functions as distrust, an absence or a failure of trust rather than as a condition of it. Trust is considered as the public assent to the delegation of responsibility and vigilance, and a necessary condition for strong economic performance. The Conference Board of Canada notes that distrust “gives rise to economic uncertainty” (2005: 3), and that many public and private sector leaders fear

that lack of public trust impedes their organizations' functioning" (p. 2). While cautioning that "unwarranted public trust could lead to abuse by unaccountable individuals" it nevertheless goes on to enumerate a number of ways in which business leaders believe distrust is damaging Canadian organizations:

- distrust can stall the launch of new products and initiatives
- public distrust might hamper the government's ability to deliver services: the new cult of accountability may stifle risk taking, innovation and the very things that make us best practice organizations
- distrust often translates into increased scrutiny and regulation, often led by closer media attention (Conference Board of Canada , 2005: 3).

The value of public trust

Instead of social trust as a mechanism that balances the delegation of social tasks with monitoring, institutions treat trust as capital that they can 'accumulate'. To the extent that critical monitoring often functions as a constraint on the freedom of action of abstract systems, it is resented by those systems, which attempt to convert it into simpler confidence or acquiescence.

The government and regulatory perspective on public trust begins with the acknowledgement of its necessity to government and to regulation. Bélanger et al. (2001: 5) explain that "citizens' trust in government is critical. In fact, citizens' trust and confidence in government's ability to protect and advance the public interest are fundamental underpinnings of Canada's democratic system." While they argue that trust is especially important in risk management, they do not define trust or its function, noting only that governments can draw on the trust they have established when they

interact with stakeholders and the public. Sims (2001:1) rests the importance of trust on the fact that “the extent to which citizens’ confidence in government has eroded in Canada, and elsewhere, has raised concerns that this might cause democratic institutions and processes to suffer.”

Hill and Dinsdale (2001: 14) are somewhat more precise in their interpretation of trust as a simple delegation of a task to experts, explaining that “trust allows government institutions to make decisions that will be acceptable to the public. As the trust of stakeholders and the public declines, much more effort must be invested in finding acceptable decisions.” It is not explained how trust allows government to make more acceptable decisions; the context suggests that what is meant is that public trust straightforwardly increases the likelihood that the public will accept decisions a risk regulator makes. This procedural interpretation is underlined by the further statement that “concerted action to make risk decisions more democratic . . . enhances the confidence in the decision - regardless of the outcome” (Hill and Dinsdale, p.14). The implication that public trust is desirable as it allows institutional latitude in decision making is echoed in a paper commissioned for the Smart Regulation initiative, in which Löfstedt (2003: 12) defines trust “in the sense of a complexity reduction thesis.” He specifies that this means that the public delegates to authority; and that “trust means acceptance of decisions by the constituents without questioning the rationale behind it.”

The Conference Board of Canada (2005) argues that in maintaining trust, regulatory agencies “ensure that individuals are able to maintain blind faith that the consequences of opportunistic behaviours [are] less likely to occur” (p.14). More

explicitly in relation to risk regulation, Mendelsohn (2003) states that “building trust into the regulatory process is necessary to prevent irrational demands for stricter regulations from the public, what can be called ‘regulatory creep’” (p.6). Kasperson et al. (1999) observe that trust produces efficient regulation, as it allows regulators’ preferred consensual style which gives them flexibility and reduces costs. Löfstedt and Horlick-Jones (1999: 75) studied the expressed desire of the UK Environment Agency for public trust, and observed that the agency “seems to view the gaining of public trust as important in order to make possible more effective and less controversial policy making.”

The general thrust of these statements is that institutional decision-making is manageable, and policy control possible, only when the public delegate decision-making power with no strings attached. This state is desired as it avoids the need to move to an outcomes-based trust (Löfstedt, 2003) in which public priorities need to be reflected in policy. When trust is gained, perceptions of risk and calls for scrutiny decline; critical attention to a function thus appears as a lack of trust and the failure of an institutional relationship. Industry and government have interpreted trust as a one-dimensional psychological state in which members of the public assent to the expert assumption of responsibility for a function, trading decision making control for freedom from the onerous duty of monitoring.

For those socially complex technologies that raise political concerns, however, society at large appears to use the two aspects of trust, delegation and scrutiny, in an active process of evaluating the political and social implications of an institutional

function against existing values and expectations.

Social trust as gatekeeper of complexity

Complex modern society is an arena of intense social relations in which individuals and groups hold each other accountable in the performance of differentiated activities. It is a dynamic category, marked by pressure to implement innovative technologies for the capital accumulation they permit, and resistance to such new complexity from groups wishing to evaluate new technological incursions and examine the implications of their social relations. Social trust incorporates both sides of this dynamic.

In the context of trust in risk regulation, the operative elements of social trust are the public assent to the delegation of the implementation and operation of technologies to elite and expert systems, balanced by the public's expectation that it will monitor the performance of those functions against social values and political principles. Politically competent citizens use social trust as an active process to subject an activity to evaluation and control, while a central concern of regulatory institutions is to reduce or avoid that scrutiny.

This tension intrinsic to the function of trust in complex modern society presents a dilemma to industry, government, and regulatory institutions: in order to gain acceptance for their performance of social tasks, they need to be open to scrutiny. Such scrutiny would openly evaluate the social benefits of a technology and its wider social and environmental impacts, allowing pressure for increased complexity to be answered

and moderated by social pressures for constraint and adaptation to social priorities.

However, governments want to avoid this scrutiny: they want free trust, public acquiescence with minimal scrutiny. This strategic approach places regulatory institutions at odds with the political functions of social trust in government institutions and technological activities in society.

Chapter 5

Risk Regulation and Trust in Complexity

As a guarantor of social trust, regulation is a central component in the dynamic of technology, risk and social complexity. It functions in the thick of the intense relations of private action and intervention, monitoring, and accountability. Regulation articulates the official profile of a technological risk that determines its management, and is able to frame it in the terms of risk and risk management that help manage public attention and demands for its control.

All of these functions, strategies and institutional arrangements are carried out within a complex social context that is approached academically from a number of different perspectives. Two that are most appropriate here are the geographic and political economy field of regulation theory, and the political science of formal regulation as an institutional activity. Bringing both approaches to bear on technology regulation in modern society permits a wider understanding of the institutional and political objectives of specific regulatory mechanisms in their shared context of an overarching social order and economic system.

Regulation theory approaches regulation from a Marxist perspective, as a broad set of social activities employed as part of the functioning and reproduction of the capitalist system. Within this framework regulation is seen as an assemblage of interrelated elements such as wage-labour relations, forms of state intervention and adherence to international regimes, and cultural values and practices, that shape, facilitate and rationalize the capitalist 'regime of accumulation'. Capitalism is seen as

inherently contradictory and unstable, and hence as relying on a 'mode of regulation' that adapts to a regime of accumulation to stabilize it and allow the system to persist. (Tickell and Peck, 1992; Whitehead, 2003; Marden, 1992; Purcell, 2002; Gertler, 2001).

The political science study of regulation focusses on regulation as legislated rules of behaviour in the economy and civil society, and on the ways that such rules are formulated and implemented. Regulation so conceived is "public law which implements collectivist goals, that is, by which the state seeks to direct or encourage behaviour which (it is assumed) would not occur without such intervention. . . . It aims to correct perceived deficiencies in the market system in meeting public interest goals" (Ogus, 1999: 223).

Generally, both fields recognize regulation as working within a market economy, but political science research is more inclined to accept the market economy as a given and describe regulation as an administrative function with political ties to its executive designers and structure. Regulation theory focusses on the primary importance of sustaining capitalism as a global system and tends to be economically oriented, explaining elements of regulation as largely directed towards supporting accumulation systems. However the two approaches are in many ways complementary; political and public administration research often has a critical analytic approach that is not unlike some regulationist literature that insists on a more political, less economically focussed interest (Purcell, 2002; Marden, 1992; Whitehead, 2003). The focus here is largely on formal regulation, but within a wider perspective that recognizes the role played by the cultural and other institutions that are integrated into regulatory regimes in support of

larger political and economic objectives.

Basics of regulation

Under the regulation theory umbrella, a mode of regulation can consist of a large range of relationships, practices and procedures, and cultural norms, adapted to the regime of accumulation that holds sway at any given time. The mode of regulation and its components are identified by their contribution to a larger economic system rather than by their standardized institutional design. This expands the scope of elements that may be seen as part of a mode of regulation beyond conventional political definitions, and that may be specific to a particular economic regime, locality, or application.

As a formal instrument of government, regulation is defined as government intervention into some aspect of civil society, seeking to “constrain or change the economic, moral, or social behaviour of individuals, families, organizations and institutions.” (Prince 1999: 208). It is a government function whose authority is derived from that government’s constitutional authority over the area regulated, and which is given more precise legal authority in legislation.

These definitions suggest a further range of concepts that are integral to regulation as a government function, on which political science and regulation theory approaches are relatively well aligned. Regulatory intervention is legitimized politically in terms of specific ideologies codified in a constitution, or in terms of more fluid ideologies adopted by particular political parties; and the use of regulation as a means of shaping economic behaviour is consistent with government policy and social values.

Many different actors in society participate in the shaping of regulation, which in turn influences the way society is shaped. This suggests that regulation is used in different ways within different political systems, and changes over time as political systems and broader social values change and evolve. The existence in society of different cultural communities results in the imposition of an economic and regulatory regime by the dominant group and the attempts by others to influence this regime. This context alerts us to the different strategic discourses used by dominant and other groups in society on contested regulatory issues, indeed to the fact that a regulatory regime and its various components are themselves part of a political discourse.

Regulation has been defined on several different levels to approach different analytical perspectives (Doern, 1998: 5). At its broadest, regulation may be interpreted as one of the fundamental governing functions of governments. Regulations, as generally speaking “rules of government,” “require justification by reference to democratically established institutions” (Baldwin, 1995: 3). Governments in democratic societies are accountable to the public in the way they exercise power and spend resources; they also seek legitimacy for their policies by linking policies, including regulations, to fundamental political principles.

Regulation is also a governmental policy instrument, along with others like taxation, spending, and service delivery. At this level we may consider the rationales that governments, and other actors such as regulated industries or public interest groups, have for preferring regulation as a means to achieve a policy goal. The process of making regulations involves a range of participants, from, traditionally, governments and

firms or industries being regulated, to more recently a wider range of 'stakeholders' that also encompasses public interest, consumer and citizen groups.

While regulation is created under legislation passed by elected representatives in Parliament, its implementation is usually delegated to bureaucrats, and is thus often referred to as delegated legislation. Strictly regulatory functions are distinct from non-regulatory ones used increasingly as alternatives to regulations, such as voluntary standards and codes, which are being incorporated into regulatory practice seen in a broader sense.

As regulation delegates responsibility for implementing legislation passed by Parliament to officials, sometimes to a broad network of officials with different roles distributed throughout government, accountability is a core principle. As Prince outlines the concept, accountability is fundamentally 'the duty of an agency or official to answer for the exercise (use, abuse, non-use) of public responsibilities and resources given to them. . . . The predominant meaning of the accountability of regulatory agencies is formal, ministerial control and responsibility to the legislature" (Prince, 1999a: 229).

The number of components embodied in regulation leads researchers to talk about regulation as a regime; that is, the elements that together contribute to bringing regulation from a policy intention to its achievement. Defining a regime as "an interacting set of organizations, statutes, ideas, interests, and processes," Doern (1998) groups four different types of regulators, according to their social sector and features, into four different regimes. Regime I, the sectoral regime, consists of industrial sectors that have traditionally been monopolies: the regulatory regime "regulates entry to and

exit from the industry and has preferred to regulate broadly through some form of profit and/or 'rate of return' regulation." (Doern et al., 1999: 13).

Regime II, the framework regime, is horizontal or framework regulation, designed to "cut across" economic sectors and not discriminate among them (Doern, 1998: 31). Health and safety or environmental regulation is framework regulation. Regime III, the government executive regime, consists of the processes within the executive level of a government for setting policy direction, including budgetary considerations, that will be expressed in regulation, and reviewing proposed legislation and regulations in terms of those guidelines. Regime IV, the international regime, reflects the fact that increasingly, regulators must consider obligations and constraints on domestic regulation imposed by international agreements, international agencies and various international dispute-settlement bodies (Doern, 1998: 36).

The public interest according to risk regulation

Risk regulation is a sub-set of regulation; it is generally framework regulation meant to protect human health and safety and the environment (Doern, 1998). Risk regulators are in place fundamentally to enforce regulatory standards under a legislative mandate. The *Department of Health Act* (Canada, 1996: 4, 2 (a1; b), for example, lists the "promotion and preservation of the physical, mental and social well-being of the people of Canada," and the "protection of the people of Canada against risks to health and the spreading of disease" as the top powers and duties of the Minister of Health. "Maintaining and improving health is the primary objective" of Health Canada's draft

Decision Making Framework for Identifying, Assessing and Managing Health Risks (Health Canada, 2000a :5). Health and safety regulators are mandated to meet formal legislative objectives of improving public health using limited public resources.

The public interest is a 'benchmark' for regulatory policy, and regulators are assumed to act in the public interest (Pal and Maxwell, 2003). The public interest in risk regulation is interpreted explicitly as protecting the public against health and safety threats, and implicitly as advancing the general public benefit of greater social affluence created by economic development. Balancing the costs of controlling the risks of an activity against the economic benefits it generates is thus an important factor in risk regulation policies, and excess social costs to control negligible health risks are considered to be health risks in themselves. Allocating risk reduction funds according to the probabilities of risks to health is the duty of the regulator, recognizing that there are huge discrepancies in the costs of various interventions to save one a year of life (Kunreuther and Slovic, 1996).

Risk regulation is commonly considered to be science-based regulation, or "policy and regulatory decision making where scientific knowledge and personnel constitute significant or effective inputs into, or are distinctive features of, the relevant decision-making processes' (Doern and Reed, 2000: 5). Regulators in Canada take an evidence-based approach to risk assessment in which "only the scientifically defensible risks associated with a particular product [are assessed], without consideration of possible benefits" (MacKenzie, 2000: 52). To some extent, health and safety regulators are obliged to use scientific risk assessment methods in order to fulfil their mandate and

other requirements. The federal regulatory policy essentially requires such methods as it states that regulatory institutions must ensure that benefits of regulation must outweigh costs, thus requiring basic quantitative analyses.

The reliance of risk management decisions on 'sound science' is in part an effort to stabilize the type of logic and expectation that drive risk management, and to place a prescribed set of criteria for making risk management decisions as an intermediary between public demands and political responses. However, as reviewed in Chapter 3, science also lends credibility to the modern economically oriented culture. Levidow (2001: 358) perceives a shift in the meaning of the phrase 'sound science', originally used to denote "public scrutiny of scientific evidence of its quality and relevance to decision-making," to being "deployed to silence doubts about whether the available evidence is adequate for safety approval of products. As a political slogan, 'sound science' tends to conceal value-laden features of safety claims, their weak scientific basis, their normative framing and their socio-political influences" (Levidow, 2001: 345). Cook (2004) concludes that as used by industry, sound science is 'self-congratulatory', "awarded by those on one side of a scientific dispute to themselves and denied to their opponents." Politicians use the phrase to refer to science that supports their policies (p 95).

Jasanoff (1998: 98) claims that quantitative risk analysis (QRA), by focussing on strictly material causes of risk, "tends to diminish our perception of human agency and responsibility"; as Latour (1993) would express it, through the practice of purification regulation avoids - prevents - any thinking about the consequences of social

transformations of nature. QRA “builds not only on objective measurements but upon underlying models of agency, causality, and responsibility. It *frames* the world,” ruling out other ways of classifying and measuring harms to the environment (Jasanoff, 1998: 96).

Scientific assessment of risk and assumptions of the nature of the public interest are often at odds with public judgements of risk and of the public interest, and hence with public priorities for risk management. From the perspective of the regulator and the scientific risk assessor, public perceptions of risk appear to be distorted, to exaggerate the unknown - usually more particularly new and complex technologies - despite accident and other statistics that rank many routine activities as posing higher risk.

Risk assessment and management professionals often express concern that reflecting public risk perceptions in risk management diverts limited public funds not only from the control of more important risks, but also from the development of social wealth, which itself adds to social well-being that increases public health and safety. They claim that risk management is inconsistent and often driven by a desire of the public to reduce already low risks, leading to disparities in funding allocated to risk reduction programs (Joint Committee, 1993; Slovic, 2001). Hammitt (2000) claims that the role of the government is not just to reflect public sentiment, as public views on risk represent ‘cognitive errors’ and have no legitimate role in risk management.

While risk assessments produce important knowledge for the management of public health and safety, probabilistic risk perspectives are also tacitly aligned with government economic priorities in ranking the risks of technologies lower than many

lifestyle risks that people tolerate, in focussing on risks without reference to values, and on assuming that benefits are counted in economic terms. Risk assessment frameworks assume a definition of the public interest, incorporating a set of neoliberal objectives into the assumptions of the social benefits claimed for technology and economic growth. The use of risk assessment thus means that risk regulatory decision making reflects economic priorities, and explicitly excludes broader value-based concerns about the use and management of technology in society. Finally, because science appears as an objective reflection of external reality, fixing a policy position in scientific terms gives authority to that policy position as rational and inevitable.

Intellectual Property

Intellectual property laws are an element in a mode of regulation meant to sustain a regime of accumulation, supporting and providing incentives for the development of new technologies. They complement the mechanisms of control of technologies in society, and are necessary in a neoliberal system that relies on continuing market development and innovation to sustain the economy.

Contemporary IP laws are part of a policy framework put in place by governments specifically to “foster a more innovative economy” (Hirshhorn and Langford, 2001: 7), based on the recognition that “left on their own, markets will not lead to adequate innovation.” IP laws “remedy this market failure by granting property rights that recognize an inventor’s exclusive right to make, use or sell an invention for a fixed term. Besides stimulating the production of new knowledge, the IP system

facilitates its dissemination” (Hirshhorn and Langford, 2001: 4).

Patents entitle the holder to a limited monopoly on the patented product or process, excluding others from “making, selling, or using an invention covered by a patent for 20 years” (Schrecker and Wellington, 2000). In return, the inventor discloses technical information about the invention, thus permitting the sharing of technological advances (CBAC, 2001). The fundamental requirement for the awarding of a patent is that the invention be new, useful, and not obvious; patents “are awarded to processes or objects of manufacture” (Krimsky, 1991; Duy, 2001; Schrecker and Wellington, 2001). The utility criterion of a patented product also stresses the importance of the purposeful design of artefacts, which are created to meet a specific objective and perform a specified task within a social setting.

Intellectual property is “a child of the European Enlightenment” (Hesse, 2002: 26). Canadian patent law, like that of many other countries, is based on the U.S. patent law of 1790 (Duy, 2001); these laws are derived ultimately from John Locke’s seminal modern distinction of private property from the natural commons (Schrecker and Wellington, 2001) in 1690.

God, who hath given the World to Men in common, hath also given them reason to make use of it to the best advantage of Life, and convenience. . . . Though the Earth, and all inferior Creatures be common to all Men, yet every Man has a *Property* in his own *Person*. This no body has any Right to but himself. The *Labour* of his Body, and the *Work* of his Hands, we may say, are properly his. Whatsoever then he removes out of the State that Nature hath provided, and left it in, he hath mixed his *Labour* with, and joyned to it something that is his own, and thereby makes it his *Property*. It being by him removed from the common state Nature placed it in, hath by this *labour* something annexed to it, that excludes the common right of other Men. (Locke, 1960/ 1690: 328-9; emphases in original).

This position assumes that it is both logically possible and socially necessary to distinguish human society from nature. It also assumes a divinely sanctioned supremacy of humans over nature and human entitlement to the use of nature, and the sense that untouched nature is common, becoming socially ordered and privately owned with the addition of labour by humans. As Jasanoff (2005: 224) notes, “human intervention in any form converts nature into commodity [and] places it in commercial circulation.”

Regulation within changing global conditions

Regulation has responded, with national economies and international economic systems, to recent shifts in political and economic policy frameworks. Regulation theorists describe this shift as the decline in Fordism, the economic system stretching from the end of the Second World War to the 1970s that was characterized by standardized mass production of consumer goods using dedicated machinery and relatively fixed job descriptions (Gertler, 2001: 275). Post-Fordist economies have been characterized by the decline of the wage-labour contract that had balanced production with consumption, and a retreat from the social policies and practices that had shaped economic activity to support the public interest (Palan, 2006: 258).

The present emerging neoliberal economic climate is often said to be a more flexible production system (Tickell and Peck, 1992; Purcell, 2002); Palan (2006) argues that the regime of regulation that is emerging in place of Fordism is the competition state. He and others (Tickell and Peck, 1992; Purcell, 2002) describe a set of conditions that characterize the new developing regime.

- an “increasingly internationalized economy” in which states are in competition with each other over market share and the attraction of capital; (Palan, 2006)
- pressure on states to adopt business-friendly attitudes, including employing efficient managerial practices and avoiding competing with business in the provision of manufacturing and services; (Palan, 2006)
- a faith in ‘market equilibrium and the ability of markets to correct themselves’. (Palan, 2006: 259)
- a shifting of responsibility and function to the private sector and NGOs (Purcell, 2002)
- a retreat from welfare, and a shift to supply side policy, emphasizing workfare and training, focussing on technology as the major driver of economic growth (Purcell, 2002)
- an increasing reliance on design-intensive industries, high technology, and business, finance and personal service functions (Tickell and Peck, 1992).

These changing economic conditions placed pressure on industrial democracies in the late twentieth century; challenges included rising deficits and debt, increasing globalization and new information technology, and pressure from business to provide environments that are congenial to investment. In addition, changing social and demographic conditions saw an increasingly educated and diverse population shifting in its expectations of government and losing confidence in government (Ford and Zussman, 1997; Paquet, 1999).

In response, traditional, rigid bureaucracies gave way in many countries to New Public Management (NPM), a less centralized, market-based approach to governing that is oriented towards providing services to clients at lower cost, and towards increased flexibility in the delivering of services by a range of government and private sector organizations (Paquet, 1999; Doern, 2002). In Canada, a modified version of NPM has been applied within a largely traditional bureaucratic structure: alternative service

delivery (ASD) is “a creative and dynamic process of public service restructuring that improves the delivery of services to clients by sharing governance functions with individuals, community groups and other government entities” (Paquet, 1997). In this model citizens become viewed as clients of government services, a shift that focusses attention on the quality of services provided, but which may also slip into a focus on citizens as simply consumers, and on efficiency at the expense of effectiveness (Jarvis, 2000; Graves, 1999; Auditor General, 2000). Governance, the “process through which a society/economy/polity steers itself” under government policy control (Paquet, 1997; Paquet, 1999) is replacing older models of top-down government provision of public services. A distributed, collaborative approach to governance allows the flexibility needed in an age of rapid change and increasing complexity.

As part of this broad shift in governance style, the regulatory system in Canada also evolved, to aim “for a results-oriented management system, coupled with new frameworks for alternative service delivery and quality standards”(Canada, 2000: 9). A number of reviews of the regulatory system in Canada since the 1980s resulted in a federal regulatory policy in 1986 (Averill and Coe, 2000), last revised in 1999. The Federal Regulatory Policy (Canada, 1999) reflects the characteristics of the neoliberal ‘competition’ state, and political analyses of the shifting regulatory environment. It requires that regulatory institutions use regulation only when it is needed and consider alternative means to meet policy objectives, ensure that the benefits of regulation outweigh the costs, keep costs to business and government to a minimum, meet international obligations, and ensure that the public is consulted and informed.

Alternatives to conventional regulation include the devolution to industry of the responsibility for establishing product and service standards and maintaining quality assurance, through such mechanisms as voluntary codes (OAG, 2000: 24-10).

The adoption of a federal regulatory policy that brings all government regulations into line with a consistent set of policy principles and requirements is a function of the development of a regulatory management regime. Executive control shifts regulation from being a 'series of one-off events' (Hill, 1999) to an instrument through which all regulation expresses and implements government policy priorities. This marks the recognition by policy makers that regulation is a means of achieving broader government policy objectives, and an increasing research focus on regulation as expressing and perpetuating policy.

Regulation has become highly integrated into the political system and agenda. Regulation includes monitoring and enforcing compliance with regulations themselves, but it is also closely intertwined with other levels and contexts of government, including executive-level agendas and policy frameworks, coordinating organizations, general legislation and framework regulations, and constitutional rules (Prince, 2000). Thus regulation is guided by and expresses broader government neoliberal agendas and policies, and helps to shape and guide the regulated sector itself.

Regulatory reform has largely been motivated by a recognition by policy makers of the link between regulation and "a strong, internationally competitive economy": the 'competitive rationale for the effective management of regulation is championed at the most senior policy levels' (Hill, 1998: 210). These changes have introduced economic

growth, and more specifically the support of innovation, as an explicit executive-level objective of all regulatory institutions and regimes within the federal government. As Niosi and Bas (2004: 233) point out, “Long-term economic growth is widely seen as a consequence of technological innovation.”

There is a certain urgency to this government economic agenda in Canada. The Conference Board of Canada (2007) explains that innovation is crucial to a modern economy.

Innovation is an essential component of productivity and prosperity. It is only through innovation, insists the OECD, only through the development and exploitation of new products, processes, services and systems, and only through the constant upgrading of the quality of what a country already produces, that countries can sustain growth and productivity.

Innovation is . . . an essential component of a high-performing economy; it is also critical to environmental protection, to a high-performing education system, to a well-functioning system of health promotion, disease prevention and health care, and to an inclusive society. Without innovation, all these systems stagnate and Canada’ performance deteriorates in comparison with that of its peers. Our competitors are not standing still (pp 2-4).

The Conference Board of Canada (2007) warns that Canada’s innovation performance is poor and traces this to Canadians’ unwillingness to take risks, related to a certain disengagement from a broader entrepreneurial social perspective:

Anecdotal evidence from many sectors suggests that Canadians are complacent and generally unwilling to take risks. Our culture is unwilling to accept the failures that are built into an environment that genuinely supports risk taking. Nor are we wholly comfortable with differentiation, success and excellence.

This culture holds Canada back in entrepreneurial and technological innovation. . . . It is this culture that must change and change quickly (p.4).

Regulation’s increasingly explicit orientation toward business and innovation is embedded deeply into the apparently neutral, and authoritative, scientific language of

regulatory protection. An evolving perspective on risk as opportunity rather than only adverse consequence shifts the emphasis in risk regulation to accepting and managing risk rather than avoiding it. The modified interpretation of risk outlined in the Treasury Board of Canada's Integrated Risk Management Framework preceded and underscores the shifting regulatory approach, which has increasingly stressed economic growth. The "business risk" model laid out in the Integrated Risk Management Framework (Canada, 2001) retains the scientific definition of risk, including both probability and consequences or extent of impact, but differs from the traditional definition of risk in including positive opportunity as a possible outcome. The traditional 'adverse consequence' concept of risk leads to a 'risk-averse' regulatory approach, which blocks innovative risk taking: the public servant needs to develop a "proactive" attitude toward risk that "promotes constructive risk taking" (Hill and Dinsdale, 2001).

The new risk-benefit management model implies proceeding with technologies with a relatively high risk profile while managing the risk through post-market monitoring, rather than avoiding the activity - and foregoing its possible benefits - as may have been done under the more traditional risk-averse risk management paradigm. The turn to risk-benefit management is integrated into regulatory practice by being actively advocated for risk managers within the public service (Doern, 1999; Doern, 2000; Hill and Dinsdale, 2001).

Regulation is a crucial aspect of the support of innovation within a country, and for the attraction of research and development to the country. Markets need regulation, and well-designed regulatory regimes can stimulate the economy and encourage

innovation, and provide an advantage to firms that locate in the country (Jarvis, 2000). The Innovation Strategy (Canada 2002a) notes that Canada's 'innovation environment is strong': regulatory barriers are the lowest among OECD countries, and "our particular strength lies in the clarity of our regulations and administration, relatively low paper burden for business, lower barriers to competitiveness, and the openness of our process" (p 63). Where there are regulatory costs, however, they are pointed out as a barrier to business and investment in the country. The Canadian Biotechnology Advisory Committee (2002a: 16) reported that "the developers of new products, whether food crops, pharmaceuticals or pesticides, claim that the Canadian regulatory regime is significantly slower in approving new products than comparable systems in other countries, and that Canadian regulations make it more expensive and time consuming for new products to get to market, thereby reducing the incentive to do business in Canada. They urge increased international cooperation to reduce the duplication of work and the amount of time required to secure approvals for a single product."

For its part, industry values government regulatory control of risk as a function that is seen to protect the public good, and to respond to public priorities. The protection function of regulation supports innovation by visibly checking a technology the public does not trust, thus rendering it both safer and more acceptable; this is the foundation of regulation as a trust guarantor. Biotechnology companies actively lobbied for strict regulation in order to 'placate the opponents of the technology', and get a 'government stamp of approval for it' (Miller and Conko, 2003). In its function of both controlling and fostering biotechnology, regulation "can be seen as a crucial enabling device without

which the dissemination of genetic technologies would be much more problematic” (Webster and Nelis, 1999: 302).

With the integration of regulation into the larger-scale economic agenda has come the integration of promotion into the regulatory mandate. Along with the emergence of the executive regulatory regime as an element in government policy, innovation is now seen “as something that can be promoted *systematically* across the economy. . . . The conscious promotion of innovation has become an important focus of economic and social policy” (Canada, 2002a: 4; 6, original emphasis).

The emphasis on regulation as a vehicle for supporting economic growth has brought to the fore a tension between conventional regulatory goals, such as health or environmental protection in the public interest, and the promotion of the regulated industry or sector. The economically oriented policy objectives that have been integrated into the mandate of regulatory institutions have expanded the responsibilities of regulators beyond the protection of the public from health and safety risks. While at its most basic, regulation’s ‘command and prohibit’ function implies a ‘negative, policing role’ that suggests “that regulation is both detached from and intrinsically antagonistic to the promotion of economic activities,” regulatory functions have more recently included “promoting the economic welfare of firms and sectors subject to regulation and participated in planning by directing activities toward public polity aims” (Prince, 2000).

The regulation-promotion tension has suggested a conflict of interest within regulatory institutions themselves. CBAC (2002a) has noted the “potential conflict between the government’s regulatory role and its role in promoting the country’s

economic interests. The fear is that in seeking to promote the exploitation of technology to capture its economic benefits, the government may downplay the risks of the technology and accentuate its benefits” (p.15).

Despite the move towards regulatory reform and cooperation with the private sector, regulation must still be managed by government in order to maintain public credibility (Doern, 2003). The inclusion of promotion in the obligations of regulatory institutions has led to questions about the role of government and regulation in championing the public interest or private economic interests and what kinds of values and priorities ought to shape policy directions, and about the lack of consensus within society on policy priorities, particularly the lack of citizen engagement in regulatory policy (Prince, 2000). It has also led to confusion and suspicion about the ultimate goal of regulatory activities such as the provision of information, which often appears to have promotional objectives; risk communication, for example, is often suspected of being designed to persuade rather than simply to inform, leading to questions of promotional goals and activities being at variance with, and ultimately undermining credibility of, regulatory activities (Prince, 2000). The Canadian Environmental Law Association (CELA) (Benevides, 2004) urges that “regulatory departments should seek to separate institutionally as much as possible the role of promoter from the role of regulator” (p.6).

Government risk regulation objectives: Trust, Innovation and Protection

The core feature of ‘Smart Regulation’, introduced as a new initiative in 2002, is the use of multiple policy instruments and a wider range of regulatory actors, to produce

better regulation (Leiss, 2003) and a broader concern for the innovation environment. In its vision of a “regulatory system that enables Canadians to take advantage of new knowledge and supports Canada’s participation in an international economy,” the External Advisory Committee on Smart Regulation (EACSR) (Canada, 2003c:1; emphasis in original) notes three essential obligations of regulators:

- **Trust:** the regulatory system must instill trust, confidence, and credibility at home and abroad in Canadian products and services, markets and institutions
- **Innovation:** the regulatory system must enhance market performance and enable innovation, competitiveness, entrepreneurship and investment in the Canadian economy.
- **Protection:** the regulatory system must demonstrate to citizens that the public interest, such as human health and the safety and protection of the environment, will be safeguarded within dynamic global markets.

Smart Regulation “has both protecting and enabling characteristics with the goal of promoting health, safety and sustainability, contributing to economic growth and reducing burden on business” (Canada, 2003a). The language used to describe Smart Regulation places the strongest emphasis on innovation as the context within which the other two objectives function, and to which they contribute; the safeguarding of the public interest “within dynamic global markets” is a frank acknowledgement of the neoliberal policy framework within which risk regulation operates. The EACSR report stresses that regulation must accommodate the fact that economic performance, environmental quality and social welfare are ‘interlinked’ (Canada, 2004a: 133), attributing these priorities to the general public:

Canadians now see social, environmental and economic goals as intertwined. They believe that there is an excessive compliance burden on business. They also accept that markets, trade and competition serve both public and private interests.

This represents an important change (p 12).

The “ultimate objective” of the regulatory management system is to “produce regulation that is more efficient, better targeted, more flexible, more credible, and has better compliance and “buy in” from the public” (Canada, 2003b: 5). A regulatory system that is shifting its alignment to innovation must still retain legitimacy and public trust. Purcell (2002) points out that in addition to the focus on accumulation, modern capitalist states are also strongly motivated to seek political legitimacy and stability. State legitimacy “requires a collective consent to be governed”, he says, and is “rooted principally in the mutual expectations a state shares with its collective citizenry.” (p.310). This becomes a particularly important objective for regulation as it represents a social contract on the terms on which a technology is accepted into society (Jasanoff, 1995). Gaining public trust requires a visible commitment to protection; however, “citizen consent need not imply that the state *actually* meets the needs of its citizens; the key is whether or not the citizenry *perceives* that the state is acting in their best interests”(Purcell, 2002: 310, original emphasis).

Protection therefore remains high on the list of formal objectives of regulation. The EACSR (Canada 2003b:1) states that “the overall objective of health, safety and environmental regulation is to proactively protect Canadians from threats to health and safety and to protect Canada’s natural environment. To that end, risk management is essential”; and regulators stress the high priority of public health protection in their mandates and operations. In a similar acknowledgement of the need for legitimacy, the 2005 draft Government Directive on Regulating (GD-R) (Canada, 2005), issued “to

strengthen the current federal regulatory system,” opens with a “commitment to Canadians” to “work with Canadians and other governments to ensure that its regulatory activities provide the greatest overall benefit to present and future generations of Canadians” (Canada, 2005: 2). The GD-R (Canada, 2005:2) places at the top of its list of commitments serving and advancing “the public interest as expressed by Parliament in legislation in such areas as health, safety and security, the quality of the environment, and the economic well-being of Canadians.”

Such health protection is achieved according to the rationality of risk assessment, within the policy framework of risk management, and according to the new risk management paradigm underwritten by the Integrated Risk Management Framework. The EACSR report (Canada, 2004a: 34) states that “at the centre of risk management is the idea that a rational, deliberative and evidence-based approach to decision making will deliver better results over time.” It de-emphasizes hazard and focusses instead on uncertainty and a calculated approach to risk taking. Risk management itself is defined by the EACSR (Canada, 2004a) as “a systematic approach to setting the best course of action under uncertainty by identifying, understanding, assessing, prioritizing, acting on and communicating about potential threats, whether they affect the public’s social, financial or economic well-being” (p.34).

While government risk regulation is portrayed as focussed on the public good, the public’s actual expectations for strict regulatory control of risk remain an obstacle to government innovation agendas, as ‘governments are held hostage to constituents’ risk aversion’ (Jarvis, 2000). Risk perception researchers and surveys have observed that the

public feel technological risks are imposed on them by other social groups, and that they do not always value the benefits. The presence of regulation implies that “those who are being regulated can not be trusted to do the right thing”(Cvetkovich and Löfstedt 1999b: 166). A survey taken in 2002 found that 38% said big business is the most important consideration in government decision making, and 29% said politicians and their friends were; only 16% of the public believe that the federal government makes decisions in the public interest (Ekos, 2002).

Furthermore, Canadians have expressed their strong expectation that the priority of regulation will be the protection of health and safety (Benevides, 2005b; Canada, 2005: 6). Public advocacy participants in workshops on the draft Directive urged that “regulators should heed the advice of the Krever Commission and that the Directive should be very clear that departments and agencies should regulate in the public interest and not in the interest of those who are being regulated” (Stratos, 2006: 8). CELA (Benevides, 2005b) recommended that

The regulatory policy should begin with an overarching policy direction that regulation is always intended to achieve the same purpose: the protection of public goods from undesired impacts of economic activity (p.6).

The public expectation is that health and safety regulation is an essential function of government, and it does not support the privatization of health and safety regulatory functions as it does for other areas of regulation (Doern and Reed, 2000). Jarvis (2000) argues that the ‘damage function’ - the severe and non-remediable consequences that may occur to the public if there are mistakes or shortcomings in risk regulation - implies that people do not tolerate experimentation or error in the regulation of health and safety

risk, and that the Canadian public has high expectations of broad government responsibilities for health and safety protection. Canadians and public advocacy groups also insist that regulation should remain focussed on regulatory means, rather than voluntary compliance means as encouraged by Smart Regulation as 'results-focussed' regulation. In large part to retain clear democratic accountability, regulation should be a government function that retains visible ties to legislation and to political representation. CELA (Benevides, 2005a) notes that "it is no coincidence that the notion of 'public good regulation' incorporates ideas of 'democracy' and 'accountability': "public good regulation means activity involving government acting as representative and guardian of the public interest in, for example, human and public health and environmental protection' (p. 6).

Despite the top priority claimed for health and environmental protection, critics argue that in fact protection takes a back seat to economic objectives. CELA (Benevides, 2005a) states that "[EACSR's] final report pays lip service to protection of public goods, and places a clear priority on the need for promotion of 'important new industries like biotechnology' and the importance of not inhibiting competitiveness, productivity, investment, and the growth of key sectors" (p. 7).

In public workshops on the Draft Regulatory Directive, public advocacy sector participants stated that the draft Directive is biased in favour of business and the economy, designing regulations "for the benefit of those who must comply, and as such does not represent a new policy direction (Stratos, 2006: 6). CELA (Benevides, 2005a) notes that the EACSR itself was made up primarily of private sector representatives and

held no public meetings, and that it “relies almost exclusively on the complaints it heard from industry about the heavy burden of existing Canadian regulations” (p.4).

Trust, innovation and protection are recognized as highly interdependent, as protection is carefully manoeuvred to gain legitimacy and public trust, which is a crucial social component for continued innovation. Regulators gain public trust by ensuring protection from private activities, and try to harness that trust to enable regulatory conditions that are favourable to industry and a country’s economic competitiveness. As Jasanoff (1995: 311) explains, regulation is a means by which states

provide assurance that the risks of new technologies can be contained within manageable bounds. Procedures are devised to limit uncertainty, channel the flow of future public resistance, and define the permissible modalities of dissent. Regulation, in these respects, becomes integral to the shaping of technology.

In order for regulation to manage public demands for the regulation of a product it is simultaneously controlling and supporting, it must construct a model of the issue that constrains opposition to certain aspects and processes it safely through prescribed channels. Regulators develop a conception that “enables [them] to devise strategies for managing uncertainty and neutralizing the most common forms of organized opposition. . . . Regulators . . . rearrang[e] a potentially limitless expanse of scientific unknowns into familiar paradigms of assessment and control” (Jasanoff, 1995: 313). Defining a technology or product as social or as natural in certain key matters is a primary strategy in such a objective. In risk regulation, regulated substances are often defined as natural, through the technical definition of risk and the use of QRA, which authorizes the exclusion of non-scientific considerations.

Public discussions on regulatory activities are confined to the technical risk issues addressed by risk assessment procedures, to the explicit exclusion of related political issues. This becomes a delicate strategic matter, as it is not the level of concern of either the public or of regulatory policy: members of the public are concerned with social, more than technical, issues, and regulatory policy and Smart Regulation have explicitly and strenuously expanded the objectives of regulation into economic policy. The goal-directed design and implementation in order to produce a particular result in a certain context form the core of the regulatory policy objectives. This aspect of technology remains a persistent focus of public and interest groups, who continue to track the intended goals and beneficiaries of technology.

The type of trust referred to by risk regulators

Government and risk regulatory institutions discuss the nature of public trust and the ways in which risk managers can gain it, but are not clear in their definitions of trust. When referring to the generalized decline of trust in government, federal government documents present a range of contributing factors. Bélanger et al. (2001:6) list several 'economic, cultural, social and psychological factors' in their context-setting to the more detailed discussion of gaining trust in risk management. The Canadian Food Inspection Agency's (CFIA) publication on risk communication (CFIA 2001a: 8) prefaces its discussion with a review of broader concepts and conditions; arguing that "credibility, confidence and trust form the foundation of democratic government," it notes a number of factors, including parliamentary accountability, citizen disengagement from traditional

political processes, cultural changes in modern society, and evolving political expectations.

Trust in regulation, particularly risk regulation of new and controversial technologies, appears to be decreasing even as the push towards increased innovation intensifies the need for greater trust. The EACSR (Canada, 2003b) notes that public trust in government and institutions is dropping, and that even though citizens are more informed and better educated than in the past, they are challenged by increasing complexity with the rapid development of new technologies and demand higher levels of ethical performance of both the public and private sectors. Public trust in risk management and regulation, however, is interpreted in the context of the lay misunderstanding of science and complex technologies. The type of trust referred to is almost exclusively a psychological, dimensions of trust approach, in which trust characteristics are described in terms of human emotions, and the essential relationships are between the individual layperson and the risk source, as mediated by the trusting relationship with a risk management expert.

Bélanger et al. (2001) describe trust as depending on integrity, competence, empathy, and openness, advising that self-confidence builds trust in individuals. Hill and Dinsdale (2001:14-15) cite the same dimensions of trust, noting that “the public . . . deal with risk in a very personal manner.” They list a set of characteristics of ‘expert risk assessment’ and public ‘intuitive’ risk views. The reliance of some government literature (Bélanger et al., 2001) on administrative research on organizational trust may encourage this perspective: this approach focusses on trust as the willingness of individuals to be

vulnerable to other individuals in an organization, and as being essential for risk-taking by those in the organization. Warah (2001) defines and discusses trust among individuals in an organization, yet also appears to assume that this framing extends to public trust in regulatory institutions and will facilitate regulatory risk-taking.

The CFIA publication on risk communication stresses the importance of trust, "the pivotal focus of risk communication" (CFIA, 2001a:17), as research has shown that trust in a risk information source influences the credibility of the message. In this document as well, trust is described in the terms of dimensions of trust, as including perceived competence, objectivity, fairness, consistency and goodwill, and also as reducing the burden of the individual faced with complex hazards (Cvetkovich and Nakayachi, 2007).

These regulatory portrayals of public trust in risk management imply a coherent image of the public and of the nature of risk. They rely on the 'deficit model' (Frewer et al., 2003) of the public understanding of science and risk, define risk issues as the expert control of technology rather than as social decision making, and focus on technical rather than social complexity. Furthermore, the matter of technology in society is treated as a 'given', a condition of the contemporary social world managed by experts, rather than an ongoing public policy debate, on which there is considerable dissent. In such a context, the public is portrayed as fearful of what it does not understand and unable to make decisions on such matters, and as susceptible to persuasion by skilful communicators. This portrayal denies that members of the public have either access to a wide range of relevant sources of information, knowledge or experience about risk issues, or the ability

to reflect on and interpret them. Foster (2000: 4-5) claims to have observed an “increasing public desire for reassurance that trusted regulators are protecting their interests and shielding them from the many harms arising from the complexities of modern life.”

Thus strong public opinion, particularly if it is counter to government policy, is often attributed to the persuasive efforts of the media and special interest groups rather than to genuine public engagement with the issues. The Colloquium on Risk Management (Canada, 1994) attributes public demands for excessive risk control to the media, which ‘have become the most influential driving force in the risk management arena’. In addition, special interest groups “have done a good job of raising awareness of problems, but now need to make a constructive shift to contributing to solutions” by encouraging the public to moderate their risk management expectations (ibid: 4). The CFIA (2001a: 18-20) notes, however, that educating the lay public is a difficult matter, given the persistent “optimistic bias” and “outrage bias” to which they are prone in perceiving risks, and because “lack of public understanding of science is complicated by the fact that people tend to avoid learning about subjects they fear.”

In this framing, public attitudes to risk are interpreted as emotional, value-based reactions to uncertainty and lack of knowledge, and risk controversies as apolitical conflicts about probabilities of harm, in which science is relied upon to help regulators balance the interests of industry and the public (Frewer and Salter, 2002). Hence risk issues are usually explained as consisting essentially of risk-benefit tradeoffs, with examples of lifestyle risks representing the more controversial technological risk

controversies (Hill and Dinsdale, (2001).

'Complexity' in these discussions of risk regulatory issues is that of technical matters that require specialized expertise to understand, rather than a more general social and political complexity; it does not recognize the political aspects of technology in society and the implicit social contract represented by regulation itself. This places the lay public in a subordinate position relative to risk management professionals and other decision makers, and overlooks their political capability on a very political issue. When the lay person is assumed to misunderstand and fear complicated technologies and to be susceptible to the agendas of skilled communicators, the image of a vulnerable public that desires a strong personal bond of trust in a competent and empathetic risk regulator follows. Personal trust in the risk regulator is thus seen to play an important part in reducing people's wariness of technology and ultimately their demands for excessive risk control.

In keeping to this vision of technological regulatory debates, regulatory institutions disregard, or deny, the artefactual character and political content of technology in society and government regulatory policy, of risk regulation controversies, and the important relevance of non-experts' political knowledge and aptitude. That is, they avoid opening debate on the very aspects and impacts of technology that are at the heart of public perceptions of risk and resistance to technology, and that appear to be the aspects of technology management that individuals monitor in deciding on trust or distrust. They purify the issue to one of natural process and scientific knowledge only, excluding consideration of the social intent of the technology and the political and

environmental implications it may have. In so doing they simplify the social context of the issue to a routine institutional function that is competently managed by experts, constructing a situation in which the public may have confidence, and does not need to exercise the more demanding social trust. As the Conference Board of Canada (2005:14, original emphasis) argues,

. . . in situations of high vulnerability, individuals often elect to trust simply because they find it more psychologically comfortable than the alternative. This blind faith does not depend on the rational calculation of trustworthiness on which most trust decisions depend, but there is evidence to suggest that it *does* depend on a lack of significant evidence that their trust has been misplaced.

Regulatory measures to build public trust in risk regulation

The orientation of regulators towards interpersonal trust in a respected expert avoids the acknowledgement of a public that is informed and competent, that critically monitors the social implementation of technology and its management by public institutions, and demands greater participation in what it sees as a political and not simply a technical process. The knowledge deficiency model adopted by regulatory institutions acknowledges the need for and value of public participation in policy decisions, but does not acknowledge that technology implementation and risk management are among such policy matters.

Efforts to build trust in risk regulation are being made by government and regulatory institutions on a number of fronts, such as risk communication, public engagement, and reflection of public priorities in policy documents. These efforts largely retain a dual vision of the public as a citizen in the regulatory policy context, and as an

uninformed non-scientist in the risk context.

In the regulatory context, efforts to build trust are based on an interpretation of the public as a citizen deserving of democratic access to decisions. There is an emphasis on procedural methods of public participation in regulation, stressing building trust through positive personal interactions with representatives of regulatory and management institutions (Bélanger et al, 2001). Public participation ensures the democratic legitimacy of the process, and is said to enhance confidence in decisions, regardless of the outcome, and by association to build trust in the institution (Hill and Dinsdale, 2001); as Löfstedt (2003) says, building trust to gain acceptance of decisions without questions about their rationale. Participants at a Conference Board of Canada (2005: 29) round table on trust reported that “consultations prior to the introduction of regulations [had a] subsequent effect in terms of increased public trust.”

The Conference Board of Canada (2005) also stresses the importance of organizations’ using external, credible ‘assurers’ to strengthen public trust in their operations. Understanding the ‘web’ of trust guarantors and intermediaries enables an organization to place itself favourably in relation to these organizations, to use them to build public trust in its operation. For financial operations this could be an audit by a reputable outside firm; for other corporate operations, it may be a wider range of information from trusted sources. Regulators enforce ‘compliance with laws and regulations’ very visibly, to demonstrate their independent commitment to the public good. Organizations are also aware of ‘lent trust’ that comes from their affiliation with or assurance from a credible institution, particularly a non-profit organization: “public and

private sector organizations were eager to ‘borrow’ trust from the non-profit sector’ (Conference Board of Canada, 2005: 30) as NGOs project an image of non-financial motivation, and commitment to community or environmental causes.

In a risk management context, the main public focus of effort is on risk communication, which, it is hoped, can educate the public in regard to risk, increase the credibility of risk messages, and, through building trusting relationships with regulators, reduce the perceived risk of regulated products and build trust in the regulatory system itself. The goal is to ‘manage’ risk perceptions to avoid pressure to reflect public demands in risk regulation. The EACSR (Canada, 2003c: 12) counts ‘managing the expectations’ of stakeholders as necessary to enable risk regulators to design rules and use instruments that are flexible and encourage innovation, particularly in health and safety areas. “People are often poor natural risk assessors and information can reduce demands for unnecessary regulation or move the emphasis to regulation where the greatest potential benefits in terms of risk reduction may be found” (Canada, 2003c: 10-11). This is a strategy Rothstein et al. (2000) call ‘opinion-shaping’ to manage the ‘gap’ between public and regulatory opinions.

Given the stability of trust attributions, the importance of people’s underlying values and attitudes, and the independence of trust and risk judgements, public participation in decision making processes may not necessarily lead to greater trust and lower risk perceptions. In fact, it has been found that the provision of more information hardened opposition to biotechnology among ambivalent or uncertain people, who then tended towards greater distrust (Poortinga and Pidgeon, 2004). Information is interpreted

in line with existing attitudes, and in the case of uncertainty and polarized debate further information served to consolidate rather than shift positions. Public participation is unlikely, by itself, to build trust (Poortinga and Pidgeon, 2004) and increased trust in managers will not necessarily reduce perceived risk or build support for a new or controversial technology (Frewer, 2003).

Regulators incorporate public participation into regulatory policy making, and make efforts to be seen as doing so. Health Canada's Health Protection Legislative Renewal initiative is being developed through a consultative process, an early part of which included national consultations (Health Canada, 1999) on public and stakeholder priorities for health protection legislation. The subsequent Legislative Proposal (Health Canada, 2003a: 10) highlights a direct reflection of the top public priorities reported in the consultation summary, in the guiding principles of the proposed act: "health and safety should always come first; public scrutiny of government actions and public engagement in decision making will be encouraged; and the Minister of Health is accountable for the administration of the Act to the people of Canada through Parliament." This response to public priorities appeals to abstract political principle rather than to detailed outcomes, and in this regard may be seeking legitimacy more than it is offering substance; there has been criticism that the text of the proposal in fact commits to less rather than greater protection and accountability than the existing legislation (McBane, 2003).

The Smart Regulation initiative positions risk regulation as the means by which trust in technologies is built, protecting the public from risk from a product and thereby

raising confidence in it. It aligns regulation's pivotal dual roles of reducing and enabling complexity by portraying it as a collective and cooperative means of managing innovative technology from which all citizens, not just elites, benefit, rather than as simply a mechanism to check the excesses of private activity in society on behalf of the public.

The Government of Canada can earn the trust of Canadians by delivering a high level of health, safety and environmental protection and by ensuring a fair, efficient marketplace. In situations of uncertainty, risk management (including risk identification, management and communication) plays an essential role in building public trust and business confidence in the Canadian market and regulatory system. Trust and confidence, in turn, can lead to improved competitiveness and incentives for investment (Canada, 2003b).

Regulation as an instrument of political strategy

Regulation consists of a network of formal regulation and affiliated external bodies, and arrangements like intellectual property law and government political and economic policy put in place to balance and sustain a neoliberal economy. It balances public interests against private, and risks against benefits. It assumes, in the public interest, the task of validating private activities and controlling risks, with the goal of securing public trust in the activity and the regulatory institution. That trust facilitates continued economic activity in society because, it is thought, it reduces public concern and attention.

Economic activity - especially innovative technology - emerges as a central priority of government, and as regulation has become more tightly integrated into the mechanisms of delivering policy throughout government and society, supporting

economic growth has become a primary objective of regulatory institutions and individual regimes. Many in the public, however, expect a regulatory focus on public health protection and stricter control of technology and industry. Because of their need to maintain political legitimacy, regulatory institutions have incorporated the dissonant objectives of supporting innovative industry and ensuring - or appearing to ensure - that public health and safety are the primary focus of regulatory effort.

In pursuing these incongruent objectives, regulatory institutions embed an evolving concept of risk that supports innovation and public health protection into an apparently conventional science-based risk assessment. The terms of risk are also meant to contribute to the effort to gain public trust, characterized as a willingness of the public to delegate to experts the responsibility of managing a complex risk and reduce the critical attention to the issue and its management generally. These objectives are linked by a desire to reduce the risk perceived in a regulated technology, and thereby reduce expectations for its control and the scrutiny of its management.

Where regulatory institutions want public confidence in government technology policy through visible attention to risk assessment, members of the public monitor broader performance to observe whether the implementation of technology in society meets their political expectations. Regulatory institutions respond to demands for a fuller evaluation of technology by removing the contentious social issues from view, embedding an innovation-friendly interpretation of risk directly into the terms of a regime that publicly stresses health protection. This combines promotion and protection not only in the same government department, but within a single risk regulation regime.

In addition, it uses those terms to construct a restricted definition of the technology, and of social context and values as irrelevant, and portrays technological innovations as providing benefits for all of society. These measures reveal a regulatory effort to naturalize technological intervention by blocking discussions of its social relations and consequences, in concert with a broader government effort to reposition the risk issue as a social benefit.

Chapter 6

Part 2: Methodological Approach

Methodology

The case studies of attitudes informing the regulation of GM foods and NHPs, and the stakeholder and public response to it, were conducted through a study of regulatory documents, research and polling data on public attitudes to GM foods and NHPs and expectations of their regulation. Extensive information on the regulatory regimes, including the development of their objectives and provisions, was gathered through government policy and regulatory documents and secondary literatures. This enabled the tracing of policy, and the definitions and risk regulatory requirements, that evolved into the final regulations and the way they are interpreted and applied. A profile of the social dynamic with which the regulations interact was built through consultation of a wide range of documents from external organizations and individuals involved in, or critical of, the regulations, as well as government information prepared for the general public that expresses the regulatory institution's engagement in that wider debate.

This research was supplemented by intensive, qualitative interviews with individuals involved in the regulation and consumption of these products. Seventeen interviews were completed between January 2006 and April 2007, and included four each from GM regulatory officials, GM stakeholders, and NHP regulators, and five NHP stakeholders and users. The participants from the regulatory offices were in key positions in the Novel Foods section, Foods Branch, and the Natural Health Products Directorate, both within Health Canada. In the case of both offices, an initial contact was

made with an executive level officer in the division, who forwarded on the names of four officers who would be appropriate participants and who were willing to take part.

In the case of stakeholders, initial contact was made to individuals who had participated in consultations on the development of the regulations and whose names were included in consultation reports. Subsequent participants were suggested by those first contacts. As the NHP stakeholders who participated in regulatory development were largely producers in the industry, three individuals who used NHPs but were not involved in the industry were included, to get a perspective from outside the industry. In the following Table 6-1, the interview participants are identified within the group to which they belonged and numbered in a single series: GM foods regulatory officials are designated GM-R 1 through 4, and GM stakeholders as GM-S and are numbered 5 through 8. NHP regulatory officials are NHP-R 9 to 12, and those interviewed as stakeholders in the NHP field are NHP-S 13 through 17. Direct references to statements from the interviews are cited in the text by group only, in order to protect the anonymity of individual participants.

| interview number | position | background & involvement |
|-------------------------|-------------------------|--|
| GMR-1 | Novel Foods Directorate | MSc microbiology; biotech research and risk assessment |
| GMR-2 | Novel Foods Directorate | BSc |
| GMR -3 | Novel Foods Directorate | MSc; biology lab experience and field trial assessment of GM crops |

| | | |
|----------|---------------------------------|---|
| GMR- 4 | Health Canada regional officer | Medical professional |
| GMS-5 | activist, farmer, and author | education in economics and theology; writes and lectures on food system and biotechnology |
| GMS-6 | farmer | active on agricultural and environment committees |
| GMS-7 | executive, GM crops association | PhD, biological science |
| GMS-8 | executive, ENGO | PhD, social science; consultant, activist |
| NHPR-9 | consultant | Msc biology and toxicology; herbalist, experience in NHPD |
| NHPR-10 | NHPD | MSc biology, ethnobotany; PhD pharmacognosy; professor |
| NHPR-11 | NHPD | B Pharm; naturopath; |
| NHPR -12 | NHPD | BA communications |
| NHPS-13 | industry producer | administration and communication; quality management; master gardener, |
| NHPS-14 | executive, NHP industry | biochemist, research and industry association |
| NHPS-15 | consumer, NHPs | BA fine arts; graduate homeopathic college |
| NHPS-16 | consumer of NHPs | BFA, professional artist, owner of natural products business |
| NHPS-17 | consumer of NHPs | MA social science |

Table 6-1. Interview Participants.

The Information Letter and the Consent form approved by the Research Ethics Committee were sent by email to all participants, who completed and faxed them back before the interview was scheduled. The text of the Information Letter and Consent Form is found in Appendix 1. As several participants indicated that they did not wish to be tape-recorded, none of the interviews was recorded; instead, notes were taken during the interview. The notes from the interviews were identified by number and stored in a folder separate from the signed consent forms. No adverse events were reported, and all interviews were congenial and relaxed.

The interviews were conducted in person or by telephone, and lasted from one to two hours. Participants within the regulatory agencies were in Health Canada's offices in Ottawa or in Quebec; stakeholders in the GM foods regime were located in British Columbia, central Ontario, Quebec and New Brunswick. NHP stakeholders were in Ontario and Saskatchewan. The interviews were open-ended and permitted participants to provide detail on aspects of the research that interested them, or to add comments on related topics they felt were important. A set of questions was devised and was tailored slightly to the four groups of participants; a copy of these was printed before the interview and guided the interview and became the notes from it.

The following is a sample interview guide.

| Group | Interview no. |
|--------------|--|
| 1 | biographical background |
| | a educational, professional training |
| | b professional role, organizational mandate, goals |
| 2 | general regulatory task, roles |

- 3 general profile of product and regulation
 - a risk profile
 - b risk regulation objectives, expectations
 - c regulatory control appropriate
 - d other objectives of regulatory regime, process

- 4 product natural or technological
 - a natural or technological
 - b what is natural or technological
 - c does technological intervention create greater risk, accountabilities?
 - d any particular value in 'natural' products?
 - e clear, meaningful distinction between traditional and GM breeding?.

- 5 trust
 - a how important is public trust
 - b is public trust in product, regulation, regulatory officials, scientific assessment?
 - c what builds trust? What do people look for?
 - d what level of trust is there
 - e is building public trust an appropriate goal for regulatory agency
 - f how does it do this? (Participation, transparency, sound science, strict control. .)

Food and Drugs Act

Both genetically modified (GM) foods and natural health products (NHPs) are regulated under the Food and Drugs Act, or “An Act respecting food, drugs, cosmetics and therapeutic devices” (Canada 1985. Justice Canada). Generally, the Act prohibits the advertising of a food, drug, cosmetic or device as a treatment, preventative or cure of disease, and their sale under a label or claim that they have that potential. The Act defines foods, drugs, cosmetics and therapeutic devices, establishes legal provisions for the control of each, and authorizes the making of regulations specific to the different products that come under the Act.

A food is defined as “any article manufactured, sold or represented for use as

food or drink for human beings, chewing gum, and any ingredient that may be mixed with food for any purpose whatever.” The provisions for food (Part 1, sections 4 through 7) prohibit the sale of food that is poisonous or adulterated; that is manufactured, prepared, preserved, packaged or stored under unsanitary conditions; or that is unfit for human consumption or contains rotten or diseased substances. The Act also prohibits false representation of any food (1(5)), deals with importation and interprovincial movement of food; and permits the making of a regulatory standard for a food. Finally, section 7 states that “no person shall manufacture, prepare, preserve, package or store for sale any food under unsanitary conditions”.

A drug is defined as “any substance or mixture of substances manufactured, sold or represented for use in

- a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,
 - b) restoring, correcting or modifying organic functions in human beings or animals, or
 - c) disinfection in premises in which food is manufactured, prepared or kept.
- (Section 2)

For drugs (sections 8 through 15) as for foods, the Act establishes proscriptions against adulteration and manufacturing or preparing under unsanitary conditions, and against deceptive labelling or selling of a drug. There are also, however, additional provisions that apply to drugs only. These include:

- provisions for regulatory standards for packaging, and respecting standards prescribed for a drug.
- inspection and licensing of manufacturing facilities and conditions (section 12)
- inspection and approval of the safety of the batch
- prohibition of distributing samples of a drug, and exemption from this

- prohibition for medical professionals.
• prohibition against the sale of a list of prohibited drugs.

Part II, Administration and Enforcement, provides for the designation of inspectors, certified by the CFIA, and empowered to inspect and enforce the provisions of the Act. It also describes the regulations that may be made to apply to the products controlled by the Act. All such products are subject to regulations about adulteration; labelling and packaging, conditions of sale, or ingredients to prevent the misleading or deception of the consumer; standards of composition and quality; and method of manufacture. All substances regulated under the Food and Drugs Act may be subject to regulatory assessment of its environmental or human health impacts before they may be imported or sold (30 1 11

Drugs are also subject to the testing of batches for safety, and conditions for the distribution of samples of drugs, and the manufacture and sale of new drugs.

The legislative intent of the Food and Drugs Act is thus entirely related to ensuring the public safety of food and drugs, addressing the quality and safety of the products, controlling the types of claims made about the product, and protection against fraud and misrepresentation. In the case of drugs, further provisions are made for the inspection and licensing of facilities and the control of access to prescription drugs. Regulations made under the authority of this Act must stay within the boundaries set out by the Act and fulfil the policy intent of the legislation without going beyond that intent (Canada, 2005).

Chapter 7

Genetically Modified Foods

The biotechnology that allows the deliberate genetic modification of organisms is, in the long history of agricultural technology, a very recent plant breeding practice. This technology was enabled by the scientific knowledge of genetics at the DNA level, and involves the deliberate insertion of a particular gene from one organism into another. This was first done successfully in 1973. The first genetically modified plant was produced in 1982 - a tobacco plant that was resistant to an antibiotic (Council for Biotechnology Information, 2007). Field trials of insect- and disease-resistant plants began in the U.S. in 1985, with the approval of the first environmental release of a GM crop in 1986. The first commercial sale of a GM plant was a tomato approved in 1994, followed by biotech soybeans, corn and cotton in 1995 and 1996 (Council for Biotechnology Information).

The term genetically modified as applied to food is ambiguous and contentious, although it is popularly taken to refer to foods made from (usually) plants that have been deliberately engineered through recombinant-DNA (rDNA) techniques. At the heart of plant biotechnology, and of the different interpretations of it, are several biological principles of plant reproduction.

A first principle is the genetic variation that exists within a species, which comes about as a result of spontaneous mutations that occur in reproduction. This variation exists at the level of the genotype, or the genetic code of the plant, and at the level of the phenotype, the traits that are expressed in the plant. A second principle is natural

selection, the process by which a particular variation survives, or reproduces particularly well, in its environment, as a result of its better adaptation to its environment than others that may not survive or become prevalent (Gliessman, 1998). These processes and characteristics occur in plant populations in nature.

Human intervention in this selection process marked the beginning of agriculture. Directed selection occurs when humans direct the genetic change in a species by changing the environment in which the plant grows, or by selectively cultivating desirable phenotypes, or plants with certain desirable traits. This process is the basis of traditional agriculture and the domestication of species, and remained so until the early modern period. It generally consists in the gathering of the seeds from individual plants with desired traits, and planting them the next year. The continuation of this practice over generations develops a relatively stable variety that is adapted to local conditions. These 'landraces' dependably produce characteristic traits, but retain a degree of genetic diversity within the population.

The more distantly related the gene pools of two plants - in a set of concentric rings beginning in the centre with a wild progenitor and its selected crop variety, and moving outward through species, genus, and beyond - the less successful are crosses between them. Crosses within the wild plant and cultivated crop varieties, considered to be within the same species, are readily made, and produce "viable and fertile progenies" (Chrispeels and Sadava, 2003: 350). Crossing that crop variety with another species in the same genus is less successful and produces less viable offspring, while crossing it with plants in another genus requires special techniques.

Successful deliberate hybridization of two species within the same genus was first carried out in the early 1700s (Lurquin, 2001), with the cross pollination of a sweet william plant with a carnation, both in the genus *Dianthus*. A hybrid is defined biologically as “a cross between two very different parents, each from a different pure-breeding line” (Gliessman, 1998: 200). Reproduction between the two lines must be done with certain techniques; the resulting hybrids are different from both parents, and often express desirable traits like high yield, or bigger seeds or fruits. The seeds from this hybrid plant, however, will not produce the same hybrid, or ‘breed true’, but express a range of traits. This means that a hybrid variety cannot be reproduced from its seeds; new seed must be produced from the parent lines and purchased from the licence holder.

Crosses between a crop species and plants from more distantly related species, or even organisms from other kingdoms, require the laboratory techniques that are used in genetic engineering. The ‘modern biotechnology’ procedures that are meant by most popular references to GM foods consist of the insertion of a gene or genes that code for a desirable trait from one organism directly into the DNA of a host organism in order to confer that trait into the host. It may also involve ‘gene silencing’, in which genes that express a trait that is undesirable are turned off. The assumptions on which the technology is based are that “a gene is a discrete and inheritable unit, occupying a particular position on a DNA molecule, with a sequence of bases having a particular function” (Nottingham, 2003: 11). The crucial characteristic of the genetic code for genetic engineering is that it is “universal: it is a ‘language’ shared by all life forms” (Nottingham, 2003: 12). That means that a gene with a particular function is expected to

express that same function in a different organism, even one of a different species.

The main steps in genetic engineering include identifying the gene or DNA segment that carries the trait that is desired, then isolating and extracting it from the host DNA and cloning it, usually in the cells of a bacterial vector. This 'vector construct' also includes 'promoter' and 'marker' genes, necessary to, respectively, ensure that the selected genes express the desired trait in the new host, and to signal that the inserted genes have been successfully incorporated into the new plant. Introducing that gene construct into the host requires getting it into the host's DNA in the cell nucleus, a difficult matter as the nucleus is not permeable to foreign cells. In early procedures this was done forcefully with a 'gene gun' that physically injected the gene construct into the host nucleus. It is also done by using a microbe as a vector for the DNA, often agrobacterium, which in nature transfers its own DNA into a host plant. Another method is electroporation, in which "plant cells growing in culture are stripped of their protective walls; DNA is then supplied to the medium and electric shock used to destabilize the cell membrane and allow DNA to enter"(Lurquin, 2002; Nottingham, 2003; National Academies, 2004).

The source for most of the genes inserted into plants to confer desired traits is bacteria. The most well known of these is *bacillus thuringiensis* (B.t.), "a soil bacterium that accumulates high levels of insecticidal proteins during sporulation" (Nottingham, 2003: 47). B.t. is selective in its toxicity, killing the larval stages of insects that eat the spores, and has been used as an insecticide for many decades. B.t. has been engineered into many commercial plant varieties, including tobacco, tomato, potato, corn, and cotton

(Nottingham, 2003; Health Canada, 2007a). The gene that confers tolerance to glyphosate, a major herbicide also sold as Roundup, was derived from the bacterium *streptomyces hygroscopicus* (Nottingham, 2003:50).

Tolerance to herbicide is the dominant trait that is engineered into commercialized crops (ISAAA, 2007), followed by insect resistance and “stacked traits” - modification for both traits. In 2006 herbicide-tolerant soybean, corn, canola, cotton and alfalfa accounted for 68% of the area devoted to GM crops worldwide. Insect-resistant crops were grown on 19% of the GM acreage, and crops with stacked traits on 13% . The main biotech crop grown is soybeans, with 57% of the global biotech crop area, followed by corn, cotton, and canola (ISAAA, 2007).

The main benefit claimed for GM crops is the reduction of pesticides used on the crops due to disease resistance or the insect resistance conferred by B.t. or other organisms (Monsanto, 2004; ISAAA, 2007). The reduction in pesticide application also reduces the fuel used in tending the crops. Monsanto (2004) cites three categories of benefits of GM crops, to farmers, livestock producers and consumers. The benefits to farmers are an increase in productivity and decrease in costs, due to reduced pesticide applications; and improved tolerance of crops to adverse conditions such as drought or heat. The International Service for the Acquisition of Agri-Biotech Applications (ISAAA, 2007) claims that ninety percent of farmers using GM crops are “small, resource-poor farmers from developing countries, whose increased income from biotech crops contributed to their poverty alleviation.” Benefits to livestock producers are improved quality of crops used for food and animal feeds.

Consumer benefits from GM plants are touted as including “advantages such as increased protein or oil, improved fatty-acid balance, or carbohydrate enhancements” (Monsanto, 2004) and foods produced with lower amounts of toxic pesticides (BIOTECanada, 2007a). Environmental benefits are also frequently mentioned, principally the reduction of the use of pesticides in the fields, and the adoption of conservation tillage, or no-till farming systems, which helps prevent soil erosion. The use of GM crops also reduces fuel required to plow and the associated fossil-fuels emissions (Monsanto, 2004; ISAAA, 2004; BIOTECanada).

By 2006, 10.3 million farmers in 22 countries were growing GM varieties (ISAAA, 2007). Proponents cite extensive world-wide experience with the technology and crops. Monsanto (2006) points out that

Biotech crops are among the most studied and reviewed foods in the world. Using well-established, internationally accepted standards of risk assessment, regulatory authorities worldwide have reviewed all biotech crops not on the market and determined that they pose no more risk than crops produced through traditional breeding methods.

A proven 10-year history of safe use supports the conclusion that the regulatory process has been successful. Experts estimate that 1 trillion meals containing ingredients from biotech crops have been consumed with no reliable documentation of any food safety issues for people or animals.

The ISAAA (2007) observed more generally that

. . . there is now substantial evidence that GM crops are safe and benefit both the environment and millions of poor farmers. “The record is clear on food safety. . . . Three hundred million people in the US and Canada have been eating it for 10 years with not even a hint of a problem.” . . . over the past 10 years the cultivation of crops modified to resist pests, such as Bt cotton, has meant farmers have applied 172,500 million tonnes less pesticide than they would have used on conventional crops. The major users and beneficiaries of GM crops are small farmers. . . 9 out of 10 farmers growing GM live in developing countries.

Opponents counter these claims, claiming risks to human health, the environment, and that “the planting of GM crops encourages monocultures that damage the environment and threaten the livelihoods of farmers who rely on conventional or organic varieties” (Coghlan, 2006a).

Scientific research describes a range of experiences with GM crops. A study in the UK, for example, found that GM crops grown under normal agricultural conditions showed “no evidence of seed depletion [on which wildlife depended] and also pointed to potential benefits for farmers of growing the crops” (BBC News, 2004). On the other hand, a genetically modified bentgrass escaped into the environment in the U.S., before it had received approval, presenting “a cautionary tale of what could happen with other GM plants that could be of greater concern” (Coghlan, 2006a).

The World Health Organization (WHO, 2005: 13) notes that the health risks of GM foods are “generally comparable to the known risks associated with conventional foods,” including allergenicity, toxicity, and nutritional quality and microbial safety. It also notes, however, that some unintended effects may arise from the use of GM techniques, due to the position of the inserted gene, or the interaction between the inserted gene and components of the host genome (WHO, 2005: 14). Potential environmental risks include effects on non-target organisms of insect-resistant GM crops, the spread of herbicide tolerance, and the “outcrossing” of transgenes, or the transfer of inserted genes from modified crops to related conventional crops or wild plants (WHO, 2005: 21).

The U.S. National Academy of Sciences (2004) reviewed the risks of genetically

modified plants, dividing the various methods for genetic modification into the categories of non-genetically engineered (non-targetted) and GE (targetted). The non-GE, non-targetted methods include traditional selection and crossing techniques, as well as embryo rescue and mutagen breeding or mutagenesis. In this last method plants or seeds are exposed to chemicals or ionizing radiation in order to induce multiple random DNA mutations, and the resulting plants are screened for valuable traits that may have emerged with some of the mutations. The targetted GE methods include the techniques that are generally considered to be genetic modification, using microbial vectors and electroporation to deliberately introduce a gene for a desired trait into a host plant. The finding was that unintended effects from genetic disruption were most likely from induced mutagenesis, and least likely from selection from a heterogeneous population. Recombinant DNA techniques used with closely related species were relatively unlikely to produce unexpected effects, but GE techniques that transfer genes from distantly related species were far more likely to result in unintended effects (National Academy of Sciences, 2004).

Another study reviewed peer-reviewed research on risks from genetic modification, in this case defined as “the insertion of pieces of heritable material from one individual to another, or the removal of genes from an individual” (Weaver and Morris, 2006: 157). They consider risks that have been associated with GM plants but are not unique to them, as well as risks that are “a direct consequence of the method used in gene manipulation.” Among the risks that are attributed to the GM method itself include:

- the inability to control the location of the transgene in the host genome

transgenes are more likely than host DNA to insert themselves into new hosts through horizontal gene transfer, and are more likely to spread to weedy relatives through cross-pollination

- GM plants are often substantially different from their conventional counterparts, due to the “interaction between the transgene and the rest of the genome, producing unpredictable results,” providing evidence that challenges the principle of substantial equivalence
- GMOs can produce unpredictable consequences unrelated to the expression of a particular gene
- GM plants may produce novel proteins that were not intended and have never been part of the human diet, thus introducing potential new allergens
- GMOs possess novel characteristics that require greater scrutiny than their conventional equivalent (Weaver and Morris, 2006).

Weaver and Morris (2006) conclude that “there is ample scientific evidence for caution” as the “process of genetic modification itself is an unpredictable, unstable process” (p.188). These studies highlight that non-targetted GM processes - especially chemical or radiation-induced mutagenesis - may have greater risks than those of some targetted genetic engineering methods but that do not raise social concerns. They also show, however, that the techniques that are generally considered genetic engineering or modification do pose risks that are not only unique to plants developed by those processes but that are also not well understood or predictable.

Nottingham (2003: 7) concludes that as genetic engineering involves transferring foreign genes into an organism rather than moving different forms of a gene within the same gene pool, as in traditional breeding, it is more likely to have unexpected effects; and that the bacterial vectors that are used may also have their own adverse qualities.

The lack of predictability is emphasized by scientists who argue that the “linear sequence of independently acting genes” on which the genetic engineering bases its goals

of precisely inserting a trait with a genetic module that expresses it, is becoming obsolete. “All genes can act to modify the effects of any other gene, through subtle environmental changes. The genome is now viewed as a network of interacting genes” (Nottingham, 2003: 14). With respect to the reliability of the benefits of GM crops, the WHO (2005) states that “no conclusive evidence on environmental advantages or costs can be generalized from the use of GM crops. Consequences may vary significantly between different GM traits, crop types and different local conditions” (p. 22).

To manage the potential for some of the environmental effects of GM crops, several agricultural practices are employed. Gene flow to neighbouring crops, for example, is minimized through the isolation of GM crops at specified distances from conventional crops. The spread of resistance to B.t. is discouraged by the growing of ‘refuges’, in which nearby plots of non-modified varieties are grown for insects to feed on to avoid over-exposure to the B.t. toxin that may induce resistance among the target insects.

A major issue in the determination of risks from GM plants is the characterization of genetic modification itself: what is the essential process in genetic modification, are sophisticated recombinant DNA techniques distinctive in themselves and do they result in new plants that are physically distinct from plants produced by other means, and in what terms can they be viewed as continuous with or different from traditional plant selection and breeding practices? There certainly is evidence to suggest that some genetic engineering techniques, perhaps particularly those that involve the direct transfer of genes between distantly related species, carry uncertainties, unpredictable results and risks that

exceed those of other less-targetted methods that rely on natural pollination within, or natural mutations among, related varieties.

Development of GM foods industry

The Council for Biotechnology Information (2007) presents a “plant biotechnology timeline” to demonstrate that the manipulation of nature has been an essential and constant factor in agriculture since the beginning, and continues in a similar vein with biotechnology today. The timeline begins at 4000 BC with early farmers saving and planting seeds from wild plants. The next entry is the creation of the first hybrid plant in 1720, followed by the publication of Mendel’s genetic research in 1866, the crossbreeding of cotton in the late 1800s and the more complex, scientifically informed hybridization and rDNA techniques of the twentieth century. Perhaps contrary to the message presumably intended by the timeline, agriculture appears to have remained relatively stable for almost six thousand years, with a series of changes that have developed into modern corporate agriculture beginning only in the modern period, after the scientific revolution and during the industrial revolution.

Beginning in the early modern period, with its new systematic rationalism, and a drive towards privatization of agricultural and genetic resources that replaced earlier seed selection and saving by farmers in previous eras, agriculture became increasingly commercialized. More deliberate plant breeding and ownership of plant variety material were facilitated by scientific research and particularly by the increasing understanding of plant genetics (Fowler, 1994). An ‘agro-industrial complex’ gradually developed as

industrial methods and products were enabled by successive scientific and technological advances (Goodman et al, 1987). This has occurred in several major phases:

In the first period, roughly before 1930, industry's confrontation with agriculture gave rise to relatively autonomous patterns of mechanical and chemical intervention. We further saw how an important qualitative, though localized, breakthrough in industrial capital's control over the biological production process - hybrid seeds - led to a major reorientation of the dynamic of industrial appropriationism (Goodman et al., p. 98).

Modern biotechnology represents the most recent incursion of technology into agricultural processes and products, and promises to "release plant breeders from dependence on the natural process of sexual fertilization as the only pathway to improved crop varieties' (Goodman et al. 1987: 103). Modern biotechnology began in the 1960s with a series of biomedical discoveries in the realm of pure science and laboratory research in cell biology, which led to discoveries that had a potential for genetic engineering (Lurquin, 2002; Krimsky, 1991).

The private development of agricultural plants and seeds emerged from public-sector variety development programs established in the late nineteenth and early twentieth centuries, in which new varieties with improved yield or climatic adaptations were created and distributed to farmers. With the development of hybridization techniques, which produced hybrid varieties that gave poor yields in the second generation, farmers stopped saving seed and needed to buy new seed each year. By the mid-twentieth century in the U.S., private seed companies began to take advantage of this new seed market, and lobbied for the shifting of funds for research and variety development to the newly flourishing private seed industry (Kloppenborg, 2004).

Seeds are the “delivery system” of new plant breeding technologies, and holding proprietary rights is “the key to control of the agricultural production process and domination of the markets for agro-industrial inputs” (Goodman et al., 1987: 108). By the 1960s pressure was mounting to extend plant breeders’ rights to cover the developers of seeds and sexually propagating species (Kloppenburg, 2004). The passage in the U.S. of the Plant Variety Protection Act in 1970, combined with declining chemical industry profits and rising grain prices, prompted a number of large multi-national corporations to acquire seed companies, along with their expertise and proprietary plant varieties. This has resulted in the consolidation of large companies and the decline of many smaller, independent seed companies, so that by 2001 four corporations - Monsanto, Syngenta, Bayer and Du Pont - dominated the transgenic seed market (Nottingham, 2003; Goodman et al., 1987). When biotechnology began to show promise, this “centralization of the agricultural-inputs sector” intensified, with more acquisitions by large chemical firms of seed companies.

Agricultural biochemistry, which had of necessity always been closely adapted to biological processes, has found in biotechnology a common technical cause with plant breeding. Research and development in the seed companies and their parent corporations has profound synergistic potential.

There is no question that corporate managers recognize the seed, and seed production and distribution facilities, as the crucial nexus for the commercialization of plant biotechnology. . . . It is the deep-pocket multinationals with major agricultural biotechnological interests - such as Monsanto, Upjohn, and Lubrizol - that are the most active participants. Such corporations are willing to make very substantial bids for key seed firms (Kloppenburg, 2004: 208).

Many market economies are encouraging the development of the biotechnology industry for its long-term economic potential. However, due to “externalities and the

long-term and uncertain results of investing in information, private firms underinvest in the creation of new scientific and technological knowledge,” leading governments to support the industry through a set of public policy programs (Niosi and Bas, 2004: 233). “National systems of innovation” have been developed by many countries, and within those countries by regions in which technology industries tend to cluster. These systems are adapted to each country’s institutions and situations, but consist generally of a consistent set of policies and programs.

To nurture the research and development of innovative technologies, universities strong in biotechnology are a first core requirement, and funding of research and laboratories, both academic research and private sector research and development, is a key component of government policy. Venture capital, which “brings funds but also complementary competencies to biotechnology firms” is also supported by public policy (Niosi and Bas, 2004: 238).

Intellectual property provisions are also a central component of the biotechnology industry, encouraging investment in research and development. The most important types of IP protection in the agricultural biotechnology industry are plant breeders’ rights and patenting. Plant breeders’ rights give rights over propagating material only, while patents give “exclusionary rights over the entire plant” (Durell and Gold, 2007: 45). Lesser (1995) argues that despite the widespread use of plant breeders’ rights, the only effective form of protection for genetically modified products is patenting.

Patenting laws support and encourage the long-term investment in research that is required to develop innovative applications. Without patent protection of intellectual

property, “no growth could occur in biotechnology” (Niosi and Bas, 2004: 238). Durell and Gold (2007: 47) note that “as technology transfer is recognized as a vital step in the progression of research products from the laboratory to the public, researchers must take their role as initial protectors of IPR seriously. Private industry will likely pass over research products that have not achieved the critical forms of IPR protection available during the research stage.”

Patent laws have been challenged to keep up with the developments in genetic engineering, and debates have arisen over whether a patent can be granted over a living organism created by biotechnology. Already by the 1930s American legislators had removed the distinction between plant developers and industrial inventors, granting rights to developers of new plant varieties; in 1970 Congress defined ‘novelty’ for the purposes of patenting as ‘whether the product is ‘a product of nature or a human invention’, judging that “patentable matter includes ‘anything under the sun that is made by man””(Krimsky, 1991:48), including a new organism itself, rather than just the process that is used to produce it. This opened the door for the patenting of novel organisms produced through genetic engineering, regardless of whether or not they were living things. The key criterion was judged to be that a ‘unique or innovative process’ was used to isolate an organism, constituting sufficient human alteration of the cell to qualify it as an ‘object of manufacture” (Krimsky, 1991) - it stops being natural and becomes an artefact.

Pressure continues to expand the scope of coverage of intellectual property laws. Products of biotechnology have been “redefined so that they are no longer considered

products of nature (and thus excludable from many patent laws), but rather products of human inventiveness. Invention is being redefined to include discovery” (Fowler, 1994: 154). As a result of debates over the patenting of biotechnology, the line between what is natural, and hence not patentable, and what is invented “has shifted over the years to allow more and more claims on the invention side of the ledger” (Jasanoff, 2005: 209).

Many patent law provisions are guided by international agreements, limiting countries’ latitude for determining what may be patented (Gold, 2001). Under the Trade-Related Aspects of Intellectual Property Rights (TRIPS), the member states of Canada, the U.S., the European Union and Japan must grant patents over certain biological material, including plants, or grant alternative plant breeders’ rights. National governments have only limited ability to decide which categories of higher life forms (HLFs) are patentable, requiring that a threat to morality or public order, or to animal, plant or human life, be shown to exist with the patenting of a product to justify refusing a patent. The EU has maintained an ‘ordre public’ criterion to permit the denying of patents for higher life forms, while Canada, the U.S., and Australia take the position that patent law and morality are separate issues (Gold, 2001).

By 2006, 22 countries grew commercialized GM crops, and another 29 had given regulatory approvals for the import of GM foods and feeds. Approvals had been granted for 107 events (specific modifications) in a total of 21 crops. Biotech crop technology is “the fastest adopted crop technology in recent history”, achieving an “unprecedented” 60% increase in the hectares devoted to it - to 577 million hectares from 1996 (ISAAA, 2007). ISAAA sums up the “global value of the biotech crop market”:

In 2006, the global market value of biotech crops . . . was \$6.15 billion representing 16% of the \$38.5 billion global crop protection [pesticide] market in 2006 and 21% of the ~\$30 billion 2006 commercial seed market. . . . The accumulated global value for the eleven-year period, since biotech crops were first commercialized in 1996, is estimated at \$35.5 billion. The global value of the biotech crop market is projected at over \$6.8 billion for 2007.

Scientific perspective on genetic engineering

Genetic engineering is aligned with both the scientific and the economic aspects of the modern view of nature and of society's relationship with nature. While science provides the necessary technical knowledge and explanatory framework in support of genetic engineering, it does not lead to a supportive position inevitably, and as to be expected there is a range of scientific opinion on genetic engineering.

There are many scientists who disagree with some or all aspects of the practice, or who recognize the legitimacy of moral and ethical opposition (Perry, 2003; RSC, 2001; Clark, 1999). Lurquin (2002), supports the development of genetic engineering for some beneficial applications, but disapproves of the commercial direction in which industry has taken the technology. He makes an important distinction between the biotechnology industry and the interests of genetic scientists: "Biotech companies . . . see huge potential profits, and their attitude must be differentiated from that of discovery-driven academic scientists" (Lurquin, 2002: 141).

A study on the attitudes of scientists in different disciplines and professional situations (Kvakkestad et al., 2007) found that all the ecologists in the sample, and most of the university scientists in the disciplines of agrobiolgy, plant physiology, evolutionary genetics and bio-ethics, opposed genetic engineering. While they had little

opinion on the benefits claimed for the crops, they stressed that the environmental effects of the crops are highly unpredictable, and did not have confidence in the research conducted by the GM industry (Kvakkestad et al.).

Nottingham (2003) supports the potential of agricultural biotechnology but argues that the applications that have been implemented are those that make the greatest profit for multinational seed companies rather than those that provide benefits for consumers or the third world. In addition, despite claims made for their potential, he believes that GM crops are unlikely to be the next 'green revolution' or the means to a more environmentally sustainable agriculture.

Advocacy of plant biotechnology does, however, rely strongly on science to describe biotechnology as a technique that produces something new, but which works with nature and builds on the natural process by which the makeup of life-forms evolves through random genetic mutations. These advocates draw on contemporary views of evolution to recognize that species are not isolated and stable, but that genetic material moves from one species to another, as seen in the evolution of viruses and bacteria; indeed, the very notion of a species as fixed and unambiguous is problematic. "Most population ecologists would admit to difficulty in defining precisely what they mean by a population, and similarly many biologists would contend that species boundaries are actually indistinct and difficult to define easily" (Perry, 2003:151; Reiss and Straughan, 1996).

Kvakkestad et al. (2007) found that scientists who supported GM crops tended to be employed in the biotechnology industry and were confident in industry research. They

believe that GM crops are not fundamentally different from their conventional counterparts and that there are benefits to be gained from them.

The development of the biotechnology industry has been accompanied by a shift in scientific concepts of nature, and by controversy over what nature is and how society should interact with it. In part this shift was a matter of expedience, as industry adjusted to public concerns about genetic engineering. Genetic engineering was conceived of as contributing to modernization, a “problem for innovation policy” (Gottweiss, 1998:163). A series of ‘product failures’, mostly in the medical biotechnology field, led to a shift in positioning of the technology from ‘a core method of a new industry to a revolutionary method to study nature’ (Gottweiss, 1998: 227). By the 1990s, Gottweiss argues, a ‘discourse of deficiency’ had developed in which plants, animals and humans were described as being “in a state of deficiency and in need of a supplemental genetic technology” (p.156).

The conventional scientific concept of nature accepted this shift fairly readily, as it begins with a concept of nature as molecular and mechanistic, and as morally neutral and thus appropriately brought under increasing human control for social benefit. Yet the advance of cell biology is moving genetic engineering into the cellular level, transforming the idea of the cell from a unit of organic life into a complex biochemical factory, a ‘machine’ that science has brought under control and can now reformulate. Genes are now seen as fungible, Krimsky notes (1991:7), as they are deliberately repositioned into new organisms.

This scientific perspective has positioned genetic engineering as supplemental to

nature rather than as interfering in or substantially changing it. The similarity of genetic engineering to traditional plant breeding or hybridization techniques is often stressed, to 'normalize' (Gottweiss, 1998: 250) genetic engineering as a continuation of traditional and natural technique. When it was first introduced, for example, bovine growth hormone (a synthetic version of a hormone that increases the amount of milk produced by dairy cows) was promoted as a technological advance on nature; after the development of public opposition to it, it was repositioned as natural in an appeal to the 'natural' family dairy farm (Buttell, 1998).

As it applies to food, the concept of natural is considered scientifically meaningless, as there is no agricultural crop used today that has not been deliberately altered by humans for desirable characteristics. Agricultural crops are human creations, and many have never integrated into the local ecosystem, requiring humans to sustain them. "Studies have shown that domesticated plants, such as crop plants, do not survive well without human care. This means that a herbicide-tolerant plant that grows outside a farmer's field has little chance of surviving or breeding with other plants" (CFIA 2003a).

Furthermore, many crops are introduced agricultural species that have no wild relatives where they are grown, and therefore are unlikely to breed with local plants. Outcrossing is said to be a risk only with those modified crops that have wild relatives; in Canada, this is restricted to canola (CFIA, 2003b).

The technology works with nature at a molecular level, and does not produce anything materially remarkable; in any case, when the technology is seen as producing a better product, it is an overall social benefit. The fact that genetic engineering introduces

changes into the genome of a species does not make it unnatural. An editorial in the journal *Nature* summed up the dominant scientific position:

. . . the same physical and biological laws govern the response of organisms modified by modern molecular and cellular methods and those produced by classical methods. . . [Therefore] no conceptual distinction exists between genetic modification of plants and microorganisms by classical methods or by molecular techniques that modify DNA and transfer genes. (Quoted in Miller, 1999: 1042).

This approach retains the assumptions of human exceptionalism and the priority of social progress that is fundamentally allied with the mechanistic model of nature, from which biological and ecological processes and contexts are stripped away. It adopts a pragmatic perspective on human intervention into nature:

Driving the field is a twin-engine philosophy: First is the idea that the best way truly to understand life is to build it. Second is the hope that these life forms could be harnessed to do human bidding. . . . “there is nothing mystical or spiritual about this. I don’t have to invoke the gods DNA is the only language used to program life on this planet To change the organism, you change the instructions in the DNA program” (Globe and Mail, 2005).

The manipulation of nature is promoted as bringing benefits to society and advancing social progress. It employs an instrumentalist human perspective on nature, through a discourse of deficiency on nature that justifies, and celebrates, technological ‘improvements’ of nature. Nature itself is essentially a set of discrete units that are assembled into different life forms, and scientific knowledge can enable humans to modify the way these are composed to create improved varieties for social use. Monsanto (2004) encapsulates all these assumptions in its public information statement on agricultural biotechnology: “In the spirit of the selective breeding practices used by farmers for centuries, and consistent with the experimental findings of Gregor Mendel in

the 19th century, agricultural biotechnology promotes improvements in plants by working with the basic DNA building blocks.”

Public attitudes to GM Foods

As has been argued with respect to risk perception in general, opposition to and concerns about biotechnology turn on much broader and more political and value-laden issues than risk assessment and conventional risk perspectives encompass. From the perspective of the scientist and regulator, public opposition is often seen as a consequence of a lack of understanding of the science involved. This is the ‘knowledge deficiency’ thesis again, in which a lack of information or understanding is seen as leading to unease with the risks of the technology, and is to be remedied with the provision of information (Prince, 2000a). Consistent with other instances of this interpretation, this position considers the public to be a passive audience that is likely overly vulnerable to media messages.

The Royal Society of Canada (RSC, 2001) noted that there are three types of risks that concern many people about biotechnology, though the terms of reference of their own inquiry was restricted to only the first type, the health and environmental risks on which conventional science and risk assessment focus. These risks have been discussed above.

A second type of risk is socio-economic risks, or political values. These concerns focus on issues associated with the biotechnology industry in society, such as the concentration of the seed industry in the hands of a few multinational corporations and

the dislocation of family farms, and a set of concerns about the impacts on farmers in less-developed countries.

A large qualitative study that was undertaken in Europe investigated non-scientists' views about agricultural biotechnologies. Marris et al. (2002) were struck by the similarity of attitudes in all five countries studied (Britain, Spain, Italy, France and Germany) and within countries, as well as by the rational and nuanced basis of the arguments. They also stressed the lack of understanding by experts of those public views: experts framed non-scientists' positions in terms of a lack of knowledge and understanding that leads to polarized and ideological positions. Non-scientists in fact, while acknowledging their lack of specialist technical knowledge, based their opinions on rational, empirical knowledge of nature, about human fallibility, and on experience with the institutions responsible for developing and regulating biotechnology. Rather than polarized and emotional opposition, Marris et al. (2002) found ambivalence and questioning of the technology and its applications in the context of their development and use. There was a strong questioning of the supposed benefits of agricultural technology, as citizens of developed countries are aware that their food supply is ample, safe and economical, so they see no need to further industrialize agriculture. And the argument that biotechnology will provide needed help in developing countries - with cost-saving technologies, for example, or nutrient-enhanced staple crop varieties - is seen as a "manipulative marketing ploy" (Marris et al., 2002: 6) as people see no evidence that these applications are being seriously pursued.

Marris et al. (2002) also elaborate on the often-cited finding that people more

readily accept biotechnology used in medicines than in crops and agriculture, because they are aware that they would directly experience the benefits of these technologies. This study clarifies that the relative acceptability of GM medicines is due to the recognition that these products are more rigorously tested than foods, their use by a patient is overseen by a qualified physician who selects and adapts the medicine for the particular case, explains the benefits and risks to the patient directly, and follows the progress of the patient through treatment (p.54). Throughout this process the patient retains the option of refusing or of halting treatment with the product.

Americans are more accepting of GM foods than Europeans are, though they are less accepting of genetic testing (Gaskell et al. 1999). Those with concerns about gene technology “tended to think principally in terms of moral acceptability rather than risk - a significant difference from the way in which experts normally judge the acceptability of new technologies” (Gaskell et al., 1999: 385). This reinforces other findings that attitudes to GM food are formed by a ‘top-down’ process in which strongly held general attitudes and values shape specific attitudes to the technology (Grunert et al. 2003).

Though the issue is generally formulated as a ‘risk’ issue, to sceptics in the public the concern revolves more around the absence of relevant benefits of the technology (Gaskell et al., 2004). People referred to dangers, including moral and democratic dangers, but were primarily concerned with the pressure to accept GM foods that appear to have no benefit within markets in developed countries (Gaskell, et al., 2004). In the case of GM foods, the apparent lack of benefits trumps assurances of the low risks involved. Governments frame the benefits of GM foods primarily in terms of economic

benefits, which do not resonate with the public, who are more likely to associate the products with ethical concerns, objection to loss of consumer control through labelling, and potential health effects (Gaskell et al., 2004). For sceptics of GM food, the largest group in the study, “GM food fails to meet the key criterion of an innovation, an improvement on the *status quo*” (Gaskell et al., 2004: 192). They thus conclude that “the ‘Achilles heel’ of GM foods is not so much the misperception of the scientific risks, but rather the perceived absence of benefit for the consumer” (p.193).

A member of Greenpeace UK (Parr, 2005) has offered an articulate expression of this attitude to technology, arguing that it is not a simplistic “pro or anti” science position:

Numerous studies of public attitudes have shown that there is no anti-science culture, rather there is considerable public questioning about who is developing what, for what purposes, for whose benefit and with what consequences. When the sums add up, as with the use of mobile phones, people are happy to engage. When they don't - as they most clearly don't with genetically modified organisms - generally people don't want the product.

Kloppenburg (2004) and Whatmore (2002) detail the embedding of corporate interests directly into the biological makeup of agricultural crops. Early, traditional plant selection and breeding focussed on developing and refining plant varieties that were better adapted to local environmental conditions and farming contexts, and that provided improved nutritional content or yield. These characteristics benefited all of society and were available to all farmers, who saved, selected and exchanged the seeds according to community and cultural needs and conventions (Whatmore, 2002; Fowler, 1994). In addition, they were always constrained by fundamental biological and ecological limits.

In its design to facilitate corporate ownership and market advantage, a GM plant becomes an economic artifact rather than a member of a natural ecosystem.

The third type of risk of biotechnology noted by the Expert Panel of the Royal Society of Canada is that of philosophical or metaphysical risk, which considers that the process of genetic engineering does not occur naturally, regardless of the existence of any health impacts. The concern is that “genetic engineering technologies give human beings powers over nature that are deeply unethical, either in themselves or in certain of their applications” (RSC, 2001: 6). These concerns ‘involve a deeper view of biotechnology in general, which is considered to involve interventions in the natural world that undermine appropriate human relationships to nature or God. . . . The critical operative concept here, clearly, is that of what is ‘natural’” (RSC, 2001: 6). This is a normative concept rather than a scientific one.

A major element of the opposition to genetic modification is “the intuition of [its] ‘unnaturalness’” (Bruce and Eldridge, 2000: 857). The “value baseline” is an explicitly moral value related to nature, rather than a more conventionally risk-related judgement. “Natural means more or less perfect and human intervention is wrong if it alters the genetic blueprint”(p. 858). Nature here appears to be a stable, coherent order, as Bruce and Eldridge (2000) noted an “implicit value judgement that a gene where it is not natural is equated to pollution’ (p. 858). Doing what is unnatural is perceived as high risk: “to make individual genetic changes at a molecular level represents such a deep and unusual intervention in nature that it cannot but carry with it many uncertainties and risks. In contrast, returning to more natural methods takes us back to safer ground, which

is believed to be less fraught with uncertainties and unsuspected dangers.” (Bruce and Eldridge, 2000: 858).

Many in the non-scientific community who perceive a value in nature in its untouched integrity, oppose genetic modification on principle, with a normative objection to tampering with nature more than a concern for physical risk. The opposition to GM foods follows on the themes discovered by researchers on the preference of natural foods and the general lack of acceptance for the social intervention into nature. Many researchers have found that differences in concepts of and values for nature are central to disagreements about the use of biotechnology (Krimsky, 1991).

Strong approval of natural in food and in associated food production values, and disapproval of technological food production methods and additives, reinforce the notion that natural/ technological is a definitive principle in risk perception and that applies perhaps even more strongly to food because of the intimate personal and social relationship people have with food. This distinction has been found to apply to and explain attitudes to genetically modified foods. Hansen et al. (2003: 118) report GM food as being described as ‘meddling’ with nature, which study participants felt no need to do, given the adequate food supply in developed countries; GM food was disapproved as being undertaken for profit and as advancing the incursion of technology into daily life. Most participants in a Swedish study were opposed to genetically modified foods, describing them as having no benefit, being a high risk and unhealthy, unethical, tampering with nature, and as used for profit only (Koivisto Hursti, 2003). In Europe, it was found that attitudes to GM foods were most strongly affected by attitudes to nature,

and also by attitudes to technology and food neophobia (Grunert et al., 2003). Haukenes (2004) took a similar approach to a study in Norway, attributing the disapproval of food additives and GM foods to a 'technological stigma' in which people have negative views of something that appears to violate or to exceed what is 'natural'.

Marris et al. (2002) also found that people often described GMOs as unnatural (p.65), and were able to provide some detail on the meaning of this perception. Contrary to a prevalent 'myth' among experts that the public are irrationally "obsessed with the idea that GMOs are unnatural" (p. 82), this study clarified that while people did consider GMOs to be unnatural, they also recognized that many other more traditional agricultural technologies, such as pesticides, and the use animal-derived feeds, and antibiotics in animal feed are also unnatural to a degree. Study participants

expressed the feeling that directly modifying the genome was qualitatively different from any previously used technique. A common viewpoint was that until now we had only been crossing already-existing organisms, within 'natural' boundaries, using 'natural' fertilization processes. But with GM technology we were now also creating novel life forms that would not have existed otherwise. . . . Genetic engineering techniques were also often described as 'pushing Nature beyond its limits' and were thought to 'upset the equilibrium of Nature' (Marris et al., 2002: 65- 66).

Advocates and sceptics of biotechnology are concerned with different aspects and influences of the technologies themselves, in addition to valuing them differently.

Proponents make arguments about the insignificance of the distinction between modifications made by natural selection, traditional breeding techniques and deliberate genetic engineering, based in a molecular and mechanistic model of nature that is concerned with the physical substance of the organism. They also argue that

biotechnology innovation creates social benefits both of improved technologies and higher living standards that result from such economic innovation. These arguments focus on general economic benefits rather than those of specific applications of biotechnology, with a degree of tolerance for the essence of the technologies that does not require detailed balancing of the benefits against the risks of particular applications.

Members of the non-scientific public, however, appear to be less swayed by the possibility of generic social benefits - describing these as accruing to companies and government agendas rather than to citizens - and are more concerned with the rationale for each individual innovation. Wholesale embracing of innovation for the sake of economic growth does not appeal to the public; what is important is the logic behind replacing a familiar and satisfactory product or process with a privately-owned innovation; if the detailed application of the new technology and its rationale are not favourable, broader-scale economic growth will not tip the balance.

GM Foods: Nature or Artefact?

Genetically modified plants are created with the silencing of a gene, or the insertion of a gene for a specific trait from another organism into the nucleus of the host plant. The technological process allows the reproduction of species that do not cross by natural processes, expanding the range of material available to plant breeders. GM plants are designed and physically constructed and maintained for the advantages they offer to farmers and livestock producers.

GM plants and other organisms clearly raise the question of hybridity; to many

they exemplify the dictionary definition of hybrid, a ‘thing composed of incongruous elements’ (OED 1976). However the tendency is for people to consider GM organisms as either roughly natural or social, rather than as physical hybrids; and whether genetically modified plants and crops are considered natural or artefactual depends on the perspective taken on both nature and on social intervention.

In a strictly scientific view, in which nature is defined at the elemental level, genetically modified plants are natural: they are composed of the same natural molecular structures as any other plant; they reproduce and grow as other plants do; and their development is analogous to processes of mutation and hybridization that have always been the engines of natural evolution and traditional breeding. While they have incorporated genes from different species that do not produce viable offspring without intervention, the modified plants that are produced are biologically plausible. Finally, the intervention of human technology is not significantly different from other forces that have shaped the development of most of the species on which humans survive, as it builds on natural processes and components and creates a more socially useful result.

However natural GM plants may be considered at the molecular level, this perspective overlooks the processes of natural reproduction, in which the lack of sexual compatibility between species is precisely what genetic modification techniques are meant to overcome, and is in fact the reason that outcrossing is not considered a risk for those crops without local wild relatives. As plant geneticist Lurquin (2002) points out, the type of modification made possible by modern gene techniques is different from anything that had been done with traditional techniques:

True, plant breeding has been going on for millennia. But splicing bacterial genes into corn and canola is not exactly what Neolithic civilizations (that developed wheat, corn, and so forth) could have done. . . . Some aspects of plant biotechnology *are* different and have nothing to do with conventional plant breeding (p. 140).

Different opinions on the character of genetic engineering stem, then, not only from concepts of nature and the biological significance of the change made, but also from attention to the type of intervention involved and its details and to its intent. From this latter perspective, genetic modification appears to be among the most intrusive of the many social interventions that humans make in nature to create artefacts. In philosophical terms, this argument begins with the assumptions that nature is, by definition, that which is independent of humans and autonomous, and has adapted through evolutionary pressures to a complex ecological environment. According to that criterion alone GM plants are not natural as they have lost their negative autonomy; however the more important aspect of their ontology is that as a consequence of their deliberate and purposeful design for an industrial environment they have become social artefacts.

There are two main aspects to the argument that GM plants are artefacts, indeed are artefacts to the most extreme degree. One is the extent and intent of human design and intentionality, the degree of abstract instrumentalism the artefact expresses.

Considered from the perspective of the qualities that define artefacts themselves, GM foods are artefacts. Like most modern agricultural products, they are modified to adapt to the outer environment in which they are meant to serve - meeting the needs of mechanized and industrialized agriculture, machinery and agro-chemical companies, processors and retailers (Goodman et al., 1987; Simon, 1981).

The other aspect is the reach into nature that the intentional design and modification takes. As Lee (1999; 2005: 65) argues, the highest degree of artefactuality is realized when human design begins at the molecular level, making the organism a social product from its very foundation. A domesticated animal is already a “biotic artefact,” but one that has been genetically engineered ‘embodies a deeper level of artefactuality’. “It allows humankind to cross boundaries between species and kingdoms by manipulating organisms, no longer at the level of whole organism but at the molecular-DNA - level”:

Humankind, via biotechnology, has captured the biological mechanisms of cows and bacteria in order to make them be what humans want them to be and not how they themselves would be in the absence of human manipulation and control. In other words, although they may still perform such biological functions, nevertheless, in carrying them out, they have been made to subvert their own respective tele. . . and made to execute a human intention and human end instead. (Lee, 2005: 65).

In Stephens’s terms (1992) such deep intervention intrinsically ‘forces against the grain’ and creates a new entity that is more an expression of abstract human instrumentalism than it is of its own intrinsic and autonomous character (also Ridder, 2007). Genetic engineering is an artefact in the “policy mode” (Stephens, 1002:192), grounded in a “motivation of instrumentalism” and “focussed on objectified objects as abstracted from context.” By all of these criteria GM plants and organisms are at the far end of a continuum from natural to artefactual, merely using components found in nature to design and construct a product. The ‘subverted teleology’ of which Lee (1999) writes is epitomized in the fact that GM organisms are no longer functioning components of natural systems, even in their modified forms, but are named, owned and profit-

generating industrial commodities that are designed to interact with industrial products and processes and explicitly not with other species in an ecosystem. These qualities make them crucially distinct from traditional farming, which worked in partnership with natural processes, and certainly within its constraints.

These two aspects of the argument of the artefactuality of modified natural elements are reflected in many of the GM plants that have been developed and licensed. These are corporate products, named and branded for the industrial purpose they were developed to serve and in some cases the industrial products they are designed to interact with. Among the products recently licensed in Canada for use in human food, for example, are Insect Resistant Glufosinate Tolerant Maize event TC6275, developed and owned by Dow AgroSciences Canada Inc.; Glyphosate Tolerant Cotton MON 88913, owned by Monsanto Canada Inc.; and Glufosinate tolerant cotton derived from transformation event LL25, from Bayer CropScience (Health Canada 2007a).

As corporate products GM seeds are property, and in this context they are referred to by their owners as technology. Monsanto, along with other agricultural biotechnology companies, asks farmers who purchase and grow their seed to sign a 'Technology Use Agreement' "to ensure that Monsanto Canada shares the value of Roundup Ready Technology with all Roundup Ready farmers" (Monsanto, 2007).

The environment that GM plants are designed to function in is a social one - agricultural, industrial, and corporate. In Simon's (1981) terms, the 'outer environment' with which their physical makeup is designed to interact is a social environment with social functional objectives. This social specificity is compounded by the fact that most

agricultural crops are not successfully adapted to the ecological environments in which they are grown and are sustained only by human care.

As thoroughly and intensely social products, then, the larger environment into which GM plants must integrate is a social one; it is the various social pressures exerted that force adaptation and survival. As property, they confer rights of use, control, profit, and exclusion, explicitly granted by patents. They also enter implicitly the social world of responsibility and accountability, which, as Delaney (2003: 160) observes is part and parcel of ownership. They are also subject to scrutiny and even resistance in this environment, as society evaluates new and challenging differentiated functions according to their social purpose and value, and monitors their implementation and management closely. Critics of GM and members of the public expect that designed, targetted modification and ownership of nature that confer rights must also confer duties, and thus stress the social aspects of GM foods and crops in order to demand the strict social evaluation and management that are designated for social products. In the process they must assert that GM plants and crops are social and not natural.

The profound intervention that genetic modification makes in nature is significant also for its more purely ecological effects. It is clear that an environment largely shaped and driven by social intervention and human choice, whether by systematic, instrumental design or by the accumulated effects of smaller scale human choices and actions, is a different, and probably less diverse, environment than one that is driven by non-human forces of selection, adaptation, and change. In a manner that is less naively categorical than McKibben's description of the end of nature, Meyer (2006) describes the "end of the

wild”:

For the past several billion years evolution on Earth has been driven by small-scale incremental forces, such as sexual selection, punctuated by cosmic-scale disruptions - plate tectonics, planetary geochemistry, global climate shifts, and even extraterrestrial asteroids. Sometime in the last century that changed. Today the guiding hand of natural selection is unmistakably human, with potentially Earth-shaking consequences (p.3).

Because of these anthropogenic changes, Meyer argues that global ecosystems have been altered by ‘weedy species’ and relic and ghost species that can no longer sustain viable populations. Up to half the species in the world “will functionally if not completely disappear, ” replaced by “a peculiarly homogenized assemblage of organisms unnaturally selected for their compatibility with one fundamental force: us”(Meyer, 2006: 4).

Development and orientation of risk regulation of GM Foods

Biotechnology is not a characteristic substance but a class of lab procedures. By the early 1970s researchers recognized that some of the potential directions and applications of the research raised serious social and ethical concerns, and convened a series of conferences at Asilomar, California, to discuss guidelines for and limits on genetic research. A framework for laboratory research and controlling biohazards that may be associated with the research was developed, focussing in particular on procedures to prevent accidental release of a modified organism (WHO, 2005: 11).

An extensive network of regulatory functions, including funding, patenting, international and inter-sectoral collaboration and positioning, developed from the early days of the biotechnology industry. Formal risk regulation also developed within this

framework. Regulation of genetically modified foods, beyond the concern for laboratory development procedures, was breaking new ground. New foods developed by other methods have not usually been subject to “specific pre- or post-market risk or safety assessment by national authorities or through international standards” (WHO, 2005: 11). The development of regulatory terms and processes for agricultural biotechnology has been remarkably international and strategic in the establishment of standard terms in which GM crops would be defined, assessed and managed. Through the entire process the guiding framework has been economic development, support of innovation and competitiveness, and overcoming, or at least circumventing, popular opposition to the products of agricultural biotechnology. The risk regulation of GM foods accomplishes much more than the control of risks to the public from GM foods.

Regulation as an institutional function is, as discussed, increasingly laden with political and economic goals. The regulation of biotechnology was initially meant to facilitate the growth of the industry, ‘contributing to order and coherence in the policy field’, and “had more to do with stimulating economic development than with ensuring that the new technology will not pose a risk to society” (Krimsky, 1991:194). Industry began to be concerned about a growing anti-biotechnology mood, though no adverse effects had been documented; in the U.S. there were fears that inconsistent and ambiguous regulation would lead to the loss of the American competitive edge in the industry. The Environmental Protection Agency began to regulate biotechnology in 1984 (Krimsky, 1991). Several large companies actively lobbied for strict regulation, both as a means to discourage the entry into the market of smaller researchers and firms, and as a

means to gain public acceptance of biotechnology products with the sanction of state regulation and safety (Miller and Conko, 2003). Industry recommendations were that regulations should be consistent among the agencies with responsibilities for regulating products of biotechnology, based on the best available science; and that there be no excessive or irrational regulation. The operative terms, according to Krinsky, (1991) were internal harmonization, consistency, ease of regulatory burden, and U.S. global competitive leadership.

A similar evolution occurred in other countries. In Germany, industry initially rejected regulation, but began to agree to “reasonable regulations which allow us to say genetic engineering must be done, is necessary, important and a blessing, and, in addition, has dangers, but these dangers can be handled by legal measures” (Gottweiss, 1998:281). In the U.K., industry had opposed regulation as implying genetically modified products are risky, but began to accept that public acceptance was necessary and that it could be “secured by precautionary regulatory measures” (Gottweiss, 1998: 305).

In many countries and within international scientific circles debate began to crystallize around certain regulatory principles and institutional arrangements, and uniform safety standards were introduced. Many countries turned to a pre-market regulatory system, “requiring the rigorous assessment of GMOs and GM foods before their release into the environment and/or use in the food supply” (WHO, 2005:11). One question was whether biotechnology regulation should be triggered by the new characteristics of the product itself, or simply by the fact that it was created through biotechnology - a ‘product’ or a ‘process’ approach. A product-based approach would

have new GM foods regulated under existing legislation and by existing institutions as variants of existing products, implying no new risks resulting from the process of production. A process-based approach would dedicate a new and separate regime to products produced by biotechnology, implying that the process itself could create special risks.

Canada and the U.S. decided to regulate biotechnology products under existing legislation, on the rationale that it is the product that is at issue and the process of biotechnology itself does not create any special risk, and that process-specific legislation would result in duplication of regulatory effort. The U.S. National Research Council and Institute of Medicine concluded that there have been no adverse human health effects from genetic engineering (National Academies, 2004). However, they note that any breeding technique that alters a plant or animals may create changes in quality or composition that could harm health, and that genetic engineering is new enough that safety concerns remain. They therefore concluded that safety evaluations should be based not on the process of production but on a case-by-case evaluation of product safety. Other countries, such as Argentina, Australia, Japan, and the European Union, regulate biotechnology products either entirely or partly under new legislation on the more precautionary assumption that the process has not yet been proved to be safe for human health or the environment.

The concept of 'novelty' has evolved over the last decade or so as a regulatory category more or less closely equated with genetically modified foods. Novelty has been interpreted in different ways and applied within different regulatory contexts, and has

evolved, in some contexts, from a simple descriptor to a carefully delineated regulatory definition that facilitates regulatory strategy (Andrée, 2002). Different interpretations and associations, and different regulatory orientations within which the concept of novelty is applied, result in a range of effect and strategic potential.

In 1993 the OECD referred to 'foods derived by modern biotechnology' as "new foods or food components" (OECD, 1993). By 2000 the report of the OECD Task Force for the Safety of Novel Foods and Feeds had adopted the category of novel foods, and clearly identified it with the "first generation of foods derived through modern biotechnology" (OECD 2000: 4). The European Union also uses novel foods as a regulatory category in its Novel Foods Regulation (European Parliament, 2007). Here novel foods are defined as foods that consist of or contain genetically modified organisms, or that were produced from GM organisms, as well as other new production processes that change the composition of the food. However, these regulations were superseded by regulations on genetically modified food and feed (European Parliament, 2003). This frankly process-based, precautionary regime requires a safety evaluation of all new foods containing or produced from GMOs, as well as environmental protection and product labelling (Andrée, 2006).

Novel foods are regulated in the EU in a process-based system in which the contained use and release of GM plants are controlled by regulations that are specific to plants developed through genetic modification (Jasanoff, 2005; MacKenzie, 2000:29). Also consistent with a precautionary and process-based approach, the Novel Foods Regulation specifies environmental risk assessment and consumer labelling requirements

for foods that contain GM products.

The approach taken by regulatory agencies to risk assessment is fairly consistent among countries (MacKenzie, 2000). Most, including Canada, have adopted a pre-market safety evaluation regime, in which risk assessment takes an ‘evidence-based’ approach that considers only scientifically based risk information and does not consider the possible benefits argued for the product. It is assumed that benefits “take care of themselves as products without obvious benefits are unlikely to have value in the marketplace” (MacKenzie, 2000: 54).

Companies applying to have a new product licensed provide research, testing and surveillance data to the regulatory authorities, who evaluate the information in the context of relevant professional expertise, additional data requested, and international peer-reviewed literature. The hazards evaluated for biotech plants are the same in most countries, built on internationally accepted principles including invasiveness, gene flow, effects on biodiversity and other ecological impacts, trait effects, genetic and phenotypic stability, expression of genetic material from pathogens, and worker safety (WHO, 2005; MacKenzie, 2000). The WHO (2005: 23) also “identified a need for postmarket surveillance [of GM foods] and therefore a product-tracing system”; however, not all national regimes have adopted this recommendation.

It is becoming a standard expectation that agricultural practices be used to protect against outcrossing and the development of insect resistance to insecticidal toxins. Growers are encouraged to follow ‘stewardship requirements’ to protect conventional crops and wild species from the spread of pest resistance or pesticide tolerance. Most

growers of B.t. corn in the U.S., for example, are following regulatory requirements that they plant “at least a 20 percent refuge - or corn that does not contain a Bt gene for controlling corn borers - and that every Bt cornfield must be located within one half mile of a refuge” (Canadian Corn Pest Coalition, 2006). Similar results are found among Canadian growers of corn and other GM crops. Such a plan would be applied, for example, with the cultivation of Bt potatoes, for which a 20% refuge is required, located no further than 800 m from the Bt crop and which is not sprayed with Bt insecticides (CFIA, 2001a).

There are several key principles used internationally in the risk or safety assessment of GM foods. One, used primarily at the stage of assessing the environmental safety of GM plants, is that of familiarity. Familiarity “means having enough information to be able to make a judgement of safety or risk” (WHO, 2005: 20). This can also assist in the determination of agricultural practices that may be required to manage any risk.

Another key principle used for the safety assessment of plant products of biotechnology is that of substantial equivalence. This concept was first used in the context of biotechnology in a 1993 OECD report (OECD, 1993), to mean that “If a new food or food component is found to be substantially equivalent to an existing food or food component, it can be treated in the same manner with respect to safety.” The properties of most conventional foods are well characterised, in terms of such factors as nutrients, toxins, allergens, and potential contaminants. Average patterns of dietary consumption are also known. A new food that is derived, through genetic engineering or other process, from a conventional food can therefore be evaluated in comparison to these

known characteristics of the conventional variety. This evaluation would include consideration of levels of toxins or other substances of significance in the new variety, increases or decreases in nutrient content, changes in allergens, contamination from processing or other sources, and the expected dietary exposure of the population to the food. (OECD, 1993). No additional safety or nutritional concerns would be expected from a modified food that is substantially equivalent to its conventional comparator.

This approach, while it is widely accepted as a regulatory principle against which biotech products are tested for safety, has been interpreted in different ways and is the focus of some controversy. The WHO (2005: 12) notes that a 2000 FAO/WHO consultation

acknowledged that the concept of substantial equivalence contributes to a robust safety assessment, but it was also clarified that the concept should represent the starting point used to structure the safety assessment of a GM food relative to its conventional counterpart. The consultation concluded that a consideration of compositional changes should not be the sole basis for determining safety, and that safety can only be determined when the results of all aspects under comparison are integrated.

The Royal Society of Canada (RSC, 2001:177 - 183) explains that the concept of substantial equivalence derived from conventional breeding, which combined genes from within the gene pool of a single species - from which undesirable traits have often been eliminated through many years of selection, and which therefore usually produced variants of “the same basic plant” (p.177). Thus “new combinations of existing genes operating within highly selected germplasm are not expected to generate harmful outcomes” (p.179). The RSC (p.182) cautions that in the case of genetically modified foods what is required is “a scientific finding that the new food does not differ from its

existing counterpart in any way other than the presence of the single new gene and its predicted phenotypic change.”

The OECD (2006: 9) likewise stresses that the concept of substantial equivalence “should be seen as a key step in the safety assessment process, although it is not a safety assessment in itself; it does not characterize hazard, rather it is used to structure the safety assessment of a genetically modified food relative to its conventional counterpart.

Millstone et al.(1999) argued that the concept was a strategy of industry, which wanted regulation as official approval of the products they had developed in order to reassure consumers. Regulatory institutions had no authority to regulate these new products under existing legislation, however, and intensive toxicological testing, as required for novel chemicals, would be slow and expensive. The substantial equivalence concept served as a signal that

As long as companies did not try to market GM foods that had a grossly different chemical composition from those of foods already on the market, their new GM products would be permitted without any safety or toxicological tests. The substantial-equivalence concept was also intended to reassure consumers, but [without information provided by toxicological tests] it is not clear that it has served, or can serve, that purpose.

Millstone et al.(1999) also argued that the concept itself remains ambiguous, with no clear designation of how ‘equivalent’ a novel plant must be in order to be ‘substantially’ equivalent.

In response to Millstone et al., Miller (1999) argued that the concept of substantial equivalence was prefigured by a scientific consensus that genetic modification is much more precise than natural genetic mutations or traditional breeding techniques, leading to

a better ability to predict 'phenotypic expression' in GM products than in traditional products. As Miller (1999) says, "the very essence of risk-assessment related to environmental protection and public health is *superior* for gene-spliced foods!" (p.1042, emphasis in original). He argues that under these conditions substantial equivalence is 'a kind of regulatory shorthand for defining those new foods that do not raise safety issues that require special, intensive, case by case scrutiny' and that "it neither specifies nor limits the kind or amount of testing needed for new foods" (p. 1042).

The fundamental definitional building blocks of product-based regulation that uses the substantial equivalence of a novel plant with its conventional counterpart are inherent in scientific concepts of nature. The focus on molecular composition exclusive of any 'contextual' factors such as process relies on the same technical logic that defends risk assessment based on the substantial - compositional - equivalence of a GM plant to a conventional variety. These principles and the regulatory definitions they support play down the distinctiveness of rDNA processes by asserting the continuity between them and the genetic modification of the genome in plants developed by traditional selection and cross breeding techniques, denying the categorical break with traditional practices that these technologies display in their ability to transcend species boundaries and the randomness of natural selection and cross-pollination. They also contend that the natural aspects of a plant are in its components rather than in the means by which a particular combination of these components was achieved. Context, whether it refers to a random evolutionary context or a human or social context of targetted alteration, is not scientifically relevant to the integrity of the composition of the resulting plant.

The use of substantial equivalence is a central mechanism for the naturalization of GM foods and the process of agricultural genetic engineering that develops them. A scientific concept of nature authorizes the strict focus on composition and content, and the explicit exclusion of the social context and even biological process factors that form the basis of public opposition.

The development of many of the key aspects of the regulation of GM foods occurred in an international arena - indeed, an international economic development arena, largely through the OECD. Regulatory and institutional arrangements and risk assessment principles were developed strategically by the industry and political economic interests from the very early days of commercialization of GM crops and foods. Parallel to the regulatory and risk management arrangements have been the revision of intellectual property laws and their application to an increasing range of biotechnology products. Together with government financial incentives and associated research and development support, these broadly regulatory arrangements have been the result of an internationally coordinated strategy to assemble a set of economic and institutional conditions congenial to the biotechnology industry. It has been up to each country to implement the specific variants of these regulatory arrangements that are most compatible with the political climate and the attitude towards biotechnology within its own population.

Chapter 8

Regulation of Genetically Modified Foods in Canada

Policy context of GM foods in Canada

Canada's biotechnology industry is credited with creating 2500 life sciences organizations and 200,000 jobs in the country, with 490 companies and \$3.8 billion in revenues in 2005 (BIOTECanada, 2007; Industry Canada, 2006). Biotechnology firms are located in a number of clusters throughout Canada, mostly in Ontario, Quebec and British Columbia (Niosi and Bas, 2004), and receive considerable support from provincial governments. The emphasis here is on federal support as the federal government is responsible for the regulation of GM crops and foods in Canada.

Biotechnology is noted as being an increasingly important engine for economic growth and has been supported and managed through a set of interacting federal government policies and governance bodies that form a major part of the larger regulatory regime for agricultural biotechnology. In the early 1980s biotechnology was targetted by the federal government for development as a key innovative technology driving economic growth, and has been promoted as such since that time (Abergel and Barrett, 2002). Industry Canada has led the federal government promotion of biotechnology since the National Biotechnology Strategy (NBS) was launched in 1983. This was a "multidimensional program aimed at fostering industrial, university, and governmental R&D in biotechnology, promoting the development of human resources, and nurturing collaboration among the different agencies" (Niosi and Bas, 2004: 236). The NBS was succeeded in 1998 by the Canadian Biotechnology Strategy, a multi-

departmental strategy to develop the different fields of biotechnology to “encourage innovations that improve health, protect the environment and stimulate economic growth - to fulfill biotechnology’s promise to build a higher standard of living and quality of life for all Canadians.”

Canada’s Innovation Strategy (Canada, 2002a) supported biotechnology as a key innovative industry and a major driver of overall economic productivity and performance. The objective of policy in this domain is maintaining global competitiveness and raising the standard of living, adopting innovations for their economic potential wherever they become available.

By 2006, the federal government was spending about \$750 million annually on biotechnology, 85% of which goes to research and development (CBAC 2006a: 53). Of the remainder, 6% is spent on regulation, 5% on policy development, and 1% each on commercialization and communications and public awareness. Agricultural biotechnology constitutes 15% of the biotechnology industry in Canada, making Canada fourth in the world in “acreage of biotech crops planted” (BIOTECanada, 2007). Over 70% of the land dedicated to canola, for example, is used to grow GM varieties ((BIOTECanada, 2007).

As part of the larger biotechnology industry and regulatory environment, genetically modified foods in Canada are situated in a series of overlapping policy contexts. As food products they are derived from agricultural crops, a context that involves relationships between, among others, seed and other agricultural input industries, producers or farmers, and processors. At this point they are governed by

agricultural policy, made primarily by government and industry groups. Agricultural policy is in turn part of larger government economic policy and global economic pressures and demands. As products of biotechnology, GM crops and foods are supported as major components of innovative industry, driven by scientific research and government and private investment, all of which is supported by a government economic policy.

At all levels regulation is employed, particularly since it has been used as an instrument to carry broader government policy. Federal regulatory policy is tailored at the individual regime level to the specific situation and needs of the industry, as well as to its own enabling legislation. As elements of the economy GM crops and foods are also subject to intellectual property laws which support the investment aspects of the industry.

Food biotechnology is a key agricultural industry, and it is at the seed and crop level that most of the industry activity occurs. The seed companies sell the approved GM seed to farmers, often under a Technology Use Agreement that prohibits farmers from replanting seed and specifies that only the seed company's herbicide may be used on the crop (Kloppenburg, 2004: 322). The producers then sell their product to processors for preparation and consumer sale.

At each of these levels, the support for innovation as a driver of economic growth remains a primary theme. Agriculture and Agri-Food Canada's Science and Innovation Strategy (AAFC, 2006) notes that competitiveness in Canada's agriculture industry, which "accounts for just over eight percent of Canada's Gross Domestic

Product” (AAFC, 2006) has deteriorated. Part of the solution is innovation, “which transforms the [new knowledge discovery] into benefits for Canadians, involving the processes by which ideas for new (or improved) products, processes, or services are developed and commercialized in the marketplace” (p. 1).

Innovation is the first theme noted in the report of AAFC’s (2007) consultations on the Next Generation of Agriculture and Agri-Food Policy: “new and innovative products and methods were seen by many participants . . . as providing a key to future profitability to primary producers and others throughout the value chain” (AAFC, 2007: 5). GM foods are thus central components in an integrated neoliberal framework of economic policy, agricultural policy, regulatory policy and regulation, usually considered with other agricultural or biotechnology products for their generic economic potential rather than for the value of any specific application.

Regulatory policy, formulated as a federal-government-wide political and economic instrument in 1999, is currently undergoing refinement under the Smart Regulation initiative. The draft Government Directive on Regulating consultation document (Canada, 2005) reiterates and elaborates on key themes in regulatory policy, stressing the importance of risk and cost-benefit analysis in setting regulatory requirements. Many of the refinements articulate ways that regulation should support and not constrain industry, such as requiring that non-regulatory alternatives be considered and that regulation is proportional to the risk to be controlled, does not “unduly affect areas it was not designed to address,” and is designed “from the perspective of those who must administer or comply with it” (Canada, 2005:5).

Intellectual property is also a crucial component of innovation policy and the regulatory system, facilitating the progress of inventions from research to commercialization. There has been pressure to adapt patent law to the products and processes of biotechnology: as part of the modification of the regulatory environment, several changes have been made to Canadian patent law since 1982 to accommodate life forms that have been genetically engineered. These include genetic material, on the assumption that it is constituted by “chemical compounds removed from their natural state,” and unicellular organisms and microbes (Niosi and Bas, 2004).

The Canadian Biotechnology Advisory Committee advised in 2004 (CBAC, 2004) that the government should review the Patent Act in light of recent court decisions on biotechnology. While Canada’s patent laws are comparable to those in other countries and Canada is a signatory of the TRIPS, it does not permit patents on animals or on whole organisms. CBAC has recommended that government move to review and update Canada’s patent laws so they can accommodate the rapid advances in biotechnology. CBAC had previously recommended that higher life forms - plants, seeds and non-human animals - “that meet the criteria of novelty, non-obviousness and utility be recognized as patentable” (CBAC 2004:4).

Biotechnology industry groups and the seed industry have lobbied for expanded patent and plant breeders rights protection in Canada (National Farmers Union, 2004; Masselink, 2005). Those who supported the extension of patent rights over invented plants in CBAC consultations (2001) of the patenting of higher life forms based their arguments on the value of commercial development. Patenting provides “economic

incentives to foster innovation”(CBAC, 2001: 16). While it is possible under the TRIPS or the Cartagena Protocol on Biosafety to refuse patents on some material on the grounds of *ordre public*, public health or morality, Canada, along with the US and Australia, “follows the minority view that patent law and morality are completely separate” (Gold, 2001: 9). This position has not been uncontroversial in Canada: in 2002 the Supreme Court of Canada denied a patent to the “oncomouse,” a mouse genetically engineered by Harvard University to be susceptible to cancer, for use in cancer research. The Supreme Court argued that extending patent protection to higher organisms raised concerns that could not be resolved by the courts, and required Parliamentary debate (Jasanoff, 2005). Nevertheless, in its final report on the patenting of higher life forms CBAC, (2002: 5) judged that patenting is largely an economic issue, and that “social and ethical considerations raised specifically by biotechnology should continue to be addressed outside the Patent Act.”

Overview of risk regulation of agricultural biotechnology in Canada

Over the last several years health applications have overtaken genetically modified food as the major component of the biotechnology industry (Doern, 2003). However food biotechnology is still a large industry in Canada, and its regulation is relatively stable. That is, being based on substantial equivalence, it is linked to the conventional regulation of traditional foods. Despite acceptances in other countries, a food must be licensed in each country in which it is to be sold. Novel varieties of canola, corn, cottonseed, flax, sugar beet, potato, soybean, squash, and tomato have been

approved for sale in Canada (Health Canada, 2007a). The GM foods sold in Canada are basic staples or ingredients in prepared foods, such as corn starch and canola oil, and are invisible to the consumer as products of biotechnology.

Agricultural biotechnology is regulated under the authority of several pre-existing pieces of legislation, administered by established regulatory institutions. The CFIA regulates the development and growth of crops of plants with novel traits, animal feeds, biofertilizers and veterinary biologics under the Seeds Act, the Fertilizers Act, the Feeds Act, and the Health of Animals Act. Health Canada regulates genetically modified foods, food additives, enzymes, veterinary drugs, and pharmaceuticals under the Food and Drugs Act. The Pest Management Regulatory Agency regulates biotechnology pest control products under the Pest Control Products Act; and Environment Canada regulates environmental effects of biotechnology products under the Canadian Environmental Protection Act. Health Canada and Environment Canada officials together decide on whether a new food product is toxic to the environment and human health, or requires further toxicological testing (RSC, 2001: 37). While no genetically modified fish have been licensed, the Department of Fisheries and Oceans will regulate any such products under the Fisheries Act.

Health Canada regulates genetically modified foods through the Novel Foods Regulations, under the Food and Drugs Act, and approves all novel foods products that are intended to be marketed for human consumption. Authorities from the CFIA and Health Canada consult on the approval of a GM crop grown for human food; these assessment and approval processes usually occur together, as applicants contact

regulatory authorities early in the development process. This collaborative approval process is meant to ensure that approval is not granted to a GM food derived from a crop that does not gain approval. Crop plants that have novel traits, as determined by the proponent, are also considered novel for the purpose of human consumption; thus this determination at the crop evaluation stage also triggers the process for the food product (CFIA, 2005d).

Much of the environmental control of agricultural crops with novel traits is governed by Part V of the Seeds Regulations on the release of seeds, which is designed to minimize the spread in the environment of seeds or genetic material from plants with novel traits. In order to be approved for unconfined release under the terms of Part V of the Seeds Regulations, a GM plant undergoes a series of evaluations in the pre-regulatory review under contained trial conditions, in which the following are considered (CFIA 2005a).

- the potential for the plant to become a weed or to be invasive of natural habitats
- the potential for gene flow to wild relatives
- the potential for the plant to become a plant pest
- the potential impact of a plant or its gene products on non-target species
- the potential impact on biodiversity

In the reviews of these impacts, regulators use the criteria of familiarity and substantial equivalence, judged according to guidelines established for each crop (CFIA, 2001d), to determine what sort of risk assessment a novel plant must undergo (CFIA 2001d). Familiarity is defined by the CFIA as “the knowledge of products with similar traits and usage . . . which may provide an accurate idea of the relevant risks in the novel

product in the absence of direct experience with it” (CFIA, 2005b). A product that is familiar, as determined by the proponent, then goes on to an evaluation for substantial equivalence under the criteria noted above. A plant that is substantially equivalent to others of its species is exempted from the requirements of notification and authorization under Part V of the Seeds Regulations, and “is not governed by federal legislation and can be commercialized without further consideration” (CFIA 2001d).

A plant that is not deemed familiar or substantially equivalent is referred for a risk assessment, which would focus on “the specificity of the inserted DNA sequences and any potential changes in environmental interactions” (CFIA 2001d). If the risk is acceptable - that is, comparable to that of its conventional counterpart - it is approved for regulation under the Seeds Regulations, Part V, which sets out controls on the release of novel seeds into the environment.

Evolution of the regulatory framework for food biotechnology

Products of agricultural biotechnology were first regulated in 1983 by Health Canada, and 1988 by Agriculture Canada, now the Canadian Food Inspection Agency (CFIA), before regulation designed to address products of biotechnology had been established. The OECD’s “Recombinant DNA Safety Considerations” of 1986 became the impetus for and the basis of the framework for the regulation of biotechnology in many countries. Biotechnology itself was not defined, however, leading each country to establish its own definitions (CFIA, 2005d).

The route by which Canada developed its scientific, product-based regulatory

approach to the pre-market notification of novel plants and foods reveals a strategic selection of regulatory definitions largely driven by the agricultural biotechnology industry and governments focussed on supporting innovation. Much of this occurred with the development of regulatory principles established to govern GM crops, and was adopted in the regulation of GM foods.

Three developments in 1988 oriented future regulation towards a product-based approach to novel crops and foods; these and other subsequent events reveal that the key elements in the regulatory framework were decided in consultations between industry and government years before regulations were implemented. Furthermore, although the Novel Foods Regulations and successive revisions of Guidelines for the Safety Assessment of Novel Foods (Health Canada 1994; 2004; 2006) present GM foods increasingly as only one component in a larger category of novel foods that require assessment, it is evident that the category of novel foods and the efforts to define their regulation and assessment originated with industry concerns about the public reception of foods produced by modern genetic engineering techniques.

The first formative development was that the draft Canadian Environmental Assessment Act (CEPA) of 1988 recommended that all products of biotechnology be regulated by Environment Canada as toxic substances (Abergel and Barrett, 2002). This recommendation was not accepted into CEPA; instead, products of biotechnology were considered 'new substances', subject to the requirement that "any person wanting to import, manufacture or sell a 'new substance' notify the appropriate Canadian regulatory authority so the product could be evaluated for potential effects on the environment and

human health” (CFIA 2005e). Under this regulatory framework, CEPA is ‘the key legislative authority to ensure that all new substances are assessed’, but exempts any biotechnology products that are regulated under other Acts.

Second, in response to the provisions of CEPA, at this time “agricultural companies were making pitches to Agriculture and Agri-Food Canada regulators asking [AAFC] to regulate them, not [Environment Canada]” (CFIA 2005e). Subsequently, in 2001, regulatory responsibilities for the environmental effects of plants with novel traits were formally transferred to the CFIA (which assumed regulatory and inspection responsibilities from AAFC with its establishment in 1997) through the Seeds Act and the Feeds Act.

Third, the Canadian Agri-Food Research Council (CARC; “a not-for-profit consortium of researchers from industry, academia and federal and provincial governments” (CFIA, 2005e) recommended a product-based trigger for safety assessments of novel foods. “Those plants which possess characteristics or traits sufficiently different from the same or similar species should require an assessment of risk.” The rationale was that any novel plant, regardless of its method of development, could pose a risk to humans or the environment. “This direction from CARC was pivotal in assisting the government in the development of a regulatory framework for novel products” CFIA, 2005e).

In 1993, federal regulatory departments agreed on a definition of biotechnology as “the application of science and engineering in the direct or indirect use of living organisms or parts or products of living organisms in their natural or modified forms”

(Doern, 2000:3). They also presented a set of principles ‘for a more efficient and effective regulatory framework for Canadian biotechnology.’

1. Maintaining Canada’s high standards for protection of human health and the environment;
2. Building on existing legislation and institutions, clarifying jurisdictions and avoiding duplication;
3. Developing guidelines, standards, codes of practice and monitoring capabilities for pre-release assessment of the risks associated with release to the environment;
4. Developing a sound scientific data base upon which risk assessments and evaluation of products can be made;
5. Promoting development and enforcement of Canadian regulations in an open and consultative manner, in harmony with national priorities and international approaches; and
6. Fostering a favourable climate for development of sustainable Canadian biotechnology products and processes (Canada, 1996, chapter 2: 4)

Also in 1993, AAFC researchers and regulators and members of industry discussed a risk-based approach to the regulation of the products of biotechnology. As well, discussions were taking place both within the international biotechnology regulatory community (such as the OECD) and Canada on “the concepts of familiarity and substantial equivalence in order to determine novelty” (CFIA 2005e).

Between 1994 and 1999, when regulations to govern products of biotechnology were under development, trials and even releases of genetically modified crops continued. This was done with considerable support of the industry from AAFC.

While regulations were under development, [AAFC] worked very closely with the industry to facilitate the development, innovation and testing of their biotech products (while there was significant political pressure to put a moratorium on all field testing and releases). . . . Applications for unconfined release were accepted . . . and the first unconfined release of HT canola was in 1995. . . .Part V [of the Seeds Regulations] was drafted in such a manner that it grandfathered biotech products that had already been released into the environment. (CFIA 2005d)

Evolution of regulatory novelty: from novel to normal

The use of the terms ‘novel traits’ and ‘plants with novel traits’ in risk regulation in Canada began with the CARC recommendations in 1988 as an alternative to the CEPA term ‘new substance’. As used for the assessment and regulation of plants with novel traits (PNT), a novel plant is one that is both “new to stable, cultivated populations of the plant species in Canada, and it has the potential to have an environmental effect” (CFIA, 2007).

The first formal notification of the introduction of regulatory pre-market notification and clearance of novel foods came in Health Canada’s Information Letter on Novel Foods and Novel Processes in 1992 (CFIA 2005). The category of novel foods was used in the 1994 Guidelines for the Safety Assessment of Novel Foods (Health Canada, 1994) to bring a wide range of novel foods under a regulatory umbrella. GM foods were a leading rationale for the Guidelines, which note that regulations for safety assessment of foods existed in many areas, including food additives, pesticide residues, and irradiated foods, but that there were none for “many novel foods, including the products of biotechnology” (Health Canada 1994:3). Indeed, “new varieties of familiar or conventional crops had been bred, sold, planted and consumed in Canada for decades without such pre-market safety assessments” until CEPA’s requirement that the ‘new substances’ produced by biotechnology required an environmental assessment (CFIA 2005e).

The options considered for the regulation of novel foods as described in the 1994 Guidelines were pre-market approval and pre-market notification. Pre-market approval

was “viewed as introducing unnecessary impediments to the marketing of novel foods, without providing a corresponding increase in the level of consumer protection” (Health Canada 1999a). Pre-market notification was considered appropriate as it allows regulators to evaluate the safety of the novel foods before they are marketed. Under this scheme, food developers submit information about a novel food they wish to market in Canada, and regulatory expert panels review the information supplied to ascertain the safety of the food before permitting its sale.

One of the objectives of the 1994 Guidelines was to help food developers determine whether a new food product qualifies as ‘novel’ and is thus subject to a safety assessment. A novel food was defined as one that has been modified such that it results from, and has been modified by, genetic manipulation, or that has not previously been used as food, or results from a process not previously used for food; or that results from production by a genetically modified organism that exhibits new characteristics (Health Canada, 1994: 7). A novel food may also be one that contains microorganisms not previously used in food, or that has been modified from the traditional product or produced by a modified process (Health Canada 1994: 7). The product orientation of novel food regulation in Canada means that even when a GM process has been used in the development of a food, regulatory pre-market notification is not required if the food product does not have a new characteristic introduced.

In 1999 new Novel Food Regulations were created as Section 28 under the Food and Drugs Act (Health Canada 1999a). These regulations take a risk-based regulatory approach and use a product-based safety assessment associated with a determination of

substantial equivalence, and the concept of novelty, as established through AAFC discussions with industry. They were presented with the generic rationale that “Rapid advances in food science and biotechnology have resulted in the development of a variety of foods that were not previously available in the Canadian marketplace, or that have been modified from their traditional composition” (Health Canada 1999a).

Under the Novel Foods Regulations a novel food is ‘a substance that does not have a history of safe use as a food’, ‘a food that has been produced by a new process’ that causes the food to undergo a major change’. The revised definition of “novel food” is narrower than that in the 1994 Guidelines, still capturing GM foods but no longer singling them out for assessment (Health Canada 1999a).

Under the Regulations “‘genetically modify’ means to change the heritable traits of a plant, animal or microorganism by means of intentional manipulation” (B.28.001). A genetically modified food that is novel is (Health Canada 1999a):

- (c) a food that is derived from a plant, animal or microorganism that has been genetically modified such that
 - (i) the plant, animal or microorganism exhibits characteristics that were not previously observed in that plant, animal or microorganism,
 - (ii) the plant, animal or microorganism no longer exhibits characteristics that were previously observed in that plant, animal or microorganism, or
 - (iii) one or more characteristics observed in that plant, animal or microorganism no longer fall within the anticipated range for that plant, animal or microorganism.

The Novel Foods Regulations retain the original CEPA requirement that the developer of a new or novel product notify the regulator of the intention to sell a novel food in Canada, and submit a prescribed set of data for the review before the sale is permitted. This information is considered proprietary and is not available for public

inspection or for external or peer review. Health Canada subject experts review this information, along with peer-reviewed literature and other relevant information, requesting additional information or toxicity studies from the proponent if necessary. The review of this information by Health Canada experts constitutes the safety assessment of novel foods. The processing of a novel food submission by Health Canada is shown in Figure 8-1.

In the 2006 revised Guidelines for the Safety Assessment of Novel Foods (Health Canada 2006a), the rationale for the category of novel foods is traced to an expanded range of sources: “the globalization of the food supply, the demand for more food sources globally, and rapid advances in food science and technology have resulted in food not previously available in the Canadian marketplace” (p. 4). The category of GM foods as those developed through rDNA engineering techniques is now in its third articulation, and has been reduced to only one sub-type in a broadened category of genetically modified foods: Genetic modification to change the agronomic, production, processing or nutritional characteristics of microorganisms, plants and animals may be achieved through traditional breeding techniques or modern gene technologies (Canada, 2006a: 4). Figure 8-2 shows the decision tree for the regulations for novel foods.

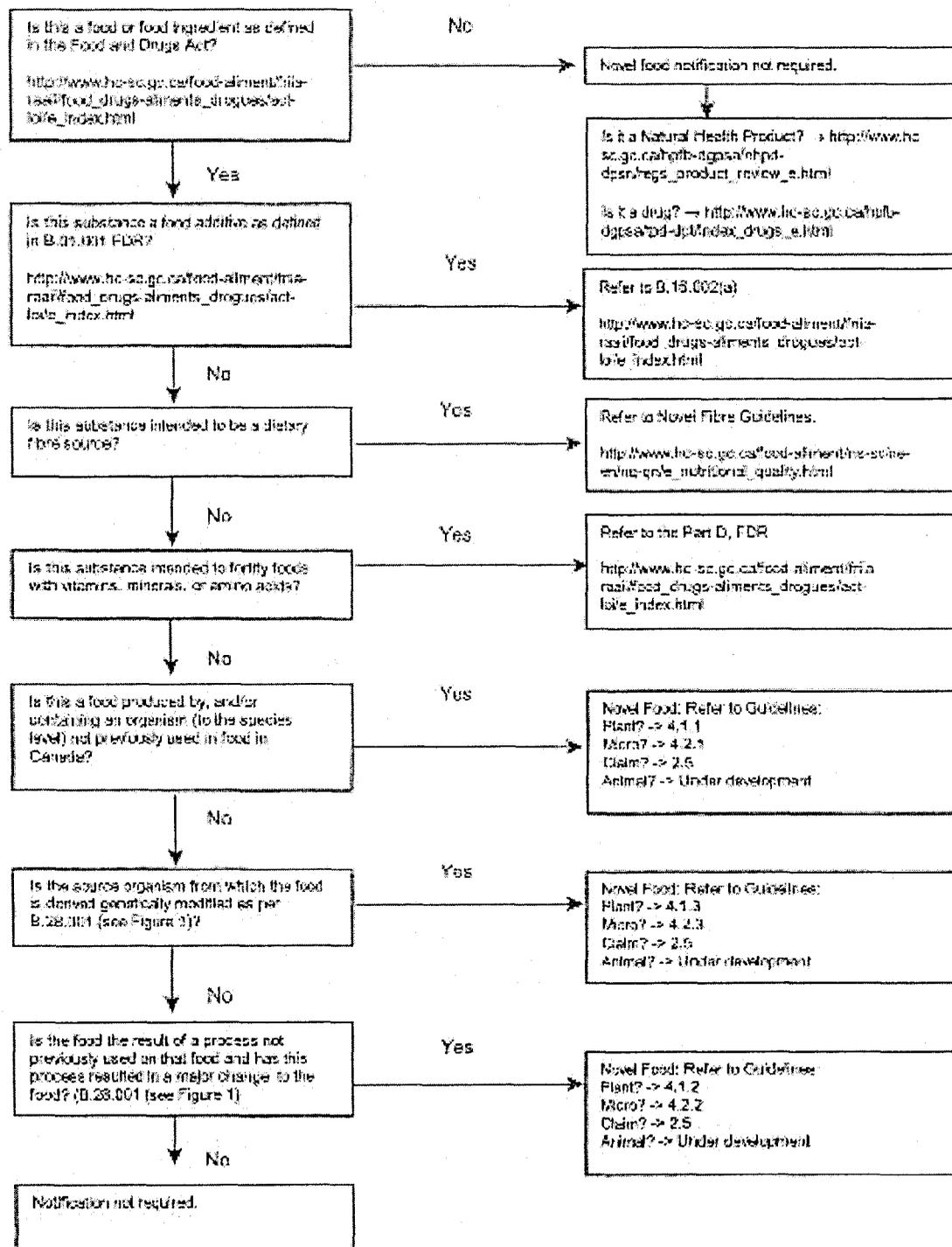


Figure 8-2. Decision Tree for the Regulation of Novel Foods (Health Canada, 2006a).

The 2006 Guidelines state that “the starting point for the safety assessment of novel foods is the evaluation of these foods relative to conventional counterparts that have a history of safe use. . . . The intention is to identify new or altered hazards relative to the conventional counterpart.” (Health Canada, 2006a: 17). Data are provided by the proponent on how the food was developed, the composition and nutritional status of the food compared to non-modified counterparts, and the potential for the introduction of new toxins or allergens (Health Canada, 2006c pt. 2: 2).

Records of the novel foods approved by Health Canada (2007a) show that approximately three-quarters of the approved products were produced with rDNA technology (the others used mutagenesis techniques, or qualified as novel due to a new processing method). All of the genetically engineered products approved after 2004, when decision documents began to show this information, attribute the novelty of the product to paragraph c i) of the definition of genetically modified foods in the Novel Foods Regulations, in which the plant “. . . exhibits characteristics that were not previously observed in that plant, animal or microorganism.” No applications referred to the deletion of a trait; and none referred to the third possibility, that “one or more characteristics observed in that plant, animal or microorganism no longer fall within the anticipated range for that plant, animal or microorganism.” The first criterion for novelty aligns the product towards a subsequent decision that the new variety is substantially equivalent to the existing comparator, while the third may imply a greater deviation from that standard profile than is compatible with substantial equivalence.

The conclusion of a comparative assessment of a novel food relative to its

conventional counterpart is that the novel food is substantially equivalent to its comparator (or, theoretically, that it is not). Once a novel food product has been declared substantially equivalent to an existing product, no further safety testing is required. All of the rDNA-derived novel foods approved by Health Canada have been found to be substantially equivalent, though the term does not appear in the decision document. The conclusion of safety evaluations of GM foods stick to the evaluative terms of substantial equivalence with respect to food safety. The following conclusion for Syngenta Seeds Canada Inc.'s "maize lines containing event MIR604," which contains two novel genes that give protection against feeding damage of the corn rootworm larvae, is representative:

The results suggest that foods derived from corn lines containing event MIR604 would not pose any greater allergenic risk than non-transgenic corn. At the expected level of consumption, there was no greater concern with corn lines containing event MIR604 than non-transgenic lines, with respect to its potential for toxicity or allergenicity (Health Canada, 2007a).

The requirements for safety for an approved food are those of the Food and Drugs Act for all foods on the market, consisting of general prohibitions against false advertizing, health claims, and unsafe or unclean foods or facilities. There is no health-risk or regulatory justification for labelling a GM food once the safety assessment declares that a novel food is substantially equivalent to its conventional counterpart already on the market. Novel food products are not required to carry a label stating that they contain GM ingredients, as under the Food and Drugs Act (1985; also CAN/CGSB-32.315-2004) labelling is mandatory only when the foods "have significant nutritional or compositional changes, or where potential health and safety risks exist that could be

mitigated through labelling.”

The paradox of novelty

In its report on biotechnology as supporting an “innovation economy,” the Canadian Biotechnology Strategy (2003) presents biotechnology as a revolutionary and socially transformative technology.

[T]he world witnessed an explosion of extraordinary advances in molecular biology, genetics, cell biology and biochemistry . . . that have revolutionized the way we live and think about life itself. . . . [The impact of biotechnology] on this century is predicted to be more dramatic and far-reaching than that of telecommunications and computers on the last, because it deals with life and living things, which permeate all aspects of our own lives.

When it comes to be regulated, however, biotechnology takes on a much more domesticated image. On the face of it, it appears paradoxical that a modified plant, developed by an innovative industry, could be both ‘novel’ and ‘substantially equivalent’ to traditional varieties. This is an important relationship, as novelty is the trigger that captures GM foods for regulation, while substantial equivalence screens them out from further regulatory scrutiny. The inconsistencies in the ways that GM foods are described, and the ambiguities in the different definitions and applications of the term ‘novelty’, suggest a slippery concept that is imposed for the purposes it serves, rather than derived from a thorough understanding of the character and effects of GM foods in society (Andrée, 2002).

Both novelty and substantial equivalence refer to a product itself and disregard as irrelevant the genetic engineering process by which it was created. A novel food is one

that does not have a history of safe use as a food in Canada, and (in the case of modified foods) that has undergone a “major change” in its physical characteristics, and is the property that captures a GM food for the distinct regulatory stream. A judgement of substantial equivalence then screens the product out of a more detailed assessment process. Substantial equivalence is assessed by comparing the novel food to a comparator variety of the same species in terms of nutrition, contamination, chemistry, and toxicology and allergenicity. This judgement may be made relatively straightforward by applicants’ attribution of novelty to the presence of a new trait rather than to the plant’s characteristics being outside the range for that species. It is evident that the degree of change required to exceed the threshold of substantial equivalence and trigger a risk assessment is greater than that required to gain it the visible regulatory definition of a novel food.

This is a difficult premise to verify, as there are no clearly established thresholds for determining novelty of a crop plant. Determination of novelty continues to be difficult at the plant breeding level. Relating novelty to substantial equivalence is made even more slippery by the lack of clear terms for that judgement as well. Millstone (1999) charged that the term has not been defined clearly enough for use as a regulatory tool; subsequent defences of the term claimed it was not meant to be a “scientific formulation” but a “conceptual tool” for producers and regulators (Miller 1999).

A further difficulty in the clear application of the principles of novelty and substantial equivalence is their different definitions in different pieces of legislation. In Part V of the Seeds Regulations, a novel trait is defined as one that is “not substantially

equivalent, in terms of its specific use and safety for both the environment and human health, to any characteristic of a distinct, stable population of cultivated seed of the same species in Canada” (RSC, 2001: 181). This definition presents novelty as not substantially equivalent, rather than simply a preliminary distinction that may include many plants that are subsequently deemed substantially equivalent, and “recognizes their potential to create a human or environmental health hazard” (RSC: *ibid*).

A third complication with the regulatory use of novelty is its contrast with novelty as used in patenting. It is worth examining the different ways that novelty is interpreted and handled by two arms of a system under a central policy to support the biotechnology industry. Novelty required to confer property rights maintains an explicit focus on the human intervention in nature that creates the novelty. In the regulatory context that imposes scrutiny and accountability, the same product’s novelty is considered only in terms of physical properties and dismisses the human intervention that created it, and functions largely as a category that signals social management and monitoring. In practice, this physical distinction is incrementally dissolved by the definitions embedded into the process, so that foods designated and approved as novel foods are subject in practice to the same conditions as regular foods.

Patenting has a longer history of using the designation of novelty than regulation does, but it has been pressured recently by the development of biotechnology to expand its applications to include biological organisms that had never before been the target of patents. Novelty - essentially the distinction between a natural object and one that ‘bears the stamp of human intervention’ (Krimsky, 1991:7) - is thus a key designation to be

achieved in the process of patenting a new product. This definition of novelty is based in an assertion of the legal significance of human intervention for property rights, and of social utility on the acknowledgement of the entity as a social product. Deliberate design and function are central and definitive and required to transform nature into private property for the purposes of awarding rights to the inventor.

The regulatory system controls the impact of social activities that are encouraged by the patent system, and thereby gains social trust. This is thought to reduce the critical scrutiny to which private interventions into nature are subject, facilitating the integration of those interventions into society. However, regulation performs this scrutiny in the terms of scientific risk assessment, rather than in the more social terms of public concerns. It uses an assessment and management framework that naturalizes the product, and excludes the significance of the activity that produced it. The step-wise normalization of GM foods proceeds from deliberate genetic modification, to novel biological variety, to substantially equivalent to traditional foods, and finally to invisible in the marketplace. In this process two major shifts in the identity of the product are effected by the terms of regulation. The first is naturalization, in which the product is described as meeting the definition of a natural food plant; the second completes Latour's purification by removing the social involvement in the product from public view.

The result of these processes for a GM food producer is that an intervention that is significant enough to designate a modified plant as novel under patent law gains its developer property rights, but is not biophysically significant enough to justify

additional, costly regulatory oversight. Put another way, the elemental approach that defines the safety requirements of regulation denies the significance of the social intervention that justifies intellectual property rights. Critics and members of the public have not overlooked the fact that while property rights and benefits are readily and firmly fixed to a novel product, regulation uses definitions that make it difficult to make the social responsibilities for a product stick as firmly. As one external stakeholder interviewed noted, if rDNA technology is the same as traditional plant development practices, “why can they call it new for patenting?” (GM-S, 2006).

Direct comparisons of the approaches to the transformation of nature by the patent system and the regulatory system are kept to a minimum. IP law and risk debates are carried out separately, minimizing the contexts in which their individual logics might undermine each other. These strategies are facilitated by the internal legitimacy of the concept of nature on which each institution proceeds, and regulatory declarations of substantial equivalence have not threatened patents awarded for novel plants.

Though opponents make an articulate case against the private ownership of biological organisms, access to decisions on the matter is largely cut off by esoteric legal definitions and process which distance other concerns and limit scrutiny from outside the field. Patent law has been called “hermetically sealed, closed off from external considerations. Modern patent law is characterised not only by its highly technical and specialized nature but also by its startling and marked isolation from matters cultural, political and ethical” (Sherman and Bently, 1998: 109). The evolution of patent law over the last century has led to the entrenchment of a set of legal assumptions and processes

that depend on the treatment of an invention as morally neutral and that marginalizes non-legal concerns (Sherman and Bently, 1998: 109). The result is that “claims about the effect of commodification on attitudes towards the environment, about distributive justice and the common heritage of mankind or the moral boundaries of the market are simply outside the field” (Boyle, 2003: 8). Thus the process of transformation, encouraged by the patent system, is kept separate from the processes of naturalization and purification by its segregation from both regulatory considerations and broader social discourse.

Regulation is the more publicly accessible of the two institutions, as it needs the profile of imposing scrutiny and monitoring of private activity in order to gain public trust. It is also the more strategically designed discourse, creating an ‘innovation environment’ that constrains the terms of public debate to narrow scientific risk terms, and rules out issues known to be of concern to many in the social debate. The regulatory concept of novelty is particularly flexible, serving as a plausible trigger for the application of due regulatory diligence and yet not implying inherent risk or invoking strict evaluation or control. The concepts of familiarity and substantial equivalence, both scientifically grounded in biochemical attributes of a plant species, are the other essential cogs and wheels that move GM foods through this naturalization.

Assessments of novel foods

Criteria and processes within the regulatory system, derived though they are from a series of ‘top-down’ strategic policy decisions, are carefully grounded in ‘bottom up’

scientific definitions that stand alone in the regulatory context as scientifically defensible risk logic and are thus insulated from their strategic policy origins. Novel food regulatory officials referred to science, safety and risk as constituting the only, and sufficient, rationale and authority for the terms and approaches of the regulatory regime (GM-R, 2006). The regulatory regime, including its definitions and core processes, such as product-based risk assessment, novelty and substantial equivalence, incorporates the key strategic terms required to enable the regulations to achieve their broad economic objectives. Risk assessment officials applying these regulatory terms and processes will achieve the innovation-supporting objectives of regulatory policy without any sort of political or economic considerations or judgments; the accurate application of due risk regulatory process invisibly exerts a policy influence without implicating regulation per se in any political bias or involvement in policy matters beyond regulators' scientific jurisdiction.

Officials in the Novel Foods Section of Health Canada (GM-R, 2006) explained in interviews that the essential aspect of regulation is the food safety assessment, which is based on knowledge of the characteristics of a comparator variety. These officials expressed their concepts of GM foods and their opinions on its use in society with scientific logic, often explicitly scientific terms. They did not make references to any policy objectives of regulation except to deny that there is any industry bias and state that they do not consider the value of the food to the industry in carrying out risk assessments. The opinions and attitudes of officials in the regulatory agency converged closely with those of the external stakeholder who is a scientist and an executive in a

biotechnology association.

The interviewees fully supported the product-based approach of Canadian regulation, as the only scientifically valid and robust approach. Food biotechnology should not be treated specially due to its process, which is rightly not recognized: the food safety mandate of the regulatory approach is appropriate, and regulators feel that they meet their mandate in ensuring that no risk gets to the market. The biotechnology industry executive likewise argued that the product-based regulation is appropriate, and that the only way to assess risk is on a product-by-product basis (GM-S, 2006)

On the understanding that molecular compounds in traditional varieties on the market can have health effects, the safety assessment permits no *additional* risk in the GM variety of the food; that is, its nutritional and safety profile is substantially equivalent to that of its traditional comparator. The scope of concern of the safety assessment is limited to safety: it verifies the novelty of the product, and expert teams from the bureaux of Chemical Safety, Nutritional Sciences and Microbial Hazards review the data provided by the applicant (GM-R, 2006; Health Canada, 2006a,;13). Several regulatory officials noted that Canada's safety assessment criteria are those agreed to internationally, and that Canada is recognized for its expertise in conducting safety assessments (GM-R, 2006). Any additional information required is requested from the applicant, and a proposal regarding the safety of the product is produced. Higher management makes the decision on the approval of the product (GM-R, 2006).

Regulatory officials agreed that there is no more risk in GM foods than in their traditional counterparts. GM foods do not pose a single, distinct risk but may have the

same risks as other foods: this is why a safety assessment is done on each product. GM foods have a good track record, and there have been no reported sicknesses from them (GM-R, 2006). The industry stakeholder pointed out that traditionally bred varieties can have health risks, as in the case of a new wheat variety that contained 300 times the gluten content of traditional wheat. He agreed that genetic engineering is a powerful technology and some concerns are justified, but that they must be looked at in relation to the traditional, familiar variety (GM-S, 2006).

As regulatory officials in the Novel Foods Section believe there is no additional risk in GM foods, they do not believe there is a need for labelling them on consumer products. One argued that there are no regulatory grounds for labelling, as the method of production is irrelevant to product-based regulation. Another believed that while people have a right to know what they are buying, this is not a safety issue and thus not a Health Canada issue. In addition, labelling requires traceability, for which detection methods are not yet adequate (GM-R, 2006).

The comparison of GM and non-GM foods is based not only on a perspective on technology, but also an implicit perspective on nature. GM regulators and the industry executive considered that nature could be defined as untouched wilderness, an area that has had no interaction with humans. They felt, however, that this was highly theoretical as the nature with which we interact is not in that form, so by that definition none of the food we eat is natural; alternatively, all of the food we eat, including GM food, is equally natural. Gardeners select seeds and cultivate them; all of the food varieties we grow in Canada have been introduced and farmed. Pet cats and dogs and most livestock species

have been selected and bred for desirable characteristics. Agricultural breeds such as triticale and beefalo are the result of cross-species hybridization (GM-S, 2006).

In addition, the regulatory officials and the industry stakeholder were not concerned about the naturalness or non-naturalness of a product or a food; the naturalness of something has no particular value. One participant explained that biotechnology is continuous with traditional practices, and uses natural components of plants. Removing a gene takes advantage of scientific knowledge that an enzyme will cut DNA at a specific point - bacteria, and our bodies, use these to break up cells (GM-R, 2006). Genetic engineering techniques adapt a natural process in a new application of agricultural process people have been using for thousands of years. Technology was not seen as categorically distinct, either in itself or from nature; one participant noted simply that "technology equals change." The regulatory participants expressed an interpretation of nature as purely material and mechanical, with no intrinsic moral qualities that would imply any human qualms about technological intervention. Likewise, there was no expression of concern that the intent or character of the intervention left any imprint on the resulting product; the foods derived from conventional and GM processes are essentially identical.

This pragmatic approach was most explicitly stated by the industry executive (GM-S, 2006) who wondered if, to many people, the idea of nature is a subjective distinction based on familiarity. He stated that:

There is no generic principle that applies [to distinguish between nature and technology]. We must look at the product created; the product, the history of the species, where it was produced.

All regulatory officials interviewed stated that genetic engineering techniques are an extension of traditional breeding. In fact there is ‘no particular scientific justification for distinguishing between them’ (GM-R, 2006). This position rests on the fact that, first, “all our agriculture is technological”: early breeding involved adaptation and selection, which genetically modifies the plant. Second, we cannot tell the difference among many GM, non-GM and organic foods. Biotechnology incorporates traditional processes of using a natural process to get a new product, and new techniques make it faster. This logic takes the non-distinctiveness of the process of biotechnology beyond the risk logic by which it is irrelevant to regulation: in practical terms, the changes in plants that rDNA processes accomplish have long been done by farmers through traditional techniques.

Several participants noted that members of the public do not understand the technology that is involved in general agricultural processes or in traditional breeding, leading to a number of inconsistent beliefs. They argue that many people object to the process of the technology per se, including processes that use high-tech procedures but do not introduce transgenes, such as cloning. On the other hand people consider the production of plants through conventional cloning techniques, or the grafting of trees, as traditional and beneficial. And many do not object to the complex but not transgenic techniques of chemical- or radiation-induced mutagenesis, perhaps because they are not aware of them (GM-R, 2006).

Challenges

Despite the growth potential of the industry, the enthusiasm of the seeds and agricultural industry, the rapid pace of ongoing scientific research and the support of government in terms of tax incentives and the arrangement of an “innovation environment,” a major challenge for the food biotechnology industry remains the lack of public acceptance of GM foods and the active opposition of several public interest groups.

Awareness of biotechnology has remained fairly constant over the last decade, with 48% being somewhat and another 8% very familiar. The remaining 44% of people consider themselves to be unfamiliar with biotechnology (Decima, 2006: 9). Canadians in focus groups were quite familiar with one or two applications of biotechnology; however, they often underestimate their knowledge, and “reveal a reasonably high level of knowledge and sophistication about biotechnology applications” (Decima, 2006: 9). Most people prefer to rely on the determinations of scientific research and do not accept arguments based on emotion. Canadians do, however, apply guiding principles to the judgements of biotechnology that extend beyond strict scientific knowledge and consider the broader social context of the purpose of the application, such as that “the proposed uses or outcomes have to be within a range of acceptability. Good science will not trump highly contentious applications that seem to fail the risk/benefit test” (Pollara-Earncliffe, 2003: 10).

Research on public opinion on biotechnology in Canada finds that people distinguish between different applications of biotechnology and have reasoned views of

these applications. People have a favourable opinion of some technologies, such as hybrid cars, computers, and stem-cell research, but other technologies are regarded less favourably (Decima, 2006: 7). The most important factors in attitudes to biotechnology are the perceptions of safety and ethical governance (Decima 2006: 6), and long-term, unknowable risks to human health and the environment (Canada, 2003 :4). The stakeholders interviewed likewise did not describe themselves as categorically opposed to all technology, or even to all biotechnology. One, affiliated with an NGO, stated that he and his organization are not opposed to all biotechnology, but to the dissemination of genetically engineered organisms in the environment. Their main concerns are with biodiversity and safety (GM-S, 2006).

Recent opinion polls have found that genetically modified foods are perceived by Canadians in a 'markedly different' and more negative manner than other aspects of biotechnology (Can Biotech Secretariat March 2005). The fact that foods and agricultural products are more strongly opposed than other applications suggests that it is not merely the technological intervention itself that gives rise to the opposition, but the social intervention into common nature and the corporate intervention into the relationship between society and its productive resources. The general attitudes towards GM foods in this study were (Can Biotech Secretariat 2005):

- people are not sure that the benefits outweigh the risks
- GM food is thought to be less healthy and 'natural' than traditional food
- environmental risks are seen to be significant, and 'there are significant concerns about the ability of regulatory authorities to assess, monitor impacts'

- the case of Monsanto and Schmeiser¹ has 'had a particularly catalyzing effect on the population, fuelling the impression that GM food is about 'big companies' making profits above all else'

GM foods and animals are expected to "make life worse over the next 20 years"

(Decima). Decima Research (2006) reports that

The main aspect of biotechnology that engenders concern is GM food. Overall attitudes toward GM food tend to be more negative than positive. The criticism derives from two areas of concern; the first is about the risks that might be involved in consuming these foods, and the second revolves around the motivations and actions of producers of GM food. In almost every focus group, the Schmeiser case and Monsanto came up as examples of concerns about GM food. (p. 8)

Several public interest groups have taken a critical stance regarding GM foods and some have mounted public campaigns opposing the technology (These include CEPA, CIELAP, the Council of Canadians; Greenpeace, Ramshorn, the Organic Consumers Association, and the Sierra Club of Canada). These campaigns focus on the unnaturalness of GM food and its development technology, the unknown risks to the environment and human health that science has not had time to discover, and on what the groups consider to be cursory and inadequate regulatory risk evaluation (Sharratt, 2002). A Greenpeace brochure advising consumers on avoiding GM foods (2005) describes them this way:

The planting of GE crops on millions of hectares of land and their introduction

¹ Percy Schmeiser is a Saskatchewan farmer who was sued by Monsanto for patent infringement. The case focussed on the claim that Schmeiser had knowingly harvested, saved and planted seed from Monsanto's Roundup Ready canola that he had not purchased. The original canola had grown from seeds that had spilled from a truck on the road and blown into his field. Monsanto won the case in 2001 and again on appeal in 2004 (GEO-PIE).

into our food supply is a giant genetic experiment. As living, reproducing organisms, GMOs are a type of living pollution that can spread across vast areas creating environmental risks that are unprecedented and possibly irreversible. . . . Health risks associated with GM foods include the development of antibiotic resistance, allergic reactions, nutritional changes and the creation of toxins. The Canadian regulatory system for food biotechnology is extremely weak, and has been criticized by many experts . . . (p.3).

Echoing these statements, the concerns expressed by members of the public, revealed in quantitative opinion surveys, and by stakeholders participating in-depth qualitative interviews for this research, cluster into three types. One is the insistence on the social context of GM food: the benefits they offer, and to whom; the rationale for their production, and the actual impact they will have on society and on the environment. The second type of concern is the rejection of descriptions of GM foods and plants as natural: stakeholders noted definitive qualities of nature and of social intervention. Third, stakeholders charged that regulatory control is inadequate and demanded greater scrutiny of the GM crops and foods that are permitted on the market in Canada. This consisted of, first, calls for regulators to be more rigorous in testing and controlling the safety of GM foods, and, second, for the provision of the information consumers need to make their own informed decisions on the foods they choose to buy.

As has been noted in many studies in Europe (Gaskell et al., 2004; Grunert et al., 2003; Marris et al., 2001), a prevalent attitude among Canadians is that GM foods do not offer relevant benefits to consumers (Decima, 2006) . Only 23% felt that GM foods have 'substantial' or 'some' benefit, while 38 % stated that they have 'not much' or no benefits. Stakeholders interviewed were likewise very clear that their concerns about GM foods include, but are much wider than, the health risks, and extend to the social context

of their implementation. An interviewee noted that we need to evaluate the benefits and the rationale for the applications of GE crops, rather than just harm to human health. He argued that there are alternatives to the stated aims of GM crops, such as pesticide reduction. Another said that “the most important question is why are we doing this at all? Why would we interfere with nature to alter plants’ makeup? People don’t want to have ‘changed’ food” (GM-S, 2006).

The stakeholders were uninterested in philosophical definitions of the identity of nature. They generally had a nuanced view of nature and emphasized that it is complex and interrelated: “life forms are constantly changing, highly fluid, complex, organic - there is complexity in nature, interactions and diversity”. They were comfortable with traditional social interactions with nature; however, rather than consider exactly where a boundary between pure nature and society might be drawn, they were concerned with describing genetic modification as clearly an intensely social activity. The determination of something’s being natural is whether or not there is ‘intervention made’ (GM-S, 2006).

Genetic engineering was described as a violent intervention that forces an organism to do something that by genetic principle it wouldn’t do in nature. One stakeholder noted that although mutations do occur naturally all the time, and that plants breeders have always worked with them, these have “not usually been of their own making.” Mutagenesis techniques, for example, take advantage of the mutations produced by a plant - albeit produced by intervention - which represents a shallower level of intervention than actually designing and re-building the genetic structure of a

plant as with rDNA. Other technological breeding methods, like induced mutagenesis “do not violently insert or delete any novel genetic constructs, with all their unforeseen and unknowable consequences’ (GM-S, 2006).

Stakeholders believed that there are risks in GM foods. “GE techniques are a shotgun method that fires the gene into a cell, and other things happen besides the desired effects.” What is created is a living organism, but it is a new form of life. These reproduce and spread, and we don’t know the impact. People are consuming alien constructs, and we do not know the effect on the entire genome of a plant when a new gene is inserted. One explained that no GM products are exactly the same as their traditional counterparts. Bovine growth hormone, for example, is not the same as the natural hormone. The act of genetic engineering itself causes problems, evidenced by the increase of allergies in the population (GM-S, 2006).

Several participants emphasized that the important distinction between GM and other plant breeding techniques is not the technical features but the political ones. One argued that “the real issue is whether the seed is a commodity or a social good.” If the aim is to gain control over the seed and the plant, selling more seeds over which one has control, in a nice package with more herbicides - at farmers’ and the environment’s expense - this puts mutagenesis in the ‘same corporate camp’ (GM-S, 2006).

The stakeholders stressed the importance of considering the social environment in which GM plants are designed to function and the economic and corporate objectives they are meant to achieve within that environment. They stressed this functional environment as distinct from a natural ecological or a traditional agricultural context.

They were also alert to the political objectives behind decisions on regulatory policy and process, believing the scientific terms to be used to present a strategically favourable image of GM foods as traditional and natural. All had become cynical about the use of the word natural, seeing it as a marketing term used to make a product seem more acceptable to the public, or a surrogate word for the increased corporate industrialization and processing of food. While they were suspicious of the use of the idea of nature to market a controversial technology, one participant also objected to the erasing of the important distinction between nature and technological interventions that occurs when biological phenomena are described mechanically and equated with technology (GM-S, 2006).

There was a strong emphasis on the scientific uncertainty about GM crops and foods, and on the contention that there has not been enough research, of the right type, to determine the long-term risks. Two of the external stakeholders took issue with scientists' narrow focus in biotechnology, arguing that broader contextual factors are important. One argued that in the use of genetic engineering scientists are oversimplifying: the ideology of the unidirectional expression of genes is all false (GM-S, 2006).

Stakeholders stressed that the true risks of GM foods are not known because the government, concerned with liability, will not test them. The attitude is "don't look, don't find." The government has shut down the labs that could have done independent testing; instead, regulators rely on industry data, which are confidential and protected from public access and peer review. The industry may withhold crucial negative safety

information, as their interest is to get their product approved. One participant argued that the government should adopt the the Royal Society report (RSC, 2001) recommendation that novel foods regulations should adopt the precautionary principle and reverse the burden of proof, conducting safety testing and an independent review of the science on a GM food (GM-S, 2006).

Challenges to regulation

Consideration of the risks of GM technologies and foods was clearly linked in stakeholders' minds to government responsibilities for risk control. Several noted that risk assessments use a narrow definition of risk, and that the reliance on substantial equivalence - which they claim is not a scientific term - serves to justify an avoidance of safety testing. One argued that substantial equivalence is based on a simplistic model of genetics, which is actually a complex function in an organism reacting to an environment: one gene can make a big difference in an organism. Regulation, which should control and monitor technologies in society in the public interest, "uses bad science as a cover-up, and the public don't know enough about science to challenge it" (GM-S, 2006).

Scholarly research and commentary has also been critical of several key aspects of Canadian biotechnology regulation. Barrett and Abergel (2002: 49) argue that the acceptable scientific terms of the risk assessment "are circumscribed by boundaries constructed by developers and government regulators." The principle of substantial equivalence as used in risk assessment, and the evidence on which it is established has

also been criticized. First, it is argued (Royal Society, 2001; Barrett and Abergel, 2002; Millstone et al, 1999; CIELAP, 2002; Greenpeace, 2005) that a substantial equivalence designation is “commonly used by governments . . . to exempt new plants from full safety assessment” (RSC, 2001: 182), and has the important effect of minimizing the scientific scrutiny of GM crops and foods, augmenting “the promotional bias of the government’ (Barrett and Abergel, 2000).

Several commentators have suggested that a rigorous assessment is not carried out to determine substantial equivalence at the crop level (Barrett and Abergel, 2000; Barrett and Abergel 2002; RSC, 2001) but that in fact a determination of substantial equivalence is based on “unsubstantiated assumptions about the equivalence of the organisms by analogy with conventional breeding.” As Barrett and Abergel (2002) note, by 2000 no applications to the CFIA had been rejected as unacceptable (p. 8) suggesting that the further assessment provided for in the Seed Regulations is not resorted to; they argue that the environmental safety of novel foods and crops is not being assured by regulations as they are currently applied.

In the case of novel foods, the Royal Society of Canada review noted that “it appears to the Panel that no formal criteria or decision-making framework exists for food safety approvals of GM products by Health Canada. Decisions are largely made on a case-by-case, ad hoc basis” (RSC, 2001: 37). As noted above, the rDNA products approved by Health Canada as novel foods have been deemed comparable to traditional varieties, based on the review of the material submitted by the proponent.

The federal government issued an initial Action Plan (Health Canada 2001b) in

response to the RSC report in which it argued that such a rigorous assessment is carried out, and that the term substantial equivalence is “not used uniformly in our current documentation.” In the Action Plan, the government stressed that its methods reflect the “latest scientific knowledge” (Health Canada 2001b), citing its participation in international work on safety assessment of novel foods, including the “CODEX International Governmental Ad Hoc Task Force on Foods Derived from Biotechnology, the OECD Task Force on the Safety of Novel Foods and Feeds, and Expert Consultations organized by the FAO and WHO” (Health Canada 2001b). Andrée (2006) argues, however, that with regard to the use of substantial equivalence, Health Canada “has yet to acknowledge the seriousness of these allegations” or to demonstrate that the concept is now used in the more rigorous, precautionary way recommended by the RSC.

The stakeholders interviewed commented on the motivation and adequacy of regulatory action, being quite aware of the role of regulation and the regulation of GM foods in particular. Their comments suggest a concern specifically with the monitoring that is necessary of a new and ambitious technology in society, and that the societal willingness to gather enough knowledge about long-term effects on a wide range of environments and to monitor its performance closely is a very important component of the acceptance of or opposition to a new technology. That is, critical monitoring is being exercised in the response to the implementation of food biotechnology, and the judgement is that it is proceeding without adequate knowledge and control.

Public attitudes to the regulation of biotechnology are parallel to attitudes to the technology itself. Decima Research (2006: 11) states that “past research in this sphere

has revealed that one of the key drivers of support or opposition to advancing in areas of technology has to do with perceptions of regulatory and ethical oversight.” Only 18 % of Canadians stated that they approved of GM foods with the usual government regulation, while 47% approved only in special circumstances or disapproved entirely.

Decima’s tracking research (2006) found that fewer than half (46%) of Canadians feel regulation of biotechnology is strict, and 37% consider it to be lax. Reasons for the scepticism about regulation are attributed to a “default” critical stance by people who do not know much about the technologies; feelings that regulators are not able to keep up with rapidly changing technologies, and concerns that not enough government resources are dedicated to this function and that “corporate influence can have undue influence of decisions made by regulatory bodies” (Decima, 2006: 11). Focus groups held recently by the CBAC (2006b) agreed that

The development of biotechnology presents risks and that Canada’s regulatory systems for safety, health, and environmental protection are of utmost importance to public confidence in this technology and its applications. This core function of government must be implemented within a credible system of ethical governance that is clear to Canadians so that the benefits of biotechnology are achieved without compromising social values. (CBAC, 2006: 65).

The most prominent criticism of Canada’s regulation of biotechnology is that it combines regulatory and promotional functions in the same regulatory regime.

Participants in CBAC’s Expert Roundtables (CBAC 2006b) recently drew attention to a “built-in contradiction” in the government biotechnology strategy that includes both regulation and promotion functions. This may be seen as “biotechnology promotion without balanced attention to stewardship” (CBAC 2006: 62; Prince, 2000b; RSC,

2001). This serves, at least in appearance, to compromise the regulatory functions in favour of promotional ones, and undermines public confidence in the independence of risk management.

The promotion of GM food commercialization as a primary regulatory mandate is a theme that the external stakeholders stressed. One argued that the CFIA is committed to industry, and that regulatory officials have “instructions not to get in the way of progress.” He cited the example of Health Canada’s drug approvals to illustrate the priority of regulatory commitment to industry: promotion is part of the Health Canada departmental agenda. Whistle-blowers are fired, and regulators are “well paid to shut up”. Another participant argued that industry has ‘hijacked’ the government agenda and process. He noted as an example that Agriculture and Agri-Food Canada managers are generic managers rather than scientists, and direct funding to corporate research priorities (GM-S, 2006).

In this regard participants in focus groups (CBAC, 2006b) noted that some objections to biotechnology stemmed from the fear that “some issues were being purposely kept from the public, and several cited the lack of labelling of genetically modified food as an example of information being kept from Canadians” (p. 65). The external stakeholders interviewed were agreed that labelling is important for consumers, and gives them the information they need to make consumer choices and send messages as citizens: one stated that ‘a product is only as good as its label’. Others assert that the campaign to avoid labelling is a liability issue: without labelling it is hard to track the source of a food, and there can be no post-market monitoring. (GM-S, 2006).

Furthermore, stakeholders stressed that there has been no debate on whether or not society wants or needs GM technology, or on alternatives to the objectives of GM crops. The debate should be political and include public consultation, and should take place before the regulatory stage. One noted, however, that there has been no such debate because 'government and industry do not want it' (GM-S, 2006). Members of the public expect that the impacts of a new technology will be thoroughly questioned and evaluated before it is widely implemented, and that government regulators are obliged to control the technology and monitor its performance in view of all important impacts, on behalf of the public. Much of the criticism of GM foods and their implementation in Canadian society under the control of government regulation hinges on two key complaints: that rights are being granted to developers to implement GM food technology without a thorough understanding of the full range of social and environmental impacts they may have; and that regulators have failed to meet their obligation to the public to control and monitor the technology in accordance with public values, blocking study of these impacts in favour of facilitating the technology's rapid and extensive implementation.

In addition to risk regulatory matters, public interest groups are concerned with the political implications of economic policy and increasing harmonization between countries (Council of Canadians, 2007) that reduces Canadians' voice in setting policy. Several have advocated labelling foods containing GM products (NFU, 2004: 10). Still other public interest groups have opposed GM crops and foods as a contemporary 'enclosure' of the natural commons through the permitting of private, for-profit

ownership of basic elements of nature. They address the issue of the patenting of natural substances in terms of privatization as “a form of expropriation (‘piracy’) of common resources” CBAC (2001a: 7). “Some felt that the interpretation of novelty, utility and non-obviousness criteria for patents over genes was too simple a test and allowed mere discoveries of genes, as they exist in nature although isolated, to be patented. They felt that the mere ability to sequence genes should not enable people to obtain a monopoly through a patent” (CBAC, 2001a: 18). Groups that oppose GMOs have expressed their disapproval of patenting of life forms such as seeds, cell lines and genes, as they are discoveries and hence not patentable. The Canadian Association of Physicians for the Environment also notes that “living entities are part of the common heritage of humankind” and that no persons should be allowed to “genetically modify any organism, seed, or cell line to obstruct their propagation in any way” (CAPE, 2000).

Opponents argue against the extension of patent rights to plants on the basis of risk to the environment and human health, and concerns about the rights of traditional farming practices (CBAC, 2001: 17; NFU, 2004; Masselink, 2005; Council of Canadians, 2006). A stakeholder interviewed argued that the ‘terminator’ technology, if permitted in Canada, will damage farmers because they cannot save the seed. The seed gets too expensive, and they get sued for saving seed. Big monopolies are buying smaller seed companies, making farmers dependent and with no options (GM-S, 2006).

Many at CBAC patenting consultations felt that moral and ethical safeguards should be established to guide the awarding of patents in a way that is consistent with Canadian values (CBAC, 2001: 5; 180); to recognize that, as Jasanoff (2005: 204)

explains, “when a patent is awarded for a biological product, it has the effect of removing the thing being patented from the category of nature to the category of artifice - a profound metaphysical shift.” In this regard calls were made for an *ordre public* provision, which has been used in Europe to “serve as moral filter” (CBAC, 2001:19), to be added to Canadian patent law.

Wider public opinions on patenting biotechnology are consistent with these stakeholders’ views, and with the value base that underlies the attitudes to biotechnology and its regulation more generally. While studies have found low levels of knowledge among Canadians of the patent system, patterns of attitudes emerge once people understand the basic rationale of patenting (Einsiedel and Smith, 2005). As Einsiedel and Smith (2005: 3) note, “publics perceive a hierarchy of acceptability that follows the same general pattern of approval for the use of the applications themselves. . . . In general, the prevailing view of patenting, particularly of higher life forms, has been found to be more negative due to the basic moral resistance people have to commodifying living beings.”

The first criterion in the hierarchy is purpose, with greater support expressed for applications that solve a problem than for those with an industrial or esthetic purpose. The purpose is also considered in the context of its contribution to, or detracting from, the public interest, with greater support being given to applications that gain social benefits than to cases “where the benefits are restricted to a few” (Einsiedel and Smith, 2005: 4).

A second hierarchy considers the object that is patented. “Acceptability declines as the object of the patent involves increasingly higher orders of life, when it crosses

species boundaries . . . or alters the organism itself” (Einsiedel and Smith, 2005: 4).

Canadians tend to be more accepting of patenting processes for creating novel organisms than of patenting the organism itself, as it does not directly appropriate a natural entity for private ownership.

With regard to the patenting of plants, most Canadians agree that patents on whole plants and parts of plants are necessary to support agricultural research. However, this support is conditional, with concerns being expressed that such patents would sanction and encourage the industrial development of ‘monocrops’, the uncertain risks of biotechnology, and the “potential abuses of power” (Einsiedel and Smith, 2005: 6).

Critics consider the implementation of GM foods in society in its wider context - the technology itself, industry interests, and risks and benefits - and determine the level of regulatory control that is appropriate. The technology itself is viewed as highly interventionist and still experimental, with large scientific uncertainties about longer-term health and environmental effects. Under these conditions people feel regulation should be strict and precautionary: however, it is thought to be too lenient, and overbalanced by government support for the industry through an array of innovation-friendly policies and encouragement of the patenting of elements of nature. This inadequacy is compounded by the fact that regulatory decisions are based on company data, which is private and not subject to peer review, and that government does not substantiate this research with testing of its own. Finally, the lack of product labelling and unconvincing efforts at public engagement discourage the legitimate public monitoring of the technology in Canada.

Priorities for gaining public acceptance

The legitimacy and persistence of public concerns and ethical issues regarding GM foods have been recognized for more than a decade, when government strategies and governance began to shift from an initially frankly commercial approach to GM foods to one that takes pains to acknowledge public concerns and the need for public consultation. It began to be acknowledged that it was necessary to assure Canadians that ‘any potential risks are being carefully managed and mitigated’ (Canada, 2003: 4). Public trust is crucial to the industry itself, as it is for business confidence and investment. Regulation must balance this need for public confidence in the control of the risks of the new technologies, in order to maintain its own legitimacy and that of the industry, with the need to be clear and supportive to investment and development itself.

In reviewing the priorities of the NBAC, the House of Commons Standing Committee on Health (Canada, 1996) observed that it had focussed too narrowly on ‘commercial aspects’ of the industry. In 1998 the National Biotechnology Strategy was revised, becoming the Canadian Biotechnology Strategy (CBS). Under the “three pillars” of biotechnology - stewardship, benefits/innovation, and citizen engagement - the CBS “explicitly recognizes the social and ethical dimensions of biotechnology along with its economic potential” (CBAC, 2006b: 52). The Canadian Biotechnology Advisory Committee was formed at that time, as an external expert committee government “charged with providing government with independent, impartial advice on important policy issues associated with the ethical, social, regulatory, economic, scientific, environmental and health issues of biotechnology” (CBAC, 2006b: 51).

Public “Information and Engagement” (CBAC, 2006b) have become focal points of advice, process and revision in discussions of the development of the biotechnology industry, particularly GM foods, which are the target of much of the public controversy. Public opinion tracking has become an ongoing component of Industry Canada’s efforts to strengthen the industry (CBAC 2006b: 56).

A top priority noted in the Biotechnology Strategy Expert Roundtable Series (2006b: 5) was an increase in public education, focussed on balanced information rather than advocacy. “Public acceptance of new/adapted innovations” is part of the innovation culture that must be developed through the Agriculture and Agri-Food policy to “foster a strong innovation system” (AAFC 2006b: 5). AAFC (2007: 10) consultations heard from participants that the federal government should “play a larger role in promoting Canadian agriculture and food domestically” by educating consumers about the role of farms and of agriculture and agri-food in Canadian society. CBAC has commissioned a number of independent research reports related to public participation and ethical issues of GM products (Mendelsohn, 2003; Pal and Maxwell, 2003; Prince, 2000a).

Gaining public trust in regulation, and thereby in GM products, has become a central objective of biotechnology regulation. This has been derived in part from the risk-perception and -communication logic that a higher trust rating is correlated with a lower perception of risk and may thus lead to greater acceptance of the technology; and in part from the growing public expectations for democratic inclusion in government decision making. While the regulatory logic of the Novel Foods Regulations precludes risk-related labelling of GM foods, a Voluntary Labelling standard was established in 2004 to

control the claims that may be made for a GM food that a producer chooses to label. The standard (Canada: 2004) “was developed to provide customer choice and does not imply the existence of health or safety concerns for products within its scope” (p. iii). It is meant to ensure that any labels placed on GM food products are “informative, understandable, verifiable, and not false or misleading.” This is a procedural gesture rather than a substantive move, as GM foods remain present but unlabelled in Canadian foods (Greenpeace, 2005).

Regulatory officials (GM-R, 2006) agreed that trust in the regulatory system is essential, but were divided on the level of public trust that exists in GM foods and their regulation. Three agreed that people trust the food supply and regulated products, saying that the public knows the regulator is working hard to ensure access to safe food. Part of this is because most people shop at large markets and do not know the source of their food. Levels of trust and concern are also thought to follow media coverage of food issues, which creates a lack of trust.

Though regulators (GM-R, 2006) believe the main location of trust is in the safety of the food supply, trust in various levels of the food system are linked: people who experience no problem with food products trust the regulator by default, and those who oppose GM technology were thought to object to the regulators as well. However this is indistinct, as one regulator believed that people do not know the roles of different government and regulatory agencies, seeing various representatives simply as ‘the government’.

The regulatory officials interviewed supported the provision of information to the

public as part of the duty of the regulator, and believed that the provision of information and consultation build trust. Regulators are responsible for telling people what they are doing, and need to provide more information on the process for risk assessment so that people become more comfortable with what regulators do. They need to be careful with the way this is done, however, as ‘outreach is often portrayed as advocacy.’ The CFIA got ‘flak’ for its information brochure on GM that looked like a promotion of biotechnology, and, in a recognition of the expectations for its core role, Health Canada has taken a more responsive position rather than initiating information campaigns. (GM-R, 2006).

Several regulatory officials observed that people often have unrealistic expectations of information provision and of consultation, taking it as participatory decision making, or expecting the regulator to have an interest in a wide range of non-scientific issues. The contention was that the public associate Health Canada with expertise rather than with promotion of a product or an industry. Health Canada’s mandate is food safety and that remains the highest priority and where the resources should be directed (GM-R, 2006).

Despite the emphasis on consultation and inclusion in policy and regulatory decision-making, the practice of such consultation has not always been successful in gaining trust. It has been noted that Canada’s regulatory process is less transparent than some others, and that it provides less opportunity for public participation. While people may participate in, or contribute to, proceedings to determine regulatory criteria, they are not offered any opportunity to participate in actual regulatory decisions. Furthermore,

Canadian regulators provide only summary information on their actual decisions, without details on information provided or rationales for decisions (MacKenzie, 2000). The information that is available and the kinds of consultations that have been attempted are a testament to the conflicting demands for and against public scrutiny. The conduct of a number of public consultations has shown the challenge that open consideration of the social aspects of interventions into nature poses to innovators, and the strategies that are used to permit some public input within narrowly prescribed terms.

Regulatory terms and mandates confine discussion to scientific, risk-related issues. Thus public consultations are announced and participation invited, but only those comments on the narrow scope of scientific regulation are deemed relevant. Health Canada and the CFIA are conducting a pilot project (CFIA, 2006) in which they post on the internet “notices of submission,” including data received, from novel food developers requesting safety assessments, and invite public comment. Reasons for this project are:

- to give the public an opportunity to provide input on scientific matters relevant to the safety assessment of each submission
- to increase transparency of the regulatory process to increase confidence in the regulatory system with respect to PNTs, and novel feeds and novel foods derived from PNTs
- to support the [of the Government of Canada] commitment to achieve greater openness regarding product information

The document inviting public comment states that “Scientific questions or information will be forwarded to CFIA and Health Canada evaluators for consideration in the assessment. Non-scientific input will be evaluated and appropriate ways of addressing it will be considered” (CFIA 2006). A Health Canada official in the Novel

Foods Section observed that 99% of the comments received are non-scientific; since as risk regulators they have no authority to deal with ethical issues (GM-R, 2006), these comments were excluded from consideration.

About 50 environmental NGOs refused to participate in CBAC's stakeholder consultations, citing "a perceived lack of independence of CBAC, and questions about the meaningfulness of the consultation process, and whether their input would have any real impact on government policy" (CBAC 2003: 4). An external stakeholder recalled that he had been involved in consultations (with NBAC in the early 1990s), where he had stated that biotechnology is significantly different from traditional science. His statements were ignored, and he and a number of other large groups refused to continue rather than legitimate the process (GM-R, 2006).

Desiring to engage a range of stakeholders on issues that are not part of regulatory considerations, in 2002 CBAC devised a dialogue tool for the discussion of genetically modified foods, which it called the Acceptability Spectrum'. The Acceptability Spectrum allowed participants to classify individual or groups of GM food products as 'acceptable', 'acceptable with conditions', 'not acceptable until more is known', or 'not acceptable under any conditions' (CBAC 2003: 5). The objective was to permit representatives of different positions to conduct "a holistic examination of the subject through the lens of five 'consideration themes' - health, environment, socio-economic considerations, ethical considerations and broader societal considerations" (CBAC, 2003).

However inclusive and forward-looking this process may have been, several

participants resigned or suspended their participation, revealing a persistent and deep aversion within the industry to straying beyond the limited territory established by the regulatory regime. The farming representative resigned, “concerned that the tool in development was not sufficiently based in science” and objected to the socio-economic, ethical and broader societal considerations that had been established aspects of the process from the beginning. Several developers’ representatives stated that though they were willing to discuss non-science issues, they did not want to judge their acceptability, and were concerned that using the Acceptability Spectrum “might lead to its future inclusion in the regulatory process” (CBAC, 2003: 13). The fate of this attempt at a more inclusive approach illustrates the awareness of industry of their vulnerability to consideration of social impacts of biotechnology, and hence of the instrumental importance of defining the issue of GM foods in scientific terms in order to rule out such discussion.

The resistance of various sectors in the agricultural and foods biotechnology industry to the introduction of broader parameters into the regulation of GM foods was visible again in Health Canada’s online public consultation in 2003 on the revisions to the 1994 safety assessment guidelines. These consultations focussed on regulating and assessing novel foods, the general context of regulation and transparency, and foods derived from cloned animals. Only the comments on the first issue were reflected in changes to the Guidelines (Health Canada 2003e), and dealt with matters of the elaboration of timelines and information requirements in the Guidelines. Comments on Part II on transparency and public input would be “used to develop and refine policies in

the area of novel foods and food biotechnology” (Health Canada, 2003e).

Two pilot projects for increased transparency were proposed for comment in the consultations, including a revised evaluation process and the use of external experts on the Food Rulings Committee. Most industry groups were “in total disagreement” with the proposal to revise the evaluation process, saying the public may be involved in the policy process but not “directly implicated in the evaluation, which should be done by experts only” (Health Canada, 2003e). Comments received on the proposal to include an external expert on the Food Rulings Committee were more favourable, though industry groups said the expert should have scientific expertise and experience in risk assessment, food systems, or biotechnologies. Other groups argued that the expert should have expertise in ethics, public health, or anthropology. In its response to the comments, the Food Directorate stated its intention to protect the status quo of the decision process, saying that “consideration is being given to minimize the impact of the pilot on the safety assessment process and keep the role and expectations of the external expert in line with those of other Food Rulings Committee members” (Health Canada 2003e).

All the external stakeholders interviewed expressed their lack of trust in regulation and the regulatory agencies responsible for GM crops and food and of government consultation. They know that regulators want the public to trust them, yet are not willing to do what people want.

In order to gain trust, the stakeholders interviewed argued that regulatory agencies should hold more independent inquiries like that conducted by the Royal Society inquiry and implement their recommendations; and they should consult with the

public and regulate as people prefer. Regulators should also engage in a range of research on GM foods, looking at the production methods of industrial agriculture and adopt the precautionary principle in regulatory control, since they claim to be looking after public safety.

Several of the more recent consultations have consisted of moderated focus groups drawn from “involved Canadians” (CBAC 2006: 61) that have solicited and then reported opinion on biotechnology matters. As an external advisory group, CBAC has carried out a number of these consultations and commissioned research reports from field experts; however, with the end of CBAC’s mandate in 2007 (CBAC, 2007) it remains to be seen if the regulatory institutions themselves are able to assume this role.

Naturalization of GM foods

Despite the absence of references to nature in regulatory documents and the rationale for their development, public information about GM foods relies heavily on analogies of genetic modification to natural processes and traditional practice. The elements of the regulatory structure - a product-based assessment of novelty, substantial equivalence and risk - dovetail together in a scientifically grounded, if contested, manner, to construct GM foods in the public view as familiar and traditional. Information prepared specifically for the public omits mention of these regulatory principles, simply assuming the domesticated identity that GM foods acquire through the regulatory process. This information stays on a rhetorical level, stressing the benefits of biotechnology and the control of risks, and diluting implications of social intervention

with references to genetic engineering as continuous with traditional plant breeding techniques.

Biotechnology innovation is promoted as beneficial to all of Canadian society, as offering “significant real and/or perceived benefits to humankind” (Canada, 1996: 1). Government policy presents biotechnology as promising both improvements on nature and benefits for all of society. It is stated, for example, that in Canada “The biotechnology innovations resulting from these scientific breakthroughs bring everything from vaccines to prevent disease, to healthier foods, to bio-fuels to replace non-renewable energy sources, to treatments enabling infertile couples to start a family” (Canada, 2003: 2).

Despite being revolutionary in their impact, GM foods are also presented as being consistent with natural processes, continuous with more traditional technologies. The Standing Committee on the Environment took pains to point out that many traditional agricultural technologies, such as breeding and hybridizing new species of fruit or livestock, have involved biotechnology. “From its inception, genetics has been a manipulative science in which the major advances reflect our increasing control over the genetic makeup and destiny of living things. . . . While the variety of gene transfers between unrelated species using rDNA techniques may not occur spontaneously or frequently in nature, it is important to note that the transfer of genes across species boundaries can, and does, occur without the use of recombinant-DNA technology” (Canada, 1996: 3).

In a similar manner the CFIA introduces the concept of herbicide tolerance,

which becomes a concern if the trait for such tolerance spreads to nearby crops or wild plants, as natural and evolutionary. In the process it also slides the development of tolerance to herbicide into a context of evolutionary adaptation. “Some plants are naturally tolerant to a specific herbicide, while other develop this tolerance in the evolutionary process of adapting to their environment (sometimes plants develop a tolerance to a specific herbicide because the herbicide was not used properly for weed management). Other herbicide-tolerant plants were developed through biotechnology” (CFIA 2003a)

The information that is contained in public fact sheets stresses that there is no meaningful difference between GM and traditional foods, through the use of terms that are used interchangeably even though they have exclusive meanings. A CFIA information brochure (2005c) defines ‘biotechnology’ as applying science and engineering in the use of living organisms, including traditional breeding and modern genetic engineering techniques. ‘Genetically modified’ refers to any organism that has been altered by any method, including traditional breeding. The term “genetically engineered” applies to “techniques that permit the direct transfer or removal of genes in that organism” (CFIA, 2005c).

However, many government and industry statements use ‘genetically modified’ apparently generically and collectively, in a context that subsumes new transgenic techniques into more traditional GM. Health Canada’s Frequently Asked Questions about Biotechnology and Genetically Modified Foods (2006c) takes a similar approach in describing GM techniques in terms of the molecular changes that result in a plant.

Genetic modification is any change to the heritable traits of an organism achieved by intentional manipulation . . . Farmers have traditionally used breeding methods to transfer desirable traits from one variety to another. The techniques of genetic modification permit scientists to transfer the genetic material responsible for these traits from one species to another in a faster and more precise fashion' (HC 2006c: 2).

Once put in place to function in risk assessments, these regulatory terms also establish a public profile of GM foods that functions in a broader political and economic agenda. The regulatory process is relatively visible and accessible and requires a stable, publicly acceptable image of GM foods based in scientifically defensible principles.

Industry likewise glosses over the distinction between traditional breeding practices and genetic engineering technologies. A BIOTECanada fact sheet (2007b) states that today's genetic engineering techniques are new only in their "precision and speed", and answers the question, "is genetic modification of crops new?" as follows:

No. The technology around genetic modification can be traced back as far as 1800 BC when the principles of biotechnology were first used to make wine, beer and leavened bread. Early farmers engaged in genetic modification when they started saving high-yielding seeds. Farmers have been using techniques such as selective breeding and cross-breeding for generations.

The Council for Biotechnology Information similarly blurs the distinctions, describing "plant biotechnology" as "the next step in the refinement of genetic enhancement techniques that began thousands of years ago with the domestication of wild plants for food production' (Council for Biotechnology Information, 2007).

GM foods are positioned by industry to appeal to public preferences for natural foods and environmentally friendly processes, and to sensitivities to technological intervention. A Communications Guide prepared by ISAAA and the Asia Food

Information Centre (AFIC, 2001) reveals the extent to which industry communications are directed by intensive consumer research. The Guide offers four key messages, “identified through research and experience,” for dissemination to the public (ISAAA/AFIC, 2001:10 -12):

- food biotechnology can contribute to food security
- foods produced using biotechnology will have direct consumer benefits
- food biotechnology is a green technology and biotechnology offers considerable benefits for the environment
- foods produced from biotechnology are safe

The Communications Guide also warns that the language used in public information on GM foods is important. “Scientific jargon, though accurate, can confuse and even alarm non-scientists, evoking negative reactions. . . . Technical terminology such as “genetically engineered”, “genetically modified” is perceived to be intimidating and held the implication that the foods had been altered by industrial methods. The terms “genetically enhanced” and “biotechnology foods” were found to be the two most suitable (neutral) forms to describe food biotechnology” (ISAAA/AFIC 2001: 10 - 13). In Canada, the term of novelty has begun to trouble plant developers, as it appears to be ambiguous and also to have negative associations among the public: they believe that “novelty” should be replaced with “a new word that has one clear meaning and a positive connotation” (CFIA 2005d).

The Guide provides a list of several dozen “words to use” (such as ancestors, concern, diversity, farmer, heritage, improved, nurture, wholesome) and “words to lose” (including ambition, economic, exploit, improved, manipulate, patent, pesticides, revolutionise, technology) when discussing GM foods with the public. It insists that

Food biotechnology needs to be discussed in everyday terms. It is important for people to understand that the technology is about seeds that are planted in the ground and that grow into plants just like any other plants (ISAAA/AFIC, 2001: 13).

Seed companies stress their link with the efforts of the small family farmer producing food for society and caring for 'our' environment rather than with corporate industry and technology. Monsanto, for example, places this statement on the home page of its website:

Monsanto is an agricultural company. We apply innovation and technology to help farmers around the world be successful, produce healthier foods, better animal feeds and more fibre, while also reducing agriculture's impact on our environment (Monsanto, 2006).

The development of GM crops is portrayed as motivated by a desire to solve problems encountered by farmers, and as offering them greater choice in seed types and farming methods. Genetically modified crops were developed, says the CFIA (2003a) "to help farmers control weeds that compete with crops for soil, space, water and sunlight. . . . Farmers may also choose to use herbicide-tolerant plants for environmental reasons" like reducing herbicide releases into the environment. Monsanto (2006) attempts to counter the industrial image of GM foods by linking the use of its products with personal profiles of family farmers. It profiles an Australian farmer who stresses the benefits of using pesticide-resistant cotton seed because it reduces the number of times he has to spray his crop. This protects the environment and saves fuel, he notes, but is also important to him because he runs a "one-man operation" and now has more time available in the evenings to spend with his children (Monsanto, 2006).

These designations and blurring of distinctions help industry to portray GM foods

as similar to natural products, as “revolutionary, innovative, highly advanced, and as ‘based on nature’s own methods’”(Sagoff, 2001: 5). The focus of the regulatory perspective on scientifically rational, safety-related aspects of GM foods further assists the invisibility of these products to the consumer by insisting there is no regulatory, that is, safety-related, justification for consumer labelling of GM foods. This position validates industry’s reluctance to use consumer labelling and highlight the technological contents of such foods (Sagoff, 2001). No non-biochemical characteristic of GM foods remains with the product at the end of the regulatory process, and the products disappear into the rest of the products on the market. The distinction of GM foods is reduced to an agricultural technicality with no relevance for consumers. As a food biotechnology industry newsletter asserted in an article on GM canola oil, “These changes to canola do not have any impact on consumers. The canola oil now on grocery shelves is essentially unchanged since biotech came into play. The biotechnology was used to make canola easier to grow. For example, canola has been made tolerant to certain kinds of herbicides that formerly damaged the crop. This has certain benefits for farmers” (Food Biotechnology Resource News, 1999: 1-2).

The profile of GM foods constructed by regulation and applied by industry plays to a naive interpretation of public food preferences and judgements of GM foods as a simple preference for natural and suspicion of new technology. GM foods are carefully presented as pure, just like natural foods, as continuous with traditional farming practices, and as bearing no substantive change of any interest to the consumer. The relevance of other concerns implicit in broader concepts of nature - benefits to

consumers, effects on the environment or long-term risks to public health, or more political questions about the private ownership of nature and corporate profit - is pared away from GM foods by the application of novelty, familiarity and substantial equivalence.

The dynamics of GM foods in Canada

The social context in which GM foods are introduced is one of conflicting values and contested politics, and exerts a strong influence on the way the foods are portrayed and managed. GM food regulation is pressured into some compromised positions by conflicting demands and expectations, which are ultimately dominated by the urgent need to encourage innovation. Powerful multinational corporations lobby national governments to create congenial conditions for them to do business, producing very strong internal and external pressure to implement these technologies and products without large costs and delays. This pressure generates resistance as members of the public want to see greater certainty and experience, and clear benefits to society, before the new technology is implemented. These tensions reflect the elements that are at work in social trust, in which pressure for public assent to increasing complexity is countered by pressure to slow and moderate that complexity.

GM foods are industrial products that are developed by large agro-chemical firms to fit into an industrial agricultural setting, and are selected and used by farmers to suit their operations, with the considerable financial and structural support of government. This social environment is carefully arranged to accommodate the new products and their

producers. Considerable public resources are committed to the development of the biotechnology industry in Canada, including the agricultural biotechnology industry. These resources, provincial and federal, and financial and institutional, constitute the regulatory environment that together supports the industry. This includes, at the federal level alone, large expenditures of public money on research and development, policy development and communications, as well as intellectual property to encourage development and investment, and formal risk regulation. It also includes managing the obstacles created by public opposition and consumer reluctance, partly by the construction of the public image of GM foods by risk regulation that naturalizes the products and minimizes public access to wider and more political engagement in the issue.

As they appear on the Canadian market in staple foods like corn starch or canola oil or as ingredients in prepared foods, GM foods are not high profile branded consumer items; consumer awareness and choice should therefore be superfluous to their market success. Many in the public are suspicious of GM foods, however, for safety and moral reasons; under these conditions, the more invisible they are to the consumer the less resistance there is to their use and marketing.

Two crucial institutional arrangements contribute to the invisibility of GM foods by ensuring that there is little access to debate on policy on the issue itself. The two aspects of the issue - the foods' value and benefits, and their risks - are handled separated as an administrative practicality, and each is subsequently removed from public debate. The benefits side, which encompasses considerations of the social value and

acceptability of genetic engineering and its economic and corporate aspects, is not open to public debate. The entire question of the place of GM foods in society that is the focus of a large proportion of public concern is encapsulated as a market issue and thus distanced from policy and institutional interventions. Public access to the debate is given to regulation, in which GM foods is defined as a risk issue and interactions confined to health risk concerns that exclude social policy considerations. As the CFIA (2001a) expresses it:

Who decides whether or not we need these products?

The Canadian Food Inspection Agency and Health Canada regulate for safety and efficacy of these products, but are not responsible for evaluating need. The issue of whether or not these products are “necessary” is left to the marketplace to determine.

The relegation of social controversy on the use of GM foods in society to a marketplace that is heavily distorted by the dedication of public funds and institutional support and by a withholding of public information about the products by a lack of labelling, closes down debate on the value and benefits of the technology. Public access to debate and policy on GM foods is funnelled through risk regulation, which easily and apparently non-politically disavows any responsibility for such policy issues by the restrictive terms in which regulation approaches GM foods as essentially natural. Through the detailed definitions and processes embedded into the Novel Foods Regulations, regulation manages to impose a minimally burdensome regime on the industry, and to confine the terms of permissible debate to narrow technical terms. One of the important achievements of the terms of the risk regulatory regime is the exclusion of the political issues that are the focus of most social concern and that are, not

incidentally, fully attended to in the broader regulatory structure. These processes effect both the naturalization of GM foods and their purification of remaining associations with social relations.

Despite regulatory language stressing the importance of gaining public trust in the products and their management, government efforts are oriented towards repositioning the products as familiar, and thus as not needing the monitoring associated with public trust - that is, arguing that there is little social significance to the activity being delegated. The concerns that are expressed are evaded rather than addressed. GM foods are naturalized in order to diminish their profile, if not to make them entirely physically and politically invisible, by defining them as biologically normal and agriculturally traditional, and part of the institutional background.

In the institutional and regulatory environment that has been constructed around GM foods, gaining genuine public trust would be a difficult matter, if that was indeed the goal. The first hurdle to public trust is the technology itself, which is new and presents fundamental moral challenges and social adjustments. This initially challenging situation is compounded by the scientific complexity and uncertainty of the products; the use of company data in risk assessments and lack of any public sector testing and data; the implementation of the technology at agricultural input stages of the food system; and the absence of product labelling that could enable consumer choice in the use of the products. These conditions amount to an almost total delegation to expert systems of the functions involved in the introduction of GM foods into society. The potential for public evaluation of the impacts of the technology, and meaningful participation in decisions on

its management, that might balance the almost total control of government and industry is largely withheld from the interested public. This imbalance is further exacerbated by the sense that regulatory oversight on the public's behalf is minimal, and is only partially visible. There are, in other words, almost no grounds allowed on which individuals in the public might build an acceptance of the technology, and its application and management in society.

Opposition to GM foods has resulted in pressures to constrain the use of the technology, and for the government regulator to exert stricter controls on it. Opponents of GM foods highlight the social context of the technology and the broad scope of its potential impacts on health and the environment. They contest the naturalization of GM foods and of genetic modification technologies in general, on the basis of a contextual definition of nature and humans' obligation to respect its integrity, the social significance of the intervention, and the intensity and scale on which their interaction must be evaluated and monitored. They also resist efforts to naturalize the products by private interests and attempt to give some profile to the social relations of the products. The challenge begins with nature as having agency and its own interactive processes that contradict the simplistic mechanistic models used to justify genetic modification. However, most commentary in opposition to GM crops and foods focusses on the intervention itself and its inherent wrongness, the way that denying respect to the autonomy and agency of nature justifies private industrial actions in society that have largely socially concerning implications.

To address this challenge and maintain political legitimacy, risk regulation terms

are adopted that superficially defuse the criticism by creating a construction of GM foods that evades the public concerns that have been expressed about engineered and unnatural foods. Regulatory efforts concentrate on constructing a desirable image of the products themselves, disengaging public attention by losing the products in the background noise of biologically and socially ambiguous agricultural practices. What results is a somewhat disingenuous approach that produces public messages that are inconsistent with regulation's own higher policy obligations and the wider network of regulatory components, including being directly contrary to intellectual property objectives and definitions for the same product.

What we are able to see in the regulation of GM foods is the range of the institutional mechanisms that are assembled to form a supportive network for the agricultural biotechnology industry, and the way they are integrated into numerous social institutions. We can also see the social response to this process, which shows a persistent effort to monitor and influence the technology, through an alertness to both the political motivation for the implementation of the technology and to the political strategies used to construct a normalized image to the public. There is a sensitivity to the appropriation of nature, an awareness of the type and scope of the social impacts that may result, and an expectation that more extensive knowledge should be gained and greater evaluation carried out before the technology is implemented with such enthusiasm.

Chapter 9

Natural Health Products

Complementary and alternative medicine

Traditionally, and still today in much of the less developed world, traditional medicines are the main line of health care (WHO, 2003; 2004). Many ancient cultures used plants for healing, including China and Egypt. Some indigenous cultures have used plants in “healing rituals”, and others, like Ayurveda and Traditional Chinese Medicine, developed systematic herbal therapies (University of Maryland, 2004).

In developed countries, an increasing number of people are turning to complementary and alternative medicine (CAM) to complement conventional medical care. The World Health Organization (WHO) reports that more than half of the population in industrialized countries has used complementary medicine at least once, including at least 70% of Canadians.

CAM, as the acronym suggests, includes alternative medicine, used separately from or instead of conventional or orthodox medicine, as well as non-conventional medicine used in conjunction with conventional medicine. Integrative medicine refers to complementary medicine being integrated into national health systems (Achilles, 2003).

CAM is used in a number of different contexts and medical paradigms. Kaptchuk and Eisenberg (2005: 10) divide the use of CAM into two main groups, “one that appeals to the general public and another that confines itself to specific ethnic or religious groups.” The first group includes professional systems like acupuncture,

homeopathy, naturopathy, or chiropractic; popular health reform, such as organic food and nutritional supplements; new age healing; mind-body therapies like hypnosis; and “non-normative scientific enterprises” like iridology and hair analysis. The second group includes religious healing, folk practices, and ethnic medicine like Traditional Chinese Medicine or Ayurvedic medicine.

There are a number of commonalities among CAM practices that distinguish them as a group from conventional biomedicine. Modern Western medicine developed in the early twentieth century into a formal orthodoxy that licensed its practices and practitioners and excluded others (Coulter, 2004). It focussed on a germ theory of disease in which the cause of disease is considered as being discreet and external to the individual, and tends to a reductionist approach. In this framework, acute conditions are given greater consideration than chronic conditions, and health is considered the absence of disease. The relationship between the practitioner and the patient is one of doctor expertise and patient compliance, and the practitioner focusses on treating the disease rather than the individual (Hughes, 2004; Wiles and Rosenberg, 2001; Coulter, 2004).

In contrast to orthodox medicine, most CAM paradigms are characterized by a set of attitudes and relationships (Mitchell and Carmack, 2005; Fulder, 2005; Coulter, 2004; Hughes, 2004). These include:

- holism: integration of mind-body-spirit, and environment and society
- individuality in diagnosis and prescription of treatment
- vitalism and conformity to universal principles on the relationship between living creatures and the environment: a belief in life force and the healing power of nature; preference for natural remedies
- health is an individual responsibility: patient is empowered, a partner in treatment with practitioner; emphasis on the patient’s perspective

- works with, rather than against, symptoms and the body's own self-healing process
- emphasis on chronic disorders and improving immunity and resistance to illness
- preference for low risk substances.

Kaptchuk and Eisenberg (1998) present a short list of shared assumptions of alternative medicine that have allowed a broad range of heterogeneous practices to cohere into “a significant coalition in their historical tug of war with conventional medicine” (p. 1). These are an embrace of a benevolent nature; vitalism, or “a rescuing connection to life-supporting cosmic forces” (p. 2); a reliance on an observational form of science; and a “spiritual materialism” (p. 3) that provides “spiritual experiences in their views of health, illness, and healing” (p.3). Naturopathic medicine, for example, trusts in nature to cure, and has confidence in the perception of a vital force or life force, working with nature to restore people's health (Whorton, 2002: 291).

Many researchers detect a pattern in the users of CAM: they tend to be between the ages of 25 and 49, to be female, be better educated and have a higher than average income (Wiles and Rosenberg, 2001). There is also a philosophical pattern in the use of CAM: users are more oriented towards a holistic philosophy that stresses the importance of body, mind and spirit in health, and towards environmental and feminist philosophies (Wiles and Rosenberg, 2001; Astin, 1998). They also want to take control of their own health and believe they are responsible for maintaining good health. Individuals who use CAM therapies tend to be more health-conscious and to “have greater feelings of control over their own life and health (Wiles and Rosenberg, 2001: 212). Part of the attraction of CAM therapies, therefore, is the individual empowerment that they offer. (Wiles and

Rosenburg, 2001; ISPSOS, 1997).

Another reason for the increased use of CAM is its relation to a disenchantment with conventional medicine and practitioners. “Disillusioned with conventional medicine and its perceived emphasis on potentially dangerous drugs and high-tech interventions, people are turning to acupuncture, osteopathy, herbalism and other ‘natural’ treatments which, they believe, are safe and free from side effects” (Carter, 1996: 12). Beyerstein (2005) refers to a “quaint bit of romanticism” that promotes holistic health care and the belief that natural remedies are “necessarily safer, gentler and more efficacious.” He also attributes the use of CAM to an “anti-doctor backlash” and a mistrust of traditional authority.

Theoretical approaches to understanding the use of CAM in society have been uneven (Doel and Segrott, 2003), and most have focussed on the reasons that people are attracted to CAM, and the use of CAM practices and the consultation of CAM practitioners. Much of the recent research on the use of CAM in modern society, including North America, has been concerned with specific CAM practices and practitioners, their use, credibility and institutional position within the medical community in society (Boon et al., 2004). Medical geography in particular has been slow to incorporate the societal orientation to CAM therapies into its scope of inquiry, being largely concerned with the efficacy of therapies and practices; since the 1990s, medical geographers have begun to shift their interests to include health and well-being (Doel and Segrott, 2003). These studies have focussed on the spatial distribution of CAM practitioners and of the population that consults them (Wiles and Rosenburg, 2001), and

on the reasons that individuals choose to become CAM practitioners (Doel and Segrott, 2003).

The use of CAM is becoming associated with the individual consumer's freedom to choose health care, and with the legitimacy of those choices. This is accompanied, and to some extent driven, by an increased availability and diversity of information in the popular media (Doel and Segrott, 2003), which has led to concern with the influence of the media in the use of CAM (Doel and Segrott, 2003). Wiles and Rosenberg (2001) refer to an increasing trend in 'smart consumerism' in the use of CAM and the rise of a "market-driven health care" (p. 221).

A primary theme has been the delegation of responsibility onto the individual that stands as the flip side of individual empowerment and freedom to choose among a growing array of possibilities. Freedom to choose also appears as the obligation to choose, and to take individual responsibility, in an institutional environment that is increasingly governed by market principles. Hughes (2004) explains that this placement of responsibility with CAM practices works with the link between physical health with mental and spiritual health, implicating patients in the status of their own health; practitioners thus encourage patients to understand their responsibility for their illness and to take personal responsibility for their own healing. However she also notes that such encouragement of individuals by professionals to take responsibility for their own health care is also taking place within conventional medicine, endorsed and supported by government health-care institutions.

Cohen (2000) describes the change in health care regulation in the U.S. as

shifting from a bias towards extreme medical paternalism, in which consumers were considered not competent or informed enough to use information to make choices on drugs, to a more 'consumer autonomy' position that assumes consumers are capable of using information to make some health care decisions. Manufacturers are responsible for providing full ingredient information, and the consumer takes responsibility for understanding it and making a competent decision to use the product.

Historically, the [health care] regulatory system has focussed on fraud control and ensuring competence. Presently, the meaning and focus of these terms are shifting away from insulating medical orthodoxy and toward permitting consumers to make their own decisions. . . . Thus, fraud control expands into quality assurance, and ensuring competence into safeguarding information flow (Cohen 2000 p.19).

This shifting of responsibility for health and healing onto the individual has been described in the late modern context of risk society (Hughes, 2004; Turner, 2004; Doel and Segrott, 2003). In the risk society the public is increasingly aware of the contingency and fallibility of established systems and expertise, exacerbated by technological revolutions in medical care and by concerns about the ability of regulation to control their possible risks (Turner, 2004). The adverse effects that are attributed to prescription drugs are unintended consequences of technical knowledge meant to improve well-being, but designed and implemented from a corporate framework, assessed by a rationalistic risk calculation, and administered within a hierarchical expert system; that is, they are a manufactured risk.

Positioning the use of CAM in this social context, Doel and Segrott (2003) consider that the "mass-mediated CAM" leads to a "failure of authority" and an

abandonment of the consumer (p. 751). The popular culture of CAM invokes a sense of anxiety about health and risks, and about the competence of conventional medicine; it then relegates to the individual consumer the responsibility for interpreting this information and using the products or services. This environment leads to a 'risk society' situation:

Such is the double game of mass-mediated CAM: it is, on the one hand, an obsessive and ultimately delirious cult of personal responsibility, panic production, trained incapacity, risk management, and gambling, and, on the other hand, a wanton abandonment, active nihilism, and radical passivity. In short, mass-mediated CAM is a perfect encapsulation of fatal strategies in risk societies (Doel and Segrott, 2003, p. 754).

Natural health products

Natural health products are part of the more general move towards CAM in industrial societies. The global market for herbal medicines was more than \$60 billion US annually in 2003, and is growing steadily (WHO 2003). The "global nutrition market" (Dionisio, 2001) - which includes natural health products (NHPs), functional foods, organic foods, supplements and natural personal care products - rose 17% from 1997 to 1999 to reach \$128 billion. This increase compares to a 2 - 3% annual increase in the conventional food industry.

Usage varies among different countries, partly as a result of different institutional and regulatory approaches. In some countries, such as China, these products are fully integrated into the conventional health care system, and in Germany, their use is incorporated into professional medicine: "roughly 600 to 700 plant-based medicines are

available and are prescribed by approximately 70% of German physicians” (University of Maryland, 2004). In most developed countries, however, they remain outside mainstream health care (WHO, 2003), and are sold over the counter, selected and administered by users themselves. The United States market in ‘dietary supplements’, the term given to the products classified in Canada as NHPs, is the largest in the world. Canadians do not use as many NHPs as Americans, in part because of stricter regulation that prohibits the sale of 42% of the products sold in the US (Dioniso, 2001).

There are consistent patterns in reasons given in research about why consumers use NHPs, most centred on the assumption that as herbal medicines are natural, they are safe. The WHO (2004) states that “in wealthy countries many people seek out various types of natural remedies on the assumption that natural means safe”, a rationale echoed by other researchers (York University, 2001; Carter, 1996; Simpson, 2003). A public survey (IPSOS, 1997) found that people claimed they used NHPs because “they don’t hurt you and may help; because regular medicines aren’t working; and alternative medicines and practices are more natural’. Most report using NHPs for ‘wellness’ and disease prevention, rather than to treat disease (Ramsay et al., 1999; York University, 2001), or to relieve symptoms, mostly of chronic conditions (Astin, 1998; Simpson, 2003).

Products and substances are valued for their naturalness, and the ecological setting of a plant used in a preparation, for example, is important. Herbalists consider a number of factors in prescribing herbs, including “the species and variety of the plant, the plant’s habitat, how it was stored and processed, and whether or not there are

contaminants. . . . Many factors affect how effective an herb will be. For example, the type of environment (climate, bugs, soil quality) in which a plant grew will affect its components, as will how it was harvested . . .” (University of Maryland, 2004).

In the United States in particular, an interest in natural and organic remedies has led to a increase in the use of herbal medicines driven in large part by dissatisfaction with the high costs and perceived risks of prescription drugs (University of Maryland, 2004). This is amplified by the relatively vigorous marketing permitted in the U.S., often with “extravagant” claims that are insufficiently scrutinized by the media (Beyerstein, 2005). Advertising for natural remedies in the US stresses both the safety of natural products and the risks of conventional medicine. Native Remedies.com (n.d.) claims that

. . . every year there are approximately 10 million negative drug reactions in the United States alone. . . . Studies have shown that people who use herbs for health care remedies account for fewer than 1 per cent of all toxic reactions to medicines.

Natural treatments for anxiety are prescription-free, doctor-visit-free . . . From age-old wisdom to late-breaking discoveries, there are an estimated 1,000 herbs for home use, giving you the control to steer your own health destiny.

These natural treatments do not have any side-effects; they assist in providing relief to the irregular and abnormal body physiological system. Natural treatments keep you close to nature’s healing powers; the confidence of being assisted induces within you a determination to cooperate with these powers to resolve your life problem.

There has been little scientific research on the effectiveness of herbal products, and little organized collection of data on their use and on adverse effects. Many scientists dispute the claims of natural substances being intrinsically safe. Scientists have shown that substances naturally produced by many food plants act as natural pesticides and are much more toxic than synthetic chemicals used in agriculture (Ames et al.,

1987). There are almost no data on the safety or the efficacy of most of the 29,000 dietary supplements that are sold in the U.S. each year (Coghlan, 2004). A review of herbal medicines found that only four of the top ten sold in the US are effective, and there is little evidence for assessing the others; many herb manufacturers do not welcome scientific scrutiny, and argue that since treatments are holistic and tailored to the patient, they are not amenable to conventional scientific testing (New Scientist, 2004). In addition, the concentrations of active ingredients vary widely among plants grown in different conditions, and among manufactured preparations (Strauss, 2004). Nevertheless, it is known that some herbal remedies, including some with long traditional uses, are inherently toxic, including kava-kava and ephedra. Serious side effects of others have been reported, including deaths and serious complications in people using Chinese herbal preparations (Carter, 1996). Others have been found to contain heavy metals as a result of their growing conditions (Strauss, 2004), or even deliberately 'spiked' with undeclared pharmaceuticals to increase efficacy (Carter, 1996).

As the WHO (2004) notes, "these trends raise concerns over the quality of the products used, their therapeutic appropriateness for a given condition, and the lack of medical follow-up." There are increasing incidences of adverse reactions to herbal products, of health dangers of herbal products used inappropriately or at improper dosage, and of contaminated products. In 2002 the WHO launched its 'traditional medicine strategy', designed to help countries "develop national policies on the evaluation and regulation of traditional medicine/CAM practices' (WHO, 2003). In

2004 the WHO produced a set of guidelines that offer advice to governments on preparing information to the public on the use of alternative medicine. “Governments should have the tools to ensure that all stakeholders have the best information about their benefits and risks” (WHO, 2004).

As the popularity of herbal products grows in industrialized countries, many governments have begun to regulate these products. The WHO (2003) noted that 70 countries have developed national regulatory programs for herbal medicine, but that there is no consistent structural model for this regulation, largely because the definitions of herbal products vary and different approaches have been adopted for manufacturing, licensing, dispensing and trading.

Australia has recently revised legislation to regulate “complementary medicines” as a “subclass of “therapeutic goods” (Health Canada, 2003f). The European regime regulates food supplements and herbal products separately. The Food Supplements Directive (European Parliament, 2002) covers vitamins and minerals used as dietary supplements, regulating these products as foods. It is meant to harmonize laws across the European Union and to protect consumer safety by establishing a list of allowed supplements and maximum doses, and labelling requirements. Herbal medicinal products are regulated as drugs under the Human Medicinal Products Directive, and must be registered with the European Agency for the Evaluation of Medicinal Products. However, a simplified registration system has been established under the Traditional Herbal Medicinal Products Directive for those herbal medicinal products intended for use “without the supervision of a medical practitioner” that have been used for at least

30 years, including 15 within the EU” (European Parliament, 2004). This exempts these products from the requirement of safety studies.

There have been court challenges to the exclusion of vitamins and minerals from the positive list established by the Food Supplements Directive, launched by the Alliance for Natural Health and “two UK trade associations” (Alliance for Natural Health, 2005). These organizations argued that the products excluded from the positive list would require costly licensing as medicines, and that doses were set “unnecessarily low” (Alliance for Natural Health, 2005). The Traditional Herbal Medicinal Products Directive is also criticized for including a narrow range of products for minor ailments only, and for capturing some food supplements in the simplified drugs regime, which includes prohibitions against some combination products, and costly pharmaceutical stability tests that are not required under the foods regimes (Alliance for Natural Health, 2005).

The United States Food and Drug Administration increased regulatory oversight over natural health products, or dietary supplements, with the Dietary Supplements Health and Education Act (DSHEA) in 1994. The DSHEA is a post-market monitoring regime, under which the manufacturer is responsible for ensuring that the product is safe before it is marketed (FDA, 1995). It defines dietary supplements as foods, thus exempting them from the strict requirements of new drug approvals. Dietary supplements that were on the market before 1994 are ‘presumed safe’ and do not require safety assessments. New dietary ingredients are considered not to be ‘adulterated’ if they have been in the food supply in a form in which they have not been chemically altered,

and if they have a history of use or other evidence of safety; proving that a new ingredient has been 'adulterated' is a responsibility of the FDA (Cohen, 2000). It has been noted that because they are largely unregulated, "herbal products are often mislabeled and may contain undeclared additives and adulterants" (University of Maryland, 2004).

The U.S. regulations prohibit claims of any specific treatment or cure, and require that dietary supplements carry full information on ingredients and allow products to have a statement of nutritional value. The label must also carry the disclaimer, "This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease" (FDA, 1995). The DSHEA gives the FDA the authority to develop good manufacturing practices (GMP) regulations for the "preparation, packing and holding of dietary supplements under conditions that ensure their safety" (FDA, 1995).

There remains debate on the balance between consumer access and safety, and between individual autonomy and the burden of individual responsibility in an unregulated market, leading to ongoing controversy over the regulation of supplements. It is not clear how much of the analysis on the increased reliance on CAM practitioners in society can be applied to the individual selection and use of NHPs, and in which country. NHPs are marketed to the consumer for self-care, and are often used by untrained laypersons. They are also used by alternative practitioners such as naturopaths and homeopaths, and by practitioners of some ethnic traditions (Kaptchuk and Eisenberg, 2005).

Concerns about consumer responsibility to choose products in mass health-care market are particularly strong in the U.S. The DSHEA was considered a victory for advocates of increased consumer access to dietary supplements (Cohen, 2000; New Scientist, 2004). However, in a partial step back towards greater regulatory oversight, in 2007 the U.S. Senate passed a “drug safety bill” that requires post-market adverse report collection and analysis for drugs and supplements. This has been interpreted by many in the supplements industry as “putting consumer access to dietary supplements at risk” (Coalition to preserve DSHEA, 2007). Groups such as International Advocates for Health Freedom criticize the U.S. participation in the Codex Alimentarius Commission, with which the new bill is consistent, arguing that the new bill ‘outlaws nutrition and turns healers into criminals’, and deepens the ties of government and “Big Pharma” (News Target, 2007).

One of the reasons for the intense backlash against this new requirement is that the DSHEA permits no health claims on a supplement, deeming that a product that makes such claims is a drug, and thus subject to the expensive testing that only large pharmaceutical companies can afford. Requiring safety measures for supplements without allowing the medical claims therefore appears to many in the supplements industry as a move motivated by the pharmaceutical industry to weaken its market competition.

Chapter 10

Regulation of Natural Health Products in Canada

Natural health products are sold in retail stores for selection and use by consumers. The NHP industry in Canada is made up “primarily of retailers and distributors, followed by manufacturers and importers/exporters” (Decima, 2005: 3).

Most of the NHP businesses are Canadian-owned and are small (Tuite, 2003), reporting gross sales of less than \$1 million (*ibid*); and most are dedicated to NHPs only. The NHP community, including researchers, producers and practitioners, is small and fragmented, consisting of industry members that compete with each other in the marketplace. Most NHPs, being composed of ingredients found in nature, cannot be patented, limiting the ability of NHP manufacturers to recover the costs of developing new products

The industry is not supported by a coherent infrastructure that represents common interests and coordinates information and communication. The NHP Regulations cover both traditional natural health products and functional foods and nutraceuticals (FFNs). A functional food looks like and is consumed as a conventional food, but has additional physiological benefits, while a nutraceutical is a product that has been isolated or purified from foods and is sold in a medicinal form (McCutcheon and Fitzpatrick, 2004). NHPs and FFNs have different and largely separate industry communities, with the FFN industry being stronger in terms of funding and research. The FFN industry follows the “drug discovery model, focussing on the isolation, characterization, and concentration of novel bioactives” in the pursuit of commercial opportunities and the development of patentable products (McCutcheon and Fitzpatrick,

2004). Efforts are being made to coordinate government and members of the NHP and FFN industries to develop a strategic plan for research. While most of the discussion here focusses on the NHP market, the distinctions between the two industries and markets are instructive.

The greatest proportion of sales are for multi-ingredient products (29% of sales), vitamins and minerals (17%), and herbal medicines (17%) (ibid: 15). Each of the other NHPs - homeopathics, animal-derived health products, other extracts or isolates, fatty acid supplements, probiotics, amino acid supplements, and synthetic duplicates - makes up 5% or less of sales. The industry represented \$3.77 billion in 1999 (Dionisio 2001).

Figures on the number of Canadians who use NHPs vary, but generally show increasing use over the last decade. According to an IPSOS poll (IPSOS, 1997) in 1997, 42% of Canadians used alternative medicines or practices, and 23% of these (10% of Canadians) used herbology. Ramsay et al. (1999) reported that 17% of Canadians use herbal remedies. The House of Commons Standing Committee on Health, in its 1998 report on NHPs, noted that 56% of the Canadian population had taken NHPs within the past six months (Committee 1998: 2). The 2005 Baseline Natural Health Products Survey among Consumers (Health Canada, 2005) reported that 71% of Canadians have taken an NHP, 38% daily. The most commonly used NHPs are vitamins (57%) and echinacea (15%) and other herbal, algal and fungal products (Health Canada, 2005b). The primary reasons given by Canadians for using NHPs were 'personal health concerns and the desire to maintain and promote personal health' (Health Canada, 2005b). NHPs are largely self-selected by consumers, often without supervision or advice from a

health-care practitioner.

Practitioners, who may be involved in the selection or use of NHPs, may be regulated by their province, or are perhaps not regulated at all. Physicians, nurses, and chiropractors are all regulated by provincial governments. Regulation of other health practices is variable: naturopaths are regulated in some provinces, while herbalists and homeopaths are not regulated in any province (Health Canada, 2000a: 7-8).

A number of CAM practitioner groups in Canada and in other Western countries are seeking professional status, ultimately “statutory self-regulation” and integration into the regulated health care system (Boon et al., 2003 :135). This process would require that the groups set educational and professional standards. In Ontario, for example, where 24 health professions are regulated, there is no longer provincial opposition to the professionalization of alternative practices such as acupuncture; however there is also no obvious need for additional health professions, and internal divisions over the practices that constitute the ‘territory’ of several groups also hampers the process.

Evolution of Natural Health Products Regulations

In Canada, the products that now come under the Natural Health Products (NHP) Regulations have long been regulated by the federal government under the Food and Drugs Act. There was, until it was dismantled in 1991, a Natural Products Division within Health Canada’s Bureau of Drug Research, which was well established and respected (Canada, 1998). However the regulation of these products was uneven because some were classified and regulated as drugs, and required high-quality and time-

consuming scientific evidence and restricted access. Others were defined as foods, which assumes low risk and no need for verification of functional claim, and which gives quality assurance only through consumer regulation and consumer guidance through labelling, and does not permit health claims. This inconsistent approach to regulation meant that access was restricted to some products regulated as drugs, whereas the quality of those defined as foods was inconsistent (Tuite, 2003). Dropping sales of such products in the late 1990s, (Waddington, 2003; de Bruyn, 2003) suggested that people wanted access to NHPs but also wanted increased assurance of the safety and quality of the products.

A 'driving force' of the development of new regulations was consumer demand for integrative health care and the ability to make informed choices about health-care options (Smith and Simpson, 2003). In response to consumer and industry pressure to protect public safety and facilitate access to products, the Canadian government moved to update the regulation of NHPs. Stricter and more coherent safety and quality assurance was required, generally seen to take the form of regulation as the government has a role to play in informing consumers' decision-making process by helping to identify the risks and benefits of NHPs (Waddington, 2003). Regulatory control of the industry, in supporting safe and informed consumer access to NHPs, converged with industry objectives of strengthening the industry by instilling consumer trust in a wide range of products by assuring their safety and efficacy.

A burdensome and expensive regulatory regime was not practicable, as the industry could not sustain it. As most NHPs are derived from ingredients found in

nature, most are not patented; this limits the ability of manufacturers to recoup the costs of research, development and clinical trials. The NHP market consists largely of small to medium sized, labour-intensive businesses that are very vulnerable to increased costs imposed by regulation and that wanted their products exempted from the onerous requirements of drug regulation (Health Canada, 2003c).

On the advice of an Advisory Panel on Natural Health Products in 1997, a full public review of the regulation of NHPs was conducted by the House of Commons Standing Committee on Health. The Committee's mandate was to "consider the objectives of providing consumers freedom of choice and access to natural health products while ensuring the quality and safety of such products" (Canada, 1998). Witnesses heard by the Committee included representatives of Health Canada and the CFIA, as well as academics and health care professionals like pharmacists, natural health products industry and health food stores associations, and individual companies and drug store chains. Chinese and other traditional and alternative medicine organizations, herbalists and growers were represented, and a number of briefs were submitted by health care advocacy groups, such as the Canadian Health Coalition and the Consumer Health Association. Finally, in an indication of the strong influence of the principle of individuals' rights to self care, there was representation from several different advocacy groups like Friends of Freedom, and Citizens for Choice in Health Care (Canada, 1998).

The Standing Committee released its report *Natural Health Products: A New Vision* in 1998 (Canada, 1998), making 53 recommendations that established the direction the regulatory framework would take. A new category of natural health

products that are safe for over-the-counter-use should be created under the drugs side of the Food and Drugs Act, and products licensed according to a risk management approach based on the margin of safety of the particular product. Products should be permitted to make health and functional claims, substantiated by evidence scaled to the type of claim, and accurate labelling of the product package required for consumer safety.

The Minister of Health accepted all these recommendations, and created an Office of Natural Health Products (ONHP) to develop a new regulatory framework for NHPs. A Transition Team was established to assist the ONHP develop the regulatory framework, and presented its final report (Health Canada, 2000b) in 2000. The Transition Team presented 51 recommendations for the policy direction for a proposed regulatory framework of NHPs. The report offered a 'vision' which stated that "The mission of the Office of Natural Health Products is to ensure that all Canadians have ready access to natural health products that are safe, effective and of high quality, which respects freedom of choice and philosophical and cultural diversity" (Health Canada, 2000b). The Transition Team recommended that a working definition of a natural health product be developed "to ensure that the legal interpretation of natural health products clearly differentiates these products from foods and pharmaceuticals" (Health Canada, 2000: iii). It also recommended site licensing, product licensing and the use of different standards of evidence required to establish the safety, quality and claim for products of higher and lower risk.

Consultations and conferences on the proposed framework were held among industry, academic and consumer groups in 1999 and 2000 (Health Canada, 2003f). A

second draft was released in March, 2001, followed by consultations, and a further draft was posted on the ONHP website in September, 2001. An industry working group was formed to provide the ONHP with ongoing communication with the industry through the process of developing the regulations, and “in addition to other stakeholders, provided the Natural Health Products Directorate with timely advice regarding the planning and implementation of the proposed regulatory framework for natural health products” (Health Canada, 2003f). The proposed NHP Regulations were published in the Canada Gazette Part I in 2001, and were followed by a public comment period. Over 600 submissions were received, and the ONHP “undertook an in-depth analysis of them” (Health Canada, 2003f). Cross-country consultations were held through 2002 on the proposed “Good Manufacturing Practices for Natural Health Product Guidance Document,” and for the Standards of Evidence for the evaluation of safety and claims of NHPs; and a Business Impact Test was conducted in order to learn the impact of the regulations on the natural health product industry (Health Canada, 2003f).

The NHP Regulations were put in place following a consultation process that included many members of the industry, which was strongly in support of regulation and the regulatory approach that was taken. Many members of industry still cooperate with regulators in ongoing industry training on the regulations and the guidance documents on compliance (NHP-S, 2006: 13).

While these consultations were extensive and generally constructive, some in smaller companies felt they had been left out of the regulatory design process, and that the larger companies had had greater input. In addition, consensus among the

stakeholders took great effort on some issues. Homeopaths, for example, were already regulated through the Drugs Directorate, but although this regulation was minimal homeopaths did not want the new regulations to require greater effort to prove their claims. And food purveyors wanted to be able to put NHP claims on foods, but there are as yet no separate functional food regulations (NHP-R, 2007) and FFNs are regulated as NHPs.

One challenge to the Regulations was mounted in the form of a Bill in the House of Commons that, if it had been implemented, would have disrupted the adoption of the NHP Regulations. Bill C-420 was introduced in the House of Commons as a Private Member's Bill. The Bill was strongly supported by a group advocating 'freedom in health care' that also launched a lawsuit against the government against the definition of some NHPs as drugs (Lunney, 2005). It would amend the definition of food in the Food and Drugs Act to include NHPs, and amend the definition of drugs to exclude foods. This would permit manufacturers to add nutrients to standard foods and to add health claims for the nutrient and reduce requirements for pre-market assessments and approvals.

In arguing for Bill C-420, MP Lunney cited "freedom of choice in personal health care", saying that the provisions now contained in the NHP regulations "have been used for years to take effective products, even those with the most scientific evidence behind them, off the market without evidence of harm" (James Lunney 2005). After debating the Bill, the House of Commons Standing Committee on Health concluded that regulating NHPs as foods would be "detrimental" as they are not subject

to pre-market review, and that the NHP regulations “were developed following extensive consultations and, thus, reflect the desire of Canadians for a regulatory framework appropriate to the level of risk associated with natural health products.” The Committee recommended not proceeding with the Bill, in November, 2005 (Parliament 2005). In February 2007 Lunney introduced a Bill to exempt NHPs from the GST, citing the need to ‘improve access to natural health products’ (Lunney, 2007).

Natural Health Products Regulations

The Natural Health Products Regulations were published in the Canada Gazette part II in June, 2003 (Canada Gazette). The regulations are administered by the newly created Natural Health Products Directorate in Health Canada, succeeding the Office of Natural Health Products which had guided the development and implementation of the regulations. The Regulations went into force in January 1, 2004, to be phased in over six years. They set down good manufacturing practices and define labelling requirements. Manufacturers, packagers, labellers, and importers had to apply for a site licence by December 31, 2005; applications for products must be made before December 31, 2010 (Boon and Kachan, 2007).

The stated purpose of the final Regulations is

To provide Canadians with ready access to natural health products that are safe, effective and of high quality, while respecting freedom of choice and philosophical and cultural diversity. (Canada Gazette, 2003: 1571).

The focal point of these regulations is consumer self-care, defined as “the activities individuals undertake for the prevention, treatment, and symptomatic relief of

diseases, injuries or chronic conditions that individuals can recognize and manage on their own behalf, either independently or in participation with a health care practitioner” (Health Canada, 2006b: 1). The ability of the manufacturer to make a functional claim for the product, which must then be verified by the regulator, is a crucial aspect of the regulations.

The NHP Regulations are aimed at those portions of the industry that sell NHPs (manufacturers, distributors, importers, packagers and /or labellers): growers, “who handle and/or treat a product in order to preserve the integrity of the raw material, are not considered manufacturers (Canada Gazette 2003: 1572). Retailers and suppliers also do not fall under the NHP Regulations (Decima 2005: 7).

Health care professionals, like pharmacists, or complementary practitioners, like naturopathic doctors or Traditional Chinese Medicine practitioners, are not expected to comply with the regulations and may thus compound products for individuals (Canada Gazette, 2003: 1572). The definition of ‘manufacturer in the NHP Regulations was drafted to make the distinction:

“manufacturer” means a person who fabricates or processes a natural health product for the purpose of sale, but does not include a pharmacist or other health care practitioner who, at the request of a patient, compounds a natural health product for the purpose of sale to that patient. (Canada Gazette, 2003)

NHPs are regulated as drugs under the Food and Drugs Act, in order, regulatory officials explained (NHP-R, 2006), to require site licensing and permit the use and verification of product claims. The definition of a natural health product in the Regulations contains both a functional and a substance component. The function

component relates to the intent of the regulations, “to capture those substances which are manufactured, sold or represented for use in:

- (i) the diagnosis, treatment, mitigation or prevention of a disease, disorder, or abnormal physiological state or its symptoms in humans;
- (ii) restoring or correcting organic functions in humans; or
- (iii) modifying organic functions in humans, such as modifying those functions in a manner that maintains or promotes health (Canada Gazette, 2003)

The substance component of the definition is “medicinal ingredient driven,”(Canada Gazette 1574) and refers to a substance, or a combination of substances, described in Schedule 1 of the Natural Health Products Regulations, a homeopathic medicine or a traditional medicine. A substance is considered medicinal “if it contributes to the pharmacological activity associated with the recommended use or purpose” (Health Canada, 2006b:2). Schedule 1 provides an inclusion list - those ingredients that can be used in NHPs. The inclusion list “indicates that medicinal ingredients of NHPs include:

- (a) a plant or plant material, an alga, a bacterium, a fungus, or non-human animal material
- (b) an extract or isolate of (a), the primary molecular structure of which is identical to that which it had prior to its extraction or isolation;
- (c) a vitamin;
- (d) an amino acid;
- (e) an essential fatty acid;
- (f) a synthetic duplicate of (b) to (e);
- (g) a mineral;
- (h) a probiotic (a term which is defined in the Regulations and is intended to capture such things as *Lactobacillus acidophilus*)

It is important to note that the Regulations, which intended to capture substances “of natural origin . . . which maintain their original structure” (Canada Gazette, 2003),

recognize, as a natural health product as defined in (b) to (e), a “synthetic duplicate” that is chemically identical to the substance found in nature.

Products licensed by December, 2006 include mostly vitamins, minerals and herbal products such as echinacea, glucosamine, or flax oil, as well as products like caffeine and pseudoephedrine tablets. In addition, children’s chewable vitamins, pain lotions, cough drops, toothpaste, anti-perspirants, shampoos, face creams and sun screens have been licensed as NHPs. (Health Canada, 2007b).

The NHP Regulations establish requirements on product licensing, site licensing, good manufacturing processes, clinical trials, labelling and packaging, and adverse reaction reporting. The site licensing requirements were phased in over two years, and product licensing as an NHP for those products previously with a Drug Identification Number (DIN) were given six years to transfer to an NPN (natural health product number; Health Canada, 2003f).

The product licensing system authorizes a product for sale in Canada, issuing the product an identification, or NPN, number to be displayed on the package. The licensing process includes the evaluation of the evidence supplied by the applicant that verifies that the product is safe and effective, and of good quality. The site licensing system requires that all manufacturers, packagers, labellers and importers be licensed, that sites have procedures for handling, storing and delivering their products and for managing records, and that the sites meet good manufacturing practices (GMPs). GMPs include standards for many aspects of the manufacture of the product, including the premises, equipment and personnel, and lot and batch samples.

Labelling requirements are meant to support safe consumer choice and use of NHPs. Labels must contain information on, among other things, product name, quantity, lot number, conditions of use including purpose, dose, any cautionary statements or risk information, and storage conditions and expiry date.

Finally, there is a post-market adverse reaction reporting system in place that requires product licence holders to “monitor all adverse reactions associated with their product. Serious adverse reactions are reported to Health Canada” which may issue a public advisory (Health Canada, 2004c). There are provisions for suspending or cancelling a site licence if GMPs are not followed or product quality not adequate.

Risk control is achieved through the Regulations by several mechanisms. First, placing NHPs under drugs in the Food and Drugs Act makes available stricter conditions than can be required for foods. Second, in accordance with the original policy intent to ‘regulate substances that are safe for over-the-counter use’, only those products that have a low risk level are included as NHPs (Canada Gazette, 2003: 1577). NHPs are therefore clearly distinguished from prescription drugs. In addition to the inclusion list, the NHP regulations contain an exclusion list (Schedule 2), explicitly excluding substances that might otherwise qualify as an NHP but that are not safe for consumer self-care. These substances include antibiotics, radiopharmaceuticals, substances that are injected through the skin, and those controlled under the Tobacco Act or sections I to IV of the Controlled Drugs and Substances Act (Canada Gazette, 2003:1576).

The third mechanism for risk control is the assessment and control carried out in the process of reviewing an application for a product licence. The applications and the

products are evaluated for quality and for safety and efficacy. Quality is assessed in terms of identity, purity, quantity and potency and tolerance limits (Health Canada, 2003g). Provisions for site licensing and for batch testing assist in the monitoring of product quality.

Safety is assessed scientifically, using a toxicological intrinsic risk approach (which does not consider exposures). Efficacy, however, is assessed from both a pharmaceutical perspective and from the perspective of different traditional healing paradigms that use the product. A member of the NHP industry (NHP-S, 2006) noted that Canada's NHP Regulations are unique in the world in "having permission to assess products from particular healing paradigms and not having to translate traditional claims into the scientific paradigm" (NHP-R, 2006). NHPD supports this diversity by having the capacity to assess products from the relevant cultural perspective, in its staff with expertise in ethnobotany, Ayurveda, Traditional Chinese Medicine and other traditional healing paradigms (NHP-R, 2006). Assessors in NHPD are careful to use the right plant, in the right dose and quality, and the right form of evidence for the claim made.

Applications may be made for a product licence under several different types of claim, each requiring a specific kind of evidence of safety and efficacy (Health Canada, 2004b). These claims are assessed "on the credibility, strength and quality of evidence provided to support the claim" (Health Canada, 2006b: 8). Health claims are permitted to indicate the "intended beneficial effect of an NHP when used in accordance with the recommended conditions of use" (Health Canada, 2006b: 3). Therapeutic, risk reduction and structure-function claims are permitted under the Regulations. Authorization of

product claims is substantiated by evidence that is scaled to the risk and the severity of symptoms or conditions named in the claim (ibid) The different types of applications include (Health Canada, 2004b)

1. compendial, which relies on NHPDs *Compendium of Monographs*, a compilation of information on well known substances. This is for those substances for which a monograph is available
2. Traditional claim, made for products used in the context of a traditional medicine paradigm, requires evidence for 50 years of safe use.
3. Non-traditional claims require more rigorous, scientific evidence, such as clinical trials, graded according to the level of claim made.
4. Homeopathic medicines, which require reference to a homeopathic pharmacopoeis listed in the *Evidence for Homeopathic Medicines Guidance Document*
5. Transitional DIN products, which have been previously regulated as drugs and have thus undergone more extensive testing and assessment to receive a DIN. These must transfer to a NPN within six years of the regulations' coming into force.

The two classes of NHP applications that require the most evaluation of evidence, as there is not always an established compendium or pharmacopoeia to refer to, are traditional and non-traditional. For these applications, applicants submit evidence to substantiate the claim they are making for the product, along with a sample of the product (Health Canada, 2004b)

Traditional medicine is defined as representing “the sum total of knowledge, skills and practices based on the theories, beliefs and experiences indigenous to different cultures, used in the maintenance of health, as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness” (Health Canada, 2004b: 4). In addition to meeting these criteria of ‘traditional’, NHPD requires that a product have a history of at least 50 years of traditional use as a medicinal ingredient within a cultural

belief system or healing paradigm. A traditional use claim must involve a product used according to traditionally used dosage and preparation methods; evidence supporting traditional use may be reference to a traditional pharmacopoeia or other sources. Regulatory officials state that there is “no conflict with cultural paradigms and other, scientific, criteria” (NHP-R, 2006 10).

For non-traditional use claims, NHPD uses a “strength of evidence grading system” (Table 10-1) that ranks the levels of evidence according to the type of claim.

| Levels of Evidence | Type of Evidence from Human Studies |
|--------------------|---|
| I | well-designed systematic reviews and meta-analyses of randomized controlled trials or other clinical trials, or at least one well-designed randomized controlled trial (preferably multicentred) |
| II | well-designed clinical trials without randomization and/or control groups |
| III | well-designed descriptive and observational studies, such as correlational studies, cohort studies and case-control studies |
| IV | peer-reviewed published articles, conclusions of other reputable regulatory agencies of previous marketing experience, expert opinion reports, referenced textbooks, Web site (if the information is peer-reviewed and there is a hardcover version of the side, eg Natural Medicines Comprehensive Database) |
| V | References to a traditional use, pharmacopoeias |

Table 10-1, Strength of Evidence Grading System for NHPs from *Evidence for Safety and Efficacy of Finished Natural Health Products*. Health Canada 2006b, p. 16.

Finally, safe consumer selection and use of NHPs is supported through labelling requirements. Among regulators, a central goal of the regulatory regime is to ensure trust in the product through credible quality control, and to “stabilize claims [made for the product] and consumer expectations” (NHP-R, 2006). The information that is on the

product label is thus all-important, as it provides assurance that the “contents live up to the claims” (NHP-R, 2006). Regulatory officials assert that once safety of the product has been assured, in order to be adequate to support informed consumer choice, an NHP label must not contradict a physician’s advice and must warn about the effects of the NHP interacting with other treatments (NHP-R, 2006).

To supplement package labelling control, Guidelines for consumer advertising for “marketed health products” - nonprescription drugs including NHPs - were issued in 2006 by Health Canada in collaboration with Advertising Standards Canada (Health Canada, 2006d). The Guidelines include a re-emphasis of the requirement that advertising include advice on reading product labels and on cautionary or risk information (Health Canada, 2006d).

The Guidelines provisions for advertizing of NHPs focus on the use of ‘natural’ as a marketing term with acknowledged power to suggest purity, lack of risk and special effectiveness. Claims of ‘natural and natural source’ are thus prohibited for a product that has been synthesized. Products may not be characterized by the words ‘naturally’ or ‘natural action’, since “all nonprescription drugs, including natural health products, modify the body’s physiological processes” (Health Canada, 2006d: 25). Guidelines on the use of ‘natural’ and ‘natural source’ on product labels suggests that ‘natural’ should refer to a product that is ‘completely the way it was in nature, just dried or ground’ (Health Canada, 2006d: 10). A product that is to be labelled ‘natural source’ can be extracted, but not processed into a derivative. If it is processed, it should be labelled as ‘from natural source’.

Information that manufacturers place on product labels under these guidelines varies. Jamieson Omega-3 Complex Salmon Oil bears the claim “healthy heart and brain function.” Its label also includes “natural sources,” “ultra pure”, and “certified free of all impurities.” A package of that company’s Vitamin C carries no health claims, but does specify that it is “prepared in a specially formulated nutrient base of natural fruit pulp, extracts, acerola, rosehips and the complete vitamin C complex of rutin, hesperidin and citrus bioflavonoids.”

Providing information to consumers on NHPs is a major focus of efforts to increase the safe accessibility of NHPs. This has been taken up by Health Canada (Health Canada, 2004a) and by government in collaboration with health professional associations (CAMline, 2005), and community organizations. This information constitutes a broad network of institutional support for consumers wishing to use NHPs safely and effectively.

Even though the safety and quality control measures apply to the assessment and approval of FFNs, the objectives that guided the development of the NHP Regulations, with their emphasis on defining and protecting the value of the natural and respecting the cultural worldviews within which traditional products are often used, are tailored more particularly to the use of NHPs.

Natural Health Products used in the Canadian context

Research (Boon and Kachan, 2007) has found that while most companies subject to the Regulations are complying with them, there were more non-compliant or only

partially compliant companies among small and medium sized enterprises (SMEs) than among larger companies. In addition, knowledge of the regulations in many SMEs, who felt they had been left out of the consultation process, was lower than in larger organizations, and compliance was reduced as a result (Boone and Kachan, 2007). Many involved in the FFN portion of the industry were actually unaware that their products are now regulated as NHPs (McCutcheon and Fitzpatrick, 2004).

People tend not to use NHPs or CAM for urgent medical conditions, such as injuries or acute infections (Public Health Agency of Canada, 2006b). Most use NHPs to maintain and promote their health, or to treat illness (Public Health Agency of Canada, 2006a), saying that CAM “fits their values about life and health” (Public Health Agency of Canada, 2006b). The Public Health Agency of Canada (2006a) reports that people in Canada, as in the rest of North America and Europe, use complementary and alternative therapies because they:

- desire to take responsibility for their own health
- are concerned about side effects of conventional treatment
- have had a disappointing experience with mainstream medicine
- are more satisfied with relationships with CAHC practitioners

NHPs are a major component of CAM; herbs and dietary supplements are ‘the most common form of CAM in North America’ (Public Health Agency of Canada 2006a) In 2005, 71 % of people surveyed in Canada reported using HNP - vitamins, herbal products or homeopathic medicines and other supplements. Canadians associate NHPs most strongly with vitamins and minerals, herbal remedies and teas, additive-free foods and organic foods, plant products and natural or organic products (Ipsos-Reid

2005: 17).

The Baseline Natural Health Products Survey Among Consumers (Ipsos-Reid, 2005), carried out for NHPD, assembled a thorough picture of the use of NHPs in Canada. The main reasons cited for using NHPs were (Ipsos-Reid 2005: 27):

- better for me than chemical products/drugs (18%)
- concerned about my health (18%)
- to help maintain and promote health (14%)
- recommended by a family member or friend (13%)
- it's chemical/toxin free (8%)

Overall, more than half of those surveyed (52%) gave reasons “related to their desire to control or influence their personal health” (Ipsos-Reid 2005: 28). Seventy per cent believe that “Canadians have the right to use any natural health product they choose” (ibid: 45), and 80 % agree that it is important to respect the role that NHPs play in some cultures (ibid: 44).

As among the industry and many users of dietary supplements in the U.S., in Canada the right to personal control and respect for cultural diversity in health care and use of NHPs is a dominant theme. A major difference between the regulatory regimes of the two countries, however, is that while the relative lack of regulatory control in the U.S. is balanced by a prohibition against the making of health claims, allowing such claims has been a predominant objective in the NHP Regulations from the outset. Regulators and industry members alike noted that NHP labelling supports safe consumer selection and use of products, and also recognizes the different cultural frameworks within which they are used. The goal of the Friends of Alternative and Complementary Therapies Society, for example, is the “democratization of health information by

promoting credible and practical information about different types of health practices across cultures” (CAMline, 2005).

There has certainly been an increase in the amount of information available on NHPs, which people must evaluate. A number of organizations and associations of those who practice, use, or research alternative health and natural health products have emerged in Canada as the field gains adherents and credibility. National organizations include the Friends of Alternative and Complementary Therapies Society, and the Canadian Interdisciplinary Network for Complementary and Alternative Medicine Research (IN-CAM), led by researchers from the University of Toronto and the University of Calgary. There are similar provincial bodies, such as the Complementary and Alternative Medicine Research Education Network of Alberta (CAMera), and The Natural Health Products Technology Cluster, which is “dedicated to increasing the size and global competitiveness of the natural health products industry in Ontario.” There are also associations of practitioners, such as naturopaths, and herbalists, such as the Ontario Herbalists Association. These organizations are in addition to health food store and other networks of retailers and producers, and other similar organizations in the United States and elsewhere that have information posted on web sites.

The NHP consumers interviewed managed their risks from NHPs partly by becoming educated about the products, their safe uses, and the best brands. None of them used the products under the direction of a health practitioner. They all asserted that users of NHPs have an obligation to learn about the products they take, to know the proper dosage and combinations they can use and the risks they need to avoid. As one (NHP-S,

2007) said,

Self-medicating can be a problem, especially without good advice. Used with intelligence, natural products do not harm. But I have seen uninformed people take natural products improperly and damage themselves - people self-diagnose, then self-treat.

I am careful in choosing brands, to avoid contaminants (like heavy metals) in the supplements, especially in fatty acids and fish oils. I read labels carefully, do my research, and buy high quality from companies I trust.

These participants agreed that the NHP regulations are important to “protect uninformed consumers and weed out contaminants” (NHP-s, 2007) and to “verify that the product is pure” (NHP-S, 2007). However, they would not rely on the regulations to keep them from harm in using NHPs ; indeed, one said that the continued availability of the products is more important to her than the health risk (NHP-S, 2007).

A more extreme, political form of this belief is expressed by the Alliance of Natural Health Suppliers, which pursues “the necessary legal, political, marketing self-regulating quality control, and scientific research initiatives to remove all unnecessary barriers to the free flow of truthful information and quality food-based medicine products and therapeutic food-style services” (allianceofnaturalhealthsuppliers.com). It insists that NHPs are foods, not drugs, and should not be subject to the strict control of drugs. This and similar groups were involved in the initiative to amend the Food and Drugs Act to reclassify NHPs as foods rather than as drugs through introducing Bill (C-420) into Parliament, in an attempt to ‘ease the punitive rules’ that govern the herbal supplements industry and are “putting companies out of business”(Staples, 2004). This appears to have been a concern of some in the NHP industry rather than a widespread

issue for the public. A Health Canada spokesperson acknowledged that “the interest in changing the rules is largely on the part of industry . . . Consumers are not beating down Health Canada’s door to do this.” (Staples, 2004).

The desire for improved access to natural health products is often associated with a lack of confidence in conventional medicine and a desire to consult alternative practitioners. As research notes (Public Health agency 2006b) people often turn to alternative medicine following disappointing experiences with mainstream medicine. Among some activists the lack of trust in conventional medicine becomes politicized and strident. One book, for example, “provides the evidence from the “Allopathic Investment Industrys” (sic) own data that the worst “Pandemic” in modern times is deliberately not only created, by also perpetuated by the “Allopathic Disease Investment Industry” interests, AND by government and public sector unions” (deathbymodernmedicine.com). From this perspective, the regulation of NHPs is interpreted as “the suppression of dietary supplements” (ibid).

The second major theme in the use of NHPs is, as their name suggests, their naturalness. This distinction is critical to the NHP portion of the industry, and expresses the central differentiation between natural products and FFNs, which are innovative, more technological products. “NHP industry members repeatedly pointed out that “natural” was the critical essence of their products; that consumers buy their products because they are natural substances that have not been scientifically manipulated” (McCutcheon and Fitzpatrick, 2004). In this regard NHP industry members distanced themselves from FFNs, which are often highly technological products, and expressed

concern about the “scientific engineering” of FFN products. The focus in the NHP portion of the industry is the products’ efficacy and safety, and relatively small, under-funded and isolated research efforts are carried out for the ‘common good’ and benefit consumer health. To members of the NHP community, FFNs are “perceived to have negative connotations associated with the pharmaceutical industry, biotech, and genetic engineering” (ibid: 10).

Functional foods and nutraceuticals are more integrated than NHPs into the funded research and commercialization infrastructure in Canada. FFNs are innovative products developed through well-funded research that is motivated by the possibility of patenting and marketing new compounds or processes, and are part of the “popular trend towards very high tech/biotech innovations” (McCutcheon and Fitzpatrick, 2004: 11). This industry is more aligned with the “value-added agriculture” and biotechnology sectors than with the NHP industry (ibid). FFNs are health products that are selected for self-care by consumers and that may make health claims, but despite being included under the NHP regulatory umbrella the industry does not share the philosophical orientation of the NHP industry and its market.

The philosophy that guided the early development of NHP regulation was strongly aligned with an explicitly naturalistic approach to NHPs. The website of the transitional ONHP was presented in earthy greens and browns, enhanced with drawings of leaves and background photographs of flowers. (This was replaced with the standard ‘common look’ website design of federal departments with the creation of the NHPD.) The Transition Team recommended that the mandate of the ONHP should be “expanded

to allow it to function as an effective catalyst for change toward a more holistic and proactive, wellness-centred model of healthcare delivery in Canada (Health Canada, 2006b). In this regard, the Minister of Health “should become the ‘Champion of the Cause’ for such a wellness-centred paradigm (Health Canada, 2006b).

In survey research, almost one third (29%) of respondents reported that they use NHPs because of “their assumptions that natural health products are natural and safe or that they may be better than conventional medications” (Ipsos-Reid 2005; 28). This breaks down into specific beliefs that NHPs are “better for me” than chemical products; they are chemical and toxin-free; they are natural, and because people lack confidence in pharmaceutical drugs (ibid). Most believe that NHPs can be used to maintain or promote health or treat an illness; and 43% believe that they are better than conventional medicines (p.38). Slightly more than one half (52%) believe that NHPs are safe “because they are made from natural ingredients”; in fact, 7% completely and another 14% somewhat agreed that “if a health product is made of natural substances, there are no risks associated with its use” (p. 47).

Interview participants from all backgrounds largely converged in their views on the risks of natural health products. Regulatory officials were very aware of the risks that some products can have, particularly some traditional combinations that are used within traditional healing paradigm; because many of these products are not selected directly by the consumer but prepared for a patient by a practitioner, as for example in Traditional Chinese Medicine, specific allowances are made, as noted, for those who make such preparations. One (NHP-R, 2006) noted that the components in some

traditional Chinese medicine can be toxic: in the preparations, especially, which are very old, complex and sophisticated, the chemicals are meant to balance each other out, although no recent studies have been done to confirm this.

The NHP consumers who were not involved in regulation and regulatory consultations stressed that like anything else, NHPs can have risks and must be used with care and knowledge. One (NHP-S, 2007) said that “some vitamins can be toxic in large doses, and some herbs can be dangerous in large doses or certain combinations.” They all noted, however, that the percentage of users who have had ill-effects from NHPs is very small in relation to the large number of adverse reactions to prescription drugs: all of them preferred not to use prescription drugs. They use supplements to treat chronic conditions and for health maintenance and promotion. One (NHP-S, 2007) argued that she does not trust conventional medicine for treatment of chronic conditions: “people don’t get cured, they get drugs.”

All NHP interview participants expressed a practical and complex perspective on the value of NHPs as natural and on the concept of nature itself. Like the individuals interviewed on GM foods, they were largely uninterested in speculating on the essential identity of nature. They used ‘natural’ to denote an absence of significant social intervention; the precise threshold of ‘significant intervention’ was not defined, and was of interest only when industrial and corporate activities became involved.

The regulatory officials interviewed noted that not all NHPs are totally natural, meaning that they are not manipulated beyond a “certain point” (NHP-R, 2006). Herbals come from plants, although some are extractions, or selections of compounds, some of

which can be patented. Homeopaths have a number of sources for their products (NHP-R, 2006). They also stressed that almost all NHPs require some form of processing - even if it is as simple as drying or grinding. Many are extractions, which can be made by traditional methods using water or alcohol, or by more modern chemical processing with solvents like acetone (NHP-R, 2006). These processes can sometimes leave residues that contaminate the product, so processing methods are attended to in safety and quality assessments.

Vitamins are almost all produced synthetically - in fact, they are not at all natural in that no vitamins exist in their pure form in nature. Synthesized vitamins are chemically identical to the natural forms, although they may contain only one of the variants found in nature (NHP-R, 2006). Transgenic organisms in an NHP would not be acceptable, however (NHP-R, 2006). One reason is that as novel foods they would require a different assessment and regulatory process; for another, they are not traditional and would not be appropriate in a product with cultural sensitivities to particular varieties.

Despite their willingness to work within a scientific framework of chemicals and compounds, NHP regulators were also interested in the complexities of plant varieties, growing conditions, preparations and combinations. Developing standards for NHPs was difficult as this variability needed to be accounted for, and debates continue on whether the whole plant is better than an extract of some of its ingredients. One argued for the use of the whole plant, as “we’ve evolved with it; and also some components counter adverse reactions of the others” (NHP-R, 2006).

Several officials believed that the “public preference for natural is a marketing thing” (NHP-R, 2006) and that a label of natural appears to “protect a product from being scary, and risky - it seems safe” (NHP-R, 2006). One official believed that most people do not really think that “natural equals safe” but that they use NHPs because they fit in with their world view, which is generally more “respectful” (NHP-R, 2006). He argued that some cultures prefer natural substances, which are accessible and cheap and are used world-wide within the culture.

Industry members likewise had a pragmatic concept of nature. One said that in the industry, ‘natural’ simply means “a product for your health that is not a drug” (NHP-S, 2006). The dividing line is not ‘natural’ as opposed to ‘synthetic’ or ‘chemical’, but rather self-care as opposed to the requirement of a prescription from a health professional for products of higher risk. One producer stated that “unnaturalness is a meaningless concept” and that modified plants are not a problem; growers “do cross-breeding in the field all the time” (NHP-S, 2006). However they did oppose genetically engineered products, as they “need more safety testing and research than they are getting,” preferably clinical trials “in recognition of their newness and our lack of understanding.”

It is in the fundamental concept of nature and its intrinsic value that non-industry users of NHPs differed most from the regulatory and industry participants. These participants identified a positive quality present in autonomous nature that has an evolutionary resonance with humans. They stated that something is natural that is “in its purest form” (NHP-S, 2007), or wild-grown (NHP-S, 2007). They prefer natural foods

because they have a “life force” (NHP-S, 2007); natural plants are “friendly, nourishing; the nutrient value herbs can have remarkable, visible effects on the body and health” (NHP-S, 2007). All life forms have an internal balance and the different components of a whole plant are compatible, giving it a holistic effect. As one said, “we are part of the Earth - the closer we can stay in tune with it, the better. Our bodies can deal with holistic, whole plants . . . better than extracted isolated components” (ibid). Another (NHP-S, 2007) said that “the body assimilates natural products better” - but that it is also a “philosophical, spiritual, intuitive decision” to use natural foods: “she feels safer, more in touch.”

One participant (NHP-S, 2007) acknowledged that “everything we use has been domesticated and is not natural. NHPs are technological in that they are prepared or manufactured, and the contents, ratios, and dosages are standardized. But we have to be realistic.” Naturalness is a spectrum, not a ‘black and white’ distinction. Products that are more natural are those that are grown from non-treated seed with no chemical products used. She prefers to buy natural foods, organic when she can afford it, and has the sense that she is “not putting so many chemicals into myself”.

Social intervention was described as a qualitative rather than a quantitative matter, as industrial interventions change a product completely, even if no chemical differences are detectable. These participants had a strong sense that a natural food that has been modified and intervened in is unnatural even if it is made to be ‘molecularly similar’: synthesized products have no “life force” in them (NHP-S, 2007). Recombining the elements of a plant (as is done with GM foods) loses the balance, the compatibility

among components found in a natural plant. This integrity is lost with intervention. Two interviewees stated that they would “never buy synthesized vitamins” (NHP-S, 2007).

These holistic perspectives on the integrity and healing power of whole, natural foods echo the position of professional herbalists. Herbalists take a holistic approach to treatment, including mental, emotional, spiritual, environmental and physical aspects of health. Their therapies “mobilize the individual’s innate capacity for self-healing,” handing the responsibility for the healing process back to the individual. (CHAofBC, 2002). Herbalists explain in detail the benefits of natural products:

Herbal medicine uses plants that do not have the aggressive and invasive action of modern drugs, but instead support the body’s own natural tendency to heal itself. Herbal products are derived from roots, stems, flowers and leaves of plants and are frequently sold in liquid extracts, capsules, tablets or teas. Herbalists prefer to use remedies extracted from a part of the whole plant, with all its biochemical constituents, rather than individual standardized extracts. It is believed that the active constituents are naturally balanced within the plant, and consequently aid in working on the body, mind and spirit in a less invasive manner.

Given the focus on supporting consumer access to diverse paradigms of health care, it is not surprising that regulatory officials stated that public trust was the reason for the development of the regulations (NHP-R, 2006). The goal is to build trust in the product by ensuring that it meets expectations (NHP-R, 2006): “trust ends up perceived in the product, in the information on the label” (NHP-R, 2006). The NPN is “proof of a review process,” and consumers also need to have confidence in the people doing the review. In that regard regulatory officials feel that NHPD is in a good position, having “gone to the trouble to have properly qualified people in traditional disciplines to do relevant reviews” (NHP-R, 2006). They also felt that the extensive and inclusive

consultations they engaged in throughout the regulation development process, which included those who would be regulated, members of the public, and aboriginal and ethnic groups, was of high quality and gained trust in the regulations (NHP-R, 2006).

Trust was considered by regulators to be earned through the active provision of information, and in openness and consultation (NHP-R, 2006). This ongoing openness and provision of information benefits consumers, through a website for sharing of knowledge and to report adverse effects and “complain to regional inspectors” (NHP-R, 2006), and also extends to outreach with “inspectors, pharmacists with lectures and meetings to ensure that all involved know the regulations.” Physicians as well need to be confident that the labelled contents have been verified, and that they can recommend products to patients (*ibid*). It is partly due to this openness that “it is clear that the NHP regulations are for consumers” (NHP-R, 2006), which also encourages support for them from industry.

Regulatory officials believed that there is strong public trust in NHPs, in both the products and their regulation. This is partly due to the products themselves - their ‘naturalness’ protects them from criticism (NHP-R, 2006); there is less perception of risk, and a greater inclination to trust government (NHP-R, 2006). One thought that it was “fortunate that NHPD did not inherit any ‘baggage’ but started from the ground up with ‘blue ribbon consultation - it’s easier to consult on new regulations than on existing ones that are attached to existing interests” (NHP-R, 2006). With GM foods, in contrast, there is some ‘baggage’ of controversy, and a general mistrust of science and government. GM foods regulation is ‘more strategic’ than NHP regulations, and has

more ‘monsters in the closet’ (NHP-R, 2006).

Those in the industry were particularly concerned that regulations build trust by assuring quality control and ensuring that claims are reasonable and verified (NHP-S, 2007). One noted that “trust is critical in a large economy”: they can’t sell products if people don’t trust them, and it’s important that claims be accurate and verified (NHP-S, 2007). They felt that regulators are responsible for ensuring the safety of the products, and that they keep the industry “on this due diligence road” and ensuring that products “get to market with good instructions.” The feeling of one industry representative is that Canadians trust consumer products because they know that the Canadian government intervenes in the marketplace and ensures that products have been approved, and that health risk and fraud have been prevented. This is an improvement on the situation in the US, for example, where the “catch me if you can” regulatory approach has led to a plummeting of public confidence in dietary supplements (NHP-S, 2007).

Despite the efforts made by regulators and producers in the industry to provide support for the consumer of NHPs, the non-industry users of NHPs were not aware of the NHP Regulations. On being informed of the regulations and their purpose, they agreed that it was a good thing that regulation prevents poor quality or fraudulent products from being sold. This is particularly important for those users who are not well informed; self-medicating can be a problem without good advice, and regulation “gives the products a certain truthfulness” (NHP-S, 2007). Accurate and complete labelling is important as it facilitates the consumer’s ability to research the product and the supplier.

Despite their general support for the regulations, these participants rely on their

own knowledge and trust primarily themselves and their own ability, and were not prepared to rely on the regulations: when asked where her trust lies when she purchases NHPs, one answered “I trust myself” (NHP-S, 2007). Two of the users interviewed consider themselves well informed on herbal products and supplements, having taken considerable care to research the products. They stay informed on manufacturers, know their suppliers, and choose brands that are established, do their own quality control, and are well regarded by naturopaths and homeopaths (NHP-S, 2007). The third participant does not consider herself well educated on natural products, but believes the onus is on her to research each product she uses. She reads company websites for information on the quality of the product she is interested in, and also seeks out the “company’s mission and their environmental philosophy” (NHP-S).

These consumers preferred to deal with small producers with whom they can establish a personal relationship; to some extent, “the trust is in the person recommending a product” (NHP-S, 2007). One stated that she finds a “comfort level with a trusted advisor and her own knowledge” (NHP-S, 2007). These individuals like to know the source of the products and buy local products when possible. While these consumers of NHPs have taken responsibility for their health and for their use of the products, they did not express any sense that this responsibility had been delegated to them, or was a burden. They also did not express concern about fraud or serious contamination of the products, perhaps reflecting an expectation that the Canadian government intervenes in the marketplace to prevent such fraud. In fact the NHP Regulations do provide, in relation to the U.S. DSHEA, strong pre-market safety and

quality control.

These individuals were more concerned about big business and industry, as the involvement of too much money creates a trust problem: big companies have “a vested interest in manipulating consumer choice” and instead of information, are inclined to provide advertising, which “makes me trust even less” (NHP-S). Large companies are also more likely to have quality control problems as communication within a large company becomes complex. These participants also do not trust the regulators to hold large companies accountable. The fact that most NHPs are not patented and are not part of big business is an advantage, as companies are motivated to produce good quality products rather than simply gain large profits (NHP-S, 2007).

All non-regulatory interviewees opposed GM foods as emblematic of non-natural, industrial food, in part for the changes that are made to the plants and ultimately our food. “Our bodies don’t know what to do with a technological product. . . the manipulation takes the life out of the food, and we don’t know the far-reaching effects”. Another said she did not feel comfortable with them, and wondered if our bodies “can absorb GM foods”: “The technology is so new that we cannot know enough about them yet - these foods would not be created in nature, and we are putting them in our bodies” (NHP-S, 2007).

The participant who is a plant producer (NHP-S, 2007) stated that the real risk of biotech is to the markets: transgenics can drift to nearby fields, contaminate organic crops and lose their certification. “The market doesn’t accept these crops; they can destroy the market.”

These participants were very clear that the process of the intervention itself is also important: “intent is everything - what people are doing and why”. One criticized the “arrogance” of the assumption that we can change nature; that we can do better. It is dangerous to break the laws of nature. They have recreated something that is not nature. GM foods have no life force.” One stated that she had “no trust in GM products” as they and science have still to “prove themselves,” and criticized the “arrogance of science that so little testing is required” (NHP-S, 2007). All agreed that GM foods should be labelled:

GM food producers and retailers must inform the consumer: we have no choice in buying this, and it's very upsetting. I would like producers of technological products to be more accountable and strictly regulated - but they can set the terms. How can we make them more accountable? (NHP-S, 2007).

The Transition Team that initially established the direction of the Regulations had recommended that (Health Canada, 2000b)

consumers should be allowed to make an informed choice through mandatory labelling of genetically modified NHPs In the interim, the ONHP should create a framework and develop standards to allow the labelling of non-GMO natural health products, including both active ingredients and excipients, and should liaise with other government departments and agencies to effect the necessary changes to make this possible.

This recommendation was not adopted in the final regulations, and there is no requirement that NHPs that contain GM products - though there are none yet (NHP-S, 2006) - state this on the label.

Attitudes of NHP users, including the individuals interviewed and members of the public surveyed in Canada and internationally, show not only a sense of self-reliance and responsibility to be informed in the choice and use of these products, but also a desire for autonomy, even mastery, in relation to their own health and in the selection

and use of natural health products. They suggested that they are able to exercise such autonomy in relation to natural products, but very explicitly that this is not possible in relation to pharmaceutical products, GM foods, or other products associated with large-scale corporations. This implies a tacit expectation, despite their professed ignoring of the NHP Regulations, that regulation in Canada makes it unnecessary for them to worry about fraudulent, mislabelled or contaminated products. It also reveals a sense that the world of nature and natural risks is one that an individual can navigate more confidently than the world of social risks.

Autonomy and the agency of nature

The social dynamic within which NHPs are used and managed in Canada is relatively non-contentious and uncomplicated. Although there is international trade in the products, the context for the development of the regulations is largely Canadian and makes connections with cultural groups and practitioners who use NHPs in Canada.

NHPs - both traditional natural products and FFNs - are selected by consumers, who have shown a strong demand for the products; they therefore need a consumer profile as high quality products. To support the industry, regulation needs to assure consumers access to safe products, a straightforward public health regulatory objective. There is otherwise not a large network of other institutional arrangements in place to support a further agenda for the industry, though efforts are being made to coordinate research on both branches of the industry (McCutcheon and Fitzpatrick, 2004). With industry and regulators working towards ensuring the availability of safe effective

products, the objectives, terms, and provisions of the regulatory regime can be aligned with the needs and expectations of consumers and terms are explicit and consistent.

The NHP regulations are able to ensure health protection and support consumer choice within different cultural contexts through a regulatory approach that combines the scientific assessment of the safety of a product with a recognition of the cultural paradigm within which it is used. Considerations of the social uses, benefits, particular preparations and cautions are not only compatible with a scientific safety assessment, but are appropriate within the framework of the regulatory regime. Support of consumer choice and respect for cultural diversity are explicit goals of the regulation, bringing a consideration of the context in which NHPs are used directly into the regulatory intent.

Risk is used in the regulations as the intrinsic possibility of an adverse effect, not restricted to the probabilistic exposure-consequence definition used in GM foods regulation. Consumers also interpreted risk as the possibility of an adverse impact, and not as a reference to the decision making of self-interested corporations. Safety assessment of NHPs is done scientifically, and regulators see no conflict between science and the consideration of culturally diverse evidence for effectiveness. The risk assessment officers in NHPD are highly trained in disciplines that bridge the physical and social sciences, such as ethnobotany and naturopathy. With this background these individuals might be more professionally inclined to include social aspects and cultural diversity in their appraisal of the uses and the risks of natural products.

The traditional NHP industry relies on a belief in the agency of nature. In this central assertion NHP industry members differentiate themselves from the FFN industry,

which is motivated by the promise of the market potential of patented innovative compounds derived from a food products. The different approaches of the two industries results less in conflict than in a disjuncture between two branches of products regulated under the NHP Regulations. However, NHP industry members consider the association with the technologically innovative character of FFNs to undermine the primary value in their own products: technology and intervention; especially commercially motivated intervention, once again appears as destructive of natural value. Likewise, part of the value in a natural product is considered to be in the very absence of such intervention.

The potential of natural substances to have a beneficial or an adverse effect on the human body is the reason that consumer access must be balanced with regulatory control. The users interviewed fully recognized and accepted this, expressing respect for nature and for the need for knowledge, information and advice. Nature is perceived as complex, with many internally balanced components, and as having a kind of ancient symbiosis with the human body and mind. The agency of nature was particularly important among the consumers, who felt strongly that nature has an integral spirit and internal balance that cannot be found in more processed foods.

Nature was understood by all participants as being composed of chemicals, but this dimension was not considered to rule out other properties or make them irrelevant to the use or the regulation of NHPs. Other factors that are acknowledged to contribute to the effectiveness of an NHP include the specific variety of plant, the conditions of its growth, the part of the plant used, and the method of preparation; in addition, it was recognized that the effectiveness of an NHP might be related to its use in traditional

preparations and cultural contexts.

Perhaps because of this shared respect for the agency of nature, interventions in nature that are required for preparation and processing the product were accepted as necessary to supply the product rather than as a categorically significant intervention. Nature in this context meant to be used: this use of nature can be a deeply cultural practice, and requires study and experience, and often advice from someone more knowledgeable. It is a use of nature that is based in a respect for its agency and complexity, and that repudiates its exploitation and appropriation and the exploitation of people by large profit-seeking companies. This use of nature takes care to retain the original composition of the plants used, in a production system in which the grower claims to work in respectful cooperation with nature in order to preserve the active properties inherent in the natural plant.

While the emphasis on natural and on individual autonomy in health care is in some degree of conflict with the presence of synthesized products, this discrepancy does not seem to pose a major problem in the market. Multi-ingredient products, many of which contain synthesized vitamins, and vitamins and minerals constitute the largest segments of the market. The unnaturalness of some natural health products, that is, does not appear to dissuade many consumers from the use of these products. Kaptchuck and Eisenberg (1998) suggest that the philosophical orientation of CAM users convinces them to interpret all CAM interventions as natural, including acupuncture needles or megavitamins. While this study considered only NHPs and not CAM practices, it may be that the apparent absence of large corporations and intense pressure to dominate the

market, as well as the carefully constructed network of support for customer autonomy and choice, avoids the crucially technological and corporate aspects about which many individuals are concerned and makes them seem less social, if not actually natural.

The claims that manufacturers may make about their products project this natural agency to the consumer, with an acknowledgment of the benefits and the risks of using the substance. Regulation protects this portrayal, prohibiting certain substances from inclusion as NHPs, and ensuring that products are not fraudulent and that consumers are informed of the risks. Manufacturers and regulators make efforts to pass on the natural product and its relationship with the user with minimal intervention: the relationship is between the natural product and the consumer, who is able to choose to use the product within his or her own cultural or personal beliefs. Manufacturers, regulators, advisors, function as intermediaries that support consumer choice and use, supplying the product, assuring its quality and the integrity of the producer; and offering advice within the chosen cultural context. Manufacturers, facilitated by regulation, strive to stay out of the way, not intervening between the natural product and user who values it, to support the main connection of the consumer with the product itself.

This dynamic preserves the control of the individual over the choice and use of the product and the choice of advisors and healing contexts, encourages individual knowledge and facilitates a valued personal autonomy. It does so partly by enhancing the direct use of a natural product and partly by avoiding the involvement of experts, hierarchy, and technology. While it is subtle, there is a strategic function for which nature is employed in the use of NHPs: the respect for the integrity of nature serves as a

constraint on technological intervention in the product, which also constrains institutional control of the production and use of the products. Regulatory officials and stakeholders described nature in terms of an amalgam of relationships, at the core of which is an absence of excessive incursions of authority and control. The established value of NHPs as being free from intervention protects NHPs themselves from such intervention and stakes out a social domain that is free of the social relations of highly institutionalized technological products. Many of those who are politically oriented towards individual freedom from institutional authorities recognize that natural health products constitute a social arena in which that demand may be viable. They use the relative freedom to sell, buy and use NHPs as a vehicle to express that political stance.

The objectives and provisions of the NHP Regulations are conducive to building and sustaining public trust in the products and their regulations. First, and perhaps foremost, their safety and quality are assured by the risk assessment regime of which consumers are largely unaware. Second, responsibility for the integration of the products in society and for their safe use by consumers is shared, rather than delegated entirely to experts and institutions. The extent to which the products penetrate the market and society is determined by the choices of individual consumers. Information about the substances in the products is widely available and usage advice is required on each product package. Not only is the introduction and management of the products shared, but their regulation is more transparent, so that those functions that are delegated can be monitored.

While trust is recognized by all participants as important, there is not a strong

sense of distrust - of the products, the motives of the industry, or the regulatory regime. The consumers interviewed essentially ignored the regulations, preferring to rely on their own knowledge and networks of advisors, even though they approved of the presence and the intent of the regulations for society more generally and certainly benefit from the risk control that is performed.

It is of course directly relevant that the products are natural - at least they bear little enough technological intervention that they are considered natural - as this in itself suggests that they raise a minimal concern for risk. It is also important to consider, however, the social characteristics that this naturalness implies, and which are reflected in the environment established by the industry and the regulatory regime. The combination of health safety regulation with a degree of individual control in the use of the products, validation of cultural approaches, and the ability of individuals to evaluate the products and monitor their control supports a relatively relaxed confidence in the products that results in a lack of concern for their control. A consumer of NHPs may delegate some, or much, responsibility in using a product, and may choose to balance and verify this delegation by as much scrutiny as he or she considers necessary.

The NHP Regulations have their detractors - one industry participant interviewed complained that their implementation has not been successful and that NHPD has been far too slow in issuing guidance documents, and some sectors of the industry demand much less regulatory control. Nevertheless, they been able to align the basic definitions and objectives to support the expectations of both industry and users.

The NHP regulations point to the practical possibility of choosing a less

conventionally narrow scientific approach to risk regulation. They also show, however, the necessity for a favourable political and social context in which the substances or activity are regulated. In particular, the convergence of industry and public, or consumer, needs and expectations allows a set of regulatory objectives and terms that are supportive of all parties, and are thus consistent and open. In the case of NHPs, the human handling of natural products is supportive of the natural potential of the plant and of the relationship the consumer has with it. Risk assessment protects consumers from fraud and hazardous products; and labelling rules ensure that full information about the product is offered, calming suspicions about a hidden corporate agenda.

An additional observation from the social environment of NHP regulations, observed in both survey research and the research interviews, is the individual autonomy and freedom to exercise personal competence in informed decision making that users value. They also value the ability to have a direct relationship, complete with demands for knowledge and responsibility, with an independent, unowned, and active nature. Social intervention that supports that objective is taken lightly and does not contaminate or degrade nature, or reduce it to the end of nature. In fact the social interventions that are carried out on NHPs are necessary in order to ensure the safety that permits such autonomy; they filter out those natural substances that are too hazardous for consumer self-selection, and protect against the social risks of fraud and processing contamination than the hazards of the natural substances. The remaining field of natural products is one that consumers feel they are able to manage.

Naturalization, purification and separation are largely absent from this consumer

and regulatory context, perhaps because there is little appropriation and transformation of nature into proprietary technology and hence little need to reconstruct the process and the product as natural, employed for the public good. These regulations, because they balance risk control with consumer choice, are able to support the industry as well as facilitate strongly valued individual relationships. They function within a context that does not inspire critical scrutiny of major technologies implemented by large corporations with a set of objectives and outcomes that are inconsistent with social values. This situation is characterized by a reasonable level of public comfort with the product, its use in society and of vigilance of its regulation; accordingly, consumers appear to have a relatively uncritical confidence in the products and their quality.

Chapter 11

Conclusions

This analysis of the regulation of GM foods and NHPs in Canada strengthens insight into social nature, risk, trust and regulation. The analytical framework brings together research threads that have focussed on social controversy over technological risk, trust in risk regulation, and the politics of the use of risk assessment in technology policy and management. These research fields have generally proceeded independently; however, the current approach that integrates the findings sheds more light on some persistent questions, such as the factors that lead a technology to become socially contentious, even when risk levels are estimated to be low; and the essential links between perceptions of risk and trust, and between trust and risk regulation. Addressing these questions through the analytical framework aids our understanding of normative assumptions of nature and culture in modern society, and the active way in which constructed categories of nature and society are used to justify social relations and, more selectively, to defend them. More specifically, this analysis outlines the manner in which the social dynamic of controversial technologies develops and is sustained.

This analysis reveals that the 'crisis of trust' in the regulation of GM foods derives in part from the neoliberal drive to promote the technology through the use of strategic interpretations of nature and risk in the regulations. This regime has not been entirely successful in quelling concerns about GM foods and their regulation: government will need to accept a more politically realistic understanding of trust and public expectations if it is to improve the legitimacy of that regime.

The integrated analytical framework

The integrated framework identifies the important characteristics of a technology, linking those that are intrinsic to the technology with the philosophical, economic, political and social context that combine to shape the regulatory dynamic of the technology. A regulation theory approach is used to trace the network of institutions and other arrangements in place to support an industry, and which are aligned with a specific policy and ideological framework (Purcell, 2002; Palan, 2006). This tracing distinguishes those situations that are socially complex and are likely to engage the contentious politics of risk, trust and nature, and suggests the factors that link the components into a coherent cluster.

The framework argues that the aggressive transformation of nature, justified by the modern concept of nature as morally empty raw material, that drives economically dynamic modern society also increases social complexity. The economic development is usually achieved with technology, planned and optimized by scientific risk rationality, which is taken to be socially neutral. From the ecocentric perspective taken by critics and many in the public, however, risk is essentially equated with technology, as they both embody the elements of social complexity that accompany technology (Beck, 1999). This social complexity is managed, to a degree, by social trust, which holds in tension the general delegation by citizens of challenging functions to experts and elites, against the maintenance by those citizens of evaluation and monitoring (Barber, 1983; Kaspersen et al., 1999). As delegation facilitates the process of further innovation, it is desired by proponents - industry and government who work to implement further

innovative technologies under a neoliberal agenda that holds economic growth to be a primary priority of national governments (Conference Board of Canada, 2005).

Government plays a key social trust function in carrying out regulation to reduce and manage the risks of the activity and implicitly to sanction it as a public good. Public scrutiny, however, delays, constrains and limits such innovation, and is consequently resisted by governments - by, for example, naturalizing the technology or the product (Latour, 1993; Plumwood, 2005). Adoption of a particular definition of nature and risk, and the application of risk in regulation, are the main means by which this naturalization is achieved.

Applying the integrated framework to a study of the regulation of GM foods and NHPs in Canada builds a contextual profile of each regulatory regime. This profile identifies the social function of the technology in society, and the roles of nature, risk and social trust in supporting that function and in shaping the social reception of the technology and subsequent regulatory responses.

The regulatory context of genetically modified foods is intensely complex and socially challenging, and invokes a demand for public attention and close monitoring. GM foods are proprietary products that serve as an excellent vehicle for very assertive capitalism: the industry is dominated by a handful of powerful transnational corporations, which have established themselves as primary inputs in the agricultural industry chain (Kloppenborg, 2004). They are heavily supported by national governments through, in the case of Canada, \$637 million a year committed to research and development, a multi-departmental network that oversees innovation policy,

agricultural policy, regulatory policy, and patent law that has been revised to permit patents for the products of biotechnology (CBAC, 2006a; BIOTECanada, 2007; Canada, 2002a; Industry Canada, 2006). Regulation formally emphasizes public health protection even while risk evaluations, which consist of a review of company data for assurance that the product meets the procedural milestones of familiarity and substantial equivalence, impose a minimal regulatory burden on companies (RSC, 2001; Barrett and Abergel, 2000). These national efforts are linked to international networks, such as industry groups, which have agreed on standards for risk evaluation and regulation, agricultural practices and other processes, and associations of scientists in the research community, establishing and strengthening expectations for assessment protocols (OECD, 1993; WHO, 2005; ISAAA).

Public acceptance of GM foods has been low, and there is widespread concern about their long-term health and environmental impacts and moral implications, their almost exclusive orientation towards economic performance and corporate profitability, without clear benefits for the public, and about the apparent inadequacy of regulatory management of these factors (Decima, 2006; Pollara-Earnscliffe, 2003). The public expects more evaluation and monitoring of these products, which proponents resist in the interests of avoiding delays, limits or additional costs to implementing the technology (Decima, 2006).

NHPs, being consumer products that rely on individual purchases, do not offer the economic opportunities that GM foods do. They have only minimal potential for patenting; the industry consists mostly of small, local or national companies, and it has

little international dimension (Decima, 2005; McCutcheon and Fitzpatrick, 2004; Dionisio, 2001). The regulations were designed to meet objectives that were established in the Canadian context, and the regulatory regime is different in Canada than in other countries (WHO, 2003; European Parliament, 2002; FDA, 1995). There are few other federal government organizations involved in the industry, and links from the regulatory regime run to other relevant regulations and standards. The industry and regulation are supported by several public health information sources to guide consumers on safe use of the products, and beyond this small network are a number of organizations of natural product producers or enthusiasts (Public Health Agency of Canada, 2006b; CAMline, 2005; IN-CAM; CAMera; Ontario Herbalists Association). The products, the industry and the regulation do not raise public risk concerns or demands for ongoing monitoring, and consumers are increasingly choosing to use NHPs (Ipsos-Reid, 2005). The value in the products' naturalness implicitly limits modifications to them, and thus also limits social control and ownership, and the escalation of complex social relations around the products.

This analysis of the factors that shape the dynamics of technology regulation describes the way that sometimes apparently contradictory elements of a regulatory regime are brought together to meet policy objectives of that regime. It also establishes a basis for the detailed comparison of the policy objectives, and public expectations, of different regulatory regimes, the ways in which those objectives may be met, and the ways that these factors affect the regime's manner of addressing public expectations for risk regulation.

Risk and technology

The second area of interest that is illuminated by considering regulatory environments in the terms of the analytical framework is that of risk. This analysis shows that an important distinction between the regulatory and the public interpretations of risk is the different aspects of the concept and practice of risk on which each perspective chooses to focus; it also shows that the regulatory approach to risk is inherently favourable to the implementation of technology.

The divergence in focus on risk leads to the major difference between technical and public risk judgements: public judgements often disregard the assessed risks to health and safety in giving higher priority to value concerns (Canada, 2001a; Hammitt, 2000), while technical regulatory risk assessments exclude the social impacts and implications of the technology from consideration.

Risk society theorists (Beck, 1999; Giddens, 2002), broadly echoed by much of the general public, are primarily concerned with risk as decision and action in situations of uncertainty. This focuses on the decisions through which risk shapes and justifies technology, and identifies risk almost categorically with the social relations of large-scale technologies. It also links the technical application of risk to a neo-liberal economic policy framework in which technology is promoted as a driver of innovative growth. Public risk concerns are thus more accurately described as concerns about the contextual implications and impacts of technology as it functions in society.

As with their focus on nature, scientists' focus in risk is on the components and mechanisms involved in generating the probability estimate of a specified event. In

incorporating elemental components and probabilities, but not the social relations of decisions to implement technologies, technical risk is culturally aligned with modern economic rationality. A stronger bias towards innovation and economic growth has recently been embedded into the concept of risk, through the recent articulation of risk as a concept and a systematic process that supports the taking and management of risk, rather than its avoidance. (Canada, 2001). Applying risk assessment in its most basic technical terms can sanction the implementation of technology without being explicitly employed to serve that purpose.

A regulatory regime can use definitions based on scientific risk to further exclude the consideration of wider impacts of a technology, which public critics consider are intrinsic to risk as the full context of technology. The contextual issues that are excluded through the logic of technical risk are the social relations at the heart of the technology, for proponents as well as for critics; their exclusion favours the proponents by eliminating criticism. Despite the insistence that the interest of risk assessment is confined to the calculation of health risks (Health Canada, 2000a), in practice risk assessment is used as a primary decision-making tool for the achievement of many corporate objectives (Canada, 2001; OAG, 1999).

The functional link between risk and the implementation of technology in society is evident in the regulation of GM foods. Through the risk evaluation, the Novel Foods Regulations approve GM food products for sale, and eliminate the social relations aspects of the technology from consideration; this assessment is the basis of the decision to approve a product. Risk is used as an apparently neutral means to justify the minimal

assessment process that GM foods must undergo, making risk assessment a key operational means by which regulation acts as a support and facilitator of GM foods rather than a constraint. Despite the grounding of this interpretation of risk in scientific definitions, however, it is evident from the viability of the NHP Regulations that it is not inevitable that risk assessment be applied in such narrow terms, or that it exclude consideration of contextual issues. It is perhaps also not optimal, as suggested by the public response to the restrictive scope defined for the Novel Foods Regulations.

Risk is a crucial element of the mode of regulation that supports the implementation of technology in a neoliberal economy, and a key means of achieving purification, by which moderns “bracket off entirely the work of hybridization, . . . of not thinking at all about the consequences of their innovations for the social order” (Latour, 1993: 41). When the elemental, non-contextual terms of risk are used to naturalize a product, those consequences are removed from view in the regulatory domain.

The strategic functions of social trust

The third important advance arising from this research concerns the function and the employment of social trust. Rather than conceiving of trust as a single social phenomenon, even if it is composed of a number of psychological components (Belanger et al., 2001), or as a commodity that facilitates societal-scale activities (Conference Board of Canada, 2005), it is helpful to understand it as an active operation of the two components of delegation and scrutiny. Instead of an insufficient supply of a basic

social commodity, it is a dynamic shaped by proponents' need for a delegation of responsibility and public desires to maintain ongoing scrutiny to evaluate and moderate the activity (Barber, 1983; Taylor-Gooby, 2006; Roese, 2002).

First it is useful to note that the function of social trust in the management of increased complexity is invoked very strategically in those situations that are perceived as high risk - those in which the degree, or pace, of social complexity is deemed excessive, or the activity is considered to have little general social benefit, by enough members of society that momentum builds for more openness, information, and opportunities for effective participation. Social trust is a central and urgent concern among proponents of GM foods (CBAC, 2006b). In contrast, natural health products, a small industry dependent on individual consumer purchases of products that are not perceived as risks, do not raise the sense that greater attention is needed (Health Canada, 2005b).

In the active function of social trust, where attention is maintained to control innovative growth, the two aspects of trust may be engaged purposefully and differentially. Proponents of GM foods clearly recognize that greater critical attention from the media and the public, due to widespread concern about the technology, would put a brake on the degree and pace of innovation that they could achieve (CBAC, 2006b; CBAC, 2003). It is also recognized, however, that democratic legitimacy must be retained by government regulation, and for government policy (Canada, 2003b; Purcell, 2002). The path traced in the development of the Novel Foods Regulations and risk evaluation protocols shows a concern to gain the delegation function of trust, but

perhaps even more to cut the amount of scrutiny that is possible, and ultimately that is desired. The regulatory regime for GM foods was designed to increase the level of trust - interpreted as a quantity in short supply - through visible references to commitments to public health and safety and internationally credible risk assessments (Canada, 2006b; Canada, 2003b). What is less visible is that the risk assessment process and risk management regimes are designed so that they selectively reduce the public attention that is possible to social relations aspects of GM foods - the area of public concern.

The strategic manipulation of the two functions of trust in order to gain an advantageous balance without losing legitimacy employs the authoritative concept of nature. That is, naturalization is used to evade social scrutiny of challenging, or otherwise questionable, actions in society. This naturalization is achieved through the risk assessment process with narrow technical definitions of nature and risk applied to the key regulatory principles of novelty and substantial equivalence. This naturalization is consolidated through the broader description of the process of genetic modification as effecting a change that is biologically similar to those that occur in nature, and as being continuous with - even in the spirit of - traditional plant breeding practices in use since time immemorial (Health Canada, 2006c; BIOTECanada, 2007b; ASAAA/AFIC, 2001). The ultimate point, it would seem, of the naturalization of a product - in the case of GM foods, a product that has been carefully designed and produced in order to be declared no longer natural but clearly an artefact and private property - is to avoid the scrutiny of the products as lucrative industrial commodities by repositioning them as natural. As such, GM foods not only offer the familiar and wholesome associations of natural foods,

but are stripped of the contentious social relations that prompt the demand for greater monitoring (Food Biotechnology Resource News, 1999; Sagoff, 2001). Thus the identification of the products as belonging in the nature category is reinforced by a restriction of access to information and processes that tie the products to the social relations that motivate their development.

Restricting consideration of social factors relevant to the regulation of GM foods is resorted to in part because the modern public is educated and confident, and persist in their assessment of the industry and the proper democratic process (Kneen, 1999; Mendelsohn, 2003; Priest et al., 2003). In addition, the definitions of nature that serve to justify different aspects of GM foods in society are themselves different, and at times inconsistent, and open recognition of this would undermine the arguments. This inconsistency appears to derive from the strategic character of the separate institutions that manage facets of the industry, and adopt the definition of nature that serves the purpose in that context, and for the audience engaged in it.

Multiple narratives of nature

The recourse to naturalization as a means to gain trust and avoid scrutiny of social relations links to the fourth major lesson to be taken from this analysis, that the modern concept of nature is multi-dimensional and malleable enough to support different interpretations, balances and emphases in different social contexts. The modern concept of nature, most broadly conceived, posits a category of nature that is separate from human culture and society, and a category of society that has emerged to be free

from the limits of nature, and sets its own course largely through its increasing control of nature. This concept offers considerable latitude in the interpretation of the character of each category, the location and permeability of the boundary between them, and the relationship and balance between the two categories. The social dynamics of NHP and GM foods regulation engage different models of nature, and use them in different ways for different purposes.

The regulatory environment for NHPs is based in a concept of nature that is roughly shared by all participants, and that tolerates a certain variability in the meaning of nature and messiness in the firmness of boundaries (NHP-R, 2007; NHP-S, 2006, 2007). The values that motivate consumers of NHPs are shared by producers and supported by the NHP Regulations. The use of NHPs is motivated by a respect for the autonomy of nature and preference for cooperative practical uses of nature. Particularly for those who use NHPs, nature has agency, intrinsic value, and a deep evolutionary relationship with humans that can give it healing power. These beliefs about nature are related to disapproval of the use of chemicals in farming and of dependence on industrial and corporate agriculture. This does not imply that all users consider nature to be benign or benevolent: all those interviewed recognized that plants and natural substances can harm people, and had adopted a position of respect.

The process for the risk control of the products was designed to incorporate cultural knowledge of, and experience with, traditional health products into conventional scientific risk assessment. Regulatory officials noted that their scientific assessment of the health risks of the products does not conflict with their recognition of the culture in

which a product may be meaningful. In accommodating these diverse frameworks, the NHP regulations do not insist that only the molecular properties of a plant are relevant to its regulation, or that scientific knowledge alone can offer credible information. Nature is seen as complex and multidimensional, affected by both ecological processes and cultural context. Science is used in risk assessments and to contribute an important component of knowledge, but not to exclude other knowledges and contextual concerns (NHP-R, 2006; Health Canada, 2006b).

The larger and more complex and contentious environment in which GM foods are set includes several different nature narratives, some of which conflict directly with others. The Novel Foods Regulations use a pared-down, modern vision of nature as definitive only at a molecular level, regardless of ecological process or human interventions (Health Canada, 2006; Miller, 2006). This is the definition of nature that enables and justifies the aggressive social transformation of nature in the first place, by presenting an array of inert, amoral physical resources controlled by a separate society; it is also this definition of nature that underlies the scientific definition of risk that is used in formal risk assessments and management.

The regulatory definition of nature functions at all levels to authorize a narrow focus on the health risks of the physical product, relative to its conventional counterpart. This concept of nature is the basis of substantial equivalence, the regulatory standard by which GM foods are declared not only safe enough to be used in Canadian food, but as essentially natural. It relies on a definition of nature that does not consider ecological evolutionary adaptation, ecological settings, or biological reproductive patterns. The use

of this vision of nature and its embedding in risk assessment readily achieves the restricted framing of GM foods as essentially traditional foods grown naturally, which have a change in composition due to modern technical agricultural techniques that is insignificant to consumers. This definition is so narrow as to be not entirely internally coherent, because the natural category is ontologically and morally secondary to the social category, to which all agency and moral consideration belong; yet, in constructing its framing of GM foods the regulatory regime focusses on the characteristics of nature and dismisses as irrelevant the social intervention that created them.

A second definition of nature that is essential to the marketization of GM foods is that used in patenting, which assesses GM foods from a conceptual framework that is directly contradictory to that of regulation, and comes to a directly opposite conclusion on the products themselves (Krmisky, 1991; Jasanoff, 1995). To qualify for a patent a product must be recognized as no longer within the realm of nature; if it is not so recognized it would be a discovery, which may not be patented. A patentable product must be a social invention, with enough ingenuity involved and change created that the result may be considered a new entity that earns the developer proprietary rights to its use. This is the essential function that lends GM foods the potential to be such powerful vehicles for capital growth, and for corporate consolidation in the industrial food chain (Durrell and Gold, 2007; Niosi and Bas, 2004).

A third nature narrative, that identifies GM foods with natural food plants and genetic engineering with traditional plant-breeding practices, is crucial within the GM regulatory environment. This narrative, while not formally grounded in authoritative

institutions like law (such as patenting), or science (as regulation is), but it is nonetheless widely used in communications with the public. This is the identification of GM foods with natural food plants and genetic engineering with traditional plant-breeding practices. This definition relies loosely on the scientific declaration that GM plants are substantially equivalent to traditional plants, but unlike the model of nature that underlies much of science and regulatory logic, it also includes biological processes and styles of human intervention (BIOTECanada, 2007b; Council for Biotechnology Information, 2007). GM foods are thus described as just like natural food crops because they contain genetic combinations that, while they do not exist in nature, are very like those that do; and because they grow in the ground like other crops (Health Canada, 2006c; ISAAA/AFIC, 2001). This perspective is a matter of personal interpretation of the essential properties of nature, as many scientists (Lurquin, 2002; Nottingham, 2003; Perry, 2003; Clark, 1999) point out that the difference between natural and GM plant reproduction processes is a categorical one, and insist that the social intent and design of GM plants are intrinsic and definitive.

The public naturalization of GM foods is completed through an identification of their development and production with traditional farming techniques (Monsanto, 2006; CFIA, 2003a). Biotechnology is said to have begun with early agriculture with the development of wine fermentation techniques, and to be continuous with the selective breeding practices that produced the many varieties of plants (and animals) adapted to many different environments and humans needs over many centuries. The comparison is extended to an emphasis on the small family farmers who choose to grow GM crops,

both in the industrialized and undeveloped regions of the world (ISAAA, 2007; Monsanto, 2004).

It is evident that the patenting and regulatory uses of nature, being part of traditions that have developed their own sets of terms and founding assumptions, are applied within their respective domains and may not transfer easily to others (Sherman and Bently, 1998; CBAC, 2001). Still, it is clear that all three nature narratives are biased towards authorizing and facilitating the exploitation of GM food crops for private capital accumulation and national economic growth. The ultimate effect of the three narratives applied in their own niches is that collectively they form a broad-based support system for the industry that secures the market potential of the product through patenting, public sanction and risk control by regulation, and its wider framing in public communications by government and industry alike.

The selective application of a nature narrative for its authority in a given institutional situation points to the very strategic and instrumentally constructed character of the GM food regulations. The fragmented and inconsistent approach to nature in different aspects of this regime could be a liability to the gaining of public trust, but is managed by the procedural habits of constricting the terms of discussion relevant to regulation, and maintaining a disciplinary and administrative separation between regulation and patenting. This ensures that, as Latour (1993) says, moderns can purify the categories of nature and society so that they do not need to think about the consequences of their transformations of nature and the implications of the hybrids they produce.

Strategy in Canadian risk regulation decision making

This analysis has argued that the concepts of risk, trust and nature are intrinsically linked and combine in a regulatory regime in a way that is specific to the characteristics of the technology context and the social dynamic of the regulation. From the perspective of each regime, we can thus see that these concepts coordinate to achieve the policy objectives for the regime.

It is primarily within the Novel Foods Regulations that risk, trust and nature are employed strategically to achieve objectives that diverge sharply from those that are stated explicitly. The GM foods regulatory environment is strongly oriented towards enhancing the industry's potential for capital accumulation, creating a dynamic in which the pressure for innovation and development are challenged by public expectations for more thorough evaluation and monitoring. The strategic character of the GM foods regulatory regime stems from the need to support innovation but also to gain public trust by visibly controlling the technology; these incongruous objectives result in a strategic regulatory regime that is marked by a number of inconsistencies.

Throughout the evolution of the food biotechnology industry and the gradual establishment of approaches to its regulation, public and interest group opposition to the industry grew. This public opposition was recognized as an obstacle to the growth of the industry and to the commitment of public resources to support it, and became a factor that had to be managed by regulation (Krimsky, 2001; Gottweiss, 1998). The determination to follow through with the initial policy of encouraging the development of agricultural biotechnology in the face of widespread international opposition led to

the emergence of a strategic approach to the regulation of GM foods that would discourage further negative attention and pressure (CFIA, 2005d). The formal risk regulation of GM foods, as the institutional mediator of public interaction with government on the social management of an activity, turns largely on retaining political legitimacy while avoiding or diminishing the public scrutiny that brings the impacts and social relations of the technology into open consideration.

The GM foods regulatory regime is couched publicly in terms of earning trust and meeting democratic expectations of participation and public protection (CFIA, 2001b; Health Canada, 2006c). However the actual definitions and provisions of the regulation do not serve to satisfy these conditions for social trust. The risk regulation provisions have been criticized repeatedly as inadequate for ensuring protection because they adopt a definition of substantial equivalence that minimizes risk assessment (RSC, 2001; Andree, 2006), and use evaluation methods that do not meet scientific standards (Barrett and Abergel, 2002). Rather than meeting expectations for public participation, the regulations exclude the social associations of the technology and its evaluation from consideration in regulatory proceedings. Virtually all of the decisions and functions related to GM foods are relegated to expert and professional bodies, out of sight and beyond the influence of the public who consume them. There is little ground for the development of social trust in the technology or its regulation.

Despite its grounding in science, this strategic naturalization is a politically unstable position. The maintenance of the naturalized risk perspective requires efforts to keep the debate within the designated terms as opponents repeatedly bring wider

concerns to the debate. These concerns are dismissed, through consultations that may not incorporate comments on ethical and social issues (CFIA, 2002; Health Canada, 2003e), isolating policy and debate on patenting from those on regulation (CBAC, 2002b), and denying that GM food products should be labelled (Canada, 2004).

This strategic approach has itself become a focal point of the political contest over the management of GM foods in Canada. The struggle is centred around critics' efforts to keep the technology in the social domain in order to debate its social impacts and relations, against government efforts to naturalize it and remove those social affiliations from sight and influence. The regime thus requires a complicated and strategic regulatory machinery to distance it from the contentious social relations that are driving forces of the industry.

The Natural Health Products Regulations were designed to provide access to safe and effective products that consumers want to use, respecting freedom of choice and cultural diversity (Canada Gazette, 2003). The provisions of the NHP regulations are aligned to achieve those objectives, and are internally consistent. The main practical task of the NHP Regulations is the risk control of those products that are deemed safe for consumer self-selection, and the provision of risk information on product labels to assist the consumer in selecting the proper product and using it safely. The regulations select out those products and substances with a high risk profile, and ensure the safety of others through a graded risk assessment and quality-control process, and full product information for consumers (Health Canada, 2004c).

The other major objective of the NHP Regulations is to incorporate the

information requirements and terms for evidence of efficacy in different cultural and medical contexts. This requires an ability to accommodate a range of non-scientific rationalities to the use of natural health products along with the scientific assessment of risk. Regulatory officials noted that this cultural recognition does not conflict with proper scientific assessment of risk (NHP-R, 2006; Health Canada, 2006b).

The straightforward and consistent NHP regime has allowed those regulations to achieve the inattentive public confidence to which GM foods regulators aspire. While monitoring is facilitated by the provision of product information and adverse event reporting, it is also made less urgent by the general approval of the products and shared responsibility for their use. The absence in this regime of neoliberal objectives that run counter to public social values and priorities frees it also from the need to meet corporate needs while appearing to give precedence to public protection and democratic principles.

The utility of a constructed nature-society duality

The constructed nature-society dualism in modern society has strong social and economic utility that is essential for a neo-liberal regime in which the transformation of nature for capital accumulation is a high priority (Smith, 2002; Lee, 1999). The fundamental utility of the strict separation of nature as an independent category of mechanistic resources devoid of agency, integrity, and moral standing or value is that it presents no intrinsic barrier to the instrumental modification, use and control of nature by humans. To complete the relationship, the attribution to human culture and society of all agency, moral consideration, and capability for rational self-direction gives society

the right to use nature to improve its own conditions (Brown, 2004).

Ecocentrists' more equal balance to nature and society highlights - by opposing - the enabling effect that a normatively separate and subordinate nature has on the possibility of exploiting nature, and the link between social relations and the manner of conceptualizing and using nature. Ecocentrists' nature has intrinsic value that humans should respect, and agency and even wisdom that are valuable to society when they are intact and not degraded by social interventions (Soper, 1995; Myskja, 2006). Those uses of nature that are respectful and do not attempt to subvert or control it do not appear to violate any boundaries; NHPs are considered to retain their value as natural products even though they have been prepared and processed for consumer use. The concept of nature that supports the regulation and use of NHPs is relatively flexible and forgiving of those interventions that respect the integrity of nature and the agency of the natural product itself. The fact that the value of an NHP is in its intact natural agency, for the consumer and hence for the industry (McCutcheon and Fitzpatrick, 2004), imposes a limit on the amount of processing and institutional control it can absorb without becoming an artefact and an industrial commodity. The pressure to respect those limits to the exploitation of nature acts as an external guarantor of a relatively low-complexity society.

In controversial situations, as in the regulatory approval of GM foods, the allocation of the products to either the natural or social category is a highly charged matter, as the meaning associated with each category fixes the identity of products that are socially contentious. At this point a separate category of nature is a necessary

expedient for proponents of those activities whose social relations exceed the tolerance of society, as it enables a strategic naturalization of the activity. This naturalization avoids the challenge to inequitable social relations that could require modification of the activity, its social impacts and implications, or its environmental impacts (Soper, 1995; Plumwood, 2003). A GM food, for example, is contentious as a patented industrial product whose owner has rights of commercial benefits and exclusion, and raises concerns about the private appropriation of nature and the increased inequality it facilitates (Sharratt, 2002). As a social product it exists in the social domain and is subject to evaluation, criticism, moderation and monitoring. Once naturalized its identity is fixed as simply a food like any other that evokes no more concern than any other food with regard to its environmental or health impacts, or suspicion of its social associations.

Those who remain attentive to the social relations of a product also rely on their characterization of it as a social product: it does not qualify as natural, and it has essential associations of the social that should be evaluated. An ideal concept of the natural serves as a normative template against which the ambiguously and contentiously social can be discerned, revealed and openly debated.

A society that is driven by increased complexity and differentiation through the transformation of nature will continue to need a normative nature-society duality. It will also continue to exploit that duality in strategic naturalization, as an expedient for avoiding social resistance to such complexity and transformations of nature.

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Appendix 1

Information for Potential Interview Participants in Research on Trust in the Regulation of Genetically Modified Foods and Natural Health Products

Interview participants are sought to take part in a study of the level and type of public trust involved in the regulation of genetically modified foods (GM foods) and natural health products (NHPs) in Canada. The research is being carried out by Anne Wiles, a doctoral student in the Department of Geography and Environmental Studies at Carleton University, under the supervision of Dr. Kenneth Torrance of that department. This study will form part of Ms. Wiles's doctoral research and dissertation.

Public trust in risk regulation has become a prominent concern in risk regulation, and has been suggested as the key to persistent public opposition to many industrial technologies that risk professionals assess as posing lower risk than many natural risks that people tolerate. The hypothesis is that beliefs about nature in modern Western society underlie conflicting attitudes to risks from different sources, and shape trust in regulation. This research will probe the way regulatory professionals and non-scientists participating in the regulation of NHPs and GM foods in Canada construct ideas of nature and characterize these products as natural or as technological, and what these designations mean to different participants. It will also examine how those characterizations relate to assessments of the risks and benefits of those products, and how participants conceive of trust in risk regulation.

This research should shed light on debates and controversies over technology development and risk control, enabling an assessment of the appropriateness of regulators' strategies to gain public trust. It will also give insight into modern attitudes to nature and the importance of attending to the ways in which they may be expressed in social and political life.

Approximately 10 participants involved in the regulation of each of GM foods and NHPs, and 10 participants from stakeholder groups or members of the public who participated in regulatory decision making processes for each product will be interviewed. Interviews will be one-on-one, and will take about half an hour. Interviews will be structured around the discussion of the research questions, but participants will be encouraged to elaborate on the issues and the broader context for expectations of risk regulation. Participants will be asked about basic concepts of nature, whether they consider GM foods and NHPs to be natural or technological, and their assessment of the risks posed by these products. They will also be asked about their understanding of trust as it applies to risk regulation, and participants from each group will be asked to comment on their understanding of the other group's position on the risks of and regulatory controls on both sets of products concerned. Challenges in meeting diverse regulatory objectives are also relevant to the study. Opinions expressed will be understood as those of participants and not as the position of their organization.

If participants agree, interviews will be tape-recorded and transcribed to written form, and the original tape recording returned to the participant or destroyed. Note-taking

will be used for interviews with participants who do not wish to be tape recorded. If necessary, a follow-up contact may be made to clarify points made in the original discussion.

Participants will be offered anonymity in the report, and will be identified only by their professional and organizational affiliation, as is necessary for the research question, with no identifying details noted. Information that may identify participants, such as signed consent forms, will be stored separately from transcripts of interviews so that comments cannot be linked to participants. Once transcribed, tapes will be destroyed or returned, and transcripts will not contain the name of the participant. Data will be stored in the researcher's home office, and will be retained, if participants agree, for five years following the completion of the research to support further study.

Discretion in the field will be respected, but anonymity in the field may be difficult to maintain in a small office and when participants are referred by a primary contact in that office. Participants may specify that their comments not be quoted directly but be paraphrased, so they may not be traced back to them, and may refuse to answer any question. Interviews are expected to be conducted in the participants' place of work as most convenient for them, but an alternative location may be selected if the participant chooses. Taking part in interviews will expose participants to minimal risk. Participation is voluntary, and no information is sought on personal matters or on relationships among colleagues in organizations.

No remuneration will be offered to participants in this study. However, participants will be offered a summary of the research findings, which may be of interest to those in both the regulatory institution and stakeholder groups, as trust in risk regulation has become an important objective of regulatory institutions. Participants may be notified of the publication of the dissertation or other publications using the data. There may be no other benefit to participants.

This research has been reviewed and approved by the Carleton University Research Ethics Committee. Participants who wish to withdraw from the study may contact the researcher. Participants who have questions or concerns about their involvement in the study may contact the ethics committee chair, at the following address.

Professor Antonio Gualtieri, Chair
Carleton University Research Ethics Committee
Carleton University
Ottawa, Ontario K1S 5B6
1125 Colonel By Drive

Anne Wiles, researcher

Dr. Kenneth Torrance, supervisor

Informed Consent Form

I have been invited to participate in an interview as part of a research study carried out by Anne Wiles, doctoral candidate in the Department of Geography and Environmental Studies at Carleton University, under the supervision of Dr. Kenneth Torrance of the same department. This study is part of Ms. Wiles's doctoral research and will be published in her doctoral dissertation. This study concerns the level and type of public trust involved in the regulation of genetically modified foods (GM foods) and natural health products (NHPs) in Canada.

Interviews will be one-on-one, and will take approximately one half-hour. The interview will take place in my place of work, unless an alternative location is more convenient for me. If I agree, the interview will be audio-taped and later transcribed; otherwise, notes of the interview will be taken.

I agree to be audio recorded and have the interview transcribed at a later date.

I do not wish to be audio recorded but agree to the researcher taking notes of the interview.

I will be asked to describe my understanding of nature, whether I consider GM foods/ NHPs to be natural or technological, and my assessment of the risks posed by these products. I will also be asked about my understanding of trust as it applies to risk regulation, and to comment on my understanding of public / stakeholders' / regulatory institutions/ position on the risks of and regulatory controls on both sets of products concerned. Interviews will be structured around the discussion of the research questions, but I will be encouraged to interpret the issues and to elaborate on my understanding of them and the broader context for expectations of risk regulation.

The information I provide and the opinions I express in the interview will be anonymous; this letter, once signed, will be stored separately from the transcript of the interview, and the transcribed tape will be destroyed or returned to me. The researcher will store the data in her home office, to which there is minimal access from outside individuals. If I agree, the researcher will retain the data for five years following the completion of the research to support further study.

I agree that the data that I provide may be retained by the researcher for five years following the completion of the research.

I do not agree that the data that I provide may be retained by the researcher for five years following the completion of the research.

The interview may be conducted away from my workplace if I prefer. Published

references to my comments will be identified only by my organizational affiliation, and if I so specify, may be paraphrased rather than quoted to prevent the discovery of my identity.

_____ **I agree that comments I make in this interview may be quoted directly in the report.**

_____ **I prefer that comments I make in this interview be paraphrased and not quoted directly in the report.**

My comments will be understood to reflect my personal opinions and not the position of my organization.

There are no risks to me foreseen by the researcher in my participation in this study, and I understand that all reasonable steps have been and will be taken to protect my confidentiality. I understand that my participation is voluntary, and that I may withdraw and refuse to answer any questions. If I withdraw, I will decide at that time if the researcher may use the data I have provided to that point or destroy the data.

I will be provided with a summary of the study results if I wish, and will be notified of the publication of other papers and the doctoral dissertation based on this study if I request.

If I have questions about my participation in this study, I may contact the researcher or her academic supervisor, Dr. Kenneth Torrance.

Name: _____

Date: _____