CANADIAN AGRICULTURAL BIOTECHNOLOGY:
Risk Assessment and the Precautionary Principle

by

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Date November 11/99
ABSTRACT

Crops developed through recombinant DNA techniques (known as “genetically modified”, “genetically engineered” or here, “rDNA crops”) are currently grown on almost 3 million hectares in Canada and almost 30 million hectares world-wide. While proponents claim rDNA crops will increase yields and reduce chemical inputs, critics point to potential environmental hazards such as gene escape, increased weed problems, non-target effects and greater reliance on chemical-based agriculture. Since the early 1980s the Canadian government has actively promoted agricultural biotechnology both through specific biotechnology “strategies” and through broader financial incentives and research programs. This promotional effort sought to boost the national economy by creating an internationally competitive and innovative agricultural sector. By the late 1980s, pressure from government, industry and (to a lesser extent) the environmental community prompted Agriculture Canada to develop regulations for agricultural biotechnology that would simultaneously provide assurance of environmental safety while encouraging continued development of the industry. The resulting policy framework—“science-based risk assessment”—has subsequently been used to demonstrate that rDNA crops are “safe”. However, data used in risk assessments are generated by crop developers and are not publicly available. Detailed evaluation of the risk assessment for herbicide tolerant canola (obtained through the Access to Information and Privacy Act) revealed significant shortcomings in the depth and breadth of questions, methods of inquiry, analysis of data, and plausibility of conclusions. I contend that closed policy-making procedures among like interests, and long-term prior commitments to agricultural biotechnology by government and industry has fostered a risk assessment framework based primarily on economic and technical considerations. While policies derive
legitimacy from a proclaimed "scientific" basis, in practice, the risk assessment is too narrow to encompass the complexities of releasing rDNA crops into ecosystems or the marketplace. More specifically, value assumptions embedded in current risk assessment policies constitute a significant barrier to implementing the Precautionary Principle, a legal and ethical framework which emphasises anticipatory action, development of alternatives and recognition of uncertainty. Effective environmental protection will require a broader decision-making framework (including definitions of "sound science") and wider participation. One means to achieve this goal is to encourage and reward long-term, interdisciplinary and participatory research within academic institutions.
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ABBREVIATIONS

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>AAFC</td>
<td>Agriculture and Agri-Food Canada</td>
</tr>
<tr>
<td>AC</td>
<td>Agriculture Canada</td>
</tr>
<tr>
<td>ATIP</td>
<td>Access to Information and Privacy Act</td>
</tr>
<tr>
<td>CBI</td>
<td>Confidential business information</td>
</tr>
<tr>
<td>CBAC</td>
<td>Canadian Biotechnology Advisory Committee (under CBS)</td>
</tr>
<tr>
<td>CBS</td>
<td>Canadian Biotechnology Stately (Canada, 1998; replaced NBS)</td>
</tr>
<tr>
<td>CEPA</td>
<td>Canadian Environmental Protection Act</td>
</tr>
<tr>
<td>CFIA</td>
<td>Canadian Food Inspection Agency</td>
</tr>
<tr>
<td>GTC</td>
<td>Monsanto’s term for glyphosate tolerant canola (line GT73 and in some cases line GT200)</td>
</tr>
<tr>
<td>GT73</td>
<td>One line of Monsanto’s Roundup-Ready herbicide tolerant canola</td>
</tr>
<tr>
<td>GT200</td>
<td>One line of Monsanto’s Roundup-Ready herbicide tolerant canola</td>
</tr>
<tr>
<td>HT</td>
<td>Herbicide tolerant</td>
</tr>
<tr>
<td>HTC</td>
<td>Herbicide tolerant canola</td>
</tr>
<tr>
<td>MOSST</td>
<td>Ministry of State for Science and Technology (Canada)</td>
</tr>
<tr>
<td>MRC</td>
<td>Medical Research Council (Canada)</td>
</tr>
<tr>
<td>MRL</td>
<td>Maximum residue limit</td>
</tr>
<tr>
<td>NAS</td>
<td>National Academy of Sciences (US)</td>
</tr>
<tr>
<td>NBAC</td>
<td>National Biotechnology Advisory Committee (est. under NBS)</td>
</tr>
<tr>
<td>NBS</td>
<td>National Biotechnology Strategy (Canada, 1983; replaced by CBS, 1998)</td>
</tr>
<tr>
<td>OECD</td>
<td>Organisation for Economic Cooperation and Development</td>
</tr>
<tr>
<td>P x C</td>
<td>Probability multiplied by consequences</td>
</tr>
<tr>
<td>PMRA</td>
<td>Pest Management Regulatory Agency (Health Canada)</td>
</tr>
<tr>
<td>PNT</td>
<td>Plants with novel traits</td>
</tr>
<tr>
<td>rDNA</td>
<td>Recombinant DNA</td>
</tr>
<tr>
<td>SSC</td>
<td>Science Council of Canada</td>
</tr>
<tr>
<td>S&amp;T</td>
<td>Science and technology</td>
</tr>
<tr>
<td>STS</td>
<td>Science and technology studies</td>
</tr>
<tr>
<td>SE</td>
<td>Substantial equivalence</td>
</tr>
<tr>
<td>WCCRRRC</td>
<td>Western Canada Canola and Rapeseed Recommending Committee</td>
</tr>
</tbody>
</table>
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CHAPTER ONE

Overview:
Thesis Outline And Literature Review

1.1 THESIS OUTLINE

1.1.1 Problem Definition

Many technologies of the late twentieth century promise great benefits yet also threaten unprecedented harm. The dynamic and contentious balance among these potential outcomes—and the many uncertainties that lie in-between—has become a hallmark of our current technological age. Indeed, some commentators have argued that ours is an entirely new kind of society, one permeated by unknown technological risks, and therefore in need of radically different methods of decision-making (Beck 1992b; Giddens 1990; Lau 1992). Biotechnology well illustrates the dilemma: Among the promises of more secure, bountiful and healthful food supplies, lie threats of large-scale, irreversible, and uncontrollable environmental damage. Decision-making about such technologies must grapple with the unknown and the unknowable, and must remain effective despite pervasive scientific, political and ethical contention.

Science has long held an authoritative role in decision-making about technology, society, environment and health. Such authority is often grounded in the purported objectivity and predictive capacity of the “scientific method”, i.e. hypothesis formulation and testing via observation and experimentation.¹ Yet compelling explanations for the special status accorded to scientific knowledge remain elusive and hotly debated. In the past thirty or so years, the authority of “sound science” has been ratified in the form of “risk assessment”

¹ Appropriate definitions of “science” is one of the main themes of this dissertation. I use this definition here because it best defines the general approach to “science based risk assessment” as conducted by both the plant biotechnology industry and government.
approaches to identifying, mitigating and/or managing environmental and health hazards.

More recently, science-based risk assessment has attained unparalleled standing in national and international policies on agriculture, trade and environment, among others. However, at the same time (although in different circles), the traditional authoritative role of science is being called into question. Sociological and philosophical studies of science have argued persuasively that science is a thoroughly value-laden process, and hence scientific knowledge is in part a product of individual, social, cultural and political circumstances. While this view neither intended nor achieved complete devaluation of scientific knowledge, it has raised important questions about the adequacy and appropriateness of strictly science-based decisions for highly uncertain, ethically sensitive and politically charged issues.

In response, political scientists and sociologists have advanced new styles or arenas of scientific inquiry. For example, in his near classic paper Alvin Weinberg coined the term “trans-scientific” to describe questions “which can be asked of science and yet which cannot be answered by science” (Weinberg 1972). Weinberg argued that public policy entails such trans-scientific questions and therefore cannot and ought not rely on “the usual institutional mechanisms of science” but rather should be settled through political and/or adversary processes. Several years later, Funtowicz and Ravetz (1985; 1992) proposed the term “post-normal science” to account for both the factual and value dimensions of scientific inquiry, and specifically to demarcate situations where facts are uncertain, values are in dispute, stakes are high and decisions are urgent. According to these authors, “normal” or applied science is inadequate in such cases; “something extra must be added onto their practice which bridges the gap between scientific expertise and a concerned public” (Funtowicz and Ravetz 1992). A number of similar terms such as “policy-relevant science” (Jasanoff 1990) and “mandated science” (Salter 1988) have been put forward to describe the type of science
conducted under, or required by, situations which are clearly political and ethically contentious, yet scientifically uncertain. All of these authors question the role science plays in policy making, and particularly whether “normal” science is effective and appropriate in such cases, or whether a different type or standard of scientific inquiry is needed. None, however, have fully articulated what an alternative type of science might entail.

These critical issues—the role of science in policy, decision-making for uncertain technological hazards, and the ability of science to address complex environmental issues—have coalesced under the umbrella of the Precautionary Principle. Formulated almost thirty ago, the Precautionary Principle has since become enshrined in over twenty declarations and treaties on the environment, many of which Canada has signed and ratified. In recent years, precaution has gained strength as a framework of environmental law and ethics, and has been applied to issues such as sustainable development, marine pollution, fisheries management, climate change and biotechnology. The Precautionary Principle states that when there are threats of serious or irreversible damage, lack of full scientific certainty should not be used to postpone measures to prevent environmental degradation. By advocating action in spite of scientific uncertainty, the Precautionary Principle has been rejected by some as an alarmist, unscientific, anti-scientific, or outright irrational basis for decision-making. Supporters of the principle, on the other hand, claim that precautionary measures require more, not less science—albeit science of a different, currently ill-defined, kind.

Thus, interpretation and implementation of the Precautionary Principle as a formal decision-making principle and reconciliation of precaution with current science-based policies on the environment, have become urgent, complex and highly contentious problems. These processes will turn on definitions of “good science”—definitions which are no longer under the exclusive purview of the scientific community. Rather, boundaries delimiting
scientific and non-scientific factors are currently negotiated among government, industry and non-government organisations. The outcome will bear on how products are traded, which technologies are “safe”, and which hazards are considered truly harmful. It is imperative that we carefully consider how—and by whom—such definitions are constructed and supported.

1.1.2 Case Study: Canadian Policies for Agricultural Biotechnology

I will address the above issues using a case study approach. Specifically, I will examine the process by which the Canadian federal government assesses the environmental hazards of agricultural biotechnology. To date, Canada has approved the unconfined release of over thirty crops produced through biotechnology. I have focused my study on the first of such decisions, the 1995 approval of a new variety of herbicide tolerant canola (HTC). The rationale and methods for case-study analysis will be discussed in Section 1.2. Here, I will provide a brief overview of the current status of agricultural biotechnology world-wide and within Canada.

Definitions

Debate over the safety and risks of “agricultural biotechnology” and “genetically engineered”, “transgenic” or “genetically modified” organisms is long-standing and ongoing. As yet, however, there is little consensus on how these terms are used, or the range of technologies they encompass. Proponents frequently argue that “biotechnology” is nothing new, that in fact brewing beer, making bread and selectively breeding crops are forms of biotechnology used and accepted for thousands of years. From this perspective, “genetic engineering” is simply a more precise form of a very old (and, it is implied, benign) technology. Needless to say, critics do not support this view but tend to distinguish the entire
process of “biotechnology” from “conventional” agricultural techniques, often using the terms genetic engineering and biotechnology synonymously. Such variations in emphasis and definition have important implications for evaluating risk and developing appropriate regulations. In fact, as will be discussed in Chapter 2, much of the risk debate turns on the question of whether or not “new” biotechnology is significantly different to warrant unique environmental and health legislation. Despite the breadth and variability of definitions, in terms of agriculture, the technology most often in question is the use of recombinant DNA (rDNA) techniques to transfer small segments of genetic material (usually one or two genes) from one organism to another. For example, the Canadian government has adopted a very broad official definition of biotechnology: “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”. Yet to date, most of the “novel” crops which have been regulated and approved for environmental release were developed through rDNA techniques. There is, in other words, an important if implicit distinction made between organisms developed through rDNA techniques and organisms developed through other conventional or biotechnological processes, despite broad definitions which suggest otherwise. These issues will be discussed more fully in Chapter 2.

To address the problem of appropriate and unambiguous definitions throughout this dissertation, I will use the terms “rDNA crops”, “rDNA organisms” and “biotechnology” to refer to the products of rDNA techniques specifically. Other terms such as “genetic engineering” or “genetically modified” will be used when quoting or summarising other sources, and will be defined as necessary.
Current Status of Agricultural Biotechnology

The first deliberate release of rDNA crops took place in the mid 1980s in the United States and France. Within a decade (1986-1995), over 3500 field trials were conducted in 34 countries using at least 56 different crops (James 1997). Commercial scale, unconfined releases began in the early 1990s in China, but gained wider publicity with the approval and commercialisation of the “Flavr Savr” delayed-ripening tomato in the US in 1994. Canada followed in 1995 with the approval of two lines of herbicide tolerant canola. World-wide commercialisation of rDNA crops has risen dramatically since 1995: 1.7 million hectares in 1996, 11.0 million in 1997 and 27.8 million in 1998.¹

Herbicide tolerant (HT) crops are the most prevalent and one of the most controversial rDNA crops on the market.² In 1998, herbicide tolerance was engineered into 71% of rDNA crops planted world-wide including soy, cotton, corn and canola (James 1997; James 1998). The rationale behind HT crops is straightforward: plants are engineered to withstand applications of non-selective herbicides such that all unwanted plants (weeds) are killed and only the crop survives. Among the claimed benefits of HT crops are (1) increased use of more “environmentally friendly” broad-spectrum herbicides; (2) use of “post-emergent” herbicides (applied after crops have emerged from the soil) thereby encouraging low-till, soil conserving practices and judicious herbicide application; (3) better overall control of weed problems because herbicides can be applied throughout the growing cycle; and (4) secured markets for patented herbicides (see Krisky and Wrubel 1996; Monsanto nd; Wilcut et al. 1996). Many of these claims, however, are only weakly supported—often through data generated by HT crop developers themselves. Opponents have countered that HT not only perpetuates reliance on unsafe and unsustainable chemical herbicides, but may actually increase weed and pest problems through persistence of HT crops in fields, spread of
HT crops to non-agricultural settings, flow of the HT gene to related wild crops and indirect effects on non-target organisms (see discussion in Chapters 3 and 4).

Types of rDNA crops currently approved for human food, animal food and/or environmental release in Canada are listed in Table 1.1. Herbicide tolerant canola accounts for over 85% of all rDNA crops grown in Canada: 2.4 million hectares of HTC—60% of the canola crop—were planted in 1998 (James 1998). Overall, Canada is the world’s third largest producer of rDNA crops (next to the US and Argentina) growing 2.8 million hectares in 1998. These numbers reflect a rapid and heavy investment in biotechnology both by the canola industry and Canadian government. In fact, international and domestic acceptance of rDNA canola is now crucial to the economic viability of Canada’s agricultural sector. During the 1997-98 crop year, Canada exported almost 600,000 tonnes of canola oil, 1.5 million tonnes of meal, and close to 3 million tonnes of seed (CCC nd). While domestic and most foreign markets for canola have grown in the past decade, there are signs that Canada’s commitment to biotechnology may have been premature: The European Union has responded to citizen’s concerns about the safety—and need for—rDNA crops by drastically cutting Canadian and US imports in 1997 and imposing an effective moratorium on commercialisation of rDNA crops in 1999. As a result, Canadian canola seed exports to the EU dropped from almost 1.2 million tonnes in 1994/95 to 11,000 tonnes in 1997/98 (CCC nd). Similarly, US corn exports to the EU plummeted from almost 70 million bushels in 1997 to fewer than 3 million in 1998 (Anon1999b). Although expression of public concern in North America pales in comparison to full-scale protests abroad, increased media attention, recent public forums and the federal government’s new “Canadian Biotechnology Strategy” (see Chapter 2) suggest that public acceptance will be the next hurdle for Canada’s biotechnology industry.
TABLE 1.1  
"PLANTS WITH NOVEL TRAITS" APPROVED BY THE CANADIAN FEDERAL GOVERNMENT

<table>
<thead>
<tr>
<th>CROP TYPE</th>
<th>ENGINEERED TRAIT</th>
<th>NUMBER OF APPROVED VARIETIES</th>
<th>TYPE OF APPROVAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>canola</td>
<td>herbicide tolerance</td>
<td>9</td>
<td>H,A,E</td>
</tr>
<tr>
<td></td>
<td>altered oil properties</td>
<td>2</td>
<td>H,A,E</td>
</tr>
<tr>
<td></td>
<td>pollination control &amp; herbicide tolerance</td>
<td>2</td>
<td>H,A,E</td>
</tr>
<tr>
<td>tomato</td>
<td>delayed ripening</td>
<td>3</td>
<td>H</td>
</tr>
<tr>
<td>potato</td>
<td>insect resistance</td>
<td>2</td>
<td>H,A,E</td>
</tr>
<tr>
<td>corn</td>
<td>herbicide tolerance</td>
<td>8</td>
<td>H,A,E</td>
</tr>
<tr>
<td></td>
<td>insect resistance</td>
<td>3</td>
<td>H,A,E</td>
</tr>
<tr>
<td></td>
<td>herbicide tolerance &amp; insect resistance</td>
<td>3</td>
<td>H,A,E</td>
</tr>
<tr>
<td>soybean</td>
<td>herbicide tolerance</td>
<td>1</td>
<td>H,A,E</td>
</tr>
<tr>
<td>flax</td>
<td>herbicide tolerance</td>
<td>1</td>
<td>H,A,E</td>
</tr>
<tr>
<td>cotton seed</td>
<td>herbicide tolerance</td>
<td>2</td>
<td>H,A,E</td>
</tr>
<tr>
<td></td>
<td>insect resistance</td>
<td>1</td>
<td>H,A,E</td>
</tr>
<tr>
<td>wheat</td>
<td>herbicide tolerance</td>
<td>1</td>
<td>A,E</td>
</tr>
<tr>
<td>squash</td>
<td>virus resistance</td>
<td>2</td>
<td>H</td>
</tr>
</tbody>
</table>

i. These are varieties of rDNA crops that have been through a risk assessment process. Many derivatives of these varieties have been registered in Canada but have not been assessed in terms of environmental risk. See Chapter 3, Section 3.6.

ii. H=food safety; A=animal feed safety; E=environmental safety

iii. Wheat and 3 varieties of corn were developed using non-rDNA techniques

iv. Animal feed and environmental safety for one variety currently under review

Current to March 1999
Adapted from CFIA (nd-b)
1.1.3 Thesis Structure

Based on the problem definition and case-study outlined above, the following questions, thesis statements and goals will structure the main arguments of this dissertation.

**Thesis Questions**

(1) What concepts of risk underlie and guide government risk assessments for rDNA crops?

(2) How were these concepts developed and how are they maintained?

(3) What is the role of science in government risk assessments?

(4) Are Canada's policies on biotechnology consistent with the Precautionary Principle?

(5) What barriers exist to implementing the Precautionary Principle in a manner that achieves its stated goals?

**Thesis Statements**

(1) Canada's policies on biotechnology are primarily guided by technical and economic priorities which are reflected in dominant concepts of risk.

(2) Risk-based policies are supported by a definition of science too narrow to encompass the complexities of agricultural biotechnology.

(3) Decision-making processes have been weighted in favour of industry interests and have excluded effective public dialogue.

(4) Narrow definitions of science and exclusive decision-making processes constitute serious barriers to implementing the Precautionary Principle.

**Research Goals and Contributions**

I aim to address the above questions and theses, through the following research goals:
(1) Trace the history and development of Canadian policies for agricultural biotechnology focusing on environmental regulations for rDNA crops.

(2) Examine how these policies are implemented by evaluating the data and decision-making process for a specific risk assessment.

(3) Identify and analyse key social and political factors that have shaped decision-making, defined concepts of risk, and presented obstacles to more precautionary approaches.

(4) Recommend procedural and substantive changes that would render decision-making for rDNA crops (and other potentially hazardous technologies) more consistent with the Precautionary Principle.

Thus, my primary goal is not to advance or defend an ethical argument for employing the Precautionary Principle over other decision-making frameworks. While I do support the general principles of precaution, I assert that we need to analyse more closely the social and political construction of decision-making and the strategic use of science in environmental ethics and policy. I take as a starting point the growing prevalence of the Precautionary Principle and Canada’s commitments (both explicit and implicit) to varying degrees of precautionary action. My interest is in how claims to “science-based risk assessment” and “safe” technologies are shaped by dominant ideas, institutions and interests (Section 1.2) and how these factors may preclude adoption of particular ethical principles. This is, in other words, a political and sociological approach to applied ethics.

The primary contributions of this dissertation derive both from the specific case study—a potentially hazardous technology currently in the Canadian marketplace—and from the possible application of my conclusions and recommendations to other similar technologies. This research should be of interest and use to a broad range of readers: government policy-makers who wish to improve decision-making processes and
accountability; scientists who are concerned about the way science is defined, applied and portrayed outside the immediate scientific community; social science researchers who tackle more academic questions about the social construction of scientific knowledge and authority, and the role of the Precautionary Principle in challenging these boundaries; the private sector who is well aware of the power of science, and should be equally informed about the Precautionary Principle; non-government and environmentalist organisations who advocate the Precautionary Principle; and members of the “general” public who, with increasing assertiveness, are claiming their right-to-know about environmental hazards and the decision-making processes that affect their lives.
1.2 METHODS

1.2.1 Theoretical and Analytical Framework

Scope of Framework

I have adopted an interdisciplinary framework to address the complex set of issues outlined in Section 1.1. This is an intentionally broad-brush approach rather than a specialised analysis through the theoretical or methodological framework of a single discipline. I contend that this approach is necessary—at least initially—to capture the breadth of issues raised by biotechnology or any potentially hazardous technology that also challenges political commitments and ethical values. As I will discuss in Chapter 4, failure to adopt a broad perspective is in fact the single most important shortcoming of current risk analyses for rDNA crops. Ideally, this type of project should be continued by a multi-disciplinary team of researchers who can bring specialised knowledge and experience to individual areas. With this in mind, the present dissertation functions somewhat like a "project plan", detailing the history and current status of the problem, identifying barriers to alternative goals and directions, and setting a course for future research and action.

Study of policy-relevant science obviously requires analysis of both the policy and the science, as well as the social context in which politics and science are brought together. This type of research intersects the fields of policy analysis and natural sciences, as well as the relatively new field of "science and technology studies" (STS), which encompasses philosophical, sociological and cultural studies of science. My research also draws on the field of applied ethics, as risk analysis and the Precautionary Principle are grounded in, and have profound effects upon, broad ethical principles such as efficiency, justice, equality, respect and responsibility. To be insightful and practical, an analytical framework for policy-relevant science must therefore be broad enough to bridge several disciplines, yet selective
enough to avoid becoming mired in the hundreds of theoretical constructs advanced in these various academic fields. To this end, I have adapted a general framework often used in public policy analysis which examines the role of "ideas", "interests" and "institutions" in shaping policy content and implementation. Many policy analysts focus on the influence of one of these factors, while recognising that all three are critical, interrelated determinants of policy choice. The following sections explain how ideas, interests and institutions are currently used to structure policy analysis, how similar frameworks are employed in STS, and how this framework will inform my study of Canadian risk assessment policies for agricultural biotechnology.

The "Ideas-Interests-Institutions" Framework in Policy Analysis

• Ideas: While the influence of ideas on individual, social and political behaviour has been a topic of study for several centuries, the use of ideas as a tool for public policy analysis has gained renewed emphasis and status in the past few years. For example, Doern and Phidd (1992) maintain that "core ideas of major institutions directly affect policy formulation especially the processes of policy-making". The authors distinguish four categories of ideas to assist analysis of such effects. In order of decreasing breadth:

(1) Ideology is "an umbrella of belief or action that helps provide political and social identity to its adherents and that serves to integrate and coordinate their views and actions on a wide range of political issues". In this context, ideologies are the broad "isms" in politics such as liberalism, socialism and conservatism. In ethics, utilitarianism, contractarianism, and deontology would also fall under the umbrella of ideology.

(2) Dominant ideas "embody a particular preference in a given policy field" and include such familiar concepts as efficiency, equity, equality and individual liberty. These ideas are
“dominant” because they are enduring and tend to permeate all policy fields, yet as any political or ethical debate well illustrates, dominant ideas are often in conflict (e.g. efficiency versus equity) and therefore require constant negotiation and re-prioritisation.

(3) *Paradigms*, unlike “dominant ideas”, are usually associated with a particular set of policies, and the specific experts and bureaucrats who institute these policies. Within this context, paradigms function as “a series of principles or assumptions that guide action and suggest solutions” (Doern and Phidd 1992).

(4) *Specific Objectives* delineate the direction of a particular policy and express preferred policy goals. Objectives are less entrenched than ideologies, dominant ideas, or paradigms and are therefore often the point of explicit debate.

**Interests:** Analysis of interests is often central to both public policy and applied ethics research. In fact, Pal (1992) suggests that there is often a tendency to explain *all* decisions in terms of “naked self-interest” thereby underplaying the role of institutional structures or cultural context. Such criticism notwithstanding, interests obviously play an important role in shaping individual and collective choice. One way to investigate this influence, is to map the relationships among interested parties who directly or indirectly affect policy-making. To this end, Pross (1992) distinguishes “policy networks” and “policy communities”. A community “is that part of a political system that has acquired a dominant voice in determining government decisions in a field of public activity...by virtue of its functional responsibilities, its vested interests, and its specialised knowledge” (Pross 1992). Policy communities can be further divided into two segments. The “sub-government” includes government agencies and institutionalised (sanctioned) interest groups, who have direct influence and established roles in policy making. This segment is usually very small
comprising "representatives of the few interest groups whose opinions and support are [deemed] essential" (Pross 1992). The second component of a policy community is the so-called "attentive public". Less formal, organised or sanctioned, the attentive public includes those groups and individuals who are affected by, or have a keen interest in a particular policy issues, and who attempt through various means to follow and influence decision-making. The attentive public exerts its greatest influence when the relatively static workings of the sub-government are fractured, thereby creating an opportunity for further disruption and change.

Many factors determine who has access to the more effective and intimate inner circle of the sub-government, and who is relegated to the ad hoc attentive public. The concept of a "policy network" helps tease out these factors. Whereas a policy community includes all actors involved (or attempting to become involved) in a given policy field—essentially a list of relevant players—a policy network describes the relationships among like and opposing interests within a community. Networks of shared interests often unite around a specific issue in order to shape policy direction and content. The concept of a policy network thus conveniently links the "interests" and "institutions" elements of my analytical framework in that interactions among some interests are supported by entrenched political institutions, while other interactions are effectively discouraged.

- **Institutions**: As the above discussion suggests, in terms of policy analysis, "institutions" refers not to specific tangible organisations, edifices or groups of people, but to the structure of government and the system of rules used to maintain, legitimise and/or change that structure. "Institutions can be thought of as configurations or networks of organisational capacities (assemblies of personal, material, symbolic, and informational resources available
for collective action) that are deployed according to rules and norms that structure individual participation, govern appropriate behaviour, and limit the range of acceptable outcomes” (Atkinson 1993a; paraphrasing Scharf 1989). A recent resurgence of institutional approaches to policy analysis has fostered many studies of strong Canadian institutions such as federalism, the constitution and parliamentarism. Coleman and Skogstad (1990) have applied an institutional approach to the study of political ideas and interests, arguing that “the preferences and values of policy actors are shaped fundamentally by their structural position. Institutions are conceived as structuring political reality and as defining the terms and nature of political discourse”. The authors outline a number of institutional associations among political actors, ranging from open pluralist networks among several state actors and interests groups, to relatively closed corporatist or “concertation” relationships involving a single government department and one or two well-positioned interests. These institutional networks will be further discussed in terms of the Canadian biotechnology policy community in Chapter 4.

Thus ideas, interests and institutions cannot easily be separated and analysed independently; they are closely related and often tightly bound. Hoberg (1993; 1996) has emphasised the need to examine all three parameters as a “package” by advancing the concept of “policy style”. A policy style embodies particular ideas, includes and excludes certain interests, and functions through specific institutions. Policy-making runs most smoothly when ideas, interests and institutions are ‘in sync’ and mutually reinforcing. Moore (1998) describes this confluence as “enabling circumstances” for specific policy directions.

While few would claim that ideas, interests or institutions have a causal role in public policy, several authors have argued that these concepts do serve critical function by exerting a general screening effect. That is, they set boundaries around legitimate questions and help
“screen out” unacceptable solutions (Doern and Phidd 1992). This process forecloses other options and directions for change, and adds further legitimacy to already dominant ideas, interests and institutions. For example, Moore (1998) states: “Among the factors potentially contributing to an idea’s salience are its ability to pre-empt, exclude, or limit the credibility of other ideas” (see also Pal 1992; Weir 1992). Mapping a policy community can illustrate whose interests are being heard in policy-making, whose are excluded, and the dynamics and outcome of these relations. Atkinson (1993a) sums the screening effect of ideas, interests and institutions by examining “access points” in policy-making: “institutions create decision processes with a limited number of access points. Generally speaking, the fewer the access points, the narrower the range of interests that will be accommodated and the fewer the options [ideas] that will be entertained”. The processes through which boundaries are built around legitimate ideas, interests and institutions, and the concomitant processes by which “access points” to effective participation are constructed or blocked, are therefore key to effective and insightful public policy analysis.

Related Frameworks in Science and Technology Studies

Analytical frameworks in STS are seldom as rigorous, well defined or explicitly delineated as in policy analysis. Few STS writers, for example, clearly articulate ideas, interests, institutions as analytical tools. Nevertheless, these concepts permeate almost all STS research. Perhaps most famously, Kuhn (1970) examined the way in which “paradigms”—variously described shared assumptions, generalisations, values and exemplars—determine the relevance, direction and conclusions of everyday science. Writers such as Habermas (1970) and Marcuse (1964) hold that science is itself an ideology used to buoy already dominant ideas and power structures. Institutional analysis has also figured
largely in STS. An early example is the work of Robert Merton, particularly his classic essay, "The Normative Structure of Science" (Merton 1942 (1973)). Merton was concerned with the norms—rules or structures—of science that maintain its functional role in society. In current STS, the "Mertonian norms" of universalism, communism, disinterestedness, and organised skepticism are rarely considered an accurate or even desirable portrayal of the way science functions. Nonetheless, Merton's work has fostered ongoing research into other organising structures of scientific practice such as peer review, authorship and publication, reward systems, and the dynamics within and between specialised disciplines. STS has since shifted away from overtly ideological (as in Habermas or Marcuse) or institutional (as in Merton) approaches to focus more on the actual content of science: the ideas, interests and institutions that sanction some scientific endeavours and ostracise other. "Actor network theory" has garnered tremendous support in this regard. Most thoroughly explained in Latour's Science in Action (Latour 1987), actor networks bear some resemblance to policy communities but extend the conditions of membership beyond human beings to include inanimate objects and abstract concepts. Indeed any entity that has some form of agency—the ability to act upon other members in the network—plays an important role. The function of a network as a whole is to articulate the interests of scientists (or their proponents) in terms of the interests of the larger community, thereby stabilising the scientists' work as necessary and valid. While useful, analytical frameworks such as actor network theory tend to get bogged down in the micro-politics of the scientific community while ignoring the larger socio-political context stressed in earlier studies. The pendulum is swinging back, however, as "cultural studies of science" re-examine questions of power relations both within science and between science and the larger community (e.g. Haraway 1997; Proctor 1994; Yearley 1991). This short overview does not do justice to the diversity and complexity of STS.
theories, but aims to demonstrate that similar analytical approaches are employed in both STS and policy analysis, and the relevance of my general ideas-interests-institutions framework to both fields.

One analytical tool which very effectively bridges these disciplines and concepts is Thomas Gieryn’s notion of “boundary work” (Gieryn 1983; 1995; 1999). Boundary work examines how a broad array of influences, including various actors, interests and structures internal and external to the practice of science, demarcate science as an institution unto itself—separate and distinct from other social institutions such as politics, law or business. This approach focuses less on the day-to-day workings of the scientific community, than on how the products of that work, scientific “facts” or “knowledge”, are held up to broader audiences such as the media and the public. In other words, boundary work examines how ideas, interests and institutions shape definitions of “good science” in variable ways, and the power such definitions can wield in different social and political contexts.

Application of the Ideas-Interest-Institutions Framework

I will use the above analytical framework to examine how boundaries have been constructed around concepts of “science” and “risk” in environmental assessment for rDNA crops in Canada. In particular, the literature review in Section 1.3 compares four concepts of risk (technical, economic, social and precautionary) that will function as key themes throughout this dissertation. Chapter 2 analyses the history and current status of biotechnology policy in Canada, highlighting the major influences that have supported or constrained policy options and defined dominant concepts of environmental risk. I will reserve detailed critical analysis of these policies until I have examined how biotechnology regulations are actually implemented in environmental risk assessment in Chapter 3. There I
evaluate data used to assess the environmental safety of herbicide tolerant canola in light of
government and industry claims to conduct “science-based” assessment. Finally, Chapter 4
blends concepts and methods from policy analysis and STS to synthesise and expand upon
conclusions of previous chapters, and to demonstrate how political and social factors function
as barriers to serious consideration of alternative environmental policies and contending
ethical principles.

The ideas-interests-institutions framework is therefore well suited to the scope and
goals of this dissertation, first because it bridges the fields of policy analysis, STS and
applied ethics, and second because it points to a broadly constructivist and critical
approach—supported by empirical studies and grounded in social/political context—that I
believe is necessary to fully address contentious and complex issues such as biotechnology.

1.2.2 Research Design and Information Sources

Why Case-Study?

There are several reasons why a case-study research design is an appropriate method
to address the larger questions of this dissertation. Most obviously, case-studies provide
detailed examples which lend depth and validity to the overall arguments. A topic as broad
as the relation among science, ethics and policy would be difficult to address convincingly
without the benefit of a case-study. I have provided a particularly detailed analysis of
environmental policies for rDNA crops in Canada, and a specific risk assessment conducted
for herbicide tolerant canola. This level of detail is necessary to understand and analyse the
role of science in policy because risk assessments are themselves conducted on a case-by-

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various rDNA crops (e.g. that they contain genes from other species, inserted through rDNA techniques). Indeed, critical discussions of agricultural biotechnology tend to speak in such generalities (Biosafety 1996; Hindmarsh 1991; Kloppenburg and Burrows 1996). However, I contend that case-by-case risk assessment demands, at least initially, case-by-case critique. To date, such an analysis has not been conducted outside government regulatory agencies primarily because risk assessment data are not made publicly available in Canada. The level of detail presented in this dissertation thereby provides an important illustration and empirical foundation for broader arguments regarding technological risk, precaution and the role of science in policy-making.

Why rDNA Crops?

In light of the above rationale for a general case-study approach, I offer several reasons why I have chosen the particular case-study of Canadian agricultural biotechnology, and HTC specifically. First, risks attributed to unconfined release of rDNA crops share characteristics with those posed by many new and contentious technologies. For example, potential harms are arguably unprecedented, irreversible and difficult to contain or trace to a single cause. The government’s decision to approve rDNA crops therefore raises serious ethical questions regarding fair distribution of risks, benefits, responsibility and blame. On the other hand, herbicide tolerant and other rDNA crops have been heralded as a safer, more natural alternative to chemical pesticides, and an environmentally friendly solution to world food shortages and ailing national economies. For these reasons, analysis of agricultural biotechnology is relevant to much current research on the politics, ethics and sociology of risk (see Section 1.3) and poses a good test for current interpretations of the Precautionary Principle.
A second reason for examining the Canadian decision to release rDNA crops is simply the growing urgency of this issue. Canada is currently the world's third largest producer of rDNA crops and has invested almost twenty years of research and development in agricultural biotechnology. To date, public debate about rDNA foods and crops in Canada has been surprisingly minimal, and as mentioned above no comprehensive policy or data analysis has yet been published. Yet there are signs the public concern is growing: increased media coverage; a recent Canadian "consensus conference" on agricultural biotechnology; growing involvement of established non-government organisations (NGOs) such as the Council of Canadians, Sierra Club and Oxfam; and unprecedented public protest. Coupled with an effective moratorium in the European Union, pressure on the Canadian government to revisit the potential hazards of rDNA crops is mounting.

Finally, herbicide tolerant canola was the first rDNA crop to be approved for environmental release in Canada. Because Canadian risk assessment protocols are based on the principles of "familiarity" and "substantial equivalence" (discussed in Chapter 2), such early decisions establish precedents and standards for further releases. Initial decisions, in other words, may allow fast-track approval of subsequent "substantially equivalent" crops. Furthermore, HTC is currently the most abundantly produced rDNA crop in Canada and herbicide tolerance is the most common trait in rDNA crops world-wide. It is important, therefore, to examine closely the rationale used to determine that release of HTC into the environment is "safe".

**Information Sources**

The main source of information for this study was primary, written documents. Current government documents were collected through a number of libraries, websites and
federal departments. However, many documents on early biotechnology regulations and
government meetings are now out-of-print. These were obtained directly from the regulatory
agency (through regulators who had worked on biotechnology issues since the early 1980s)
and through researchers who had previously collected such works. I did not employ a
"sampling" strategy for the document analysis, but attempted to obtain all available
government documents directly related to regulation of rDNA crops. I cannot claim my
sample was exhaustive, but based on cross-references and interviews, I am confident that the
data are comprehensive.

A second major source of written information was risk assessment data obtained
through the Access to Information and Privacy Act (ATIP). ATIP requests entail a written
letter to the relevant government department stating the type and extent of information
desired. The department has 30 days to respond, although retrieving and sending the
documents may take longer. Our first correspondence to Agriculture and Agri-Food
Canada (AAFC) in February 1998 requested risk assessment data for all rDNA crops
approved for environmental release at that time. AAFC responded (March 1998) with an
estimate of 14,000 pages and $2850 to fulfil the request and a recommendation that we
narrow our search. We subsequently revised our request (April 1998) to include 4 varieties
of herbicide tolerant canola. According to ATIP, this data was sent out for "third party
review" in early June 1998. We received the final data September 30, 1998. Fees were
waived by the ATIP office due to the length of time required to fulfil our request (P.
Scherling personal communication, 1998). Further details on the data released and withheld
are provided in Chapter 3, Section 3.3.1.

In addition to primary written sources, my research questions and data were informed
by a series of interviews conducted September 1997-September 1998. Interviewees included
academic scientists conducting risk assessment, Canadian government regulators and NGOs working on agricultural biotechnology issues. All of these interviews were face-to-face, semi-structured (based on pre-established questions but subject to variation depending on the interviewee) and open-ended (answers did not have a definite end-point). Initial interviews were tape-recorded but I found this was not an effective method for discussing contentious issues, and added undue strain to the conversation. Subsequent interviews were recorded through extensive note-taking. Additional information on specific issues was gained through personal communication with a number of researchers, regulators, industry representatives, NGOs and individuals involved in, or concerned about agricultural biotechnology.

A final source of information might be loosely termed “participant observation”. Throughout this research, I have attended many conferences, workshops and meetings on agricultural biotechnology issues. “Participants” at these events included government regulators, NGOs, industry, academic scientists and members of the general public. These events guided the direction and content of my research by vividly illustrating the arguments of, and dynamics among, key players in the biotechnology debate.

The diversity of information sources consulted for this study was necessary not only to document the regulatory process, but to understand its implementation and the variety of forces that have shaped biotechnology debates in the past few years. The breadth and depth of information, as well as the fact that I have discussed my findings with key players in the case study, adds to the validity of my final conclusions about the risk assessment process in Canada, and hopefully lends itself to a more convincing discussion of the larger issues. However, it would be contradictory to my overall thesis to claim this work is the final and absolute word on risk assessment for rDNA crops. I have presented a key piece of the puzzle—a piece which is necessary to gain a larger view of the relationship between science,
policy and ethics—but this does not in itself constitute the entire picture. Possible directions and methods for further research are presented in Chapter 4.
1.3 LITERATURE REVIEW: CONCEPTS OF RISK AND METHODS OF RISK ASSESSMENT

As discussed above, this dissertation draws on a wide range of literature and theoretical frameworks, including political science, STS and applied ethics. Rather than attempt a comprehensive literature review of each of these fields, in this section I will focus on concepts of risk. These concepts form an effective and very important link between science and policy through the practice of risk assessment. As such, concepts of risk form the overarching theme of my thesis, and permeate most debates on environmental and health hazards.

1.3.1 Risk Assessment as a Decision-Making Process

Conceptions of risk and methods of decision-making in unknown circumstances are arguably as old as human civilisation. Covello and Mumpower (1985) trace the first risk analysis to the Tigris-Euphrates valley in 3200 BC. The foundations of current risk analysis, however, were laid in the 16th and 17th centuries during the rise of capitalism and science, and later in the 18th and 19th centuries through the development of probability theory and statistical laws (Covello and Mumpower 1985; Hacking 1990). Such political and intellectual ideas fostered a keen interest in quantifying and ultimately controlling—or “taming”—uncertain events (Hacking 1990), and fundamentally altered the fields of insurance, engineering, demographics and public health, among others.

The practice of “risk analysis” as a professional discipline, particularly as applied to technological and environmental hazards, is a relatively recent development. Golding (1992) and Jasanoft (1987) attribute the rise of risk analysis in the US to health and environmental legislation of the 1970s. In fact, both Canadian and US governments (and others) had routinely performed risk analyses for potential toxins and carcinogens since the early 1970s.
The rise of the environmental movement later that decade, however, placed new regulatory demands on government and new predictive demands on science. Techniques used to analyse hazards in relatively closed systems were extrapolated to diffuse hazards in open systems (such as air and water quality), and to complex, large-scale projects (such as hydroelectric dams and nuclear power stations). While controversies over the "correct" methodology for carcinogen and toxics risk analysis are long-standing (e.g. see Harrison and Hoberg 1994; Jasanoff 1986), the challenge of environmental risk analysis heightened doubts and debates over the role of science in regulatory affairs.

A persistent theme in these disputes has been separation of the scientific process of risk assessment from the political process of risk management, and a correlative explicit or implicit separation of scientific and value-laden questions. Many publications on risk analysis divide the entire "analysis" into three stages: risk assessment, risk management and risk communication. Risk assessment is often further divided into hazard identification, risk characterisation, and risk estimation. According to "classical" (Brunk et al. 1992) or "naive positivist" (Shrader-Frechette 1991) views, risk assessment is a strictly "scientific" process, free of prescriptive statements or value judgements. The outcome of risk assessment is therefore a "purely empirical and mathematical" (Brunk et al. 1992) calculation often expressed as the probability of a hazard multiplied by the magnitude of the consequences (P x C). Only during the subsequent risk management stage, according to this view, are social and political factors legitimately brought into the decision-making process, and a measure of risk "acceptability" determined. In the final step, risk communication, analysts aim to convey their findings to other interested parties and the larger public in an accurate and comprehensible way.
In drawing strict boundaries around what is, and what is not a scientific question, the above account of risk analysis reveals as much about underlying conceptions of science as it does about notions of risk. That is, the classical view implies that science can and should maintain legitimacy by assuming an objective and disinterested position, effectively independent of social and political context. In this way, science gains the role of neutral arbiter, even within politically and ethically charged situations. This is a powerful role indeed. As stated by Brunk et al. (1992), by this view the “judgements that various persons and interest groups within a society make about the acceptability of risks...are more or less ‘rational’ depending upon how closely they approximate the ‘objective’ determination of risk done by scientific risk estimators”.

How predominant is this view of science and risk analysis in current policy-making? Harrison and Hoberg (1994) claim that while both US and Canadian regulatory authorities “purport to distinguish between risk assessment and risk management” in practice these processes are “not always sequential”. Similarly, through a case study of Canadian technology regulations, Brunk et al. (1992) have shown that both risk assessment and risk management are reciprocally influenced by the “value frameworks” of all involved parties. In the US, the National Academy of Sciences (NAS) commissioned a report in 1983 in part to study the feasibility and merits of separating risk assessment and risk management. According to Jasanoff (1987), the NAS conclusion that risk assessment is indeed influenced by policy considerations prevented this procedure from being institutionalised in the US. Nonetheless, the terminology used in the NAS report contributed to an influential albeit informal distinction between scientific processes of assessment and political processes of management by suggesting that the credibility of science lies in perceived value-neutrality: “Even the perception that risk management considerations are influencing the conduct of risk
assessment in an important way will cause the assessment and regulatory decisions based on them to lack credibility" (NAS 1983). Jasanoff (1987) concludes that the boundaries between risk assessment and risk management are fluid, and that US policy contains examples both of separation and fusion of these stages of risk analysis.

Despite, or perhaps because of this ambiguity, the role of science in policy-decisions remains powerful. I will return to the question of “boundaries” in Chapter 4 after looking closely at the specific case of rDNA crops and the concepts of risk and science that underlie and support policy decisions.

1.3.2 Theories of Risk

Division of risk analysis into distinct, specialised tasks, and choice of methods to fulfil those tasks, derive from—and can be rationalised by—underlying theories or concepts of risk. As Bradbury (1989) has argued, concepts of risk have profound policy implications. It is therefore important to examine the foundations and theoretical assumptions of current risk assessment strategies, and to trace their impact on decision-making processes. Such an analysis has not been conducted for biotechnology regulations in Canada, nor have the conceptual foundations of the Precautionary Principle been adequately compared to other theories of risk.

I will not attempt a comprehensive review of risk theory here (see Krimsky and Golding 1992 for a good introduction and overview). Rather, I will focus on several concepts of risk that are most relevant to the HTC case study, i.e. those actually employed in the HTC decision, and those that I will argue ought to have been employed. More specifically, I will examine four broad concepts of risk—technical, economic, social and precautionary—in terms of four characteristics of risk—reality of risk, role of science, normative framework
and methods. This somewhat idealised framework, summarised in Table 1.2, is not intended as a set of inviolable categories, but as a means of clarifying and comparing different approaches to technological hazard, and highlighting the political consequences of background assumptions.

Four Characteristics of Risk

(1) Reality of Risk: At the most general level, concepts of risk are grounded in assumptions about the reality of those risks (Renn 1992). A general distinction is often made between “realist” and “constructivist” views, although these terms carry a great deal of philosophical baggage and are neither definitive nor mutually exclusive (see Hess 1997). In fact, Hacking (1983) argues that such perspectives are best thought of as “attitudes” or ways of “thinking about the content of natural science” rather than strict doctrines. This seems a useful perspective for our purposes: working definitions of realism and constructivism provide tools to examine the assumptions which shape concepts of risk, and the implications of using these concepts in policies settings. I define “realist” theories of risk as those which imply that specific, identifiable hazards and risks are physical “real” components of technologies and activities. I define constructivism as the claim that hazards and risks are, to some extent, constructed through social processes, including the processes of scientific investigation and risk assessment. This position does not imply the complete absence of danger, or that all risks are mere perceptions. Rather, constructivism holds that the type and magnitude of danger is constructed through human (social) processes rather existing contiguously with a particular technology. This is an anti-realist stance which contends that risks do not simply exist as an intrinsic element of technologies; rather they are
TABLE 1.2
COMPARISON OF RISK THEORIES

<table>
<thead>
<tr>
<th>CONCEPTS OF RISK</th>
<th>REALITY OF RISK</th>
<th>ROLE OF SCIENCE</th>
<th>NORMATIVE FRAMEWORK</th>
<th>METHODS</th>
</tr>
</thead>
<tbody>
<tr>
<td>TECHNICAL</td>
<td>•realist</td>
<td>•expert-based</td>
<td>•analytical and prescriptive</td>
<td>•frequency estimations through:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>•high predictive ability of science</td>
<td>•standard setting; mitigation of consequences</td>
<td>-experimentation</td>
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<td></td>
<td></td>
<td>•uncertainties manageable</td>
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<td>-modelling</td>
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<td></td>
<td>-extrapolation</td>
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<td></td>
<td></td>
<td></td>
<td></td>
<td>-probability assessments</td>
</tr>
<tr>
<td>ECONOMIC</td>
<td>•realist</td>
<td>•usually expert driven</td>
<td>•prescriptive</td>
<td>•cost- or risk-benefit analysis</td>
</tr>
<tr>
<td></td>
<td></td>
<td>•uncertainty is recognised but calculations still possible</td>
<td>•utilitarian</td>
<td>•expected utility</td>
</tr>
<tr>
<td>SOCIAL</td>
<td>•constructivist</td>
<td>•examines power and legitimacy of science</td>
<td>•generally analytical or critical; some versions are prescriptive</td>
<td>•social, cultural and political analyses</td>
</tr>
<tr>
<td></td>
<td></td>
<td>•recognises ignorance and indeterminacy</td>
<td>•some versions advocate democratic process</td>
<td></td>
</tr>
<tr>
<td>PRE-CAUTIONARY</td>
<td>•not well examined or articulated; generally realist</td>
<td>•recognises limitations of, but retains vital role for science</td>
<td>•prescriptive and activist</td>
<td>•weighted cost-risk-benefit analysis</td>
</tr>
<tr>
<td></td>
<td></td>
<td>•generally focused on uncertainty; some versions recognise ignorance and indeterminacy</td>
<td>•often derived from principles of justice, and/or ecocentric philosophies</td>
<td>•maximin</td>
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<td>•participatory processes</td>
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<td>•proactive research</td>
</tr>
</tbody>
</table>

socially contingent and politically mediated. Constructivist perspectives will be discussed in more detail below.

(2) Role of Science: The realist-constructivist distinction is important because assumptions about reality bear on assumptions about knowledge, specifically the role of scientific knowledge. If risks are a part of the physical world, independent of say, individual perceptions and cultural conditioning, then the appropriate role of science is to uncover and evaluate these risks. Stated more generally, “scientific realism says that the entities, states and
processes described by correct theories really do exist” (Hacking 1983). In other words, the merit and validity of risk assessment is a function of accuracy in predicting real risks. Uncertainties, in this view, derive from insufficient data or knowledge but these temporary deficiencies can and should be identified and rendered manageable through appropriate controls and further study. Not only does the expertise and authority of science remain unscathed in a realist concept of risk, but other (public, or lay) assessments based on first-hand experience, traditional knowledge or other ways of knowing, are deemed secondary, if irrelevant or irrational compared to scientific approaches.

On the other hand, if risks are constructed through individual, social and political circumstances, the role and capabilities of science are less clear—science cannot simply ‘uncover’ a correct, universal, measure of risk. Added social dimensions magnify uncertainties beyond the realm of a temporary deficiency of data, and natural science is rendered only one of several means of understanding risk.

(3) Normative Framework: As Renn (1992) notes, concepts of risk are at once descriptive, outlining states of current and future possible events, and normative, implying that specific actions can and should be taken to avoid undesirable situations. This normative element can take several forms including prescriptive methods of decision-making, analysis and criticism of existing processes, and/or direct action ‘on the ground’. Furthermore, some concepts of risk are grounded in a specific ethical framework which guides the means and end goals of risk assessment.

(4) Methods: Finally, as I have discussed above, concepts of risk underlie and support particular methods of assessment, and thereby shape the types of questions that are asked in a particular issue, the techniques used to address those questions, and ultimately the conclusions upon which policy choice is based.
Thus far, I have used the term “risk” in a broad sense to mean “potential for adverse effect”. However, before continuing, it will be helpful to define more clearly the terms hazard, certainty, risk and uncertainty. A hazard usually refers to a specific adverse event or impact such as cancer (in toxicology) or decline in populations (in environmental assessments). If we know this event will occur, we are working in the realm of certainty. “Risk” describes situations where an event could occur, and where probability of that occurrence is known or can be calculated (betting on the flip of a coin is a common example). Uncertain situations are those where the probability of a specific outcome is not known and cannot be accurately calculated. We know what to look for, but cannot predict when it will occur. Various types of uncertainty will be discussed below. For simplicity, I will continue to use the term “risk” in a generic way, unless otherwise specified. The following section describes three concepts of risk in terms of the characteristics outlined above. Section 1.3.3 compares these concepts with elements of the Precautionary Principle.

**Technical Concepts of Risk**

Broadly characterised, a technical approach to risk “conceives risk as a physically given attribute of hazardous technologies: objective facts, which can be explained, predicted, and controlled by science, are separated from subjective values” (Bradbury 1989). Renn (1992) provides four examples of technical risk analyses: actuarial assessments which rely on statistical calculations and are derived from the insurance field; toxicological studies which rely on extrapolation from high-dose responses in laboratory test animals, to low-dose responses in humans; epidemiological studies, based on models of cause and effect relationships within populations; and engineering assessments of potential failures in technical systems such as nuclear reactors.
These technical approaches share several features (see Renn 1992). First, they attempt to calculate the frequencies of specific events through observation, statistics and/or modelling. Second, they average these events over time and space to estimate the probability of future adverse events. Third, they focus on predicting and mitigating consequences, usually expressed as physical harms. Furthermore, most technical assessments of health and environmental hazards are quantified in probabilistic terms. Here, risk is calculated by the “classical” method previously discussed: probability of an event multiplied by the magnitude of its consequences (P x C). For example, in engineering, risk may be calculated as the probability of component failure (system reliability) multiplied by the overall impact of failure, perhaps determined through event-tree analysis and expressed as number of fatalities (Crossland et al. 1992). In cancer risk assessment, probability is a function of exposure to, and potency of the suspected carcinogen, and consequences are expressed as increased cancer or mortality rates (see Harrison and Hoberg 1994).

Technical concepts of risk have met with criticism on several fronts. First, these approaches rely upon extensive information about complex, interrelated systems, usually limited to the knowledge of “experts”. As Crossland et al. (1992) state, estimating engineering risk...

...requires access to a wide range of data on failures that have occurred in the past, a substantial body of scientific knowledge about the various processes that are intended to occur or that could occur in the system, and a similar breadth of knowledge concerning the behaviour in the environment of material that could be released and the response of people, structures, etc. suffering exposure to those materials (Crossland et al. 1992).

Technical assessments also require vigilant monitoring of effects, and information feedback from past (and expected future) failures. Such information requirements can often be fulfilled only through reductionist approaches that assume the probability of system-wide hazards can be estimated by examining individual sub-components. These methods tend to
underrate system uncertainties and overlook important cumulative and synergistic effects (Howard 1997). While assumptions of the technical perspective may be appropriate for some engineering structures or toxicological assays, the technical approaches listed above were not designed to assess hazards in open-ended complex systems such as ecosystems. Consequently, these approaches tend not to fully recognise or accommodate the limitations of scientific knowledge, and hence place an exclusive and/or inappropriate degree of trust in scientific expertise. This top-down approach fosters one-way communication from experts, to the public—a situation that could ultimately increase uncertainties through lack of adequate communication and/or information sharing (as discussed in Chapter 4).

A second shortcoming of technical approaches is that they were developed primarily as tools for risk assessment or risk estimation, processes characterised as separate and more objective than the political task of risk management (discussed in Section 1.3.1). As Brunk et al. (1992) state, in classical interpretations, risk estimation is “a purely factual judgement of the level of risk...free of social and other value judgements. It is simply a measure of the magnitude of the harm involved in the event a hazard occurs, multiplied by the probability of its occurrence, both thought to be purely empirical and mathematical problems”. As we have seen, however, several authors have argued convincingly that, in practice, risk assessment and risk management are co-dependent activities, and that both are guided by “normative and conceptual assumptions necessarily brought to bear on the process” (Brunk et al. 1992; see also Harrison and Hoberg 1994; Longino 1983). Bradbury (1989) suggests that most risk assessors (and for that matter, scientists) are aware that value judgements cannot be expunged from risk assessment processes. Nevertheless, she claims “the policy implications of this inevitable element of human judgement are frequently obscured or overlooked.” That is, characterising risk “as an objective fact” excludes key social, political and ethical questions.
from the assessment process and may thereby focus decision-making on a very limited set of problems.

A final criticism of technical concepts of risk is that they are one-dimensional; they reduce all risks to a single measure such as physical harm or a single formula such as "probability X consequences". These calculations ignore the fact that people attach different values to different types of harm. Psychological studies have revealed a number of risk attributes—in addition to probability and sheer magnitude of harm—that significantly affect risk perceptions and overall acceptance. These often-cited attributes include voluntariness, personal control, certainty and expert consensus, familiarity, visibility, and quantity and distribution of benefits (reviewed in Camerer and Kunreuther 1989; Otway and von Winterfeldt 1982; Slovic 1992). Such individual and social elements of risk are excluded from technical accounts. Indeed, an "implicit assumption here is that social preferences can be expressed in engineering terms and used in the regulatory process to reduce uncertainty, ambiguity and delay—in essence an attempt to model social and political behaviours with the technical tools and philosophy of the natural sciences" (Otway and von Winterfeldt 1982).

To summarise, in terms of the four characteristics of risk outlined in Table 1.2, technical analyses presume a direct correlation between observations of nature and actual harms; a realist stance. While technologies are recognised as human creations, they are not analysed as products of a particular social structure or context. Subjective elements of risk assessment may be included, but only insofar as human error may affect the frequency of adverse events, or calculations of that frequency. Technical concepts presume conditions of "risk", i.e. that probabilities of events can be accurately predicted, and uncertainties accounted for, if not eliminated. As such, the natural sciences maintain a strong authoritative, if not exclusive, role in risk assessment while risk management remains the
mandate of politicians or administrators. The technical perspective is highly analytical in that predictions about the workings of complex systems are drawn from observations and relationships among sub-components. This analysis aims to set standards and avoid or mitigate adverse consequences primarily through the methods listed in Table 1.2

Economic Concepts of Risk

Economic concepts of risk encompass a spectrum of ideas on rational choice, decision-making under risk and uncertainty, utilitarian ethics, and maximisation of benefit-cost ratios. In general, the economic approach attempts to incorporate individual and social preferences by translating technical measures of "harm" into units of "value" or "utility" and then aggregating individual preferences for available course of action, and balancing possible outcomes to achieve overall maximum value.

In policy applications, economic concepts of risk take the form of cost-benefit analysis, or more accurately, risk-benefit analysis (as decisions usually involve situations of risk or uncertainty rather than straightforward calculations of cost). The basic calculations are similar to those used in technical assessments discussed above. Numerical values are attached to the probability and magnitude of specific events (the P x C formula) but the products are summed for each possible outcome of a given policy option, giving an overall estimate of "expected value" or "expected utility". This calculation allows comparison of several options; the best choice has the greatest average value. Economic concepts are therefore not inconsistent with the technical concepts of risk outlined above: Technical approaches may be used in the assessment process, while cost and risk-benefit calculations are generally considered a method of risk management.
Despite the incorporation of some technical methods, economic theory nonetheless marks a significant departure from strictly technical concepts of risk. To appreciate this difference, it is useful to distinguish between the two general forms of economic risk mentioned in the previous paragraph: expected value and expected utility. Traditional cost-benefit analyses entail calculations of expected value (EV), where a quantifiable and generalisable single unit (i.e. monetary value) is used to measure and balance the costs and benefits of a particular action. According to Pearce (1994) EV is a risk-neutral concept because “it implies that a unit of loss is valued equally to a unit of gain”; that is, preferences for costs and benefits are weighed equally using a single and objective unit, money.

Unlike methods of technical risk assessment and EV theory, expected utility (EU) theory attempts to accommodate subjective preferences for different types of benefits and harms by transforming one-dimensional units of measure (such as mortality rate, or monetary value) into measures of “utility”. Utility refers to the subjective value that an individual attaches to a given outcome, and utility functions therefore allow “weighted” analyses in which aversion to particular harms (e.g. involuntary, unfamiliar or disastrous events) can be factored into the overall calculation. Pearce (1994) contends that EU is therefore an inherently risk-aversive concept. In theory, EU does have the potential to address risk aversive preferences within society yet translation of preferences into utility functions remains problematic, as will be discussed shortly.

Economic concepts discussed thus far operate under conditions of risk where known probabilities are attached to measures of value or utility. However, most policy decisions on environmental harms involve situations of uncertainty where the probability of a specific outcome is unknown. A further adaptation of economic theory adjusts for uncertain conditions by including subjective judgements of probability. This process, known in
statistics and decision theory as Bayesian inference, involves estimating the initial probability of an event based on prior beliefs about the system under study, and then modifying those initial assumptions (according to a formula) as more data are gathered. The details of Bayesian theory are beyond the scope of this review, however two points are worth emphasising. First, the initial subjective probability estimates are never fully expunged from Bayesian calculations because final estimates of probability depend on initial assumptions (Berger and Berry 1988; Dawes 1988). Thus, Bayesian inference allows us to ‘get on with’ gathering data, drawing probabilistic conclusions and making informed choices while explicitly accounting for subjective assumptions and uncertainty. Second, the premises of Bayesian inference have been applied to a moral philosophy of social welfare. By this theory, individuals aim to maximise expected utility under conditions of uncertainty using subjective estimates of probability (see Harsanyi 1975).

Although economic concepts of risk purport to address deficiencies in purely technical perspectives (e.g. by including subjective preferences and accounting for uncertainty), much of the criticism levelled at the technical approach has been directed equally at “economic rationality”. This may be because policy decisions often employ a combination of technical and economic frameworks. Objections specific to economic concepts have focused primarily on (1) decisions based on aggregate preferences and (2) the utilitarian foundations of risk-cost-benefit calculations. These points are discussed in turn below.

(1) Economic theory requires translating individual or societal preferences into units of value or utility. This requirement raises several significant problems:

• First, are “preferences” the right place to start? Are preferences good indicators of value or utility, or are they contingent upon prior values, local circumstance and opportunities, and
available knowledge? If the latter is more accurate, satisfying preferences may not necessarily increase overall well-being (Kymlicka 1990; O'Neill 1996).

- Second, how can preferences be measured? Two general methods have been proposed. “Revealed preference” models, or so-called “bootstrapping” approaches (Pidgeon et al. 1992), attempt to derive current preferences by examining reactions to similar risk situations in the past. This approach has been criticised for inappropriately extrapolating from statistics and past experience, and thus perpetuating the status quo by assuming that risks accepted in the past were indeed “acceptable” (Shrader-Frechette 1991; Slovic 1992; see also Pidgeon et al. 1992). “Expressed preferences” models seek to address these deficiencies by using questionnaires and psychological tests to ascertain directly current preferences toward risk situations. However, limitations of this approach have also been noted, namely that responses are influenced by the scope and framing of questions, and the assumption that direct surveys and laboratory experiments can elicit accurate indicators of values (Shrader-Frechette 1991; Slovic 1992). While both revealed and expressed preference models have contributed to understanding risk behaviour, neither approach examines the social factors bearing on the formulation and expression of individual or societal preferences.

- Third, how can preferences, values and utilities be compared? Economic theory presumes a commensurable unit of measurement across all possible outcomes. Yet several critics have noted that values and attitudes toward risk are multi-faceted if not “irreducibly plural” (O'Neill 1996; see also Otway and von Winterfeldt 1982; Slovic 1992). People value different states and things for many—not always consistent—reasons, and therefore may be unable or unwilling to aggregate all preferences into a single measure, or to express an overall preference for one option at the expense of another. Even if this type of calculation is possible in theory, practical decisions about issues affecting all of society would become
extraordinarily complex. Indeed, economic models of decision-making were initially
developed for individual choices. Applicability to societal decisions remains questionable
despite the widespread adoption of cost-benefit policies by government and other institutions
(Shrader-Frechette 1991).

(2) Many critics of economic theory object to its utilitarian foundations which
prescribe aggregating individual preferences and choosing the option with the best overall
utility. Although the philosophical debate among utilitarian and other moral theorists has a
long history, the main points of contention are relevant to current decisions and policies
based on risk-cost-benefit frameworks. Critics claim that utilitarianism is prescriptively
flawed, that it does not provide an ethically sound basis for decision-making because trade­
offs involved in maximising overall utility may strive for equality, but tend to ignore
principles such as justice and fairness in the distribution of harms and benefits. In other
words, economic frameworks focus more on a specific outcome or consequence, but less on
the procedures used to reach that end point. As Otway and von Winterfeldt (1982) warn, “by
claiming a universal rationality they [economic concepts of risk] have ignored the value and
belief differences which lie at the heart of the debate.” Proposed alternatives to economic
rationality, such as procedural, ethical, ecological or communicative rationality (Bartlett
1986; O'Neill 1996; Shrader-Frechette 1991; Young 1995) stress the need for broader
participation, constructive dialogue and multiple decision-making tools, rather than a single
over-arching rule.

A second objection to the utilitarian framework is that it is descriptively, as well as
prescriptively flawed. Psychological studies have demonstrated that neither lay-people nor
qualified experts actually make decisions consistent with maximising expected utility.
Rather, people are subject to a number of heuristic principles or biases which are not
"rational" according to economic theory. For example, "representativeness" describes the tendency to base probability on resemblance; an event is judged more likely if it is similar or familiar to prior events. The "availability" bias grants a higher probability to events which are easily imagined, and a lower probability to hazards that are not readily brought to mind. A bias toward optimism is simply the attitude that "it can't happen to me" (see Camerer and Kunreuther 1989; Slovic 1992; Tversky and Kahneman 1990). Camerer and Kunreuther (1989) argue that biases in probability judgements are particularly acute when assessing low probability, high consequences risks (such as those associated with environmental hazards). The authors therefore emphasise a need for alternatives to economic concepts of risk in policy-making.

To summarise (see characteristics in Table 1.2), economic concepts of risk are realist. While it is recognised that people attach individual and subjective values to various risk situations, the actual hazards are presumed to exist independently of these values, and independently of socio-political situations. Risk analysis is therefore a matter of determining preferences, attaching values or utilities to these preferences, and choosing the best option on the balance of cost, risks and benefits. Excluded from these calculations is critical examination of the reasons people hold particular values, the social contexts that shape these values, and the political structures that allow or suppress their expression. Final decisions claim to encompass societal values, and theoretically public expressions of risk preferences could be included through direct participation in decision-making. However, compared to social and precautionary concepts outlined below, economic concepts of risk do not require direct participation of non-experts. The purported predictive abilities of scientists and managers remain intact, and uncertainty is restricted to unknown probabilities which can be estimated and partially amended through expert judgements. EV and EU theories are highly
prescriptive, they suggest how people *should* behave under conditions of risk and uncertainty, rather than attempt an accurate description of how people really do make decisions. As stated above, this normative structure is based on utilitarian principles of maximising net value or utility, operationalised through risk or cost-benefit analyses.

**Social Theories of Risk**

Like economic concepts of risk, social concepts encompass a diversity of ideas and disciplinary backgrounds. Many social concepts derive from early work in classical sociology and/or from more recent sociological and cultural studies of science and technology. These foundations are reflected in the underlying assumptions and types of questions posed by social theorists, as well as in the methods used to address those questions. Each of these perspectives marks a significant break from technical or economic concepts discussed above.

A unifying theme among social concepts of risk is the premise that technological hazards and our knowledge of those hazards are critically influenced, if not completely constructed by social and political factors. As Bradbury (1989) states, the social perspective "conceives of risk as a socially constructed attribute, rather than as a physical entity that exists independently of the humans who assess and experience its effects." Thus, compared to technical and economic concepts, social concepts of risk sit squarely within a broad constructivist paradigm. As mentioned earlier, there are however various shades and forms of constructivism. For example, Hess (1997) distinguishes radical and moderate constructivism. The radical version holds that the physical world is largely a social construct; in our case, there is no 'reality' of risk. This view is consistent with the argument that all forms of knowledge are equally valid because none are capable of capturing the reality of...
nature ‘out there in the world’. Moderate constructivism, also called constructive-realism, holds “that scientific theories and observations are constrained by a real, material world, but not completely so. Social variables and cultural values also play a shaping role” (Hess 1997). In other words, scientific knowledge can map onto a real world in meaningful and insightful ways, even as our understanding and experience of this ‘real’ world is significantly and continuously shaped by social and cultural factors. While these differences are important, all social concepts of risk maintain that analysis of the social conditions under which risks are produced and assessed is vital to understanding and ultimately averting technological hazards. Thus constructivism is not only a philosophical position, but also a particular methodology. This review will focus on the influential work of Ulrich Beck, Anthony Giddens, and Brian Wynne, with a brief discussion of several other important works on social concepts of risk.

Although initially working independently, Beck and Giddens devised strikingly similar theories of risk and modern society. Beck’s Risk Society, (1986; English translation 1992) and Giddens’ Consequences of Modernity (1990) have proven extremely influential contributions to the social analysis of technology and risk. Both Beck and Giddens, as well as other writers on “risk society” or “knowledge society” (see essays in Stehr and Ericson 1992) take as their starting point a fundamental disjunction between traditional hazards of pre-industrial or early modern times, and the “modernisation risks” (Beck 1992b) or “new technological risks” (Lau 1992) of late modernity. While we continue to face the more mundane hazards of previous times, these writers argue that current social change, if not outright social crisis, has engendered distinctively new types of technologies and hazards which pose unprecedented dangers, and necessitate new institutions of hazard assessment. Nuclear technology, ozone depletion, global warming and genetic engineering are frequently
cited examples. The argument contains both descriptive and prescriptive elements: not only are we confronted with a new type of hazard, but we—the public, social movements, and the “safety bureaucracies” of science, economics and law—are challenged to alter our behaviour and responsibilities accordingly.

What distinguishes current technological risks from the hazards of earlier times? An important feature of the new “risk profile” (Giddens 1990) is that hazards are extended across time and space, and across societal classes and institutions. Adverse effects of new technologies are potentially of global magnitude and threaten irreversible and irreparable harm. At the same time, these effects are often diffuse, intangible and intractable, and may be difficult to pin to any single cause. Compared to traditional dangers, new technological hazards are therefore invisible to the naked eye and imperceptible through everyday knowledge and experience. Beck and Giddens claims that such dangers are only made visible through “the perceptive organs of science” (Beck 1992a) and other expert systems (Giddens 1990). Using radiation to illustrate the point, Beck asks: following the Chernobyl accident “what would have happened if the weather services had failed, if the mass media had remained silent, if the experts had not quarrelled with one another?” His response, “No one would have noticed a thing” (Beck 1987).

Thus, while partly created through scientific research, “modernisation risks” also give rise to a powerful new role for scientific knowledge. Indeed, science becomes the only legitimate language of risks—even opposing voices must adopt a scientific language to maintain credibility. Insofar as scientific knowledge is necessary to understand, accept or oppose technological hazards, the public becomes dependent on science, a dependency which must be rooted in trust. Giddens (1990) defines trust as confidence in the reliability of a person or system which “expresses a faith in the correctness of...technical knowledge.”
According to this argument then, the public must have “faith” that experts have presented an accurate and timely representation of impending danger.

The irony of this situation is that just as science “becomes more and more necessary” to interpret and convey risk information, at the same time it becomes “less and less sufficient” (Beck 1992b). The calculative, expert-based methods of risk assessment used in technical and economic concepts of risk, fail under the scale and complexity of new technological risks. This failure, however, derives not only from an inability to collect and process sufficient scientific data, but suggests a depth of uncertainty “that compromises the very idea of expertise” (Giddens 1990). Recognising that uncertainty extends beyond problems of unknown probability or insufficient data, several authors have developed taxonomies of uncertainty to capture what Hansson (1996) generally terms “great uncertainty”. As shown in Table 1.3, great uncertainty includes a range of unknowns beyond the technical and methodological uncertainties addressed by decision theory or applied science. Here we enter the realm of “post-normal science” introduced at the beginning of this chapter. Post-normal science operates at the limit of knowledge, under conditions of “epistemological uncertainty” (Funtowicz and Ravetz 1992; 1994) or what Wynne (1992b) terms “ignorance”, situations where we often “don’t know what we don’t know.” Hansson’s (1996) taxonomy of “great” uncertainty is more extensive, comprising four categories: demarcation, consequences, reliance and values (briefly described in Table 1.3). Other writers have described various forms of “political uncertainty” as an additional component of great uncertainty. For example, Proctor (1994) argues that a “smoke-screen” effect is often created by proponents of hazardous technologies in an “effort to jam the scientific air waves with true but trivial work, the net effect of which is to distract from what is really going on.”
<table>
<thead>
<tr>
<th>TYPE OF UNKNOWN</th>
<th>UNKNOWN FACTOR</th>
<th>TYPE OF UNCERTAINTY</th>
<th>REALM OF INVESTIGATION</th>
<th>PREDICTIVE ASSUMPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>RISK</td>
<td>probabilities and consequences known</td>
<td>TECHNICAL &amp; METHODOLOGICAL UNCERTAINTY</td>
<td>APPLIED SCIENCE &amp; DECISION THEORY</td>
<td>DETERMINACY</td>
</tr>
<tr>
<td>UNCERTAIN PROBABILITY</td>
<td>probabilities incompletely known or not calculated</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DEMARCATION UNCERTAINTY</td>
<td>unknown options and/or scope of decision unclear</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CONSEQUENCES UNCERTAINTY</td>
<td>unknown outcome</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>RELIABILITY UNCERTAINTY</td>
<td>consensus among, capability of, and trust in experts is unclear</td>
<td>EPISTEMOLOGICAL UNCERTAINTY</td>
<td>POST-NORMAL SCIENCE</td>
<td>INDETERMINACY</td>
</tr>
<tr>
<td>VALUE UNCERTAINTY</td>
<td>disputed, unclear or unknown values at stake</td>
<td>GREAT UNCERTAINTY</td>
<td></td>
<td></td>
</tr>
<tr>
<td>POLITICAL UNCERTAINTY</td>
<td>unclear or unarticulated interests and commitments</td>
<td></td>
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</tr>
</tbody>
</table>
Such political uncertainty may compound other types of uncertainty if key issues are unnoticed, unarticulated or devalued (see also Clark and Majone 1985; Tickner 1998).

The idea that uncertainty can be produced or magnified by social circumstances and commitments is captured in Wynne's (1992b) more encompassing notion of indeterminacy. Wynne points out that “scientific knowledge proceeds by exogenizing some significant uncertainties, which thus become invisible to it.” While this is a normal process in scientific research, “the built-in ignorance of science towards its own limiting commitments and assumptions is a problem only when external commitments are built on it as if such intrinsic limitations did not exist.” The gap between the presumed, and often necessarily closed conditions of experimental research, and the open-ended, socially contingent circumstances in which science is applied, creates situations of indeterminacy. In the area of policy-relevant science, external social and political commitments are always attached to scientific research, and science-based decisions are always created within, and launched back into, the social arena. Wynne therefore contends that indeterminacy is a pervasive element of all decision-making. Failure to appreciate the inherently conditional nature of scientific knowledge and to unearth the assumptions and commitments built into its conclusions, is to invite further uncertainty: deterministic outcomes are expected from essentially indeterminate systems.

Thus Beck, Giddens, Wynne and others argue that risk is an inherently social and political concept, closely tied to prevailing structures of authority, ideas of legitimate knowledge, and the social commitments of all parties. In particular, hazards associated with modern technologies cut across the institutions of politics, law, science and economics, and blur distinctions between expert and non-expert, science and politics, risk and risk assessments, and knowledge and reality. While science has thus far maintained its authority, the predictive and controlling ability of scientific knowledge is increasingly called into
question. Beck claims this situation—diffuse, collective and ambiguous causes and effects of hazards, and a partial breakdown in formal institutions of authority—creates critical, sometimes strategic gaps in the distribution of responsibility, leading to an overall state of "organised irresponsibility" (Beck 1992b).

Although I have highlighted the works of a few writers, social concepts of risk share several common elements as summarised in Table 1.2. First, there is an underlying presumption that risk is essentially a socially mediated phenomenon rather than strictly a physical property of technologies. This premise places scientific knowledge in a new light. It is no longer the way to understand and predict hazards, but rather one of several constructors of those hazards. Science has a vital role in risk assessment, but it ought not be an exclusive one: science provides important, albeit limited knowledge, and must learn to recognise the conditional nature of its legitimacy. Thus understanding and predicting hazards (as far as either is possible) requires not just technical studies of nature and technological systems, but sociological and political studies of the people and institutions who co-create technologies and risk assessments and interact within wider society. This emphasis shifts the goal of risk studies from merely uncovering pre-existing hazards and overcoming technical uncertainty, to understanding the relationships between technology, values, and the creation of social as well as physical harms and uncertainties.

Some social theorists of risk, particularly those highlighted in this review, advocate a reconfiguration if not a democratisation of science as a necessary means of confronting the uncertainties of new technological risks (as will be discussed in Chapter 4). However, it is worth stressing that in general, the social studies of science and technology (STS) do not derive from a particular ethical standpoint (for example in contrast to utilitarian based decision rules) nor do they generally assume an advocacy role (for example compared to the
Precautionary Principle). Indeed, contemporary STS has been criticised for its failure to assume an active, prescriptive position, and therefore its failure to have significant impact on policy decisions (see Hess 1997). There is a vital need for thorough, well-grounded sociological and political analyses of risk, which, at the same time recognise a role for "engaged" academic research. As I will argue throughout this dissertation, stronger ties are needed between STS and more openly activist views such as those espoused by the Precautionary Principle.

1.3.3 The Precautionary Principle

The Precautionary Principle is primarily a legal concept which has been presented as an alternative to, and a fundamental shift from, strictly economic and technical foundations of decision making. As stated by O’Riordan and Jordan (1995), the precautionary principle "captures an underlying misgiving over the growing technicalities of environmental management at the expense of ethics, environmental rights in the face of vulnerability, and the facilitative manipulation of cost-benefit analysis." In this sense, the Precautionary Principle challenges traditional concepts of authoritative knowledge, scientific and legal proof, calculative accuracy, and claims of "value-free" decision-making.

Simply stated, the Precautionary Principle advises "better safe than sorry". More accurately, if less clearly, the principle has been summarised as "better to be roughly right in due time, bearing in mind the consequences of being very wrong, than to be precisely right too late."13 This statement captures the essence of the principle: the need for active measures to anticipate and circumvent potentially serious harm despite persistent scientific uncertainty regarding causality.
History Of Concept

The conceptual and theoretical foundations of the Precautionary Principle were born out of opposition to current fields of environmental science, law and management, and were kindled by environmental movements of the 1970s. McIntyre and Mosedale (1997) claim the principle arose as a “rejection of the assumptions inherent in the traditional ‘assimilative capacity approach’” of environmental management, namely that “science can accurately predict threats to the environment; science can provide technical solutions to mitigate such threats once they have been accurately predicted; there will remain sufficient time to act; and, acting at this stage results in the most efficient utilisation of scarce financial resources.” Although in some sense, the Precautionary Principle is an extension of—rather than a complete departure from—existing legal obligations of prevention (Gullet 1997), the principle does challenge norms of international environmental law in which states are responsible for environmental harm caused to neighbouring states only after harm has occurred (Hickey and Walker 1995). In contrast, the Precautionary Principle obliges states to recognise situations of risk and uncertainty, and to anticipate and avert potentially harmful effects.

The core ideas of the Precautionary Principle were first translated into government policy in the 1970s in Germany. Here, the concept was known as vorsorge, which is derived from notions of “providing for” and “caring for” and can be translated as “beforehand, or prior care and worry” (Boehmer-Christiansen 1994). At the policy level vorsorge encompassed several key elements, summarised by Boehmer-Christiansen (1994). It is worth reviewing these early concepts of precaution as many have been lost or significantly revised in subsequent interpretations. Vorsorge entailed: (1) socialised planning and heavy state influence which implied an ideological opposition to free market doctrines; (2) forward,
active and anticipatory measures to avoid environmental harm, with a strong emphasis on planning and research and a vital role for science in the early phases of policy development; (3) measures to stimulate the economy through replacement of polluting industries with innovative ‘green’ technologies; (4) decisions based on a number of criteria including, but not limited to “sound science” with the aim of pursuing “complementary goals without becoming subject to the accusation of irrationality” and including social and political as well as environmental harms; and (5) a strong *moral* requirement to avoid environmental damage, recognising that the “promulgation of these targets may therefore become the responsibility of every citizen, industrialist and administrator.”

**Current Status**

The Precautionary Principle was first invoked in international environmental agreements in 1987 in the Protocol on Substances that Deplete the Ozone Layer (known as the Montreal Protocol) and the Second International Conference on the Protection of the North Sea (Gullet 1997; Hickey and Walker 1995). The principle has since been invoked in over twenty international laws, treaties and declarations. To date, most applications of the Precautionary Principle have addressed emissions of chemical pollutants, particularly into marine environments. However, more recently, the precautionary approach has been extended to climate change, energy production, natural resource conservation (*e.g.* fisheries), genetic engineering, and general efforts toward sustainability. Not all applications entail binding agreements; many are non-binding declarations, general guidelines, or simply prescriptive statements or critical analyses of existing practices.

Despite an increased presence and endorsement in international arenas, the practical significance of the Precautionary Principle is debated. For example, with its incorporation in
the Rio Declaration of 1992, several commentators claim the Precautionary Principle has reached the status of international customary law\textsuperscript{15} (Cameron 1994; McIntyre and Mosedale 1997). If this is the case, “a state which has endorsed the principle would be liable if it caused harm in the future through activities which today are strongly suspected (but not proven) to cause substantial harm” (Gullet 1997). This is extremely significant as over 170 countries, including Canada, have signed the Rio Declaration. In contrast, however, O'Riordan and Cameron (1994) claim that the political influence of the principle in both the Rio Declaration and the Maastricht Treaty remains “very marginal”. Ironically, this lack of political teeth is often attributed to the substantive uncertainty of the principle (Hickey and Walker 1995; McIntyre and Mosedale 1997). Conditions required for triggering the principle, methods of implementation, and specific obligations imposed by its endorsement remain ambiguous and inconsistent, as will be discussed more fully below. Recent efforts by academics, lawyers, policy-makers and activists have attempted to clarify key concepts and values inherent in the Precautionary Principle and devise mechanisms for its application to specific policy issues.\textsuperscript{16} Despite enduring ambiguity, several key concepts are included or implied in most interpretations and have been identified as constituting the core of the Precautionary Principle.

\textit{Interpretations and Core Elements}

It is useful to outline a range of strong to weak versions of the Precautionary Principle. Briefly, weaker forms emphasise balancing the costs and benefits of precautionary actions, and place greater faith in the accuracy and certainty of scientific evidence. Strong forms explicitly challenge the legitimacy and capabilities of science, are less willing to trade environmental welfare for economic benefits, and are often related to ecocentric or “deep
green” values (O’Riordan and Jordan 1995). With this spectrum in mind, core elements of the Precautionary Principle can be identified as follows (see summary, Box 1.1).

i. Ethic of Protection

The primary goal of the Precautionary Principle is protection of the environment from anthropogenic harm. O’Riordan and Jordan (1995) describe this goal as “safeguarding ecological space.” However, the philosophical grounding of the Precautionary Principle has not been thoroughly examined or articulated. Attfield (1994) suggests that precaution is best understood not as a basic or absolute principle in itself, but as derived from more general ethical principles. As such “the principle has a built-in hypothetical or conditional aspect” and must answer to more fundamental values and goals. These values and goals differ among strong and weak versions of precaution. For example, strong versions have been associated with a bio- or eco-centric ethic that recognises an intrinsic value and moral considerability of non-human beings and ecosystems, and prescribes a corresponding duty of care. In contrast to the “assimilative capacity” approach to environmental management discussed above, the underlying assumption is that ecological systems are inherently vulnerable and cannot absorb an infinite amount of perturbation without irreversible adverse effects (Gray 1996; Gullet 1997; McIntyre and Mosedale 1997). Such a perspective represents a marked break from the utilitarian values underlying strict cost-benefit frameworks—a shift from an “economic and anthropocentric stance to a primarily eco-centric point of view” (McIntyre and Mosedale 1997).

Other interpretations of the Precautionary Principle, however, do not advocate such a radical shift. For example, weaker versions such as the Rio Declaration stipulate “cost-

<table>
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<th>BOX 1.1 Core Elements of the Precautionary Principle</th>
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<td>• Ethic of protection</td>
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effectiveness" as a qualifying condition and thereby retain an essentially utilitarian foundation. Cost-effectiveness is hotly debated among advocates of precaution and is discussed in greater detail below.

Yet another version of Precautionary Principle eschews strictly utilitarian ethics but retains an anthropocentric focus. Citing the moral philosophy of John Rawls, Shrader-Frechette (1991) and Tickner (1998) ground precaution in more fundamental principles of justice and fairness. Rawls has argued that expected utility, and utilitarian principles in general, are inappropriate ethical bases for a just democratic society (Rawls 1971; 1974). Instead, Rawls uses the “maximin” decision rule to explain and lend support to his contractarian theory of “justice as fairness”. Under conditions of uncertainty, the maximin rule “directs our attention to the worst that can happen under any proposed course of action, and to decide in light of that” (Rawls 1971). The best option, in other words, is that which maximises the worst (minimum) outcome, thereby avoiding the worst possible scenario.

Although Rawls firmly states that this “unusual” rule applies only under specific conditions (unknown probabilities; unacceptable potential outcomes; indifference to maximising gains), he suggests several reasons why maximin should be employed over expected utility models when these conditions hold (Rawls 1974). Two reasons particularly relevant to the Precautionary Principle are (1) maximin is risk averse; it avoids unacceptable outcomes and aims to protect those worst-off and most vulnerable in society; and (2) in contrast expected utility calculations, decision-making under maximin requires less information. Specifically, precise or complete knowledge of the probability of each outcome is not needed under this rule; advocates claim it is easier to predict the worst possible case than the probability of the best outcome.
ii. Proactive and Anticipatory Approaches

Most interpretations of the Precautionary Principle stress the need for proactive measures to anticipate and prevent potential harms at the source, rather than reactive measures which aim to mitigate, eliminate or compensate for harm once it has occurred. A distinction among reactionary, preventative and precautionary measures is frequently asserted. Reactionary measures aim to mitigate and control hazards ‘downstream’, i.e. after harm has occurred. Preventative measures aim to reduce impact, prevent harm, and establish suitable regulations once a pollutant or harm has been identified and cause-effect relationships established. In contrast, precaution “applies to the more problematic area of uncertainty, possible irreversibility and collective environmental responsibility” (O’Riordan and Cameron 1994; see also Gullet 1997). The difference between prevention and precaution appears subtle, but precaution entails a more active stance toward uncertain harms, and therefore requires a conscious effort to anticipate, investigate and forestall environmental harm.

To date, several forms of precautionary action (both strong and weak) have been advocated and employed. For example, (1) standards for the development, replacement and/or banning of particular technologies, often expressed as a duty to employ “best available technology” (BAT), “clean production methods” or “best environmental practices”; (2) assessment protocols, most frequently in the form of environmental impact assessments (EIA) required by many national and international regulations; (3) research into the causes and effects of environmental harm, with particular attention to long-term or “meso-scale” planning and continuous vigilant monitoring to observe, learn from and thwart unexpected adverse effects; (4) development of “cleaner” alternatives to polluting technologies; and (5)
measures to ensure public access to information, and in some versions, public participation in decision-making.

**iii. Action Despite Scientific Uncertainty**

One of the most frequently cited differences between the Precautionary Principle and strict cost-benefit analysis is explicit recognition of the inadequacy of existing scientific knowledge to accurately predict, and hence balance, the benefits, risks and costs of new technologies. Because scientific uncertainty is often persistent and pervasive, the principle advises that we not wait for conclusive scientific evidence of cause-and-effect relationships in the face of potentially serious harm. As stated by O'Riordan and Jordan (1995), the “problem for science in the precautionary mode is that its normal reliance on experimentation, theory falsification, verification, consistency and predictability is thoroughly challenged.” Many statements of the Precautionary Principle reflect such a qualified, if not skeptical, view of scientific knowledge, and stress that such uncertainty must not stall precautionary measures. As we have already seen, however, uncertainty is an ill-defined and equivocal concept that permeates all aspects of science and decision-making, and all elements of the Precautionary Principle. I will reserve further discussion of these issues for subsequent sections of this dissertation.

**iv. Shifting Prior Assumptions and The Burden Of Proof**

Evaluation of hazards under the Precautionary Principle is often compared to evaluation of guilt in a legal context, particularly with respect to prior assumptions, standards of evidence and more generally, burden of proof. Although the analogy is neither precise nor unambiguous, these concepts are frequently used to distinguish precautionary approaches
from more “risk-taking” positions and it is therefore important to consider how they are defined and applied.

A “prior assumption” is essentially a default position regarding the innocence or guilt of an accused person, or the safety or harmfulness of a product. In criminal cases, the accused is innocent until proven guilty. In scientific investigations (at least ideally) the null hypothesis, stating no effect, is maintained until sufficient evidence is gathered to accept the alternative hypothesis, that there is indeed an effect. A key question in risk assessment and the Precautionary Principle is whether the same prior assumptions do, and should, apply; i.e. whether technologies ought to be considered safe until proven hazardous, or hazardous until proven safe. The answer to this question determines who holds the “burden of proof”, and on which side a judgement should err.

Burden of proof, as it is commonly used in law and risk assessment is actually comprised of two elements: (1) “burden of proof” *per se*, also called “burden of persuasion”, which is an onus placed upon one party to prove a disputed issue and (2) the “standard of evidence” which is the degree of certainty by which a particular issue must be proven. In criminal cases, the onus or burden of proof rests on the party who must challenge the prior assumption that the accused is innocent (*i.e.* the prosecutor). In environmental and public health risk assessments the burden of proof is often said to rest unfairly on the public or its governmental representatives to prove a product is hazardous against a presumption of safety. For example, low dose radiation poisoning (Conner 1997), carcinogens (Proctor 1994) and exotic, potentially invasive species (Ruesink et al. 1995) are said to be “innocent” until the public raises convincing evidence to the contrary. In other cases, however, the burden of proof is said to lie with the developers of the technology in question. Most pharmaceuticals fall into this category because developers must convince government regulators of the safety
of their product prior to commercialisation. However, it is important to recognise that even such cases, once a drug is on the market, the burden shifts to the government (or often the public) to challenge its “proven” safety (Abraham 1994). According to the Precautionary Principle, it is unfair that the public shoulder the burden of proof for any public health or environmental hazard. A precautionary approach therefore entails shifting this burden to the developers of potentially hazardous technologies. Proponents would be required to demonstrate that the activity in question does not pose unreasonable harm, that there are no less-damaging alternatives and/or that there is a need for the proposed technology. The rationale is that those who stand to gain from an activity ought to assume the responsibility and costs of demonstrating its safety: “It is those seeking to carry out an activity who are being asked to justify themselves” (McIntyre and Mosedale 1997).

The standard of evidence in criminal law is “beyond reasonable doubt”. The party carrying the burden of proof must convince the jury—beyond reasonable doubt—that the accused is guilty. Should the jury err, it should err on the side of innocence: better to acquit a guilty person than convict an innocent person. Similar standards of evidence apply (again ideally) in scientific research. Should error occur, it should fall on the side of the null hypothesis; it is better to claim no effect when there really is one (false negative or type II error) than to claim there is an effect when in fact there is none (false positive or type I error). Science, like criminal law, tends to be conservative and claims an effect only when proven “beyond reasonable doubt”. While the legal definition of “reasonable doubt” is controversial and often “left to the good sense of the jury” (Paciocco and Stuesser 1996), in science reasonable doubt is usually defined in terms of statistical significance, e.g. that the probability that an effect occurred by chance is not greater than 5% (p=0.05). The Precautionary Principle questions whether such strict standards of evidence are appropriate for all inquiries.
In particular, many environmental and public health problems entail low frequency events, low dose effects, and long-term often multi-generational impacts that are not amenable to statistical analysis or experimental falsification. The Precautionary Principle therefore recommends alternative standards of evidence for such inquiries, for example considering a “balance of evidence” and/or shifting the current bias in scientific research in favour of Type I errors or false positives—erring on the side of caution. Precise standards of evidence under the Precautionary Principle, however, have not been fully developed and, to date, remain a source of ambiguity and controversy (see section below on “Triggers and Evidentiary Thresholds”).

v. Cost Effectiveness

Analysis and weighing of the costs and benefits of precautionary action are an important feature in many interpretations the Precautionary Principle, and were included in the original German formulation. Currently, cost-effectiveness is stressed in weak and moderate versions, but is often omitted from stronger versions of the principle. Extended or weighted cost-benefit analysis is not necessarily inconsistent with weaker precautionary measures. Pearce (1994) describes the relation as “a presumption in favour of not harming the environment unless the opportunity costs of that action are, in some sense, very high.” In other words, in the precautionary mode, the benefit-cost ratio should be relatively high. This form of cost effectiveness is often framed in terms of the “proportionality rule” which states that precautionary measures should be adopted in proportion to the benefits accrued. Maintaining proportionality requires frequent examination of the effects of implementing precautionary activities, and possible reconsideration of initial decisions (O’Riordan and Jordan 1995).
Stronger interpretations of precaution question whether attempts to define and relativise costs and benefits simply beg the question. Attfield (1994) writes: “what counts as the ‘excessive costs’ cannot be determined independently of a determination of when precaution is on balance necessary; for where precaution is necessary, the costs of precaution cannot be excessive, however much conventional economics may represent them as such.”

Similarly, O’Riordan and Jordan (1995) ask “[i]f a possible outcome is potentially destabilising to the natural order or to social equity, can it truly be regarded as a realistic option to the point where lost ‘benefits’ ought to constitute a ‘sacrifice’?” Such strong forms of precaution often prohibit technologies “unless there is certainty that there are no detrimental effects” (Pearce 1994; emphasis original) and disallow even a heavily weighted cost-benefit analysis on the grounds that economic welfare should not be traded for environmental protection, and/or that our predictive abilities are inadequate to make such prescriptions.

In practice (and in politics), it is difficult to completely ignore all measures of costs and benefits, and in fact most precautionary policies retain some version of cost-benefit analysis. Nonetheless, it seems generally accepted that if cost-benefit analysis is to be made consistent with precautionary approaches, it must be radically altered to include non-monetary elements such as societal values, dangers imposed on future generations, damage to non-human beings, and recognition of uncertainty and ignorance.

Problems And Opposition

i. Inconsistent Interpretations and Applications

Although most versions of the Precautionary Principle share the core elements listed above, many commentators have criticised the lack of a uniform interpretation or set of
guidelines for implementing the principle. For example, O'Riordan and Cameron (1994) state that “precaution is rather universally understood, not commonly interpreted.... There is neither an agreed yardstick, nor a consensus as to how it should be applied.” In reviewing existing statements of the Precautionary Principle, Hickey and Walker (1995) note the variability of form, content, scope and binding effects, and argue that the “global community needs a more specific rule of restraint adaptable to a wide range of new environmental circumstances, rather than isolated agreements that share only a general preference for pollution prevention.” Attfield (1994) goes as far as to suggest that at present, precaution is more a manifesto than a consistent and applicable principle.

Such flexibility and generality raises critical questions about the scope of obligations imposed by the Precautionary Principle, and leaves sufficient room for lip-service and inaction. Yet several commentators argue that precaution need not be defined in precise and binding terms to be an effective and influential principle (Boehmer-Christiansen 1994; O’Riordan and Jordan 1995). Cameron (1994) holds that the Precautionary Principle is inherently general; specific applications will require secondary legislation. On the other hand, Hickey and Walker (1995), note that the “substantive content” and “precise obligations” of incipient international environmental laws must develop through practice over time (i.e. the process of developing customary law); the current ambiguity of the Precautionary Principle is neither anomalous nor flawed. As such, it is important to analyse in detail the ways in which precautionary measures are currently invoked and implemented—the difference between regulatory statements and regulatory practice—as well as to identify barriers, contradictions or necessary modifications to existing core elements listed above.
ii. Triggers and Evidentiary Thresholds

Critics of the Precautionary Principle often point to vague standards of evidence required to trigger the principle and, once invoked, to declare a technology harmful or safe. Should precautionary measures apply to all action and all technologies? How much information do we need before an activity is ranked as “potentially harmful” or “reasonably safe”? At least one critic has pressed the issue by claiming that the Precautionary Principle should be applied to itself: if we are uncertain that the principle is required, we should take measures to avoid unnecessary, potentially harmful (from an economic point of view) applications and consequent missed opportunities (Cross 1996).

Most interpretations of the Precautionary Principle specify the types of activities or harms sufficient to trigger precautionary measures. Frequently cited are hazards that are irreversible, bioaccumulative, persistent, toxic and/or otherwise “serious”. This list reflects the origins of the Precautionary Principle in addressing effects of chemical pollutants. More recently, the scope has been broadened to include, for example, involuntary risks, risk of loss rather than gain, and low probability/high consequence risks (Pearce 1994). Furthermore, several authors have included all activities that approach a critical environmental threshold or impose a “critical load” on the environment (O’Riordan and Cameron 1994; Attfield 1994; Pearce 1994). Thus, while the Precautionary Principle explicitly rejects the need for conclusive scientific proof or certainty regarding these potential harms, it clearly recognises that some evidence of harm is required. As Hickey and Walker (1995) note, “requiring precautionary measures to be taken on the basis of speculation about mere possibilities of harm and causation, without any rational basis in sound scientific data, is also generally rejected.”
Evidentiary thresholds are a problem not only for triggering the Precautionary Principle but also under the terms of the principle itself. Once the burden of proof is shifted, proponents must demonstrate that an activity or technology does not impose risk of harm. As the impossibility of proving "no effect" is well known, some threshold of "sufficient proof" is needed, even in strong versions of the principle. How much evidence is enough? How do we know a substance is toxic or will bioaccumulate? What constitutes a "critical load" on the environment? What is irreversible harm? When is a technology "safe" or an alternative more safe?

Several statements of the Precautionary Principle define evidentiary thresholds in vague terms. For example: "...where there is reason to believe that damage or harmful effects are likely to be caused..."\(^\text{18}\), "...where there is reason to assume that certain damage or harmful effects...are likely to be caused...."\(^\text{19}\) Other statements simply cite the "threat"\(^\text{20}\) or "potential"\(^\text{21}\) of serious or irreversible damage as sufficient reason for invocation of the principle. More explicit standards of evidence have also been proposed. For example, Tickner (1999) advocates the "balance of evidence" approach discussed above (see also Brunk et al. 1992; Harrison and Hoberg 1994; Peterman and M'Gonigle 1992). By Tickner's approach, "uncertainty criteria" (e.g. plausibility of effect, coherence with existing knowledge, attention to false negatives) and "decision-stakes criteria" (e.g. spatial and temporal scale of potential effects, reversibility, degree of complexity and connectivity) are weighed, and the balance of evidence is used to determine whether precautionary or preventative action is warranted. However, Brown and Zaepfel (1996) argue that even this standard of evidence is too strong to be consistent with the Precautionary Principle because it requires evidence that harm is probable rather than simply possible.
For the present—and perhaps interminably—such criteria remain open to interpretation, circumstance and good collective judgement. Cameron and Abouchar (1991) advise that we “must invest some trust in the possibility that the change of consciousness we have experienced in our scientific, philosophical, and political understanding of environmental problems will extend to the interpretative consciousness of lawyers and decision-makers when they approach the meaning and effect of these threshold words.”

iii. Antagonistic Toward Science?

Like many aspects of the Precautionary Principle, its relationship to science is ambiguous and contentious. Because the principle advocates action despite scientific uncertainty and does not rely completely on scientific knowledge and methods, critics have dismissed precaution as inherently irrational, non-scientific or even anti-science (Cross 1996; Wildavsky 1988). In some sense, these are valid critiques. The Precautionary Principle does indeed challenge the current authority and primacy granted to “expert” scientists and scientific data. Its basic premise is that science cannot sufficiently predict all possible outcomes of our actions, and that we cannot afford to wait through a series of fumbled attempts. Furthermore, as we have seen, there exists a set of legitimate questions as to the form and standards of scientific knowledge that are required both to trigger precautionary measures, and to subsequently analyse potential harms through a precautionary lens. Nonetheless, the preceding discussion, as well as other commentaries, have emphasised that science plays a vital, if somewhat altered role in precautionary decision-making. In fact, Tickner (1999) argues that the “Precautionary Principle calls for more, not less science to better understand the complexity of ecosystems and the impacts of different stressors on them.” Yet what model of scientific investigation can accommodate the complexity and uncertainty upon which precaution is premised? Several authors have recommended
increased public participation as a means of openly acknowledging, if not overcoming, uncertainties. For example, O’Riordan and Cameron (1994) suggest a more “civic” science which would require “widened participation of groups producing scientific advice”; “that participants should have equal status; no participant should have institutionalised power over others”; and that “procedures and debates within groups should be open and publicly accessible.” Such a move toward participatory decision-making suggests a new role for science under the precaution principle, one of “co-problem solvers” rather than isolated “experts” (Barrett and Raffensperger 1999). Prospects and directions for such a “precautionary science” will be discussed in greater detail in Chapter 4.

The Precautionary Principle versus Other Concepts of Risk

Table 1.2 summarises the major premises of Precautionary Principle as compared to technical, economic and social concepts of risk. Direct comparison is difficult partly because various interpretations of precaution may condone or denounce aspects of other concepts, such as cost-benefit analysis, and partly because proponents of precaution tend not to talk in terms of “risk” at all. For them, risk implies inevitable trade-off and suggests a degree of certainty that the Precautionary Principle explicitly denies. Nonetheless, examining precautionary approaches in the context of other dominant risk frameworks is necessary if the principle is to be implemented in a meaningful way.

Despite the focus on uncertainty and a skepticism toward the predictive capabilities of scientific knowledge, I would argue that most interpretations of the Precautionary Principle maintain a fundamentally realist perspective. Hunt (1994) notes that weak forms of precaution tend to recognise uncertainties in the sense of “facts beyond science’s current eyesight”. Only stronger forms, of which few have been implemented, recognise the
indeterminacy of scientific knowledge and the broader range of social and political hazards implied by this concept. While the Precautionary Principle is fundamentally an “activist” position (in that it prescribes active measures to change the status quo), the ethical grounding for this position is variable. Weak versions of precaution are founded on utilitarian principles, while stronger versions cite an ecocentric philosophy or general principles of justice and fairness. Precautionary methods also range from weak to strong and may include weighted risk-cost-benefit analysis or maximin decision rules, participatory processes to address issues of fair representation, and/or proactive research to forestall environmental harm.

Preview of Subsequent Chapters

To reiterate the outline of the following three chapters, in Chapter 2, I analyse the history and development of biotechnology policies in Canada to determine how key concepts of risk have become embedded in current environmental regulations. This analysis encompasses the ideas, interests and institutions that have shaped biotechnology policies and have, I will argue, constructed significant barriers to implementing the Precautionary Principle. Chapter 3 investigates how biotechnology policies have actually been implemented in the form of “science-based risk assessment”. Here, I unearth the “private face” of risk assessment by examining previously confidential data generated by Monsanto and approved by federal regulatory authorities. Finally, Chapter 4 ties together the influential role of ideas, interests and institutions with the concepts of risk discussed in Chapter 1, and suggests how we might move toward a more effective, appropriate and “precautionary” science.
Endnotes: Chapter 1

1. From the Bergen Ministerial Declaration on Sustainable Development, 1990.

2. As stated in the Canadian Environmental Protection Act, 1988.


4. Herbicide tolerance was probably the most controversial rDNA crop until the announcement of “terminator technology” in 1998. Seeds saved from “terminator” crops will not germinate. The technology has provoked strong reaction against agricultural biotechnology in general, especially in developing countries.

5. I am grateful to Elizabeth Moore (University of Toronto, Political Science) for insightful discussions on the role of ideas in policy analysis (Moore 1998 and personal communication, 1998-9).

6. The term “ideology” is somewhat problematic and ambiguous, often carrying overtones of false, misguided or purposefully distorted ideas (Eagleton 1991). Many researchers in political science and STS prefer the term “discourse” to convey the breadth and potential power of a set of ideas, without implying that one position is necessarily more sincere or truthful than another. I prefer the term ideology as defined by Doern and Phidd (1992).

7. A discussion and decision-making process in which a citizen’s jury designs and poses questions to a panel of “experts”. Held in Calgary, March 1999. See Chapter 4.

8. For example, a recent action in which protesters distributed information about “unlabelled GE foods” at supermarkets across Canada (see Scoffield 1999).


10. The ATIP request was submitted in collaboration with E. Abergel, Department of Environmental Studies, York University.


12. Rawls (1971) is perhaps the best known contemporary critic of utilitarianism. His views are supported by Shrader-Frechette (1991; 1994) and reviewed by Kymlicka (1990).


15. Customary law is defined as “evidence of a general practice accepted as law” and is accompanied by legal obligation. The status of customary law results from extensive and uniform use among states (Cameron 1994; quotation from Article 38 of the International Court of Justice).

16. For example, the Wingspread Statement on the Precautionary Principle (1998) was composed by an interdisciplinary group of academics, politicians and activists. See also Gullet in progress; Tickner in progress).

17. Defined in O’Riordan and Jordan (1995) as 25-100 years.

18. Nordic Council’s International Conference on Pollution of the Seas (1990); emphasis added.
19. Paris Convention for the Prevention of Marine Pollution from Land-Based Sources (1989); emphasis added.

20. For example, the Rio Declaration (1992), the Bergen Declaration (1990), and the Framework Convention on Climate Change (1992).

CHAPTER TWO

Inquiry:
Environmental Policies for rDNA Crops in Canada

2.1 OVERVIEW

This chapter traces the history and development of Canadian biotechnology policy beginning with early risk debates of the 1970s and stretching through four subsequent phases to the present. During this period, Canada's biotechnology industry grew from a handful of pharmaceutical companies in the early 1980s, to a multi-faceted industry with over $1 billion in annual revenue (1995 figures; NBAC 1998). This tremendous growth, I will argue, was largely due to the generous and sustained support of the Canadian federal government. Also during this time, however, government and industry adapted to various dynamic, often conflicting influences, not the least of which was a growing pressure to implement environmental safety procedures. This analysis addresses a number of key issues which bear on the methods and conclusions of environmental regulations that were eventually adopted by the Canadian government. First, what broad policies for biotechnology have been established in Canada, and what general principles guide biotechnology regulation? Second, when were these policies adopted in relation to industry development and commercialisation of biotechnology products? Third, what factors influenced development of biotechnology regulations, and how were these factors accommodated? Finally, who was involved in the decision-making process and who was excluded?

While the government publishes "fact sheets" and public documents outlining current biotechnology regulations, these descriptions are insufficient to explain fully how regulations are actually implemented, and provide little background or rationale for the overall structure of biotechnology policies. Information in the following sections is therefore drawn from
personal communication, structured interviews, out-of-print documents, workshop proceedings, published analyses of related policy fields, as well as official government publications. These documents and conversations reveal the diversity of pressures—key ideas, interests and institutions—that have molded risk assessment frameworks and shaped current government policies for agricultural biotechnology.

2.2 CANADIAN BIOTECHNOLOGY POLICY

2.2.1 Early Risk Debates

The present controversy surrounding large-scale release of rDNA crops is rooted in a long-standing political and scientific debate as to whether rDNA techniques create inherently new organisms and thereby pose unprecedented health and environmental hazards. While the history of these early debates in the US has been meticulously compiled and analysed by several authors (Bird 1993; Krimsky 1991; Wright 1994), analysis of the Canadian situation has, to date, been lacking. In this section, I will provide background for an indepth study of Canadian biotechnology policy by highlighting the main trends and points of contention in early discussions of biotechnology risk and regulation.

Debate over the safety of rDNA organisms began shortly after the first rDNA experiments were published in 1972, and gained wider attention during the 1973 Gordon Conference and the 1975 Asilomar Conference held in the United States. Both of these meetings focused on the unintentional escape of rDNA organisms from laboratories, and the safety of scientists working within the lab. The 1973 conference led to calls for a voluntary moratorium on some rDNA research and for the formation of a biosafety committee within the US National Academy of Sciences (NAS). The subsequent Asilomar Conference in 1975 aimed to evaluate potential hazards of rDNA organisms, and received wide coverage from the
media. Conference participants recommended that rDNA research continue albeit under federal guidelines, which were established thereafter by the US National Institute of Health (NIH) in 1976, and the Canadian Medical Research Council (MRC) in 1977 (Krimsky 1984; Krimsky 1991). While the NIH guidelines were specific to rDNA technologies, the MRC guidelines set containment levels for small-scale experimentation with both rDNA and conventional micro-organisms, as well as viruses and cells in tissue culture (Krimsky 1984). These guidelines were revised in subsequent years “with progressive relaxation justified by continued safe experience” (NBAC 1987-88). Both sets of federal guidelines were developed and implemented through advisory committees, the Recombinant DNA Advisory Committee (est. 1974) in the US and the Biohazards Committee (est. 1975) in Canada. The eight member Biohazards Committee comprised both scientists and non-scientists, and sought advice from the larger scientific community (Eddy 1983; Krimsky 1986).

While the guidelines and safety committees instituted in the mid 1970s might well be construed as models of prudent—even precautionary—regulation by the scientific community and government policy-makers (Berg and Singer 1995), there are several reasons why these actions were not intended and were not sufficient to address the imminent, more complex issue of deliberately releasing rDNA organisms on large unconfined scale. First, risk questions assessed in federal guidelines were narrowly focused on laboratory safety and the accidental development and/or escape of “super-strains” (Berg and Singer 1995; Regal 1998). As such, the “MRC guidelines [were] written primarily for the research laboratory where small volumes of culture are encountered” and made no specific provisions for unconfined release (Krimsky 1984). The “guiding principle behind the development of the [NIH] guidelines was containment” and initial NIH guidelines in fact explicitly prohibited intentional release of rDNA organisms into the environment (Krimsky 1991). Thus as
Wright (1994) points out, the growing prospect of deliberately releasing rDNA organisms on a large scale "negated one of the principles of their safe handling—that they should be contained".

A second reason why the MRC and NIH guidelines were inadequate in the long-term was that they did not extend to research conducted in the private sector, despite the growing dominance of private biotechnology firms. While the existence of guidelines may have exerted some pressure on industry to conform—if only to maintain good public relations—federal initiatives applied only to research funded by the NIH or MRC (Krimsky 1984; Krimsky 1991). While both the NIH and MRC later initiated a program of voluntary compliance for the private sector, the guidelines were not legally binding and thus were difficult to monitor and enforce. Several reports by the Science Council of Canada (SCC) concluded that existing oversight of rDNA technologies was therefore inadequate (Eddy 1983; Krimsky 1984; SCC 1982). Indeed, a 1983 SCC report concluded that now was the time for MRC to "pass the baton" to health and environmental regulatory agencies, and to formulate legally binding regulations for rDNA technologies (Eddy 1983).

While debate over the hazards of rDNA techniques and organisms continued through the mid 1970s, by the end of the decade there appeared a growing consensus within the scientific community that rDNA technology posed minimal hazards. These conclusions significantly influenced future government policies. Susan Wright (1986) traces the origin and impetus of this powerful consensus to three scientific conferences held in the mid to late 1970s. She argues that a primary concern of scientists at these conferences was overregulation of research by external (governmental) sources, and that this focus narrowed the scope of debate to a single, improbable hazard: the inadvertent creation of an epidemic pathogen from the only bacterial strain then used in rDNA experiments. The apparent
agreement among conference participants that this was an unlikely scenario was
“subsequently cited repeatedly in scientists’ testimony, in policy documents, and in
statements of officials in the [US] Department of Health, Education, and Welfare and the
National Institutes of Health to justify the claim that there was little cause for concern”
(Wright 1986). Plans to draft new US regulations specific to rDNA technologies were
consequently dropped and the NIH guidelines were weakened. Similarly, Health and Welfare
Canada had drafted new rDNA regulations based on the MRC guidelines, “but because of
questionable aspects and low estimates of the risks, the regulations were held in abeyance”
(SCC 1982). This “consensus” had a profound and lasting effect on the biotechnology debate
in that it marked “a major change in the principles guiding NIH policy... the burden of proof
was transferred from scientists, to show that genetic engineering was safe, to the general
public, to show that it was dangerous” (Eddy 1983; see also Wright 1986). Indeed, the
marked lull in scientific and political controversy from the late 1970s to early 1980s provided
a sufficient window of opportunity for the biotechnology industry to become firmly
established in US and Canadian government policies and economies. This “first phase” of
Canadian biotechnology development is the point where I begin more indepth analysis of the
political construction of biotechnology “safety”.

2.2.2 Phase One: Science and Technology “Push” (1980-1985)

Background Studies for Biotechnology Development

In 1980, the federal Ministry of State for Science and Technology (MOSST)²
published a background paper called Biotechnology in Canada—a paper that initiated the
“first phase” in “a process to develop a federal policy for the promotion and development of
biotechnology” (MOSST 1980). The paper outlined growing areas of research and
development, specifically the use of micro-organisms in energy production, mining, pest management, fermentation technologies, bioremediation and development of health care products, as well as the “long term possible opportunity” of manipulating bacteria for nitrogen fixation, and developing new plant varieties “tailored more specifically to requirements”. Despite these opportunities, the paper also emphasised the current lack of expertise, education programs, and industrial activity in Canada, particularly compared with investment in, and growth of, biotechnology industries throughout the US and Europe. The report advised that, rather than attempting to exploit all possible applications, Canada should identify and focus on key areas of biotechnology “which are worth exploiting in a Canadian context.”

Building on this report, in 1980 MOSST established a private sector task force on biotechnology, stating that “biotechnology held an enormous development potential and that it was essential that Canada take full advantage of the opportunities” (cited in Task Force on Biotechnology 1981). The terms of reference for the task force were, among others:

• to advise the Minister on the possibility and suitability of instituting specific policies and programmes designed to allow Canada to take advantage of the opportunities offered by biotechnology
• to review possible ways of encouraging and promoting the required research and development and assuring that the results...will be used to meet economic and social development needs
• to submit recommendations... including a plan of action to ensure that Canada can take full advantage of the advances in biotechnology (Task Force on Biotechnology 1981)

While the task force was required to consult with government, industry and universities as needed, the terms of references made no mention of public consultations, or the need to regulate the incipient Canadian biotechnology industry. The final report of the task force (Task Force on Biotechnology 1981) echoed the concerns and urgency of the earlier MOSST paper, namely: a “badly eroded” scientific community in government and
academia; “rapidly shrinking federal research capability and highly fragmented and
unfocussed university effort”; and a lagging and non-competitive industrial sector relative to
concurrent growth in biotechnology research and development abroad. In absolute terms,
Canada was indeed lagging behind the US. Whereas over 80 private biotechnology firms
were founded in the US in 1981 alone (Krimsky et al. 1991), only two Canadian firms were
formed in the same year, although many others were established throughout the 1980s and
1990s (Heller 1995). The MOSST task force therefore urged “[i]f for no other reason than
the necessity of maintaining a competitive marketing position with respect to other countries,
Canada’s resource-based industries in particular must now accelerate their exploration of the
exciting possibilities offered by biotechnology” (Task Force on Biotechnology 1981).

To this end, the task force outlined elements of a 10 year development plan, the
objective of which was to “create in Canada the climate which will encourage the
establishment and growth of a variety of industries which are built upon biotechnology.”

Essential elements of this objective included:

• Long-term commitment by all sectors including a lead “coordinating and
catalysing” role for the federal government
• Stimulation of industry through financial incentives and tax shelters
• Financial commitment to develop a science base “appropriate to the
development of biotechnology”
• Increased international collaboration, and if necessary enactment,
modification, or elimination of “regulations or legislation which, if not
addressed, will leave Canada at a serious disadvantage relative to the rest of
the world...” (Task Force on Biotechnology 1981).

More specifically in terms of regulation, the task force recommended a general review
and elimination of inhibitory sections of the Patent Act, introduction of Plant Breeder’s
Rights as a form of intellectual property protection, and continued use of existing MRC
rDNA research guidelines with an added system of voluntary compliance for the private
sector.
The two MOSST reports set the tone for future biotechnology regulations in Canada. Recommendations of the 1981 task force formed the basis of the first National Biotechnology Strategy which was established in 1983 and remained in effect until 1998 (described below). In view of this enduring influence, it is worth emphasising the limited definitions of biotechnology used in the preliminary studies and the apparent discrepancy between the initial vision of a Canadian biotechnology industry, and the current situation in which rDNA crops are grown on almost 3 million unconfined hectares of land. Given that rDNA techniques for plants were not developed until the mid 1980s, it is not surprising that both MOSST reports focused on use of micro-organisms and fermentation technologies already well developed in Europe, the US and Japan. For example, the 1981 paper defined biotechnology as the use of microbial, animal or plant cells or their constituents to provide goods and services. New cellular and molecular techniques were regarded as extensions of existing technologies which have “greatly magnified the range of applications to which biological processes can be directed.... It is this broadened range of fermentation which is now known as biotechnology” (Task Force on Biotechnology 1981; emphasis added). While the 1980 background paper acknowledged the long-term, “futuristic” possibility of deliberately releasing viable rDNA organisms, it too focused on contained industrial processes of microbial fermentation (MOSST 1980).

Implementing the first National Biotechnology Strategy

Heeding recommendations of the MOSST task force, in 1983 the federal government allocated $22 million over two years to establish and implement the first National Biotechnology Strategy (NBS) and over $100 million to fund national biotechnology research centers (NBAC 1984). Over $3 million of the NBS funding went to Agriculture Canada,
more than was allotted to any other sector (SCC 1985). The objective of the NBS was to “provide federal policy guidance and programme support to encourage the concerted action necessary to make commercial progress” in biotechnology (NBAC 1984). Toward this objective, the strategy established seven National Biotechnology Networks “to promote communication and cooperation between scientists and users of research” (Hollebone 1989), as well as financial incentives for industrial development and technology transfer, and a new National Biotechnology Advisory Committee (NBAC).

Members of the first NBAC were appointed by MOSST and included 25 representatives from the private sector and government. Their mandate was to advise the Minister directly on the development of biotechnology, provide guidelines and “ensure that the advice of industry and the universities is a major factor in the federal government’s programs in this increasingly important field” (MOSST 1984). The committee’s first report, published in 1984, was prefaced by the following position statement:

The overriding priority for the Committee [NBAC] is to persuade the federal government that if Canada is to take advantage of the current window of opportunity in biotechnology, the pace of development must be accelerated through substantially greater investment, both in the science base and in technology transfer and development programmes (NBAC 1984).

In the report, NBAC reiterated the urgency expressed in previous MOSST papers: existing efforts of Canadian industry, science, and government towards developing biotechnology were inadequate to remain competitive on a global scale. Measures to redress this situation included increased tax incentives and financial assistance for industry; further pressure to revise intellectual property laws to “signal to potential investors and the R&D community that Canada has an environment conducive to commercial investments and activities in biotechnology”; programs to increase technology transfer from university to industry; general
strengthening of science and technology capabilities; and improved communication and networking within Canada and the international community.

**Economic Pressures and Science and Technology (S&T) Policy**

This explicit “technology push” (Task Force on Biotechnology 1981) of the federal government—initiated by the early MOSST studies and operationalised by the NBS—is best understood in the context of concurrent economic trends and federal policies on science, technology and industry. As Canada’s economic situation steadily deteriorated in the recession of the 1970s and 1980s, concern for the national economy and industrial performance emerged a major public policy issue (Globerman 1978) and was indeed foremost in government reports on industry and technology at that time. For example, two reports by the Science Council, *Forging the Links* (SCC 1979) and *Hard Times, Hard Choices* (SCC 1981), and a report by the Economic Council of Canada, *The Bottom Line* (ECC 1983) outlined symptoms of Canada’s economic and industrial decline: soaring federal debt, increased inflation and unemployment, falling productivity, decreased exports and increased imports of manufactured goods. The 1979 SCC report concluded that the current situation “can only be described as a massive failure of the country’s industrial system” (SCC 1979).

While there are indicators that Canada was worse-off, the recession had directly affected all industrialised countries, and by the early 1980s there was a growing movement to stimulate national economies and international competitiveness through innovative, research intensive, high-technology industries. No doubt this pressure was felt in Canada, perhaps exaggerated by Canada’s signing of the General Agreement on Tariffs and Trade (GATT) in 1979. The problem was that “Canada had nothing resembling a systematic national policy
for science and technology. Various piecemeal programs were scattered across a wide array of government departments and agencies, but there were no nationally established goals and this area was only weakly represented in Cabinet by the MOSST” (Stritch 1997).

Into this pressurised environment, the SCC advanced a new strategy of “technological sovereignty”, a process that “directs attention to the importance of technology in the modern industrial process and to the manner in which that technology is integrated into the industrial system” (SCC 1979). Achieving technology sovereignty, according to the SCC, would entail long-term restructuring of the economy, increased cooperation between government and the private sector, strengthening of Canada’s technological capabilities, and specialisation in a few key R&D intensive technologies. Singled out as the most promising—albeit currently lagging—technologies for this type of economic regrowth were electronic engineering, computer technologies, and biotechnology (SCC 1981).

By the mid 1980s several changes were afoot. The NIH prohibition on environmental release of rDNA organisms was lifted in 1983, allowing field testing in the US and increasing the pressure for Canadian biotechnology to compete. In the same year, the Canadian government announced a broad new policy for technology development, and MOSST was re-organised to “reflect the pervasive nature of science and technology in economic and social policy” and to strengthen the ministry’s historically weak role in government decision-making (Stritch 1997). The new technology policy emphasised once more that “Canada’s productivity performance...has been steadily weakening over the past decade” and that poor productivity growth “has severely eroded our competitiveness” (MOSST 1983). Policy initiatives therefore reflected familiar themes of innovation, technology transfer, government/university/private sector alliance as well as measures to address the potential social impacts of technological change, particularly in terms of employment and training.
Three technologies were again highlighted as major components of the new policy, microelectronics, communication and “one of the most important emerging technologies”, biotechnology (MOSST 1983). Thus, while biotechnology was explicitly promoted, it was not the only technology that received an enthusiastic push from the federal government. The National Biotechnology Strategy was one component of a broader technology promotion program.

These new policies and strategies however, did not signal the end of Canada’s technology promotion, or bring reprieve from economic problems. The 1984 Task Force on Federal Policies and Programs for Technology Development cautiously stated that the current “unforgiving economic climate is creating new demands on our capacity to innovate. Canadian industry is just beginning to respond to this challenge, and still has a long way to go” (MOSST 1983-84). New S&T policies and increased financial support for biotechnology were announced throughout the mid and late 1980s (see below).

The hearty welcome in 1983 of a national program to support biotechnology was therefore perfectly in line with domestic policies on S&T policy and international trends in industrial innovation. Biotechnology promised enormous economic, social, scientific and industrial potential at a time when Canada was struggling on both a national and international scale. And while the “long-term possibility” (MOSST 1980) of unconfined release of rDNA micro-organisms and plants was recognised, more tangible and immediate benefits lay in the development of health care products and contained processes of microbial fermentation—the safety of which had been sanctioned by MRC and NIH guidelines and a purported consensus within the scientific community (Eddy 1983; Krimsky 1991; Wright 1986).
Growing Concerns

The "concerted action" of the Canadian and US federal governments to promote biotechnology in the early 1980s did not entirely escape critique or concern. Shortly after the NIH prohibition was lifted and the Canadian NBS was announced, debate over the safety of deliberate release began to heat up in the scientific community. Scientific conferences were held in the US in 1984 and 1985 specifically to address issues of deliberate release. In contrast to the purported consensus of the 1970s, participants of these meetings concluded that unconfined release of ecologically competent organisms raised new concerns and required new regulations (Halvorson et al. 1985; Regal 1998).

In Canada, a series of reports published by the Science Council analysed the adequacy of existing MRC biosafety regulations, the potential biological and social hazards of biotechnology, and the role of science and the public in policy-making (Eddy 1983; Krimsky 1984; Miller et al. 1981; SCC 1982). For example, in 1980 the SCC sponsored a workshop and published the proceeding under the title Biotechnology in Canada: Promises and Concerns (Miller et al. 1981). As in the reports discussed above, one of the "promises" and "concerns" expressed in the SCC proceedings was Canada’s poor competitive advantage relative to the thriving European and US biotechnology industries. In fact, the consensus among participants was that Canadian biotechnology should be “aggressively pursued” and that the government ought to “provide a supportive climate”. However the SCC proceedings also identified a range of concerns not articulated by MOSST, NBS, or NBAC:

While the new biology has commercial potential, laboratory accidents, deliberate misuse of new techniques, unexpected interactions with the environment, harmful effects of commercialisation on the academic molecular biology community, and the creation of products with harmful long term effects are very real possibilities. Regulation, controls, and education must, therefore, be components of our development strategy. At this early stage in its industrial involvement, Canada is in a position to weigh both the promises
and the concerns of biotechnology before economic forces take over (Miller et al. 1981).

Commentaries by David Suzuki (who had declared a “personal moratorium on recombinant DNA research”), Stuart Ryan, a lawyer and member of MRC’s Biohazards Committee, and other members of the workshop emphasised the uncertainties of rDNA technologies and organisms, the potential negative effects of university-private sector affiliations on the scientific community, and the need for regulations beyond the current MRC guidelines.

A more resounding critique of the federal government’s position on biotechnology and other “value-scientific” issues, was set forth in the SCC’s 1982 report, Regulating the Regulators (SCC 1982). It is worth reviewing this document in some detail because it highlights the very problems facing the Canadian federal government and biotechnology industry today, and yet were effectively ignored in the intervening 15 or so years. While recognising the pervasive economic incentives and technological imperative driving high-technologies in general, the 1982 report strongly advised proactive measures to address complex social and ethical issues as well as the “potentially self-propagating, irreversible and large-scale” biological hazards posed by the “new biology”. The major insight of Regulating the Regulators, however, was the identification of several barriers to radically new styles of decision-making and more effective regulations for biotechnology. These conclusions, summarised in Box 2.1, were supported by two subsequent publications of the SCC that analysed existing MRC guidelines and recommended regulatory amendments (Eddy 1983; Krimsky 1984). Although none of the reports explicitly invoked the Precautionary Principle, there is remarkable similarity between the following barriers to regulatory change, and the core elements of precautionary action.
• **Overriding economic goals.** According to the 1982 report, a major barrier to new decision-making processes or regulations is the "powerful economic incentive for industrialised nations to seek and exploit technological innovation, even in the face of recognised scientific uncertainties and ethical dilemmas". Given this overriding incentive, additional or alternative measures are likely to be seen as "impositions on an already overloaded policy process and as impossible demands of the scarce resources of a department" (SCC 1982).

• **A limited notion of "public process".** The 1982 report argued that existing decision-making processes for rDNA technologies in Canada were not truly public processes, particularly in comparison to the adversarial style of the US government. For example the report claimed that the "Canadian process is characterised as open because there was no formal exclusion. Interested persons were allowed to participate on a regular basis. Because formal rights of participation did not exist, and the dates and agendas of meetings were not announced publicly, we do not characterise the process as public" (SCC 1982; emphasis original). The SCC noted the lack of encouragement and funding of public interest groups to allow for "fair representation of diverse interests" and concluded that "statutory requirements for broader and better public participation are needed" (SCC 1982). These points were echoed in the 1983 SCC report (Eddy 1983). Through comparison of rDNA regulations in Canada, the US and the United Kingdom, the author asserted that existing MRC guidelines and procedures of the Biohazards Committee were primarily administrative concerns, handled in a relatively

<table>
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<th>BOX 2.1 Barriers to Effective Biotechnology Regulation Identified by SCC</th>
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<tr>
<td>• Overriding economic goals</td>
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<td>• A limited notion of &quot;public process&quot;</td>
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<td>• Limited accountability and access to information</td>
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<td>• Entrenched incrementalism</td>
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<td>• Lack of foresight</td>
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<td>• Failure to address broad social and ethical issues</td>
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closed fashion by the bureaucracy, and “not suited to contentious matters”. In contrast, NIH guidelines and committees in the US were openly political, and therefore evoked greater public controversy over the issues of genetic engineering. The report concluded that the Biohazards Committee “has over its lifespan pursued, with conscientious thoroughness, its role of seeking, through a nonpublic process, acceptable levels of risk” (Eddy 1983; emphasis added).

• **Limited accountability and access to information.** In criticising the government’s failure to record and make public the scientific rationale and data used in decision-making, the SCC (1982) cautioned, “[i]f the responsibility and basis for a decision are not recorded or if background documents are not freed from the seal of Cabinet secrecy, there is no way to separate scientific reasoning from political negotiation.” Traditions of Cabinet secrecy, ministerial responsibility, “informal consultations with selected interests” and lack of Freedom of Information legislation further compromised governmental accountability on value-scientific issues.

• **Entrenched incrementalism.** The 1984 SCC report (Krimsky 1984) examined existing Canadian health and environmental legislation to determine whether oversight of biotechnology would require new laws or whether issues could be accommodated under existing frameworks. The author found “important gaps in the Canadian regulatory system with respect to the potential health and ecological impacts of biotechnology” in part because “[m]ost of the leading environmental statutes were not explicitly enacted for controlling biological agents or products derived from those agents” but were developed primarily for chemical and radiation pollution. The hazards posed by biotechnology were, in other words, unprecedented in Canadian environmental legislation. In particular, the author pointed out that the existing Seeds Acts, which regulates the sale, labelling, importing, and exporting of
seeds, does not recognise rDNA seeds as requiring additional testing, and therefore does not control field testing of genetically engineered strains, or incorporate potential ecological effects of new varieties. As such “no agency reviews genetically modified seeds prior to field testing” (Krimsky 1984). The author recommended a legal interpretation of the Seeds Act and, if necessary, amendments to incorporate current omissions.

• Lack of foresight. The 1982 SSC report emphasised the “low priority given to early warning and preventive mechanisms in the decision-making process” and the “short-term nature of political attitudes which hinders our ability to deal with long-term scientific and ethical problems” (SCC 1982). Recommendations of the 1984 report reiterated these concerns: “It is easier to regulate a technology before rather than after it becomes incorporated into the economy.... One should not wait until a technology results in a demonstrated hazard before some action is taken to monitor or regulate its effects” (Krimsky 1984).

• Failure to address broad social and ethical issues. Both the 1982 and 1983 SCC reports argued that existing guidelines and structure of the Biohazards Committee were not adequate to address the social and ethical issues raised by biotechnology. In fact, the entire premise of the 1982 document was that “value-scientific” issues require new decision-making processes and the greater attention of the federal government. The authors recommended that “when risk assessment is part of a policy process, the social, political and value assumptions underlying the evaluation of risk, and the trade-offs involved in making a decision must be stated and justified in light of the final decisions. This information should be contained in a public record of the decision-making process” (SCC 1982). As we will see, these are recurrent problems in Canadian biotechnology regulations and will be discussed further in Chapter 4. As an interesting side-note, the SCC was abolished in 1992. According to Stritch
(1997) this decision was “partly for budgetary reasons and partly because its independent
criticisms had often embarrassed the government by highlighting the failures of S&T policy.”

**Summary: Phase One**

The dominant ideas and conflicting pressures of the early 1980s were well
summarised by a further Science Council study, *Seeds of Renewal* (SCC 1985). Published in
1985, this was the first report specifically to address plant and agricultural biotechnology, and
the last significant report of the “science and technology push” phase of Canadian
biotechnology policy. On one hand, *Seeds of Renewal* identified “opportunities that the
Canadian resource industries could realize if the public sector and private business work
together to ensure the speedy and aggressive adoption of advanced biological techniques.”

Foremost among these opportunities was increased world trade in technology-intensive
products, such as genetically engineered crops:

...Canada has an enormous stake in agricultural development. Approximately
50 per cent of Canadian farm income comes from exports.... In the long term,
Canadian agriculture can develop only through the expansion of export trade.
Important opportunities exist. If realised, they could revitalise the farm
industry. Although biotechnology offers no “quick fix”, backed by effective
policies, it could offer the support required to maintain Canada’s competitive
position (SCC 1985).

On the other hand, however, the report emphasised that despite tough economic times,
capitalising on the potential benefits of biotechnology will require additional government
spending to promote S&T, and further incentives for the private sector to engage in research
and development. Thus S&T policy in general, and promotion of biotechnology in particular,
were perceived as *means* to address the larger issues in federal economic policies, primarily
by boosting Canada’s competitive advantage in the international arena. Yet the Science
Council repeatedly advised that the MRC safety guidelines and procedures of the Biohazards
Committee be reviewed and, if necessary, replaced by legally binding regulations and a broader framework for decision-making (Eddy 1983; Krimsky 1984; SCC 1982; SCC 1985). Given the apparent urgency of Canada's economic situation, the optimism placed in a strong biotechnology industry, and the relative calm in the scientific community, it is not surprising that a costly and time-consuming overhaul of environmental legislation or long-term ecological testing of rDNA organisms were of low priority. However, the 1985 report of the Science Council noted two reasons why environmental regulations might nevertheless be a worthwhile endeavour: "A healthy regulatory environment for the commercial development of biotechnology is essential, not only to allay public fears of the new technology, but also to encourage corporate participation. Good regulations can promote development; the absence of clear guidelines may retard it" (SCC 1985; emphasis added). I will argue that this was precisely the rationale and direction followed by the Canadian government and industry in subsequent phases of biotechnology policy.

2.2.3 Phase Two: Guidelines and Field Trials (1986-1992)

"Increasing Pressures"

In 1988, Dr. Jean Hollebone, then a senior bureaucrat with Agriculture Canada and one of the key developers of Canada’s biotechnology policies stated:

Increasing pressures have been felt by the regulatory agencies from many quarters to develop regulations that are rigorous but not overly restrictive. These regulations must provide assurances that the products can be used without adversely affecting humans and animal health, and the environment. At the same time, the regulations must not be so restrictive or time-consuming to fulfil that industry loses its competitive advantage and seeks markets outside the country (Hollebone 1988).

As this quotation suggests, Canadian regulations for deliberate release of rDNA crops were not developed in isolation, but in reaction to "increasing pressures" such as renewed debate...
within the scientific community and the growth imperative of industrial and economic sectors. Regulations were also devised in close concert with Canadian and US regulatory developments, and the goals of international organisations such as the Organisation for Economic Cooperation and Development (OECD). It is therefore difficult, and perhaps unnecessary, to establish a precise chronology of policy developments as events, organisations and interests were often inextricably bound. Nonetheless, to appreciate how key concepts and values became embedded in regulatory policies and led to the “safe” release of rDNA crops, it is important to situate Canadian policies in the context of these diverse pressures.

In the mid 1980s, public opposition to unconfined environmental release in the US was galvanised by several proposals to field test rDNA crops, the most sensational of which was an “ice-minus” strain of bacteria intended to prevent frost damage to plants. Jeremy Rifkin, then an outspoken critic of biotechnology, sued “ice-minus” proponents (University of California and the National Institute of Health) sparking heated public meetings, media attention and political debate (Krimsky 1991). Controversy also flared in the scientific literature, with several ecologists advocating a risk aversive position toward unconfined release, and molecular biologists defending a pro-risk stance (see Brill 1985; Colwell et al. 1985; Sharples 1983; Sharples 1987; Szybalski 1985). As revealed in the Agriculture Canada quotation above, the potential hazards of commercialising rDNA organisms were becoming difficult—and politically unwise—to ignore.

Two documents published in 1986-87 significantly influenced the burgeoning debate as well as future regulations for deliberate release of rDNA organisms: the OECD’s *Recombinant DNA Safety Considerations* (OECD 1986), and the US National Academy of Sciences’ *Introduction of Recombinant DNA-Engineered Organisms into the Environment*
(NAS 1987). These documents shared several principles which later became central to the US and Canadian regulatory frameworks. Foremost, the documents asserted that rDNA organisms and techniques do not pose unique hazards and therefore do not require new, separate regulations. As stated by the NAS, the “risks associated with the introduction of rDNA engineered organisms are the same in kind as those associated with the introduction...of unmodified organisms and organisms modified by other genetic techniques” (NAS 1987). The OECD claimed that there is “no scientific basis for specific legislation to regulate the use of recombinant DNA organisms” and that “[a]ny potential environmental impacts of agricultural and environmental rDNA organisms are expected to be similar to effects that have been observed with introductions of naturally occurring species or selected species used for agricultural applications” (OECD 1986). In fact, both documents claimed that the environmental effects of rDNA organisms are more predictable than those of conventional varieties due to the precision with which genes can be transferred.

According to the NAS, it follows from these premises that “there is adequate knowledge of the relevant scientific principles, as well as sufficient experience with rDNA engineered organisms, to guide the safe and prudent use of such organisms outside research laboratories” (NAS 1987). The OECD was less sanguine about the current level of scientific knowledge but assured that “additional research and experience with rDNA [organisms] should certainly increase our ability and precision to predict the outcomes of introductions of rDNA organisms into many varied environments” and further that “the means for assessing rDNA organisms can be approached by analogy with the existing data base gained from the extensive use of traditionally modified organisms” (OECD 1986).

Through these documents, the NAS and the OECD effectively established a rationale for case-by-case and product-based biotechnology regulations that are currently used in
Canada and the US. By this framework, rDNA organisms are regulated according to
ccharacteristics of the final product, and not on the basis of the process through which they
were created; there are no characteristics common to all rDNA organisms which identify
them as requiring special oversight. Each assessment must therefore be made individually
according to existing regulatory practices for non rDNA organisms. The NAS and OECD
documents also laid the foundations for the currently powerful concepts of “familiarity” and
“substantial equivalence”. As will be discussed below, these concepts function as triggers for
environmental risk assessment in Canadian regulations by comparing “novel” plants to
similar crops already in use.

Moving Toward Guidelines and Regulations

With the adequacy of existing regulatory principles and rationale for product-based
regulations clearly affirmed by two influential organisations, Canada’s main priority was to
clarify the jurisdiction of current statutes and departments. Statutes relevant to biotechnology
were administered by three federal departments who would later become lead regulatory
agencies, Health and Welfare Canada, Environment Canada, and Agriculture Canada.
Division of power among federal agencies was, at the time, unclear and none had established
formal regulations for release of rDNA organisms. Although the 1983 National
Biotechnology Strategy outlined plans for a working group on safety issues, it was not until
1985 that an Interdepartmental Committee on Biotechnology (IBC), comprised of regulators
from departments of Health, Environment, and Agriculture, was formed. A number of
subgroups and ad hoc working groups on safety and regulations were established by various
federal departments throughout the late 1980s. These committees agreed upon several
principles for biotechnology regulation: build on existing legislation; regulate product rather
than process; harmonise national regulations with international developments; and use risk assessment as a general framework for oversight.

In 1986, the IBC commissioned a report on the current regulatory situation in Canada. The resulting *Henley Report* outlined "examples of jurisdictional inconsistency and weaknesses in environmental legislation" (NBAC 1987-88) and was not taken into further account (CFIA interviews, 1998). A similar study, the *Beak Report*, was commissioned by MOSST and published in 1987. This report had considerably more influence, spawning the first comprehensive document on biotechnology regulations in Canada, the 1988 *User's Guide* (MOSST 1988). This guide assisted regulators and industry in determining which regulations and departments were responsible for specific biotechnology products. With regard to agricultural products, the *User's Guide* clearly established that new plant varieties and seeds produced through rDNA and other genetic techniques would be covered under existing provisions of the Seeds Act, and administered by Agriculture Canada. This statement was made in due time, as confined field trials of rDNA crops had already commenced in 1988 (Caldwell and Duke 1988). As for large-scale releases, the *User's Guide* assured that Agriculture Canada was "currently investigating the data requirements for field-scale testing" (MOSST 1988). In the interim, small-scale field trials would continue to be assessed on a case-by-case basis.

The results of Agriculture Canada's 'investigation', released in two parts in 1988 and 1989 (Caldwell and Duke 1988; Kalous and Duke 1989), set out several premises that would later form the basis of Canada's formal regulations. Through interviews with plant biotechnologists and reference to the scientific literature, the first part of the report (Caldwell and Duke 1988) identified the "major risks" of releasing rDNA crops as "weediness, toxicity of edible plants, production of plants with unfavourable traits and transmission of exotic
genetic material to other species”. Despite this list, the report also concluded that “recombinant DNA technology is an exact method of plant variety development and poses no more risks than the more traditional methods of plant variety development”. Furthermore, “plant biotechnology has proven to be of less risk than genetic engineering of other organisms” and inadvertent effects such as weediness or gene flow will likely be detected in the greenhouse before release and/or be controlled through crop rotation and herbicides. In general, the first part of the report concluded that the probability of hazardous effects of releasing rDNA crops was low and therefore, “regulation may be introduced to minimise whatever risk exists but this must be done without harming the industry” (Caldwell and Duke 1988). Somewhat inconsistently, the subsequent part of the report stated that “genetically engineered plant materials” are being regulated because the risks are poorly characterised and potential ecological impacts are unknown (Kalous and Duke 1989).

Having identified relevant potential hazards of rDNA crops, the report considered various policy options: new legislation, regulations under existing legislation or guidelines. New legislation would be binding and comprehensive but would require a laborious approval process via Cabinet, Parliament, and Senate. Regulations under an existing Act are equally binding but can be amended without revising the entire Act. Finally, guidelines are not binding and therefore less easily enforced, but are much more flexible than regulations or new legislation. The report concluded that flexibility and efficiency was of utmost importance: policies “must not be overly restricting or complicated” and must “be able to evolve with the changes in the industry” (Caldwell and Duke 1988). Moreover “by excluding extravagant testing requirements, the financial burden that could be incurred by completion of an application is greatly decreased” (Kalous and Duke 1989).
To this end, the report recommended that small-scale field trials be regulated through guidelines, larger-scale tests be regulated through established provisions of the Seeds Act, and that there “is no need to develop further regulations for the commercialisation of genetically altered agricultural crops varieties” (Kalous and Duke 1989). These recommendations were put forward despite acknowledgement that there were no provisions in the Seeds Act to regulate field testing other than existing procedures for variety registration (Caldwell and Duke 1988). The variety registration process is required prior to commercialisation of any new crop variety imported to, or developed within Canada. Registration is conducted through field trials known as “co-op” or “variety” trials. These tests are mid-scale and may or may not employed confinement procedures. Variety trials therefore fall somewhere between small-scale confined trials and large-scale unconfined release. New crops varieties are registered according to agronomic performance, pest resistance, quality and varietal purity. However, the trials do not aim to assess potential environmental hazards of crop, as the Agriculture Canada report explicitly pointed out.

The report further established that all data submitted by proponents applying for field testing permits would be considered confidential. While both the Canadian Agricultural Research Council and NBAC had previously recommended an independent scientific advisory committee to oversee field trials (NBAC 1987-88), Agriculture Canada concluded that “administration of this committee would prove very difficult” because “problems of confidentiality would arise” and “the time to complete a review would increase dramatically

| BOX 2.2 |
| Recommendations for Biotechnology Regulations 1988-1989 |
| • administered by Agriculture Canada |
| • decided on a case-by-case, product basis |
| • follow flexible guidelines for small-scale tests |
| • follow existing provisions of the Seeds Act, according to the process of variety registration for large-scale release |
| • communicated to the public via abridged statements |

(Caldwell and Duke 1988; Kalous and Duke 1989)
if a committee was required to discuss and debate over each trial” (Kalous and Duke 1989). Due to lack of resources, detailed reports of government decisions were deemed not feasible but short summaries would be released “detailing only the type of field trial, provincial location, and a brief note on the terms and conditions of the trial” (Kalous and Duke 1989). Thus, in addition to blurring definitions of small-scale release, large-scale release, field-testing, variety trial testing and commercialisation, the recommendations of this report (summarised in Box 2.2) set the general framework and standards for the gathering and sharing of information during future rDNA crop risk assessments.

**Domestic and International Influences**

Despite (or perhaps because of) Agriculture Canada’s limited and somewhat vague regulatory proposals, in 1988 Cabinet sent a directive to all relevant federal departments calling for the establishment of a “clear, coordinated regulatory system for the products of biotechnology” (Hollebone 1993a). Likewise, the 1987-88 NBAC Report asserted the “urgent” need for a “healthy regulatory climate in Canada” both to protect the public from potential health and environmental hazards, and to ensure a viable and internationally competitive biotechnology industry” (NBAC 1987-88). Such a “healthy” regulatory system, according to NBAC, not only requires clarification of existing legislation, but means to “engender public confidence” in biotechnology through open processes to bring public “perceptions” of risk in line with “actual” risks as defined by experts: “The higher the level of public confidence in the fact that risks are being well managed, the closer the perceived risks match the actual risks, the more ‘economic sense’ the regulatory system makes” (NBAC 1987-88). NBAC also called for a flexible system that could adapt to, and incorporate “known”, “potential” and “hypothetical” risks, while adhering to “internationally accepted
scientific risk assessment principles” and providing a stable and predictable regulatory climate for industry.

Throughout this time, Canadian, US and OECD regulators met frequently to coordinate and “harmonise” policy frameworks (CFIA interviews, 1998). Indeed, international harmonisation was a main priority of the OECD, a trade-based organisation whose mandate is to “build healthier economies, create more employment, and foster trade for the benefit of OECD and non-OECD countries alike” (OECD nd). This interest is clearly stated in OECD documents on biotechnology: addressing safety issues will not only protect health and the environment but will also promote “international commerce and the reduction of national barriers to trade” in the products of biotechnology. Therefore “[a]ny approach to implementing guidelines should not impede future developments in rDNA techniques” (OECD 1986). Canada supported efforts toward harmonisation, recognising that continued export of agricultural and other product depended on consistent and mutually agreed standards of safety and regulatory oversight (Hollebone 1988; NBAC 1987-88; CFIA interviews, 1998). Increased, liberalised trade was in fact high on Agriculture Canada’s policy agenda in the late 1980s especially as the Canada-US Free Trade Agreement (CUSTA) was signed in 1988. The resulting competitive pressure was well reflected in Agriculture Canada’s 1989 policy review, entitled Growing Together (AC 1989).

The Growing Together “vision” of Canada’s agriculture and food industry emphasised the importance of export markets, the “life-blood of many segments of Canada’s agri-food industry”, and particularly trade in grains and oilseeds “the backbone of our positive trade balance in agricultural products” (AC 1989). Technology was identified as key to increased efficiency, productivity and competitiveness: “One clear challenge will be to ensure that we can develop and apply new technology more rapidly than our competitors”.

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Biotechnology applied to canola production was cited as one specific area to pursue. The report outlined several “pillars of reform” as means to attain a highly competitive, technology-based agricultural sector. Foremost, market demands rather than production capabilities should determine direction of agricultural technology—a marked shift from the “science push” of the early 1980s to a “market-pull” strategy. In this process, the government should maintain a supportive role through increased “partnerships” and a “new understanding” with industry and consumers, but government programs and policies should not “mask market signals”. Rather, “[w]e must ensure that we do not face more regulatory obstacles than do our competitors.” Industry must therefore move toward greater self-reliance in managing production, responding to markets, absorbing risks and ensuring product safety. In fact, in Growing Together, the government absolved itself of many responsibilities for ensuring the safety and quality of food products by moving this issue into the marketplace, and onto the shoulders of industry and consumers.

A further pillar of proposed agricultural reform identified by the policy review was environmental sustainability, no doubt influenced by the 1987 Brundtland Commission report which advanced the concept of sustainable development. The Growing Together report supported efforts to conserve soil, water and wildlife habitat, but at the same time emphasised that regulation, conservation, economic growth and technological advance must not be mutually exclusive:

We must recognise that modern technology, safely used, is the keystone of modern agriculture. Our policies should not be to ban or prohibit this technology, but to ensure its safe use. We should recognise that agriculture is not sustainable without the use of much that is referred to as modern technology, and accept the challenge of finding the safest ways of using it (AC 1989).

Regulators within Agriculture Canada were thus under pressure from industry, trade organisations and the federal government to implement a harmonised, predictable and
flexible framework that would “ensure safety” as well as expedite the development of agricultural biotechnology. At the same time, Agriculture Canada’s research and policy branches called for increased exports and a competitive, technology-based and self-reliant private sector and a research branch that “was more responsive to industry needs and priorities” (Moore 1998). NBAC, comprised primarily of private sector representatives, maintained this pressure in their 1991 annual report (NBAC 1991). Subtitled Capturing the Competitive Advantage in Canada, the report advised: “Federal regulations are a critical determinate of the cost and time required to bring a new biotechnology product to market. Current delays and regulatory uncertainties are discouraging new research and investments in commercial facilities, driving up the costs of innovation and undermining public confidence” (NBAC 1991).

A significant move to reconcile these pressures was achieved in 1990 with the enactment of the Plant Breeder’s Right Act. Intellectual property protection in the form of plant breeder’s rights had been on the policy agenda since 1978, but the confluence of political ideas and pressures in the late 1980s, particularly the emphasis on innovation, competitiveness, and self-reliance in the private sector provided a favourable climate for passing legislation (Moore 1998). Plant Breeder’s Rights grant to developers exclusive legal rights to plant varieties for a period of 18 years. The new legislation was intended to stimulate and support private investment in plant breeding by providing financial return through royalties and sales (AC 1985).

Despite this general shift to a “market pull” strategy, new government S&T programs also ensured that the “science push” initiated in the early 1980s continued well into the 1990s. A new broad technology policy called “Innovaction” was launched in 1987, resulting in a stronger and more prestigious department of Industry, Science and Technology
(incorporating MOSST). In 1988, the government announced $1.3 billion of new funding to promote research and development of priority technologies including biotechnology (Stritch 1997) while in the same year, regulators at Agriculture Canada complained that “[l]ack of resources is the critical limiting factor affecting the speed of regulatory development” (Hollebone 1988; emphasis original).

**Influence of the Scientific and Environmental Communities**

In addition to these myriad pressures and incentives, at least two additional forces influenced the direction of Canadian biotechnology policies during the late 1980s and early 1990s: debates within the scientific community, and activities of the broad environmental community. In 1989, the US National Academy of Sciences published a second report on regulation of “genetically modified” organisms, a category which included classical, cellular and molecular technologies (NAS 1989). The report built upon key principles outlined in the 1987 NAS report. That is, regulations should be product- rather than process-based, because organisms developed through rDNA (molecular) techniques do not pose unique hazards relative to organisms developed through conventional or cellular methods: “Crops modified by molecular methods in the foreseeable future pose no risks significantly different from those that have been accepted for decades in conventional breeding” (NAS 1989). From these premises, the NAS constructed a framework for regulation centered around the concept of “familiarity”. In evaluating the risks of small-scale releases, we should ask “Are we familiar with the properties of the organism and the environment into which it may be introduced?” Familiarity means “essentially similar to known introductions” and is assessed at the phenotypic level. If an rDNA crop is deemed familiar to existing crops that are “proven to present negligible risk” then the risks of releasing the rDNA variety are also
deemed negligible and field testing may commence. Together, the concept of familiarity and premise that rDNA techniques do not present unique hazards, have proven very powerful in Canadian and US biotechnology policies by providing a flexible but "scientifically-based" (NAS 1989) framework for risk assessment (Barrett and Abergel in press; see also discussion below). As in the earlier documents discussed above, the NAS report deferred more complex issues surrounding large-scale, unconfined release to a later date, except to note that experience gained through small-scale trials can be used to gauge the potential impacts of larger-scale release.

Discussion of deliberate release by the scientific community was not restricted to the NAS however. A number of research and discussion papers devoted to the potential hazards of rDNA organisms were published in the late 1980s and early 1990s. For example, in 1989 the Ecological Society of America (ESA) outlined a set of criteria for determining the level of regulatory oversight required for specific types of "genetically engineered" organisms (those modified through cellular and molecular techniques; Tiedje et al. 1989). The ESA’s criteria were more detailed than those proposed by the NAS, OECD or Agriculture Canada, but comprised the same general review categories: attributes of the genetic alteration, the parent organism, the modified organism and the environment into which the organism will be released. While the ESA supported “the timely development of environmentally sound products” of biotechnology, they also cautioned that “precise genetic characterisation does not ensure that all ecologically important aspects of the phenotype can be predicted for the environments into which an organism will be introduced” (Tiedje et al. 1989). The report therefore emphasised the current lack of ecological studies on the effects of rDNA organisms and called for more interdisciplinary research and education.
Many other scientific papers on the effects of releasing rDNA crops were published at this time, raising issues such as gene escape through hybridisation, increased weediness, evolution of insect resistance to modified traits, and socioeconomic impacts of agricultural biotechnology in general (for example see Colwell 1988; Gould 1988; Hodgson and Sugden 1988; Keeler 1989; Mooney and Bernardi 1990; Pimentel et al. 1989) A complete review of these papers is beyond the scope of the current discussion, but it is important to note that such potential hazards were actively and inconclusively debated within the scientific community during the period that the Canadian government was formulating guidelines and approving the first field tests of rDNA crops.

A final set of pressures influencing Canadian biotechnology policies during this second phase came from various corners of the environmental community. The late 1980s saw a resurgence of public concern for the environment, similar to the first wave of environmentalism in the early 1970s. Perhaps one manifestation of this resurgence was the 1990 publication, Biotechnology’s Bitter Harvest (Goldberg et al. 1990) a collaborative report by several environmentalist organisations in the US. Bitter Harvest was the first publication to address specifically the “threat to sustainable agriculture” posed by rDNA herbicide tolerant crops. In addition to outlining the potential environmental and health hazards posed by herbicides, the report strongly condemned the US government for spending public money on research and development of herbicide tolerant varieties, thereby perpetuating dependence on agri-chemicals. Bitter Harvest was remarkably influential; it was cited in numerous scientific publications and precipitated sharp cuts in US federal funding for herbicide tolerant crops (Duke 1996).

In Canada, the federal government responded to increased public concern and demand for government action on environmental issues in part by strengthening the historically weak
role of Environment Canada (EC). New environmental legislation, Canadian Environmental Protection Act (CEPA), was enacted in 1988, and the $3 billion “Green Plan” was launched in 1990; both were administered by Environment Canada. Although the Green Plan had no explicit provisions for regulation of agricultural biotechnology, it did stipulate that a regulatory regime to address the environmental risks be established by 1995 (Hollebone 1993a). The relationship between CEPA and biotechnology regulations, however, was (and continues to be) more complex and ambiguous.

CEPA is a broad and complex statute which replaced the former Environmental Contaminants Act of 1975. Drafting of CEPA involved extensive public consultation, and included a proposal to consolidate all biotechnology regulations under single legislation. Specifically, under CEPA, new biotechnology products would be regulated as potential “toxic substances” and subject to risk assessment by Environment Canada. The proposal would therefore have removed Agriculture Canada’s existing authority over rDNA crops under the Seeds Act, and was, unsurprisingly, not well received by Agriculture Canada officials or by the NBAC. According to one regulator, Agriculture Canada felt that regulation of biotechnology products under CEPA would have stifled the Canadian industry, and that Environment Canada did not fully recognise biotechnology as an “enabling” technology that did not pose new hazards and therefore did not require new legislation (CFIA interviews, 1998). The 1987-88 NBAC report also strongly advised against the proposal, stating that voluntary compliance under existing guidelines “has worked very well” and that the long notification and testing periods required by CEPA “could result in such serious delays that development of the products of biotechnology in Canada would not be worthwhile from a commercial point of view” (NBAC 1987-88). Due in part to these concerns, the proposal was not incorporated into CEPA in 1988. CEPA would cover only those
biotechnology products not already regulated under existing legislation—and Agriculture Canada’s jurisdiction over rDNA crops through the Seeds Act had already been established in the 1988 User’s Guide.

At that time, however, there had been no formal amendment of the Seeds Act to officially incorporate biotechnology products, and debate over the scope of CEPA continued well after its enactment in 1988. For example, speaking at a symposium in 1989, a regulator from Environment Canada stressed political, social and scientific reasons for implementing comprehensive new biotechnology legislation. In particular, Environment Canada pointed to a potential conflict of interest within Agriculture Canada: “Associated with the development of this technology...are a wide number of concerns about issues of government accountability and objectivity; and about the ability to assess a technology that is being promoted so resolutely and which could possibly result in untoward environmental and health impacts” (McIntyre 1989). The author did not mince words in outlining inadequacies of the existing regulatory system:

• A narrow and fragmented approach to environmental protection
• A reactive approach to environmental pollution
• No commitment to effective inspection and enforcement
• No commitment to the polluter pays principle
• No incentives for an aggressive regulatory agenda
• No effective role for the public
• No effective link between environment and economy or between environment and health (McIntyre 1989).

As all of these points are explicitly incorporated into CEPA legislation, regulation of rDNA crops under this Act would have significantly altered the existing “guidelines” for rDNA crop assessment.

However, CEPA also stipulated that within 5 years of enactment, a Parliamentary committee would undertake a comprehensive review of the Act’s provisions. Consequently,
debate over application of the above principles to biotechnology was revived in 1994 and remains ongoing in 1999 (see below). Thus, while neither CEPA nor the Green Plan had a direct or immediate impact on the regulation of rDNA crops at the time of implementation, both heightened government incentives to balance environmental issues carefully (if symbolically) with the existing Conservative agenda of privatisation and fiscal restraint (Hoberg and Harrison 1994).

The pressure on—and obligations of—government to address environmental issues was further intensified by Canada’s participation in the 1992 United Nations Conference on Environment and Development (UNCED, better known as the “Earth Summit”) and subsequent signing of the Rio Declaration and Convention on Biological Diversity (CBD). Specifically, the Rio Declaration explicitly endorsed the Precautionary Principle stating:

In order to protect the environment, the precautionary approach shall be widely applied by States according to their ability. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.

The CBD made only oblique reference to precautionary action, but mandated that consideration of biodiversity be included in all aspects of decision-making. Article 19.4 of the CBD specifically addressed the safe transfer, handling and use of “living modified organisms” defined as organisms “resulting from biotechnology that may have an adverse effect on the conservation and sustainable use of biological diversity” (CBD nd). However, the Article specified no more than the obligation of contracting parties and trading partners to share available information on the use, safety regulations, and potential adverse impact modified organisms. *Agenda 21*, the action plan resulting from UNCED, devoted an entire chapter to biotechnology. While *Agenda 21* clearly endorsed some applications of biotechnology as contributing to sustainable development, it also calls for “internationally
agreed principles on risk assessment and management of all aspects of biotechnology” (Agenda 21 1992). The implications and logistics of implementing these agreements were left to subsequent meetings of the “Ad Hoc Working Group on Biosafety” whose negotiations to develop a Biosafety Protocol for safe “transboundary” (international) movement of living modified organisms are ongoing in 1999. Nevertheless, Canada’s signing of the UNCED documents was significant in that it entailed an explicit commitment to international dialogue on the safe use of rDNA organisms, as well as to the principle of precaution as stated in the Rio Declaration.

Despite these diverse and often conflicting pressures exerted by various levels of government, industry, the scientific community, international organisations, environmentalists and the general public, Agriculture Canada approved over 600 field trials of rDNA crops during this second phase of biotechnology policy. These crops were assessed on a case-by-case basis under principles co-developed with the OECD and US officials. It was not until the third phase of policy development that specific regulations for the environmental risk assessment of rDNA crops were implemented.

2.2.4 Phase Three: Regulation and Commercialisation (1993-1997)

A New “Regulatory Framework for Biotechnology”

In January of 1993, a press release from federal government announced a new regulatory framework for biotechnology, the goal of which was “to minimise environmental risks while fostering competitiveness through timely introduction of biotechnology products to the marketplace” (Canada 1993). The press release outlined the benefits of biotechnology and assured that the regulatory framework “will enable the biotechnology industry to maximise opportunities while minimising concerns about human health and safety and the
environment” (Canada 1993). An official document detailing the components of the new framework was published later that year (AAFC 1993). Biotechnology, as defined in this regulatory document, “includes technologies used by humans for thousands of years (plant breeding) as well as a series of powerful new technologies such as genetic engineering” (AAFC 1993). The framework covered several products under the umbrella of biotechnology including “genetically modified plants” which were defined as a plants modified through “alteration of genetic materials” using rDNA and other techniques. While billed as “new”, this framework only formalised principles that were set out in earlier documents (shown in Box 2.3). According to the regulatory document, this approach “recognises and builds on the knowledge, expertise and infrastructure already present in the traditional regulatory areas. It is, therefore, both economically and scientifically sound” (AAFC 1993). Thus, although it was not inherently “new”, the framework seemed to ease the growing pressure for Canada to establish regulatory procedures: Speaking at an interdepartmental workshop later that year, one Agriculture Canada regulator assured that the new framework “sends a signal of confidence to the domestic and international markets” (Hollebone 1993a).

**Guidelines for Confined Field Trials**

The 1993 regulatory framework called for a safety review or “assessment of environmental impact” of genetically modified crops prior to confined field trials. Data requirements for these assessments, drafted in 1993 and amended in 1994\(^9\) (AAFC 1994b) are outlined in Box 2.4. While this list appears quite stringent and comprehensive, several qualifications are worth noting. First, all information is gathered and submitted by the proponents/developers of the crops. Second, data “requirements” are actually guidelines, and many can be waived. For example, the ecology and life-cycle of the parent plant need only
be supplied if the plant “is new or uncommon in Canada, or if the species differs significantly from the non-transgenic form” (AAFC 1994b).

Similarly, information on the stability of gene constructs, border sequences, altered ecological characteristics of the modified plant, and fate of gene products need only be provided “if available”. Finally, public notification is “strongly recommended” but is not required.

While the focus of this dissertation is risk assessment for large-scale unconfined release, the data and procedures used to evaluate confined trials are important because, as will be described in Chapter 3, in practice “confined” and “unconfined” stages of release are often difficult to distinguish. As recommended by the OECD and NAS, data gathered in small-scale trials are used to assess the potential hazards of unconfined release, even though small-scale trials may not be specifically designed to test such parameters. The regulatory document for confined field trials states that information gathered during small-scale tests “can be used to assess both performance and, to some extent, environmental safety of the modified plant material, assuming the trials are designed for these purposes” (AAFC 1994b; emphasis added). However, confined field trials, by

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**BOX 2.3**

Guiding principles for Canada’s 1993 Regulatory Framework for Biotechnology:

1. Regulation based on the characteristics of the product (including a review of the process by which it is made)
2. Science-based risk assessment
3. Protection of health and the environment
4. Building on existing legislation and areas of responsibility

(AAFC 1993)

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**BOX 2.4**

Data Guidelines for Confined Field Trials

Description of:
- plant material prior to modification (habitat and reproductive mechanisms)
- genetic modification (traits, gene constructs, method of introduction, mode of action, and fate of gene product when ingested)
- modified plant material (expression and stability of trait, toxin production, and changes in traits “that might confer an ecological advantage or disadvantage”)
- trial site (location, management, plant species related to test crop, fauna)
- trial protocol (size, seeding, isolation methods, spraying, harvesting, and post-trial land use)
- “monitoring capabilities and intentions” and plans to notify the local public

(AAFC 1994b)
definition, aim to prevent interaction of the rDNA crop with other organisms—the government guidelines were established precisely for this reason. Exemptions to reproductive isolation may be made, for example in outcrossing studies expressly designed to test gene flow, but there are no requirements to conduct such tests. In short, the 1994 field testing guidelines (AAFC 1994b) outline safety measures for testing the performance and efficacy of new rDNA crops and information required to determine if appropriate safety measures have been taken, but do not in themselves constitute an environmental risk assessment.

Assessment of Unconfined Release

With regard to unconfined release, the “new regulatory framework” announced in 1993 (AAFC 1993) stated that no trials have yet been approved in this category, and that “more detailed environmental evaluation is necessary” before approval would be granted. A document outlining proposed assessment criteria for unconfined release was drafted in 1993, and published in 1994 as Assessment Criteria For Determining Environmental Safety Of Plants With Novel Traits (AAFC 1994a). Data requirements specified in this document will be discussed in detail in Chapter 3. In this section, I will focus on the background, principles and main steps of the risk assessment process.

As discussed above, Canadian biotechnology regulations were developed in close collaboration with other national and international regulatory bodies, and particularly the OECD. In 1993, the OECD published the first document that explicitly addressed the regulation of large-scale and unconfined rDNA crop production, OECD Safety Considerations for Biotechnology: Scale-Up of Crop Plants (OECD 1993a). This document expanded upon and formalised several regulatory concepts that were raised in earlier
publications, and were subsequently enshrined in Canadian risk assessment practices.

Foremost among these principles was the concept of “familiarity”. While the US National Academy of Sciences first advanced the concept of familiarity for small-scale field trials in 1989 (NAS 1989; discussed above), the OECD applied the concept to “scale-up” from small-scale to large-scale releases. Familiarity, according to the OECD, is a flexible, science-based criterion which can be used to “facilitate” hazard identification, risk assessment and risk management by identifying aspects of rDNA crops for which there exists sufficient “knowledge and experience”. Familiarity is gained by releasing rDNA crops in a “stepwise” manner from confined field trials, through large-scale releases, to eventual unconfined commercialised use.

This “stepwise development and evaluation”, the second of several regulatory principles formalised by the OECD, allows information gathered at each step to be used in the safety assessment of subsequent, less confined, stages of release. However, the OECD recognised that some ecological effects will be scale-dependent and may not be detected in small-scale releases or “until a cultivar is grown at commercial scale for several years.... It may be necessary, in these cases, to scale up to obtain the knowledge and experience to make a determination of safety” (OECD 1993a). Risk assessment protocols for such effects were not specified beyond reliance on familiarity, continued large-scale release and “risk management” techniques. According to the OECD, risk management is clearly separated from risk assessment and primarily entails control and mitigation procedures: a “relatively low degree of familiarity may be compensated for by appropriate management practices” (OECD 1993a). As we will see (below and in Chapter 3), these principles—familiarity, stepwise release, separation of risk assessment and risk management and reliance on control measures—are firmly entrenched Canadian risk assessment procedures for rDNA crops.
The principles of Canadian risk assessment were influenced not only by the OECD and US National Academy of Science, but also by United Nations organisations such as the Food and Agriculture Organisation (FAO) and the World Health Organisation (WHO). Most significantly, the concept of “substantial equivalence” was established in the early 1990s through a series of FAO/WHO collaborations and OECD documents (FAO and WHO 1996; OECD 1993b; WHO 1991; WHO 1995). The FAO and WHO were primarily concerned with food safety and human health issues. Substantial equivalence was therefore developed as a regulatory tool for determining the relative safety of foods derived from rDNA organisms, rather than for assessing the environmental safety of rDNA crops. Otherwise however, substantial equivalence fulfilled a function similar to the concept of familiarity, *i.e.* providing a standard and point of reference from which to assess the safety of new rDNA organisms or products. Canada was the first country to apply substantial equivalence to environmental risk assessments; neither the US nor the European Union followed this approach. According to regulators at the Canadian Food Inspection Agency (CFIA)\(^{10}\), however, several countries in Central and South America have recently adopted Canada’s regulatory framework as a basis for their own national risk assessment protocols (CFIA interviews, 1998).

The implications of employing familiarity and substantial equivalence as key regulatory concepts are examined in detail elsewhere (Barrett and Abergel in press). In the present context it is important to emphasise how these concepts establish standards for risk assessments. The overall framework of the “safety-based model” developed by Agriculture and Agri-Food Canada (AAFC)\(^{11}\) is illustrated in Figure 2.1. As described in the 1994 Regulatory Document on unconfined release (AAFC 1994a), this framework applies to all “plants with novel traits” which are defined as:

A plant variety/genotype possessing characteristics that demonstrate neither familiarity nor substantial equivalence to those present in a distinct, stable
population of a cultivated species of seed in Canada and that have been intentionally selected, created or introduced into a population of that species through a specific genetic change (AAFC 1994a).

Deliberate choice of the more benign term, “plants with novel traits” to replace the earlier “genetically modified” plants, reaffirms AAFC’s commitment to product-based regulation; rDNA crops were not singled out as requiring additional oversight (CFIA interviews, 1998). However, as mentioned in Chapter 1, in practice it appears AAFC (and now CFIA) does regulate on a product-basis as all of the “plants with novel traits” that have undergone a risk assessment under the guidelines for unconfined release were developed using rDNA techniques (CFIA nd-b; see Table 1.1). This seems a tacit acknowledgement that rDNA crops are perhaps ‘more novel’ than crops developed through other techniques.

As shown in Figure 2.1, familiarity and substantial equivalence function as triggers for the entire risk assessment process. Crops deemed familiar or substantially equivalent do not require an environmental risk assessment and are regulated under legislation applicable to all crops. As defined in the 1994 Regulatory Document, familiarity is “the knowledge of the characteristics of a plant species and experience with the use of that plant species in Canada” (AAFC 1994a). Elsewhere, AAFC has stated that the “principle of familiarity may provide an accurate idea of the relevant risks in the novel product in the absence of direct experience with it” (AAFC 1996d). For the purposes of environmental assessment, familiarity is determined through the four criteria listed in Box 2.5. An rDNA crop is considered familiar if each of these criteria are familiar. Notably, new combinations of otherwise “familiar”

<table>
<thead>
<tr>
<th>BOX 2.5 Criteria for Determination of Familiarity</th>
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<tr>
<td>• plant species</td>
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<td>• introduced trait</td>
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<tr>
<td>• method of introducing the new trait</td>
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<tr>
<td>• method of cultivation</td>
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(AAFC 1994a)
FIGURE 2.1
"SAFETY-BASED" MODEL FOR REGULATION OF "PLANTS WITH NOVEL TRAITS"

PROPOSAL BY DEVELOPER

Familiarity/Substantial Equivalence

NO

YES

AAFC/CFIA

"SAFETY ASSESSMENT" → RELEASE

NOT REQUIRED

CASE-BY-CASE
"SAFETY ASSESSMENT"
based on:
• Field Trials
• Previous Releases
• Existing Literature

RISK MANAGEMENT DECISION

“ACCEPTABLE RISK”

RELEASE

Familiar/
Substantially Equivalent

Precedent for Future Proposals

Adapted from AAFC (1994a)
criteria are not considered “novel”. Thus to date, all rDNA crops submitted to AAFC/CFIA have been deemed familiar (CFIA interviews, 1998).

Substantial equivalence, as defined in the same Regulatory Document (AAFC 1994a) is “the equivalence of a novel trait within a particular plant species, in terms of its specific use and safety to the environment and human health, to those in that same species, that are in use and generally considered as safe in Canada, based on valid scientific rationale.” Five categories of potential environmental effects are used to determine substantial equivalence (listed in Box 2.6). A final criterion for substantial equivalence is whether the engineered genes are “the same as those previously approved by AAFC in the same species” (AAFC 1994a). Substantial equivalence therefore operates at the level of species rather plant variety. If it is known, based on “data or sound scientific rationale”, that the rDNA crop “will not result in altered environmental interactions” (listed in Box 2.6) then the plant is considered substantially equivalent to existing crops and is approved for unconfined release under the Seeds Act. If potential for altered environmental interactions is not known, the rDNA crop must undergo a case-by-case “safety assessment”. I will examine this process, otherwise known as a “risk assessment”, in Chapter 3.

However, I should emphasise here that the sequential and delineated regulatory process outlined in the Regulatory Document and in Figure 2.1, is somewhat idealised. In practice, determination of substantial equivalence and “safety assessment” are two aspects of the same procedure. A safety assessment aims to determine substantial equivalence through the criteria listed in Box 2.6. In other words, an rDNA crop is either deemed substantially
equivalent prior to assessment (thereby obviating further testing) or it is deemed substantially equivalent through an assessment. In either case, “plants with novel traits” are ultimately deemed to be equivalent to—and hence as safe as—plants already grown in Canada. Furthermore, once a crop is approved and released, it is, by definition familiar and substantially equivalent to existing crops and may therefore function as a standard for further assessments. This is a crucial point: initial approvals set new standards of “novelty” by which further applications are measured.

The regulatory scheme outlined in Figure 2.1 remains in operation in 1999. When first introduced in 1994 however, the principles of familiarity and substantial equivalence satisfied many requirements previously identified as desirable in a regulatory framework: this was a “science-based” (Hollebone 1993a) and “efficient” framework that “saves resources” (Hollebone 1993b) and was consistent with a product-based approach, yet also flexible enough accommodate knowledge gained as new products are released into the environment (Barber 1993).

First “Consultation”

According to the 1993 press release, the “new regulatory framework” would ensure “the development and enforcement of Canadian biotechnology regulations are open and include consultation” (Canada 1993). Similar assurance was provided directly by AAFC regulators: “The federal government is committed to an interactive process that involves regulatory departments and other interested parties” (Hollebone 1993a). In partial fulfilment of this commitment, the “Biotechnology Strategies and Coordination Office” was established in 1993 to organise consultations on (then) proposed regulations for unconfined release described above. The first of such consultations was held in November 1993 and was
attended by representatives from government, non-government organisations (NGOs), the private sector and academia. While this seems a laudable effort, the scope of the discussion was explicitly curtailed by the organisers. Brian Morrisey, Assistant Deputy Minister of AAFC's Research Branch opened the meeting by highlighting the "virtually limitless" benefits of biotechnology and emphasising that "the consultation would focus on the scientific data requirements to assess the safety of a biotech product" and aim to "build consensus on the approach to regulating agricultural products of biotechnology; regulations which must be consistent with other federal and international approaches (Morrissey 1993). Despite such attempts to focus the dialogue on scientific and regulatory issues, representatives of consumer and environmentalist organisations were vocal in their opposition to the government's position on biotechnology. Restricted access to information, inappropriate extrapolation of existing legislation, lack of public participation and debate, and failure to address ethical issues were identified as shortcomings of the current regulatory system. Industry and government speakers, on the other hand, stressed the advantage of a "competitive regulatory framework", the potential economic costs of overregulation, and the need to harmonise policies with international trading partners. No similar consultation was held until 1998 (see below).

The Pressures of International Trade

Thus, as in earlier stages of biotechnology policy development, government regulators faced intense, and often conflicting pressures from several interest groups. However, the mid-1990s saw the rise of powerful new ideas, interests and institutions in the form of the World Trade Organisation (WTO), the Uruguay Round of GATT, and the North American Free Trade Agreement (NAFTA). Negotiations under these "free trade" agreements and
organisations are proving to be pivotal determinants for agricultural and environmental standards. With respect to safety issues raised by biotechnology, the key articles under GATT/WTO and NAFTA are agreements on “Sanitary and Phytosanitary” (SPS) measures.

The SPS agreements set standards for the types of biosafety measures member countries may legitimately employ without posing “non-tariff trade barriers” and hence “distorting” free trade. Measures adopted to protect human, animal and plant health, in other words, must not be “arbitrary” but must be:

- based on scientific principles
- not maintained without sufficient scientific evidence
- based on a risk assessment “appropriate to the circumstances”
- “necessary”
- avoided if “there is another measure reasonably available, taking into account technical and economic feasibility, that achieves the appropriate level of protection and is significantly less restrictive to trade” (as stated in Articles 2 and 5, WTO; Chapter 7, NAFTA; cited in Esty 1994; see also CBD nd; Dawkins 1997).

Both GATT and NAFTA allow these criteria to be waived under specific circumstances. For instance the controversial Article XX of GATT exempts actions designed to protect public morals and human, animal and plant life or health. However, Article XX was amended during the Uruguay Round: The major environmental clause is now focussed on exemptions for actions related to conservation of exhaustible natural resources. Furthermore invocation of Article XX must not violate the “necessary” test which has been interpreted under GATT to mean “least-GATT-inconsistent”, or in other words, least trade restrictive (see Esty 1994; Smith and Jukes 1997).

The 1994 SPS agreements were (and continue to be) crucial to Canada’s policies on rDNA crops because they specified that all regulations and risk assessments must be firmly grounded in scientific principles. Decisions based on other principles may be disputed through the WTO as non-tariff trade barriers. As stated by Esty (1994), “there can be no absolute litmus test for the bona fides of environmental policies. There are, however, two
aspects of real environmental concerns that separate them from ones that do not merit unilateral trade actions: scientific underpinnings (versus value judgements) and significant (versus incidental) harm or threat of harm” (emphasis original). Thus, the litmus—or legitimacy—test for international environmental standards lies in agreement on the definition and application of scientific principles.

Under the WTO, such scientific principles for SPS agreements are established by three organisations: the Codex Alimentarius Commission (CAC or “Codex”), the International Plant Protection Convention (IPPC) and the International Office des Epizooties (for animal regulations only). The most influential of these standard-setting bodies is Codex, a United Nations organisation established in 1962 and currently operated through the Food and Agriculture Organisation and the World Health Organisation. Codex aims to harmonise standards for food safety, labelling and inspection, both as a means of protecting human health and of reducing barriers to international trade (FAO and WHO 1999). Although Codex is primarily concerned with food safety and human health issues, the Codex general principles on risk analysis establish the terms under which food products can be legitimately traded or protected under the WTO, and thus the extent to which environmental, ethical, cultural and “other factors” can be considered. Negotiation of these issues by the Committee on General Principles has been ongoing since 1995. At that time, it was established that non-scientific factors could be considered only if they are relevant to health protection and promotion of fair practices in trade; routine consideration of socioeconomic and environmental factors was ruled out (CAC 1995; Smith and Jukes 1997).

Working definitions for risk analysis were not put forward until 1999. According to Codex, risk analysis should be based on “sound science” and consist of three distinct steps: risk assessment, risk management and risk communication. Risk assessments should be
based “to the greatest extent possible” on quantitative information, consider all relevant scientific data, account for worst-case, long-term, and synergistic effects, and whenever possible include numerical expressions of uncertainty. The impact of uncertainty, and the possibility of including factors other than science should be considered at the risk management stage. The non-government organisation, Consumer’s International, has consistently pushed for inclusion of the Precautionary Principle in Codex guidelines. The 1999 Codex document on risk analysis states that “it should be possible to apply the Precautionary Principle” in situations “where scientific evidence is insufficient or negative effects are difficult to evaluate” (CAC 1999). Despite this partial success, acceptance of the Precautionary Principle by all Codex delegates awaits consensus on its definition and scope of application. Risk communication, the final step of risk analysis, has yet to be formally addressed by the Codex committee.

The precise role of science and “other factors” in Codex—and hence WTO and ultimately Canadian—safety standards will be established through precedent-setting cases. The first case to challenge the SPS agreement of the WTO was the proposed European Union ban on US beef containing growth hormones. The US won the initial case against the EU in 1997, after the WTO claimed the EU had not conducted a scientific risk assessment of the safety of meat containing growth hormones. However, the case is still under consideration by the WTO and Codex committees. Several Codex delegates have called for inclusion of “other factors” in the hormone assessment, such as negative environmental effects, animal welfare, need for the technology, consumer concerns and societal values (CAC 1999).

Whether these factors will be considered “legitimate” or “technical trade barriers” in the beef hormone case and in similar cases, such as Canada’s moratorium on the use of recombinant bovine growth hormone (rBGH or rBST) and the EU’s policies on rDNA organisms, awaits
dispute resolution at the WTO and decisions by Codex (Palmer 1999). In this regard, it is perhaps worth mentioning the composition and decision-making process of the Codex Commission. There are currently 160 member countries (including Canada) and only governments of these countries have voting rights at official proceedings. While, “observer status” is granted to non-government organisations, this group and is heavily dominated by industry representatives. For example, according to McCrea (1998), of the groups currently granted observer status, 104 are industry funded, 6 are health and nutrition foundations and one is a consumer group (see also Dawkins, 1997).

The International Plant Protection Convention (IPPC) is the other standard-setting body for plant-related SPS measures that is officially recognised by the WTO. Established in 1951 under the Food and Agriculture Organisation of the UN, the IPPC is currently endorsed by 107 governments, including Canada. The Convention has been amended twice since 1951, once in 1979, and recently in 1997 to reflect the IPPC’s new role in the WTO:

The SPS Agreement identifies the IPPC as the organization providing international standards for measures implemented by governments to protect their plant resources from harmful pests (phytosanitary measures). The IPPC complements the SPS Agreement by providing the international standards that help to ensure that phytosanitary measures have a scientific basis for their placement and strength and are not used as unjustified barriers to international trade (IPPC nd).

The 1997 amendments establish that member countries can restrict imports of plants or plant products only for phytosanitary reasons which have been “technically justified” through a “pest risk analysis”. The process of pest risk analysis was outlined in 1996, and was defined as the evaluation of biological and or other scientific or economic factors to determine whether a pest should be regulated and the strength of measures that should be taken. As in the Codex guidelines, the IPPC stresses that such measures should be “least trade restrictive”. The revised IPPC has not yet entered into force as only 10 countries have signed the
document as of 1999 (excluding Canada). It is notable that no version of the IPPC makes specific reference to, or provisions for, the potential hazards of rDNA organisms.

Thus, since 1994, the WTO, Codex and the IPPC have gained enormous influence over internationally recognised standards of “sound science” and procedures of risk assessment. The burden of proof rests on WTO members who wish to impose higher standards, and to date that justification must be based on scientific rationale. In essence, then, the SPS barriers are the technical agricultural and food safety standards (Smith and Jukes 1997). As a member of the WTO, Canada is obliged to conform to these standards—a pressure reflected in the adamantly “scientific” basis of the 1993 and 1994 regulations on rDNA crop safety.

Policy Reforms at Home

Throughout the early-mid 1990s, the federal government continued to exert pressure on biotechnology regulators through a series of legislative and policy reforms. In 1994, the new Liberal government initiated a general review of science and technology policy, conducted through the National Advisory Board on Science and Technology (NABST). Published in 1995 (NABST 1995), the review emphasised that research into the underlying causes of health and environmental issues is an effective means to prevent further problems and reduce long-term costs. The Advisory Board therefore recommended spending 0.5-1% of the federal research budget to this end.

The federal government responded directly to the recommendations of the NABST review in the document Science and Technology for a New Century, which included an “Action Plan” for AAFC (AAFC 1996a; Canada 1996b). This document reiterated the government’s seemingly chronic anxiety over Canada’s lagging science and technology
sectors, and emphasised AAFC’s commitment to increase agri-food exports to 30% above 1995 levels by the year 2000. Programs such as the Matching Investment Initiative, launched in 1995, sought to address this situation by creating stronger, more efficient and market-responsive partnerships between government and industry: “The fundamental reality is the marketplace. Canada must produce what the world wants to buy. We must do it cost-effectively. We must diversify. We must build strategic alliances internally and internationally” (Minister of Agriculture cited in (AAFC 1996a).

Despite this emphasis on continued growth, Science and Technology for a New Century also reflected the Liberal government’s stated commitment to sustainable development through the convergence of economic and environmental policy (Toner and Conway 1996). The government recognised an important role for science not only in creating new technologies, but also in “assessing risk, anticipating and avoiding threats to health and safety and lessening harmful effects” of these technologies (Canada 1996b). As noted in AAFC’s Action Plan, safety is “a prerequisite for the agri-food industry to gain entry to market” (AAFC 1996a). While these statements suggest greater awareness and a higher priority of environmental safety issues, interestingly, rDNA crops were portrayed not as a potential threat, but as the solution to both environmental and economic pressures. Indeed, biotechnology was touted as a component of the new “preventative” approach: “Relating to preventative approaches, 15 to 20 new crop varieties of cereals, oilseeds, forages and speciality crops will be released each year to the turn of the century” (AAFC 1996a).
This emphasis on prevention may have been in response to recommendations for strengthening the Canadian Environmental Protection Act (CEPA) which were drafted by the House of Commons Standing Committee on Environment and Sustainable Development in 1995. As discussed above, CEPA mandated regulatory review within 5 years of its enactment in 1988. This review began in 1994 and culminated in the report *It's About Our Health* (Canada 1995a). The comprehensive report, based largely on consultations with interest groups, made 141 recommendations toward the “overarching policy goal” of promoting sustainable development. Five principles were promulgated in support of this goal (see Box 2.7). The Precautionary Principle seemed one of the more contentious principles, with at least two industry organisations expressing concern that the Precautionary Principle may be invoked in lieu of good science, or as one participant stated, “as a cloak for inadequate science” (Canada 1995a).

Nonetheless, the Standing Committee noted that inclusion of the Precautionary Principle in CEPA “would be endorsing previous general commitments made in the 1990 Bergen Declaration" and the 1992 Rio Declaration” while also recognising that “the principle is still evolving and requires further elaboration” (Canada 1995a). As such, the committee advised that the Precautionary Principle be incorporated into CEPA as a guiding principle, and be included in the preamble of the Act to allow for interpretative flexibility. With regard to biotechnology in particular, *It's About Our Health* revived earlier proposals that CEPA provide assessment standards for *all* biotechnology products, including those currently under other federal Acts. Other legislation would prevail over CEPA only if “notification, assessment and regulatory standards are at least equivalent to those prescribed under CEPA” (Canada 1995a; emphasis added).
The government responded to the Standing Committee's recommendations in *A Renewed CEPA* (Canada 1995b) and subsequently as Bill C-74 which was introduced in 1996. In contrast to the Standing Committee's proposals, the government supported a "safety net" approach to biotechnology legislation by which CEPA would regulate only those products *not* currently covered by existing legislation; rDNA crops would remain in the jurisdiction of AAFC and the Seeds Act. With regard to the Precautionary Principle, the government stressed that "science is an integral part of decision making under CEPA" and that the "Government is committed to a risk-based approach to decision-making" (Canada 1995b). Hence it was proposed that *both* science and the Precautionary Principle be incorporated into CEPA's preamble as guiding principles. Furthermore, the government endorsed the Rio Declaration's version of the Precautionary Principle which is qualified by cost-effectiveness; the Standing Committee did not recommend such a qualification. Bill C-74 was not passed due to the dissolution of Parliament for the 1997 federal election. However, a similar bill, C-32, is now before Senate. In C-32, the government has maintained its position against consolidated biotechnology regulations and in favour of "cost-effective" precautionary measures despite recommendations of the Standing Committee.

**Legislative Amendments**

Thus as of 1996, no new legislation for regulation of biotechnology had been enacted. However, it appears that proposals to regulate rDNA crops under CEPA provided a final incentive to amend the Seeds Act, and thereby establish through legislation that AAFC does in fact have regulatory authority over plant biotechnology. This amendment was passed into law in December 1996. According to the Regulatory Impact Analysis Statement the framework for biotechnology regulation established in 1993 (AAFC 1993) provides oversight
of rDNA crops that is equivalent to standards under CEPA. Furthermore, AAFC has the required “experience and expertise” for environmental assessment whereas Environment Canada “lacks this expertise or experience”. The legislative amendment did not change the “regulatory framework” of 1993 or risk assessment procedures for unconfined release previously developed by AAFC (AAFC 1994a). Rather the risk assessment procedures were added to the Seeds Act such that the broad framework outlined in Figure 2.1 is now statutory. However, the specific data requirements required for environmental assessment (see Chapter 3) were not included in the amended Act. These requirements, as well as procedures for confined release remain as more flexible, easily revised guidelines rather than binding regulations.

In 1997, shortly after establishing the regulatory authority of AAFC, the federal government transferred responsibility for all federal food inspection, including environmental assessment of rDNA crops, to the newly created Canadian Food Inspection Agency (CFIA). While still reporting to the Minister of Agriculture, CFIA is an interdepartmental agency that amalgamates food inspection and animal/plant health activities of AAFC, Health Canada, Fisheries and Oceans Canada and Industry Canada. According to CFIA’s first Corporate Business Plan, the move to a single agency aims primarily to “enhance effectiveness and efficiency” of federal regulatory activities and also “facilitates a more uniform and consistent approach to safety and quality standards and risk-based inspection systems, contributes to consumer protection and facilitates market access...” (CFIA nd-a). Indeed, creation of CFIA responded to the diverse internal and external pressures described above and briefly outlined in their Business Plan: a trade-dependent agricultural sector; new regulations and commitments under the WTO; increasing consumer awareness and “anxiety” over food safety; fiscal restraint and downsizing of AAFC; and the need for “greater autonomy” in
providing food inspection services. The latter point appears to be an indirect reference to accusations of conflict between the promotional and regulatory interests of AAFC which were highlighted during the CEPA review process. However, it remains questionable whether CFIA represents a truly “autonomous” or indeed more “effective” body for regulating environmental releases of rDNA crops. Neither the regulations for environmental assessment nor much of the regulatory staff have changed with the establishment of CFIA. Furthermore, the Agency is primarily concerned with food-related hazards such as inspection of food imports and processing facilities, and have adopted science- and risk-based inspection methods to maintain quality control. While not inherently detrimental to, or inconsistent with, environmental assessment, the scope and principles of food inspection are vastly different from the ecosystem and biodiversity focus of Environment Canada and CEPA. Moreover, CFIA has not quite divorced itself from the promotional position of AAFC. CFIA’s mandate places equal emphasis on effectiveness and efficiency, a balance reflected in their stated objectives: “to contribute to a safe food supply and accurate product information; to contribute to the continuing health of animals and plants for protection of the resource base; and to facilitate trade in food, animals, plants and their products” (CFIA nd-a).

**Variety Trials and Commercialisation**

The diversity of influences and commitments described in this section created a dynamic and highly charged “Phase Three” of Canadian biotechnology policy. Throughout this phase, and despite these pressures, AAFC made considerable progress in the commercialisation of agricultural biotechnology. The urgency to establish environmental regulations and to market emerging varieties of rDNA was clearly expressed in the meetings of the Western Canada Canola and Rapeseed Recommending Committee (WCCRRC).
Established in 1991, the WCCRRC is a non-profit organisation representing interests of the Canadian canola industry. One key function of the committee is to develop guidelines for variety registration trials. The assessment criteria used in these trials, and the integration of variety trials into unconfined environmental assessment will be discussed more fully in Chapter 3. Relevant to the present discussion is the fact that variety trials for rDNA canola began in 1992 under semi-confined conditions (using border rows or destruction of crops after flowering or harvest). However, as this chapter has revealed, assessment protocols for rDNA crops were not formalised until 1993 for confined release, and 1994 for unconfined release. In other words, rDNA canola had entered the “pre-commercial” stage of development before environmental assessment regulations were in place—or indeed before a suitable comparison or control variety (known as a “check” variety) for rDNA crops had been established. This situation seemed to generate great concern among members of the WCCRRC, who stressed in early 1994 that the lack of guidelines “continues to delay Canada from exploiting the opportunities inherent to transgenic canola” (WCCRRC 1994b). The guidelines introduced later that year were apparently insufficient to move rDNA canola to market as quickly as desired. Poor yields of herbicide tolerant canola (HTC) decreased the number of “merit” points needed to pass the variety trials (discussed further in Chapter 3). To compensate, the WCCRRC—with the sanction of AAFC—voted to add an extra 8 merit points to HTC to reflect the importance of herbicide tolerance trait and to decrease barriers to commercialisation. This move is a clear expression of the confidence and heavy investment in agricultural biotechnology of both the canola industry and the federal government (Griffiths 1997; WCCRRRC 1994a). Herbicide tolerant rDNA canola was approved by AAFC for unconfined release and commercial-scale growing in March 1995—the first rDNA crop to
be commercialised in Canada. The data used in this “science-based” assessment and decision will be examined in detail in the following chapter.

2.2.5 Phase Four: Increased Public “Awareness” and “Confidence” (1998-)

In many ways the present phase of biotechnology policy continues trends and debates ongoing since 1980. However, recent government documents and policy proposals have a slightly different tenor that may well distinguish “Phase Four” from previous stages. This difference lies in a heightened concern within government and industry about public approval of biotechnology products and confidence in the regulatory system. It appears public acceptance may be the ‘final frontier’ for commercial success.

The 1998 NBAC Report, Leading the Next Millennium (NBAC 1998), is a remarkable combination of unequivocal promotion of the biotechnology industry and strong support for increased public participation. The report begins with a “wake-up call” to government and industry: “The extent to which Canada adopts biotechnology and pursues its development and application will significantly determine the country’s future economic status and its role in world affairs”. More than just an economic boon, biotechnology, according NBAC, is vital for a secure and environmentally sound food supply: “Without biotechnology as a powerful ally there may not be enough food in the future, and the use of traditional chemical techniques will fail to combat pests effectively, while creating extensive environmental hazards”. Canada must therefore face “some public policy challenges” in order to capture these opportunities and benefits. One of the main challenges outlined in the report is maintaining a competitive edge in international markets. In fact NBAC paints a vivid picture of the current “race to successful commercialisation”—the stakes are high and “there is no room for complacency”. NBAC recommended a number of policy measures necessary for
Canada to become a world leader in biotechnology, many of which are similar to previous policy recommendations and initiatives: more extensive tax incentives for industry; greater support for government-industry-university partnerships and technology transfer programs; increased funding for basic and applied science research, particularly in molecular sciences; recruitment drives to attract biotechnology professionals to Canada; and promotion of biotechnology in schools. Not surprisingly, regulations were portrayed as an essential yet potentially detrimental element of biotechnology policy. NBAC endorsed strict adherence to “science-based risk assessment” in setting environmental standards and recommended that regulators “build on their accumulated experience with the underlying science needed to assess risk, in order to reduce unnecessary information demands on industry”. NBAC further cautioned against accepting any criteria other than science in negotiating WTO or Biosafety Protocol agreements on trade.

In marked contrast to earlier NBAC reports, however, *Leading the Next Millennium* emphasised that generating “public confidence and trust” is essential for a strong regulatory system, and that “public awareness and input, and broad public consideration of the social-ethical dimensions of biotechnology” are critical to a thriving industry. NBAC acknowledged that to date “there are only limited formal mechanisms that standardise the collection and incorporation of public input” and essentially *no mechanisms* for government-citizen dialogue:

Canada remains one of the few remaining industrial countries lacking a national, publicly accountable advisory body to manage a national dialogue on biotechnology.... [T]here is no overarching mechanism for holding a non-partisan, national conversation about biotechnology. Nor are there public policy tools for systematically and consistently incorporating socio-ethical considerations into public policy formulation and decision making (NBAC 1998).
These are strong statements from an advisory body whose mandate is to foster development of the biotechnology industry. To redress this shortcoming, NBAC recommended that “consistent and transparent” communication and feedback routes be established between government and the public, and that the government publish clearly understandable summaries of regulatory decisions *including the rationale used to support those decisions*. More significantly, NBAC advised that its own mandate and structure evolve to formally incorporate public opinion and socio-ethical issues. A new advisory committee should be “arm’s length” from government (notably not from industry) and comprise “eminent” researchers from a number of fields including ethics, communication, education and social sciences. While the greater value attributed to public dialogue and socio-ethical factors signals an apparent shift in policy priorities, it is unclear how these measures will be made consistent with strict adherence to “science-based risk assessment”. It seems NBAC attempted to include, or at least appease, all interest groups. However, there remains considerable doubt as to whether increased public participation was recommended out of concern for democratic values and public welfare, or whether the need to “generate” broad public support is merely a means to expedite “successful commercialisation”.

Building on these recommendations, in August 1998, the federal government announced a “renewal” of the National Biotechnology Strategy initially launched in 1983. Under an updated name, the “Canadian Biotechnology Strategy” (CBS) sought to revise the policy framework and institutional structures that guide biotechnology development and regulation in Canada. According to the press release, the “strategy will ensure that biotechnology continues to enhance Canadians’ quality of life in terms of health, safety, the environment, and social and economic development” (Canada 1998b). The NBAC report played a significant role in the revisioning process, as did a number of “stakeholder
consultations” which took place in five cities during the spring of 1998. The deliberate and structured consideration of stakeholder or “public” interests again suggests greater government commitment to inclusive decision-making. However, the agenda and attendance of these meetings were carefully planned and subsequently criticised by public interest groups. For example, the consultations were by invitation and participants were chosen by an interdepartmental government committee. A subsequent news story described the meetings as “industry love-ins” with participants lists comprised primarily of industry groups and federal or provincial government (Anon 1998). Nonetheless, consumer and public interest group representatives attended at least two of the meetings, in some cases at their own insistence (B. Kneen, personal communication, 1998). Discussions were structured around “consultation documents” which proposed a vision, objectives, principles and organisation for the new strategy. Slightly modified versions of the proposals were later incorporated into the official CBS which, similar to the NBAC report, reflects a deliberate effort to address public participation and social-ethical issues while supporting continuous growth of the biotechnology industry.

The CBS vision is to “enhance the quality of life of Canadians in terms of health, safety, the environment and social and economic development by positioning Canada as a responsible world leader in biotechnology” (Canada 1998a). This vision is to be realised through several goals among which are:

- to “ensure that Canadians have access to, confidence in, and benefit from safe and effective biotechnology-based products and services”
- to ensure an effective science base and make “strategic investments to support biotechnology”
- to position Canada as an “ethically and socially responsible world leader” in biotechnology
- to “improve public awareness and understanding of biotechnology through open, transparent communications and dialogue” (Canada 1998a).
While the precise mechanisms for fostering public "awareness and understanding" have not been outlined, the CBS adopted NBAC’s recommendation to establish a new "arm’s length" advisory committee, the Canadian Biotechnology Advisory Committee (CBAC). The new committee will provide advice to Ministers on "the ethical, social, economic, scientific, regulatory, environmental and health aspects of biotechnology" as well as advising on policy direction and examining the risks and benefits of biotechnology (Canada 1998a). CBAC membership will be determined through public nomination and final appointment by the CBS task force which is operated through Industry Canada.

Thus, both the recommendations of NBAC and the renewed biotechnology strategy reflect a higher regard for public opinion on biotechnology and a greater effort to "communicate" in public fora. I will discuss the rationale for—and limitations of—this effort in Chapter 4. For the moment, it is worth speculating on some of the factors that may have precipitated this shift. Most obviously, biotechnology products needed a market. By 1998, Canada had approved commercial release of 13 varieties of rDNA canola, 14 varieties of corn, as well as several varieties of soy, potato, tomato and flax. And while "consumer acceptance" had been mentioned in previous reports and policy documents, no concerted effort had been made to discuss with the public their preferences or concerns about eating products of agricultural biotechnology. It appears government and industry suddenly realised that the public were their ultimate customers and further surmised that these customers were rather uninformed. According to the CBS document, "for the most part, Canadians appreciate the potential benefits of biotechnology" but there are some "gaps in consumer awareness and understanding". Specifically, "people often do not know about or do not understand the benefits to them of various biotechnology applications" and often do not know how their national regulatory systems applies to biotechnology.
The urgent need for public “awareness and understanding” of biotechnology was highlighted by events in Europe and the United Kingdom. There, several political and cultural factors led to widespread and successful public protest and civil action against “genetically modified organisms” (GMOs).\textsuperscript{14} Several grocery store chains, schools and restaurants have banned all GMOs, and activists have blocked grain shipments from North America, demonstrated outside research laboratories, destroyed field plots of rDNA crops, and called for a comprehensive EU labelling policy which is now under development. The EU ceased further approval of rDNA crops in June 1998 and drastically reduced imports. One year later, the EU called for new monitoring and risk assessment protocols for all GMOs, a review of all currently approved GMOs, and an effective moratorium on further approvals until new regulations are in place (Anon 1999a). While the power of negative public reaction has been made abundantly clear, the Canadian government appears optimistic that increased public “awareness” will generate the support—and much needed market—to sustain continued growth of the domestic biotechnology industry.

2.3 CONCLUSIONS

The chronology of biotechnology policy in Box 2.8 graphically illustrates the sequence of events that have culminated in a firmly established Canadian biotechnology industry and a fully committed Canadian federal government. I will reserve detailed analysis of the factors—ideas, interests and institutions—that have shaped this timeline until I have examined how biotechnology regulations and principles are actually implemented, the subject of Chapter 3. Before proceeding, however, it is worthwhile highlighting the key trends identified in this chapter.
The most apparent trend in Box 2.8 might be summarised as “promotion before regulation before consultation”. Regulations for risk assessment were implemented 10 years after the first promotional “strategy” was launched. The main impetus for these regulations arose not from a direct concern that rDNA crops pose inherently new risks, but from industry demands for a predictable business climate, and government interests in stimulating trade and investment. In terms of public consultation, a full fifteen years of R&D preceded even modest attempts by the federal government to ascertain public input on—much less approval of—agricultural biotechnology. Even now, as the Canadian Biotechnology Strategy gets underway, the main goal of consultations is to “build public confidence and awareness” (Canada 1998a) rather than foster two-way dialogue and interaction.

This timeline reflects economic incentives to develop a strong and stable biotechnology industry that have been pervasive and unrelenting since the early 1980s. Biotechnology was heralded as one of several innovative ‘high’ technologies that would strengthen a lagging science and technology sector and thereby pull Canada’s economy out of recession. The agricultural sector’s traditional reliance on export markets, and increased commitment to international trade through GATT, WTO and NAFTA, meant that environmental regulations must be similarly globalised or “harmonised”. In this respect, science played a dual role in biotechnology policy: it was recognised not only as an essential
foundation for biotechnology R&D, but also as a "sound" basis for environmental regulations. Indeed, throughout their development, guidelines for risk assessment were explicitly and resolutely "science-based". To the present day, the Minister of Agriculture reassures the public that regulations entail "comprehensive scientific review" (Doan 1999) and are "based on the latest and best scientific knowledge we have" (Vanclief 1999). Curiously however, "science" has never been defined in this context. What does a "comprehensive scientific review" or a "science-based risk assessment" encompass? The following chapter addresses these questions by closely examining the risk assessment for herbicide tolerant canola.
Endnotes: Chapter 2

1. The Science Council of Canada was created in 1966 to analyse and advise the government on science and technology issues, recommend policy directions, alert the public to the impact of science and technology on their lives and stimulate discussion among government, industry and academia (SCC 1985).

2. MOSST was created in 1971 “to formulate policies to encourage the development of science and technology in support of Canada’s economic and social goals” and was also responsible for allocating resources and establishing science and technology priorities (MOSST 1984). MOSST was incorporated into a new department of Industry, Science and Technology in 1987.

3. These were the “priority research areas” recommended by MOSST and included nitrogen fixation, plant strain development, human and animal health care, cellulose utilisation, waste treatment, mineral leaching and metal recovery, and aquaculture (Hollebone 1989).

4. Issues defined by three characteristics: public interest in the problem and outcome; complex information that is difficult to evaluate; the need to balance many “quality-of-life” values in reaching decisions (SCC 1982).

5. Access to information legislation was enacted in June 1982.

6. A “new” variety is defined by “altered genetic constitution”.

7. CARC was established in 1974 to advise on the state and needs of national programs for agricultural research and development. Revised in 1994, CARC’s current mission is to provide leadership in coordination and networking of research and technology transfer, and to act as a catalyst for building consensus on research prioritisation in Canada (CARC nd).

8. Plant varieties are defined under the International Convention for the Protection of New Varieties of Plants (UPOV) to which Canada is a signatory. Varieties must be “new, distinct, uniform and stable”.


10. One of the first tasks of the new Liberal government after election in 1993 was a major restructuring of federal departments and overview of respective mandates. In the process, Agriculture Canada was renamed Agriculture and Agri-Food Canada (AAFC) in part “to include representation of ‘downstream’ users of agricultural products” (Moore 1998). Regulatory responsibilities were shifted in 1997 to the Canadian Food Inspection Agency. I will refer to this department by the name in use during the time period under discussion.

11. See note 10

12. Held in May 1990, The Bergen Conference on Sustainable Development was attended by 34 countries including Canada. The Bergen Declaration outlines concrete measures for addressing the causes of climate change and specifically endorses the Precautionary Principle (UN Environment Program, www.unep.ch/iucc/fs220.html).

13. This statement is mandatory for all proposed legislation and is published in the Canada Gazette Part 1. See Chapter 4.

14. The reasons for increased public protest in the UK and Europe constitute a separate study. Several significant factors include: the analogies to “Madcow” disease and resulting political controversy; a stronger tradition of public involvement, protest and coalition building among non-government organisations; exposure of industry-ties within government biotechnology advisory committees; and new left-of-centre governments several countries (Carr and Levidow 1999).
CHAPTER THREE

Case Study:

*Environmental Risk Assessment for Herbicide Tolerant Canola (HTC)*

3.1 PURPOSE AND SCOPE

In Chapter 2, I identified the broad principles and influences that have shaped Canada’s biotechnology policies, and that bear directly on regulations for release of rDNA crops into the environment. However, a complete policy analysis must examine not only how policies are established and what they intend, but also how polices are actually *implemented*. Such a detailed analysis reveals how key regulatory principles and guidelines are interpreted, employed and modified over time. This is particularly important when policies are contingent on flexible guidelines, implemented on a case-by-case basis and when the data are neither publicly available nor independently reviewed. As I have discussed, risk assessment criteria and guidelines for unconfined release were established in 1994, but these remain subject to interpretation of the regulators and the applicants (AAFC 1994a; Canada 1996a; CFIA interviews, 1998). Moreover, data on environmental impacts must be obtained through the lengthy and expensive ATIP process, and once gathered by ATIP, is subject to further “third party review” before it is released (P. Scherling personal communication, 1998). Third parties, in this case, are the proponents who originally submitted the data to the government; third party review grants proponents an additional opportunity to restrict the release of information by claiming it is confidential business information (C. Warfield personal communication, 1999). Detailed analysis of risk assessment data for rDNA crops may therefore reveal important discrepancies between, as it were, the “public” and “private” face of biotechnology regulation in Canada.
As revealed in Chapter 2, the principle of “science-based risk assessment” has been central to Canadian biotechnology regulations since the late 1980s when policies were first developed. This chapter examines how science-based risk assessment has been operationalised in environmental risk assessment for a specific variety of HTC: Monsanto’s Roundup-Ready glyphosate tolerant *Brassica napus* line GT73, approved in March 1995 (AAFC 1995a). Section 3.2 outlines criteria used in AAFC risk assessments for rDNA crops, and data that must be gathered and submitted to AAFC by the crop developers. Section 3.3 summarises data collected by Monsanto for approval of Roundup Ready canola. In Section 3.4, I examine how this data was used to conclude that HTC is safe. Finally, Section 3.5 and 3.6 summarise my evaluation and relate my conclusions to risk assessments for other rDNA crops.

### 3.2 INFORMATION REQUIREMENTS FOR AAFC RISK ASSESSMENT

#### 3.2.1 Assessment Criteria

Assessment criteria for environmental risk assessment of rDNA crops are outlined in Regulatory Document 94-08 (AAFC 1994a). This document covers the unconfined release of all “plants with novel traits”—plants that proponents have deemed *not* familiar or substantially equivalent to existing plants in Canada. The five categories of potential effects used as criteria in environmental risk assessments are listed in Box 3.1. Two points regarding these criteria should be emphasised. First, as I

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<th>Box 3.1</th>
<th>Criteria for Environmental Risk Assessment as Outlined by AAFC:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Potential for:</td>
<td></td>
</tr>
<tr>
<td>(1) becoming a weed of agriculture or invasive of natural habitats;</td>
<td></td>
</tr>
<tr>
<td>(2) gene-flow to wild relatives whose hybrid offspring may become more weedy or more invasive;</td>
<td></td>
</tr>
<tr>
<td>(3) becoming a plant pest, e.g. through toxicity or allergenicity;</td>
<td></td>
</tr>
<tr>
<td>(4) impact on non-target species, including humans;</td>
<td></td>
</tr>
<tr>
<td>(5) impact on biodiversity.</td>
<td></td>
</tr>
<tr>
<td>From: (AAFC 1994a)</td>
<td></td>
</tr>
</tbody>
</table>
discussed in Chapter 2, these are the same criteria used to determine substantial equivalence (outlined in Box 2.6). The risk assessment process, in other words, aims to determine substantial equivalence. Second, all of the assessment criteria concern comparative and relative effects: the rDNA crop is compared to a non-rDNA “counterpart” plant.

Counterparts are non-rDNA varieties from which the rDNA crop was derived, or a similar genotype/phenotype combination of the same species. This method of testing is derived from the pre-commercial variety trials described in Chapter 2 in which all new crop varieties are compared with existing lines. To this end, AAFC has published a series of “companion documents” which outline the biology of non-rDNA crop species and are intended to be used for comparison purposes during the risk assessment. After extended debate in 1993 and 1994, the WCCRRC and AAFC decided the parental line “Westar” (the most prevalent B. napus variety in Canada) is a suitable counterpart for HTC (WCCRRC 1993a; WCCRRC 1993b; WCCRRC 1994a; WCCRRC 1994b). The companion document for B. napus was published in 1994 (AAFC 1994c).

### 3.2.2 Data Guidelines

In addition to the assessment criteria in Box 3.1, the Regulatory Document also outlines the data that may be used to fulfil these criteria (reproduced in Table 3.1). Applicants are also requested to summarise “anticipated relative effects” of the rDNA plant in the tabular format shown in Table 3.2.

While these categories appear comprehensive, it is important to recall from Chapter 2 that data specifications are “flexible” guidelines and not regulatory requirements. As stated in the Regulatory Document, “assessment will be part of the continuum of research, development, evaluation and commercialisation of plants with novel traits.... This document
TABLE 3.1
SUMMARY OF DATA REQUIREMENTS REQUESTED BY AAFC FOR ENVIRONMENTAL ASSESSMENT OF “PLANTS WITH NOVEL TRAITS”

INTERACTIONS OF THE PNT. Relative phenotypic expression of ________________ (variety/genotype designation), a derivative of ________________ (plant species), relative to its counterpart.

Complete the following table as appropriate: (this information is to determine whether there are significantly different/altered interactions resulting from the PNT’s novel gene products, which could potentially cause the PNT to become a weed of agriculture, become invasive of natural habitats, or be otherwise harmful to the environment). In completing this table, applicants may consider it unnecessary or inappropriate to provide certain information. In these instances information requirements may be waived if valid scientific rationale is provided.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Comparative Description&lt;sup&gt;1&lt;/sup&gt;</th>
<th>Change&lt;sup&gt;2&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Habit (annual, biennial, perennial)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vegetative vigour (biomass)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overwintering capacity (plant counts)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Flowering period&lt;sup&gt;3&lt;/sup&gt;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time to maturity&lt;sup&gt;3&lt;/sup&gt;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Seed Production&lt;sup&gt;4&lt;/sup&gt;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dormancy&lt;sup&gt;3&lt;/sup&gt;</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reproductive Characteristics: • Outcross frequency within species (0-1, 2-20, 21-100%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Cross Pollination vectors</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Fertility - male</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Fertility - female</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Self compatibility</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Asexual</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(Table 3 and 4 in Regulatory Document 94-08 (AAFC 1994a)
TABLE 3.1 (continued)

<table>
<thead>
<tr>
<th>Stress Adaptations:</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Biotic*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abiotic</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Pesticide</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Residual Effects:</th>
<th></th>
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</thead>
</table>

<table>
<thead>
<tr>
<th>Composition:</th>
<th></th>
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</thead>
<tbody>
<tr>
<td>Protein</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lipid</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Others</td>
<td></td>
<td></td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Endogenous Toxins (Define)</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Non-Endogenous Toxins:</th>
<th></th>
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</thead>
</table>

<table>
<thead>
<tr>
<th>Other Observations</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
</table>

1. Include unit of measure, where appropriate.
2. Provide ratio, percentage change (for quantitative characteristics only) or visual description, where appropriate.
3. Approximate dates (month/day), and days from seeding.
4. Approximate yield (per ha) divided by seeding rate (per ha) for corresponding crop kind.
5. Determine viability before, and after set periods, of seeds buried in rot-resistant bags in the soil.
6. List life forms with which the PKT interacts differently from the unmodified plant or counterpart. Use the species-specific companion documents for guidance.
7. Include any observed residual effects on growth/development of any three of the five indicator species (forage grass or forage legume or annual cereal or corn or oilseed). See Appendix IV regarding conduct of residual effects trials.
8. Identify the major compositional components important in the commodity and any other observed composition changes.
9. Identify any introduced toxins and provide information on concentration, persistence and purpose.
TABLE 3.1  
(continued)  

Summary of Anticipated Relative Impacts of Release of _________, a PNT of _________ (species).

<table>
<thead>
<tr>
<th>Effects of Release</th>
<th>Degree of Change</th>
<th>Geographic Scope</th>
<th>Duration</th>
<th>Relative Impact</th>
<th>Degree of Change</th>
<th>Geographic Scope</th>
<th>Duration</th>
<th>Relative Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biodiversity: Plant populations</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Animal populations</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Microbe populations</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Substance presence/persistence</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sustainability</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Agronomic-Silvicultural Practices</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Resource conservation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other concerns</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Overall Environmental Quality Changes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### TABLE 3.2
**SUMMARY OF ANTICIPATED RELATIVE EFFECTS OF HTC**
(by Monsanto as submitted to AAFC)

<table>
<thead>
<tr>
<th>Effect of Release</th>
<th>Natural Ecosystem</th>
<th>Agro-Ecosystem</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>A</td>
<td>B</td>
</tr>
<tr>
<td>Biodiversity:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Plant Population</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Animal Population</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Microbe Population</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Substance Presence or Persistence</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Sustainability</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Agronomic Practice</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Resource Conservation</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Other Concerns¹</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Overall</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Environmental Change</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Legend:
A, Degree of Change
B, Geographic Scope
C, Duration
I, Impact
0, no change
+, positive change
N/A, not applicable

¹ We consider the use of Roundup herbicide in the Agro-ecosystem to have a beneficial impact from use of an environmentally friendly herbicide and less total herbicide needed for crop production.
and its guidelines should be considered flexible and will likely evolve as more experience is
gained" (AAFC 1994a). That is, assessment criteria, reporting procedures, data requirements
and decision-making processes may change according to the specific application and previous
experience—the essence of a “case-by-case” process. For example, according to CFIA
officials, data may or may not be submitted in the form specified in the Regulatory Document
and shown in Table 3.1 (CFIA interviews 1998). Furthermore, applicants are accorded
considerable discretion in fulfilling data requirements: “Applicants may consider it
unnecessary or inappropriate to provide certain information. In these instances, information
requirements may be waived if valid scientific rationale is provided” (AAFC 1994a;
emphasis original).

AAFC reaches a conclusion on the environmental safety of rDNA crops based on data
and arguments presented by proponents, in this case Monsanto. AAFC does not conduct in
house experiments to supplement or verify submitted information. However, according to
CFIA, regulators do consult scientific literature and relevant “experts” and may request
additional information from applicants if necessary (CFIA interviews 1998). The Decision
Document for Monsanto’s line GT73 was published in March 1995 (AAFC 1995a). This
statement is used in the following analysis to examine how AAFC assessed, interpreted and
communicated the data provided by Monsanto. My analysis therefore draws mainly on the
risk assessment performed by Monsanto since they gathered the data and presented the core
argument according to AAFC guidelines. For the most part, AAFC responded to (and largely
agreed with) this argument. Where necessary, differences in approaches and opinions will be
noted.
3.3 DATA PROVIDED BY MONSANTO TO SUPPORT THE SAFETY OF HERBICIDE TOLERANT CANOLA

3.3.1 Data Released and Withheld

We submitted ATIP requests for four lines of HTC approved in Canada from 1995-1997: Monsanto’s glyphosate tolerant canola, lines GT73 and GT200; and two lines of AgrEvo’s glufosinate ammonium tolerant HTC. We requested information relevant to assessing environmental impacts, specifically data required to complete Tables 3 and 4 in the Regulatory Document (see Table 3.1). While Monsanto released data on Roundup Ready canola, AgrEvo withheld all risk assessment documents on their line of HTC, claiming it was confidential business information (CBI).\(^1\)

The ATIP office supplied over 500 pages of Monsanto’s data regarding the environmental safety of HTC line GT73. This consisted of:

- A summary report of 47 pages
- A “supplementary volume” of approximately 200 pages which provided methods and raw data for some tests
- Approximately 300 pages of checklists which were used to record observations during field trials.

According to ATIP officials, all but one page of requested data were released (P. Scherling personal communication, 1998). The withheld page contained letters from canola researchers regarding the variability of the Westar variety.

Some raw data for Monsanto’s HTC line GT200 was also included in the ATIP documents but GT200 was not discussed as a separate line in the summary report. Rather, Monsanto uses the term “GTC” in some cases to refer to both GT73 and GT200 (R. Ingratta personal communication, 1998). According to CFIA, Monsanto applied for approval of GT200 as substantially equivalent to GT73 (M. MacLean personal communication, 1999). This approval was granted in March 1996 (AAFC 1996e).
The presentation of Monsanto’s data made interpretation difficult, particularly as there were few clear cross-references between summaries, conclusions, methods and raw data. To address this problem, I sent a draft of the following sections (3.3.2 and 3.3.4-3.3.9) to CFIA for review and comment. The revised summary below incorporates the minor changes suggested by the chief regulator of the Plant Biotechnology Office, and can therefore be considered an accurate summary of the data. The Monsanto representative responsible for the risk assessment was unavailable for an interview, but addressed several of my questions in writing (as noted throughout this chapter).

To facilitate analysis, the data supplied by Monsanto will be discussed under AAFC’s five assessment criteria listed in Box 3.1 above, although information was not organised into these categories in the industry report. General methods used by Monsanto and conclusions drawn by both Monsanto and AAFC will also be examined. (NB: Unless otherwise specified, quotations hereafter are by Monsanto, as stated in documents supplied by ATIP.)

3.3.2 General Methods Used in the Risk Assessment

The aim of Monsanto’s report was to “assess the substantial equivalence of GTC to non-modified B. napus varieties of canola in commercially significant properties”. The standard for substantial equivalence was that GT73 “performed in a given test in a manner consistent with being a selection from Westar canola”. Monsanto states that all tests directly compared GT73 to Westar by growing the two lines side-by-side. However, according to the data, there were two exceptions to this method: an outcrossing experiment where a test line other than GT73 was used, and an experiment to test herbicide efficacy where control and test sites were planted in different geographic locations.
Tests were performed over a two year period (1993 and 1994 seasons with some tests performed in sites planted to canola in 1992). Data were drawn from private field trials and experiments conducted by Monsanto, and from 1992 and 1993 WCCRRRC variety trials for Westar and 1993 trials for GT73. The variety trials were conducted according to procedures outlined by the WCCRRRC (see Chapter 2 and Section 3.4.3 below). Monsanto stated that this breadth of data was necessary to include the full range of characteristics expected for Westar varieties because GT73 represents only a portion of the variability found in the Westar line. This variability was attested to in supporting letters which were withheld by Monsanto (see Section 3.4.3 below).

### 3.3.3 Description of the Novel Gene Products

"The exact nature" of the novel genes in GT73 “is considered confidential business information by Monsanto” (AAFC 1995a), and was not included in the ATIP documents. However, AAFC’s Decision Document provides a brief description. GT73 contains two novel genes, both of bacterial origin. The first gene, CP4, is a bacterial version of the plant gene EPSPS. In plants, this gene encodes an enzyme involved in amino acid synthesis and is inhibited by glyphosate. The bacterial form is not inhibited by glyphosate and therefore provides a degree of glyphosate tolerance when inserted into the plant. The second gene, GOX, degrades glyphosate to AMPA and glyoxylate (Wells 1995). This activity is required because glyphosate accumulates in some plant tissues and is degraded slowly, if at all, by plant enzymes (Sherman et al. 1996). Two additional sequences were inserted into GT73: a constitutive promoter and a transit peptide to direct newly translated CP4 and GOX proteins to chloroplasts, the site of glyphosate activity. According to the Decision Document (AAFC
1995a), the GOX and CP4 genes are present in single copies and are stably integrated into the 
*B. napus* genome. No antibiotic resistance markers were used.⁴

### 3.3.4 Weediness and Invasiveness

Increased weediness and invasiveness in agricultural environments were assessed 
through several parameters including seed dormancy, silique shattering and dispersal, 
overwintering capacity as a plant, adaptation to biotic and abiotic stress factors, control with 
herbicides, and allelopathic effects on other crops. These parameters are considered in turn 
below:

- **Shattering and seed dormancy** were assessed primarily by counting volunteer canola plants 
in various field sites—the same methods and much of the same data were used to test both 
parameters. “Volunteers” are plants that grow from seed left after harvesting. The rationale 
is that the number of volunteers will reflect (1) seeds fallen after shattering and (2) seeds 
lying dormant from one field season to the next and thereby give an indication of the overall 
weediness of HTC.

Volunteer canola seedlings were counted in 3 sites in 1993 and 5 sites in 1994 where HTC and non-modified canola had been grown the previous year. Each site was divided into 
8-10 plots, ranging in size from 0.25 m to 1m. Half of the GTC plots were treated with 
glyphosate as volunteers emerged; half remained untreated. Volunteers were counted in each 
plot then averaged for the whole site. The number of volunteers across all sites was highly 
variable, for example ranging from under 100 to over 1000 per m² in HTC plots in 1994, and 
one of the 1993 sites showed significantly more volunteers in the Westar plots. However 
when all site counts were averaged, no significant difference (p=0.05) between HTC and 
controls was calculated in either year.
Monsanto reported a number of problems with these tests which contributed to variability among sites. In 1993, for example, generally poor weather conditions increased seed loss and variability of the data, a killing frost and "more mature" control plants were reported at one site, and another site also experienced adverse weather conditions and had no control data. Variability at a third site (of 3 total sites) was attributed to dry conditions. In 1994, counts were taken in different-sized plots at each site then normalised to plants/meter². Statistical differences between HTC and Westar control plots at one site were explained by the fact that test and control plots were planted at different elevations on a hillside and therefore snow melted and soil warmed faster in the test sites. An additional test in 1993 did not have data for the Roundup-treated GT73 plot but showed no significant difference between the untreated GT73 and control plots. In total, complete data were obtained from 2/4 sites in 1993 and 4/5 sites in 1994.

Monsanto acknowledged the potential inadequacy of using such volunteer counts to assess shattering, noting that volunteers will also be produced by "spillage and other mechanisms of seed loss at harvest" and that number of seeds lost to shattering depends on environmental factors and physical disturbances. They stated however that "Brassica seeds do not have any special or specific adaptations to facilitate widespread disbursal [sic] (they do not blow in the wind or stick to animal fur) so the shattered seed will remain in close proximity to the original site" (not cited) and suggested that "counting volunteers overestimates shattering but addresses the main issue of potential invasiveness".

A second more direct test for shattering was used in 2 sites in 1993. Catch pans were placed along crop rows (4 replicates) as canola began to ripen. Fallen seeds were caught and counted. No significant difference (p=0.05) was noted between GT73 and control Westar. However, the same adverse environmental conditions that affected volunteer counts at one
site (noted above) were "also responsible for variability of seed loss data". Furthermore, HTC plots at this site were slower to mature than control plots and were harvested "somewhat green". Reliable data were therefore obtained from one site only. Despite these problems and inconsistencies, Monsanto concluded that "based on two years of monitoring the evidence shows no difference between Westar and GT73 in its shattering properties."

Seed dormancy was assessed by the same volunteer counts that were used to assess shattering (described above). In addition, a second study was conducted to test longer term dormancy. Volunteers were counted in 1994 in 2 sites where canola was grown in 1992 and seeded to barley in 1993. No volunteer canola was reported in these sites. These volunteer counts were supported by seed germination studies in which germination rates for HTC and four control varieties (Westar and 3 other B. napus varieties) were compared in laboratory and field settings. Germination rates for HTC were significantly different (p=0.05) from 2/4 control varieties in the field (significantly lower than one variety; and significantly higher than another). However, the control Westar seed was 2 years older than other control and HTC varieties, and therefore exhibited very low germination rates. Overall, it was concluded that HTC "is not changed in dormancy potential versus the unmodified counterpart".

Conclusions on seed dormancy were also supported by indirect reference to scientific literature: "There is no evidence to support increased dormancy of GTC as a consequence of the genetic modification..." (no references given).

•Overwintering capacity as a plant was determined through "observations" that "GT73 behaves in a manner consistent with Westar and any other spring canola currently in commerce in Canada" in that it is an annual plant and germinated seeds do not survive the winter. No data were provided or cited.
• *Adaptation to abiotic stress factors* was similarly determined through “observations by cooperator's over two years of field testing” that HTC and Westar controls “perform equivalently” toward drought, heat, and frost. No data were provided or cited and the effects of other abiotic factors were not reported.

• *Adaptation to biotic stress factors* was assessed only in terms of resistance to the fungal pathogen, *Leptosphaeria maculans* (Blackleg). Twenty additional biotic factors including pathogens, symbionts, competitors, and consumers were listed in the companion document (AAFC 1994c) but were not considered by Monsanto. Variety trial data from 1993 and a nursery experiment conducted by Monsanto showed similar disease ratings (i.e. highly susceptible) for HTC and control Westar. “Observations” from 1993 and 1994 variety trials also stated that “no differences in disease and insect susceptibility can be seen between GTC and Westar”. Based on this information, Monsanto concluded that “GTC has not demonstrated any observable difference in adaptation to biotic stress factors relative to Westar”.

• *Control of HTC with herbicides* other than glyphosate-based herbicides was determined to be “equivalent” to Westar controls in 1994 field tests. In these tests, HTC and control sites were planted in different geographic locations for unexplained reasons. “Effective” or “good” control of HTC volunteers was achieved with 2,4D and sulfonylurea-based herbicides.

• *Allelopathic effects on wheat and barley* were tested in apparent (not explicit) compliance with AAFC’s requirement to assess residual effects of HTC on growth and development of any 3 indicator species (AAFC 1994c). Wheat and barley were chosen because these crops are typically rotated with canola. Assessments were made by planting barley and/or wheat in fields where: (1) HTC and control Westar were grown the previous year (4 sites in both 1993
and 1994; 1993 data not included in summary report); (2) canola and wheat were planted early in the season, tilled under, then replanted with barley (one year; one site), and (3) canola was grown 2 years prior (one year; one site; only wheat tested). Allelopathic effects of HTC were assessed by comparing the number of barley or wheat plants in previous HTC or control Westar plots. Some HTC plots had been sprayed with Roundup, others were not. No statistical difference in the number of plants (p=0.05) was reported between HTC and control plots. Data on the total yield of barley and wheat were forthcoming at the time of the Monsanto report.

Contingencies such as adverse weather conditions, different topographical locations of test and control plots (discussed under seed dormancy and shattering tests above), different sized count plots, different treatments in different sites, and a plot that was “inadvertently cut by the large combine working in the area” contributed to the variability of results across trial sites. Nevertheless, Monsanto stated that “based on the results of these field experiments we conclude that plots of GTC are equivalent to Westar in allelopathic potential.”

**Invasiveness in non-agricultural ecosystems.** Although some of the above results from experiments in agricultural settings could be extrapolated to non-agricultural environments, the only test specifically designed to assess invasiveness into natural settings was seed germination rates in a roadside ditch. This experiment consisted of one trial in which 50 seeds of GT73 and Westar control were planted in 4 plots each 1m²; 2 of the 4 plots were mowed to simulate disturbance, and 2 were left undisturbed. None were sprayed with Roundup. Germination rates were not significantly different between control Westar and HTC (p=0.05) and no seedlings remained after two mowings. Based on these results, Monsanto concluded that “there are no differences between Westar and GT73 in terms of
invasiveness as measured by survival in a roadside ditch” and further that “GTC will not become invasive of natural habitats”.

Several other tests of “reproductive and survival biology” were used as evidence that GT73 was not more weedy or invasive than control plants. Vegetative vigour, flowering period, and time from seeding to maturity were assessed by “observations” or “documented visual observations” of variety trials over 2 years (no data provided). Seed production was similarly assessed in variety trials and in “private data” (latter not reported). Pollen production and viability was assessed through total yield data in 1992 and 1993 (data not reported). Self compatibility of GT73 was demonstrated by the fact that self-pollination produced progeny plants that were homozygous for the glyphosate tolerance genes.

Most tests concluded no significant or detectable difference between HTC and controls. The exceptions were maturation times and seed production which showed a “slightly lower yield” for HTC versus controls, and a one day delay in maturity for HTC. A total of 15 reports of delays in HTC maturity in 1993/1994 were documented in the variety trial monitoring sheets documented. Several problems and sources of variability were noted in these tests such as older control seed stock used in germination studies, a “poor seed source” of HTC used in seed production studies, and variation of seed production from site to site due to “local weather, soil, disease and pest conditions”.

Based on the above data and observations, Monsanto was able to “confidently conclude that GTC has no increased potential of becoming a weed relative to unmodified B. napus.” This conclusion was further supported by several “facts”: field work has demonstrated that HTC and unmodified B. napus are substantially equivalent; B. napus is not listed in the weed compendiums, Weeds of Canada and Weeds of Ontario; and glyphosate tolerance provides no selective environmental advantage.
AAFC agreed with Monsanto’s conclusions, stating that “GT73 was neither more invasive nor more persistent than Westar” in undisturbed habitats, that volunteer plants in agricultural settings can be “managed by growers using alternative herbicides” and overall that “GT73 has no altered weed or invasiveness potential compared to currently commercialised canola varieties” (AAFC 1995a). A caveat was added that should rDNA canola resistant to other types of herbicide be approved in the future, careful crop management should be promoted by extension personnel to avoid development of volunteers with resistance to multiple herbicides, and consequent loss of these herbicides as effective control tools.

3.3.5 Gene-Flow

Analysis of gene flow and introgression of herbicide tolerant genes from *B. napus* to other crops was based on “observations” by Monsanto of intraspecific crosses, and published literature on both intra- and interspecific crosses deemed “relevant to natural field conditions.”

• *Intraspecific outcrossing:* Monsanto cited several published reports of outcrossing variability among *B. napus* varieties in which outcrossing rates were dependant on weather conditions, plant density, pollinator activity and distance between male and female plants. Although Monsanto noted that up to 30% outcrossing has been reported, they concluded that outcrossing frequency between HTC and Westar in field conditions was much lower, *i.e.* 5% for plants in contact and 0.1% for plants separated by 225 meters. This conclusion was supported by a single field experiment in which HTC plots were surrounded by Westar control lines. Westar seed was harvested at various distances from the HTC plots and germinated seedlings were tested for Roundup resistance. GT73, the HTC variety under
review, was not used in this study; for unexplained reasons other HTC varieties were tested. No details of the procedure or raw data were provided.

- **Interspecific outcrossing:** Monsanto’s report considered gene flow into 3 Brassica species: *Brassica rapa* (syn. *B. campestris*, wild turnip), *Brassica juncea* (Indian mustard), and *Brassica nigra* (black mustard). Crosses with *B. rapa* and *B. juncea* were cited as “low frequency” events resulting in less fertile hybrids than *napus x napus* crosses. Monsanto therefore concluded that gene flow from HTC into *B. rapa* “will not be effective in establishing large populations” in natural settings, and that outcrossing from *B. napus* to *B. juncea* “is not a significant mechanism for gene flow.” Similarly, the risk of gene flow from HTC into *B. nigra* was considered “negligible” or “essentially zero” based on lack of hybrid fertility and low incidence of *B. nigra* in Western Canada. Introgression of HTC genes into *B. nigra* through intermediary (“bridging”) species such as *B. rapa* and *B. juncea* was not determined “to afford a reasonable method for gene transfer”.

- **Intergeneric outcrossing:** Monsanto reviewed the outcrossing potential between *B. napus* and two non-Brassica species. It was concluded that gene flow and formation of hybrids with increased weediness between *B. napus* and wild radish, *Raphanus raphanistrum*, was “highly unlikely”. This conclusion was based on the reported difficulty of creating fertile hybrids in artificial conditions and a lack of reports for naturally occurring hybrids. AAFC studies “to better define” the outcrossing potential between dog mustard, *Erucastrum gallicum*, and *B. napus* were ongoing at the time of the Monsanto report. The modest conclusions that fertile hybrids between HTC *B. napus* and *E. gallicum* would be no different than non-HTC and would occur at a lower frequency than crosses between *B. napus* and *R. raphanistrum* were therefore based on “preliminary communications” and “predictions” by Monsanto. In the concluding section (but not in the body of the report), Monsanto further stated that gene
escape into wild mustard, *Sinapis arvensis*, “will be essentially zero in western Canada”.

Lack of evidence for naturally occurring crosses among relatives of *B. napus*, and for crosses between *B. napus* and other related weedy species was also noted.

Other factors such as the reported stable integration of the glyphosate tolerance genes; lack of reported horizontal gene transfer mechanisms; control of weedy relatives with herbicides; and published literature showing HTC does not “persist as predicted”, as well as claims that interactions of canola in the environment are “highly familiar” and the “glyphosate tolerance trait will offer no selective environmental advantage” contributed to Monsanto’s overall conclusion that “there is no meaningful potential to generate a plant pest as a result of gene-flow” from HTC.

In response, AAFC noted the potential for outcrossing between *B. napus* and 4 other Brassica species, as well as the potential for 3 intergeneric crosses. However, AAFC states that introgression of the glyphosate tolerant gene into these populations would not confer a selective advantage in the absence of glyphosate application. Because herbicides are used only in “managed ecosystems”, other chemical herbicides could be used to control glyphosate tolerant hybrids. Furthermore, widespread resistance to glyphosate could be avoided through “sound crop management practices”. Consequently, AAFC concluded that although gene flow is possible, it “would not result in increased weediness or invasiveness” of hybrid populations (AAFC 1995a).

### 3.3.6 Plant Pest Potential

Altered potential for HTC to become a plant pest was assessed through 3 criteria: effects on predatory and beneficial insects, compositional analysis of the HTC, and toxicity of the novel gene products. The only reference to the effects of HTC on insects was that “no
differences” between HTC and control Westar were noted during variety trials. No data or observations procedures were provided.

Compositional analyses and toxicity tests were conducted as part of a food and feed safety assessment under 1994 draft guidelines.\textsuperscript{5} This assessment was necessary because GT73 was developed for livestock feed. For compositional studies, two seed sources from 1992 (grown in 3 and 7 locations) and one source from 1993 (grown in 4 locations) were tested in terms of amino acid, fatty acid and oil composition, and proximate analysis.\textsuperscript{6} Defatted canola meal was tested for glucosinolate content, percent protein, and chlorophyll and sinapine content. No statistical analyses were done for these tests “because variation was expected due to the genetic background of GT73 and since samples were not taken from replicated plots.” Expression levels of novel protein products, GOX and CP4, were calculated in leaves, seeds, and toasted meal. Statistical comparison of novel protein expression could not be done because expression levels in control plants were too low to be detected. Nevertheless, Monsanto concluded that relative to total protein in the plant, GOX and CP4 expression was “very low”.

Toxicity tests of the two novel gene products (CP4 and GOX proteins) were assessed by protein characterisation, digestion of the proteins in simulated mammalian gastric and intestinal fluids, and acute oral toxicity in mice. Protein characterisation was important because the protein samples used in digestion and toxicity tests were not derived from canola, but were produced in large quantities in the bacterium, \textit{E. coli}. Monsanto cited company reports showing bacterium-produced protein to be a “suitable substitute” for low quantities of proteins available from canola. For the GOX tests, only partially purified protein samples were obtained. Western blots revealed a short half life of the novel proteins in digestive fluids. Oral toxicity studies showed no statistically significant differences in body weight or
food consumption and "no observable pathologic changes" after 7-9 days. These studies were used to show that the CP4 and GOX gene products are not toxic and to "support the safety" of both proteins.

Overall, Monsanto claimed these tests showed HTC to be "substantially equivalent" to Westar and that HTC "is not a plant pest." AAFC concurred with this conclusion: "...plant pest potential has not been inadvertently altered" (AAFC 1995a).

3.3.7 Impact on Non-Target Species

Effects on non-target organisms were not explicitly addressed in the Monsanto report, other than the studies outlined above. However, AAFC relied on allelopathic studies of HTC on barley and peas (no reference given for the pea study) as "indirect evidence that soil microorganisms involved in maintaining soil fertility are not negatively affected" (AAFC 1995a). Together with the toxicity studies described above and database searches for homology to known toxins and allergens, AAFC concluded that "unconfined release of GT73 will not result in altered impacts on interacting organisms... compared to current varieties of Westar" (AAFC 1995a).

3.3.8 Impact on Biodiversity

Monsanto concluded that the data presented in their report, as well as the fact that the herbicide tolerant gene "does not confer a selective environmental advantage, and the potential for gene flow to weedy relatives is zero in Canada" serve to "demonstrate that...there is no potential negative impact of unconfined release of GT canola and progenies derived from traditional breeding on biodiversity." It is unclear how Monsanto arrived at the conclusion about weedy relatives given the discussion of introgression above. AAFC also
concluded that the potential impact on biodiversity of GT73 was equivalent to that of varieties such as Westar. However this conclusion was not based on lack of gene flow (which AAFC acknowledged) but on “the nature of the trait (glyphosate tolerance) that may be transferred” (M. MacLean personal communication, 1999).

Significantly, Monsanto also addressed the potential effects of increased use of Roundup on biodiversity. This is interesting because one of the purported benefits of HTC is decreased herbicide use. For example, Monsanto claimed that the active ingredient of Roundup, glyphosate, has been “employed as a highly effective and completely safe weed control tool throughout the world” and will not adversely affect biodiversity “more than any other approved herbicide”. Yet at the same time, Monsanto claimed that some adverse affects of herbicide use have “been accepted due to the benefit afforded by weed control on increased yields and an ensured food supply. The use of Roundup tolerant cultivars...offers additional benefits like reduced total herbicide load on the environment and considerable cost savings to the farmer. These benefits will add to Canada’s international competitiveness.”

3.3.9 General Conclusions

Monsanto concluded that “data and information related to the biology of GT73...demonstrates that GT73 is substantially equivalent to its non-modified counterpart in all relevant parameters.” More specifically, Monsanto claimed:

1) “GTC will not become invasive of natural habitats”
2) “GTC is not a plant pest”
3) “outcrossing of the GT genes to wild relatives can potentially generate hybrids with only B. napus, B. rapa and B. juncea at a low frequency; and these hybrids will not be weedy, or more invasive”
4) “outcrossing of GT genes to B. nigra, R. raphanistrum, and E. gallicum pose no significant environmental risk due to the extremely low frequency of hybrid formations and the poor fertility of the hybrid generated”
5) “there is no potential negative impact of unconfined release of GT canola and progenies derived from traditional breeding on biodiversity”.

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A summary of "anticipated relative impacts" of unconfined release was presented in table form, as required by the AAFC Regulatory Document (Table 3.2). The positive effects of HTC on sustainability and overall environmental quality noted in the table reflect Monsanto's conviction that HTC affords "more environmentally sound [agricultural] practices", and that Roundup offers "superior weed control" and may reduce the need for other herbicides. Other than these positive effects, and the opportunity to use Roundup during the growing season, Monsanto claims the HTC "will be cultivated and harvested in a manner equivalent to Westar."

AAFC agreed with these overall conclusions, stating that GT73 "does not present altered environmental interactions when compared to existing commercialised canola varieties in Canada, and is considered substantially equivalent to canola currently approved...." Consequently, "unconfined release into the environment [of] GT73 (and other B. napus lines derived from it, provided no other novel traits are introduced) is therefore considered safe" (AAFC 1995a).

3.4 EVALUATION OF HTC RISK ASSESSMENT AND DECISION-MAKING

3.4.1 Framework for Evaluation

Among the goals of this dissertation are to examine working definitions of science, to demonstrate that boundaries around "good science" are partially constructed through social and political processes, and to suggest these boundaries ought to be re-drawn in some cases. If definitions of "good science" are indeed contingent upon circumstance, what standards should we use to evaluate the Monsanto/AAFC risk assessment data? In this chapter, I will evaluate the data against Monsanto's and AAFC's own proclaimed standards. AAFC purports to use "science-based risk assessment" (AAFC 1993) to regulate the environmental
hazards of rDNA crops, and as mentioned above, data requirements for environmental assessment can be waived based on "valid scientific rationale" (AAFC 1994a). The 1996 Regulatory Impact Analysis Statement also affirms that the existing regulatory framework "provides for a sound scientific data base on which to assess risk and evaluate products" (Canada 1996a). The current Minister of Agriculture has also affirmed that "our safety assessments on new agricultural products are thorough, complete and scientifically sound" and that no rDNA crop is commercialised "unless it is safe, based on the latest and best scientific knowledge we have" (Vanclief 1999).

However, nowhere in these publications or statements is "science" clearly defined. Some AAFC and CFIA documents refer to "existing knowledge and experience" (AAFC 1993; Hollebone 1993a) or available scientific information (CFIA 1998b). Interviews with CFIA regulators revealed that empirical, experimental data and peer-reviewed literature constitutes a scientific basis for risk assessment (CFIA interview, 1998). Amendments to confined field trial guidelines made in 1996 suggest a similar standard: "Experiments to be considered for review for a determination of environmental safety...must be conducted following statistically valid experimental designs and protocols (i.e., to generate data that is acceptable for inclusion in a peer reviewed research publications)" (CFIA 1996). Monsanto too has publicly claimed to rely on peer-reviewed science to test the safety of rDNA crops (Lambie 1999).

Given these statements, it seems fair to ask whether the risk assessment data submitted for HTC conform to broad standards and norms of academic science. While I recognise that such norms and standards are themselves subject to various influences, and are not necessarily representative of, or appropriate for, all scientific work—a point I will explore more fully in Chapter 4—AAFC and Monsanto have nonetheless implied that their scientific
data is on par with that of peer reviewed scientific literature. The following evaluative framework aims to test this claim:

1. Scope of inquiry: Did Monsanto address the criteria outlined by AAFC in Regulatory Document 94-08? Are the questions and goals of the assessment relevant and appropriate to the problem of potential environmental harm from large-scale unconfined release of HTC?

2. Methods of assessment: Are experiments appropriately designed to address stated questions and support final conclusions? Are experiments consistent, replicated and controlled?

3. Data and reasoning: Are the data statistically valid? How complete is the evidence relative to existing, published scientific literature? What types of data were gathered and how were data used to support conclusions?

4. Conclusions: How are uncertainty and limitations of the study addressed? Are the conclusions plausible based on experiments and data submitted in the report?

For each evaluative question (1-4), I will draw on specific examples from the HTC data to illustrate my point, rather than attempt to discuss all the data under each category.

### 3.4.2 Scope of Inquiry

How did Monsanto and AAFC frame key questions about the environmental hazards of HTC? First, it is important to emphasise that both parties framed the central problem of risk assessment as a comparative and relative one: the effects of HTC versus its unmodified "familiar" counterpart, Westar. All subsequent questions were addressed within this overall framework.

Several researchers have criticised environmental risk assessments for rDNA crops as too narrowly focused on efficacy and agronomic criteria to address the complexity of ecological interactions and hence environmental hazard (e.g. Biosafety 1996; Ingham and
Holmes 1995; Parker and Kareiva 1996; Purrington and Bergelson 1995; Rissler and Mellon 1996). Monsanto and AAFC ostensibly moved beyond a narrow focus to consider factors such as invasiveness, adaptation to stress factors, and effects on non-target organisms and biodiversity. While extending the scope of inquiry seems a step in the right direction, both Monsanto and AAFC drew broad and definitive conclusions about these issues from very limited data. Furthermore, neither party extended their inquiry far enough to consider the full spectrum of relevant potential harms posed by large-scale HTC release. My criticism is therefore levelled at (1) the depth of responses to specific questions; and (2) the breadth of questions on the table. In both respects, the HTC risk assessment is, in fact, narrowly focused on agronomic characteristics, and set within the confines of regulatory hurdles that are unrelated or peripheral to environmental hazards. Several examples below illustrate this point.

**Depth of Questions**

It is difficult to argue that Monsanto thoroughly examined criteria such as adaptation to abiotic and biotic stress factors, plant-pest potential and effects on non-target organisms and biodiversity. The conclusion that HTC and Westar adapt equally to abiotic stresses, for example, was based on unrecorded observations of the effects of drought, frost and heat during two field seasons. Other abiotic factors that may affect the biology of HTC and/or interactions of HTC with other organisms were not considered, for example physical, chemical or mineralogical composition of the soil (Landbo and Jorgensen 1997; Morra 1994), changes in exposure to light (e.g. through shading, weather or planting site; Fredshavn and Poulsen 1996), and longer term patterns such as effects of temperature cycles on seed dormancy and germination (Landbo and Jorgensen 1997). In view of the potential combined
impacts of these factors, Tomlin (1994) recommends that reviewers of risk assessments “should insist” that climate and soil data be provided “by citing latitude and longitude, and soil and climate surveys.”

Biotic stress factors were given similar cursory appraisal. Monsanto’s sole test for biotic stress was resistance of HTC to Blackleg infection. This priority is understandable only in the context of pre-commercial variety trials. Because Blackleg infection causes serious crops losses in Canada, prospective canola varieties are graded and awarded merit points according to degree of Blackleg resistance (Griffiths 1997; WCCRRC 1998). From an agronomic and marketing point of view, it is therefore imperative that new canola varieties are not more susceptible than check varieties. However, in terms of assessing the wider impacts of unconfined HTC release, other biotic stresses such as competing plant species, foragers, and other pathogens (AAFC 1994c) will likely have a similar or greater impact than Blackleg.

The “plant-pest” potential of HTC, defined as increased toxicity or allergenicity, was assessed by toxicity studies and compositional analyses. The scope of these tests was influenced both by variety trial requirements and by the fact that HTC line GT73 was developed for livestock feed and therefore was required to pass feed safety standards. Indeed Monsanto’s tests seemed better suited to the latter purpose than to environmental safety: toxicity of isolated proteins was tested in mammalian systems only; compositional analyses were restricted to seeds and meal (which are fed to livestock) and examined only those parameters required for feeds assessment or for variety trials. The relevance of these tests to other organisms is questionable. For example, several insect species feed on canola leaves, seed pods, buds, flowers, stems and roots (Turnock 1990). While adverse effects of HTC on these insect pests might not seem a concern from an agronomic point of view, direct or
indirect effects on other insects may present more of a problem. For example, laboratory studies have demonstrated adverse effects on lacewings and ladybugs that have eaten insect pests fed on rDNA crops (Birch et al. 1996-7; Hilbeck et al. 1998). Such indirect effects could reduce populations of “beneficial” (pest-eating) insects, thereby increasing pest problems. More recently, experiments have demonstrated lethal effects of pollen from corn plants engineered with a *Bacillus thuringiensis* gene on monarch butterfly larvae (Losey 1999). While none of these studies were conducted on HTC, they do suggest that rDNA crops may have unforeseen effects on insect populations, and perhaps more importantly, that detection of these effects requires that experiments be designed for this purpose. Angle (1994) further emphasises the potential for such complex and indirect effects among soil organisms, noting that because these populations are “tightly linked to one another via competitive, predatory or associative effects, changes in the populations of a single organism can have the potential to affect a large proportion of the soil population.” He suggests that effects could be amplified in intensive agricultural systems which have relatively simple soil ecosystems and may be more vulnerable to small changes than diverse ecosystems.

Effects on non-target organisms and biodiversity, other than the above toxicity and compositional studies, were not directly addressed or tested in the HTC assessment. It is, in fact, difficult to determine how the three categories of hazards (plant pest potential, non-target effects, and impacts on biodiversity) were distinguished. Technically, all organisms affected by HTC are “non-target” (the novel gene is targeted to a chemical, not an organism), again suggesting that identification of such effects in both agricultural and non-agricultural ecosystems would require deliberate effort. Checklists on the variety trial monitoring sheets did not include a space for effects on non-target organisms—these trials are designed to monitor crop growth, not insect, microbe or bird populations (see Figure 3.1). Monsanto did
FIGURE 3.1
EXAMPLE OF MONITORING SHEET USED IN VARIETY TRIALS

1993 FIELD MONITORING OF
ROUNDUP TOLERANT CANOLA TRIALS

Objective: Compliance with terms and objectives of confined field trials. Provide additional information to ensure safety to the environment.

- Make observations at least twice monthly for the growing season.
- Compare control (nontransgenic) to transgenic lines for similarities and differences in the following:
  - Disease (resistance/susceptibility)
  - Insects (resistance/susceptibility)
  - Weediness (susceptibility to other herbicides, unusual proliferations)
  - Vigor (vegetative)
  - Sprayed versus Unsprayed Transgenics

Transgenics versus Nontransgenic Canola Plants (Please /)

<table>
<thead>
<tr>
<th>1. Disease</th>
<th>No Diff.</th>
<th>Diff.</th>
<th>N/A</th>
<th>Diff. Observed (Explain)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Insects</td>
<td>/</td>
<td>-</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>3. Weediness</td>
<td>/</td>
<td>-</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>4. Vigor</td>
<td>/</td>
<td>-</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>5. Other?</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td></td>
</tr>
</tbody>
</table>

Sprayed vs Unsprayed

Comments: Serious stage differences

Beaverlodge Research Station
Beaverlodge, AB
Date: July 7, 1993
Location

Signature

CONTAINS TRADE SECRETS OR OTHERWISE CONFIDENTIAL INFORMATION OF MONSANTO

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examine the effects of HTC on barley and wheat yields, but again the scope of these tests was defined not by considerations of environmental hazards *per se* but by concerns for crop rotation efficiency.

Based on this data, both parties made broad claims that HTC will not become a plant pest, and will have no greater impact on non-target organisms or biodiversity. By way of contrast Morra (1994) suggests that “to fully assess the biological impact of transgenic plants it is critical to comprehensively monitor behavioural changes [in affected organisms]. It is necessary to determine not only acute toxicity, but the chronic impact of subacute concentrations, alterations in feeding behaviour and in the case of insects changes in moulting frequency...” and to assess these effects at different life stages. With the recent approval in Canada of almost 30 rDNA crops, including 15 lines of five HT crop types⁷, as well as combinations of novel traits within a single crop, it also seems wise to consider cumulative and synergistic effects of novel gene products. In this light, Tomlin (1994) recommends that assessments of rDNA organisms “should use similar protocols as conventional pesticides for comparing non-target effects.”

*Breadth of Questions*

Both Monsanto and AAFC focused on the *direct* effects of HTC. Secondary or indirect effects of releasing HTC on a large scale escaped the narrow purview of the HTC risk assessment primarily because neither party was operating at the systems level; the focus of their concern and assessment was simply two new genes. If we broaden the scope of inquiry just slightly, a whole new range of potential environmental harms becomes apparent.

The effects of HTC commercialisation on herbicide use is perhaps the most obvious example. One of the potential benefits of HTC, as described by Monsanto in their risk
assessment, is reduced “herbicide load” on the environment. Monsanto’s 1997 Annual Report tells a different story:

“Net sales for Agricultural Products set another record in 1997, led by significant sales volume increases for the family of Roundup herbicides. Increases...in over-the-top applications of Roundup on Roundup Ready soybeans, cotton and canola; and an increase in the acres of major row crops planted world-wide drove sales of Roundup herbicide to a new high” (Monsanto 1997).

Monsanto owns 11 of the 14 glyphosate herbicides registered in Canada (PMRA 1999a) and prohibits use of competitors’ herbicides on Roundup Ready crops through strict licensing agreements with farmers. Critics have noted that such agreements ensure a market for Roundup after the patent expires in 2000 (Lappe and Bailey 1998).

Roundup is promoted as an environmentally friendly herbicide mainly because it can be applied judiciously after crops and weeds have emerged (as opposed to worked into the soil) and because it is said to be immobile and quickly broken down by soil organisms. However, there remains controversy over the safety of glyphosate and Roundup, particularly as applied on large scales. For example, the Northwest Coalition on Alternatives to Pesticides (NCAP) reviewed scientific studies of the toxic and ecological effects of glyphosate (Cox 1995a; Cox 1995b). The reviewer concluded that glyphosate may leach into surface and ground water and may persist in soils for a few days or up to several years depending on conditions. A number of adverse effects of glyphosate have been reported including toxicity in beneficial insects, earthworms and mycorrhizal fungi, reduced nitrogen fixation by soil bacteria, and possible carcinogenic and reproductive effects on higher organisms. Toxicity tests are usually conducted on active ingredients only (i.e. glyphosate), but concerns have also been expressed regarding the “inert” ingredients of Roundup, such as surfactants and neutralising agents (Cox 1995a; Greenpeace 1996; Lappe and Bailey 1998).
Monsanto is careful in their risk assessment to state that “glyphosate, the active ingredient of Roundup, has been approved for use in Canada...” (emphasis added).

Uncertainty over the safety of glyphosate-based herbicides, and the changes in herbicide application brought about by herbicide tolerant crops, have sparked further controversy over acceptable glyphosate residue levels in and on HT crops. Prior to 1991, glyphosate was registered in Canada for pre-plant or post-harvest use only. Consequently, no residue tolerances were established because glyphosate was not sprayed directly on crops. However, the advent of herbicide tolerance crops required registration of glyphosate for pre-harvest use—a practice that increases total glyphosate residues left on the plant and stored within the plant. Maximum residue levels (MRLs) were set by Health Canada in 1991 (Canada 1991) and revised in 1998 (PMRA nd). A Decision Document on pre-harvest use of glyphosate was issued by AAFC in 1992 (AAFC 1992).

A number of safety and trade-related concerns were discussed in the Decision Document, including residue effects on seed germination and seedling vigour, the need to “dilute” sprayed crops with unsprayed yields to lower overall residue levels, drift of glyphosate during application procedures, concerns about “wildlife, wetlands and other natural areas”, and harmonisation of international residue levels to avoid trade restrictions. Partly to “balance the two diametrically opposed considerations, i.e., the interest in using the technology [pre-harvest use of glyphosate] versus any possibility of customer or trade reaction,” it was agreed that Roundup labels will include the following specifications:

- Do not apply to crops grown for seed. Do not apply to barley grown for malting. Avoid overspray or drift to important wildlife habitat is such as bodies of water, shelterbelts, woodlots and other cover on the edges of field frequented by wildlife. Leave a 15-meter buffer zone between the last spray swath and the edge of these habitats. Do not expose or contaminate any body of water or non-target vegetation by direct application, spray drift, or when cleaning or rinsing spray equipment. Do not apply by aircraft (AAFC 1992).
Despite these cautions, several other issues regarding pre-harvest use of glyphosate have not been addressed. Most significantly, while AAFC approved pre-harvest use of glyphosate on canola, Health Canada did not include canola in their list of maximum residue levels. The 1991 MRLs were revised in 1998, with the MRL for soybeans (the other major Roundup Ready crop in Canada) jumping from 6ppm to 20ppm. MRLs for other crops were unchanged (PMRA nd). The upper limit of 20ppm is consistent with current standards of Codex Alimentarius Commission (advisory to the World Trade Organisation; see Chapter 2), and the US has allegedly tripled its residue allowances to accommodate herbicide tolerant crops and international standards (Lappe and Bailey 1998).

Glyphosate not only accumulates on the surface of sprayed plants, but is stored within tissues such as meristems, fruits and nodules where it is broken down slowly, if at all, by plant enzymes (Sherman et al. 1996). The GOX gene was inserted into HTC line GT73 precisely for this reason: GOX degrades glyphosate to AMPA and glyoxylate. While this device may appear duly cautious, both GOX and CP4 proteins are transported to the chloroplasts, the site of glyphosate activity, and it is therefore unclear how glyphosate is degraded in other (non-chloroplast) tissues. Non-degraded glyphosate may be included in overall residue counts for crops (assuming tests are done and MRLs established), but the effects of glyphosate accumulation in non-crop or hybrid plants must also be considered.

While I have not attempted a thorough evaluation of all scientific evidence on the potential effects of glyphosate, several points seem clear. There is considerable controversy and uncertainty regarding the status of Roundup as an “environmentally friendly” herbicide; Canadian maximum residue levels for soybean have more than tripled since the advent of rDNA HT crops; glyphosate sales have risen dramatically in the same time period; and finally, none of these points were addressed in HTC risk assessment by Monsanto or AAFC.
The environmental effects of glyphosate are not peripheral to the hazards of HTC. Rather, they are an inseparable and intentional consequence of large-scale release of herbicide tolerant crops.

One can cite many other examples of the indirect environmental effects of HTC. For example, further intensification of agriculture and reliance on monocultures threaten to exacerbate the weed and pest problems that HTC and other rDNA crops claim to solve; closing of foreign export markets due to environmental concerns will likely have serious social consequences for canola farmers (Greenwood 1999); and the spread of herbicide tolerant crops to nearby fields may adversely affect social as well as ecological communities. The latter case was illustrated in a recent dispute between Monsanto and a Saskatchewan farmer. Monsanto claimed the farmer had grown Roundup Ready canola without a license while the farmer claims the canola spread to his field from neighbouring fields. In response to such events, Monsanto has "hired full time investigators to follow up on all seed piracy leads" (Monsanto 1998) and according to the Washington Post has subsequently sponsored a "toll-free 'tip-line' to help farmers blow the whistle on their neighbours and has placed radio ads broadcasting the names of noncompliant growers caught planting the company's genes." According to the report "those tactics are fraying the social fabric that holds farming communities together" (Weiss 1999).

Critics of biotechnology and industrial agriculture have outlined many other effects of rDNA crops on social structures, cultural norms, and individual and communal values (e.g. Shiva 1993; Shiva 1997). I have focused here on effects that might reasonably be included in a self-proclaimed "environmental assessment" of HTC, while at the same time raising the question of where appropriate boundaries of such an inquiry should lie. I will return to this question in Chapter 4. However, even within a narrower concept of environmental risk
assessment, the above analysis suggests that the scope of the HTC study was critically limited in several respects. First, assessment categories specified by AAFC were given only cursory appraisal by Monsanto and did not consider the full range of potential effects, even as outlined in the scientific literature and regulatory documents. Second, the scope of questions and definitions of harm did not extend beyond direct, “clear and present dangers” of HTC (Krimsky and Wrubel 1996). Complex synergistic and cumulative effects, and downstream consequences of HTC for ecological, agricultural and social communities were not deemed within the mandate of risk assessment. I contend that these boundaries of relevant harms were largely determined by the policy context. Environmental risk assessments were conveniently piggy-backed to other regulatory hurdles and were therefore constrained by business and/or political agendas (see Chapter 2). For example, livestock feed assessments limited concepts of non-target effects, toxicity and plant pest; requirements for variety registration limited the goals of assessment to efficacy and agronomic traits relative to the check variety; and AAFC’s framework of familiarity and substantial equivalence limited standards of assessment to no greater impact than current agricultural practices. Thus, the risk assessment might appear to “work”—to answer the question “is HTC substantially equivalent to conventional varieties?”—but only as defined by the intents and purposes of the participating parties, Monsanto and AAFC.

3.4.3 Methods of Inquiry

"...particular representations are already committed to particular kinds of interventions...”

(Fox Keller 1992)

As the above quotation suggests, methods of inquiry and “intervention” are largely dictated by the way in which key problems and potential solutions are framed. I have argued that the scope of the HTC risk assessment was bounded in part by political and commercial
interests. This argument is further supported by detailed examination of the methods used by Monsanto to determine safety of HTC.

Monsanto drew on two sources of data for their assessment, private field tests and public variety trials. Private, confined field trials have been conducted in Canada since 1988, however official guidelines were published by AAFC only in 1993 and revised in 1994 (see Chapter 2). These guidelines outline containment procedures for field trials, but do not specify the type of data to be collected. As discussed in Chapter 2, the regulatory document states that “information gathered from these trials can be used to assess both performance and, to some extent environmental safety of the modified plant material, assuming the trials are designed for these purposes” (AAFC 1994b) but there are no specific requirements or guidelines for conducting experiments related to environmental hazards. Private trials may include criteria needed for an environmental safety assessment (CFIA interviews, 1998), but are generally designed to test the efficacy of the newly developed trait and overall performance of the crop prior to entry into public variety trials. In fact, as of 1994 private data may substitute for the first year of variety trials. Private data need not be submitted to AAFC as part of the environmental safety assessment and are not routinely monitored by AAFC or other parties (WCCRRC 1993a; WCCRRC 1993b; WCCRRC 1994a; WCCRRC 1994b). However, according to CFIA, government regulators “reserve the right to ask for all records of confined field trials if warranted” (M. MacLean personal communication, 1999).

As discussed in Chapter 2, variety trials are legislated under the Seeds Act to ensure agronomic performance and uniform quality of Canadian crops. Until 1995, canola variety trials were overseen by AAFC in cooperation with the WCCRRC. Crops are awarded merit points for market-related characteristics including glucosinolate and erucic acid levels, yield, maturity, oil and protein content and Blackleg resistance—testing for these parameters is the
purpose and limitation of the variety trials. To reiterate, neither private field tests nor variety trials are specifically designed to address the risk assessment criteria outlined in AAFC’s Regulatory Document 94-08 (AAFC 1994a). In fact, at the time of the HTC risk assessment strict compliance with the assessment criteria outlined in the Regulatory Document was impossible: this document was published in December 1994; Monsanto’s risk assessment was submitted to AAFC in October 1994 and tests were carried out 2 years prior. In other words, in terms of federal risk assessment regulations, Monsanto did not even know what to look for. Setting aside this rather significant problem for the moment, how suited were Monsanto’s scientific methods to the assessment of environmental hazards?

Scale and Context

The scale of the HTC risk assessment was limited both geographically and temporally. While the precise dimensions of private and variety trials are neither standard nor explicit, commercial-scale plantings are clearly on a different order of magnitude from “confined field tests”. As a rough comparison, variety trials guidelines suggest that trial plots be 4 rows wide, 5 metres long, with 3 replicates (WCCRRC 1998) for both official variety trials and private testing. Amendments to the confined field trial guidelines in 1996 advised that confined trials be no larger than one hectare and include no more than 5 sites per province (CFIA 1996). According to US researchers, small scale trials used for risk assessments in the US range from 10 to 100 acres (Lappe and Bailey 1998; Snow and Palma 1997). In contrast, in 1996 rDNA herbicide tolerant canola varieties were grown on 100,000 hectares in Canada; by 1998 this figure had risen 2.4 million hectares. No herbicide tolerant crops—hybrid or rDNA—have been released on this scale in Western Canada prior to release of HTC in 1995 (G. Coy, personal communication, 1999).
The problem, of course, is that some impacts of HTC are likely to be scale-dependent. The OECD specifically addressed this issue in their "scale-up" procedures for rDNA crops: "Some events may not be detected until a cultivar is grown at commercial scale for several years. This is normal..." (OECD 1993a). Other commentators have been less complacent about scale-dependent effects and have emphasised the inadequacy of small-scale trials to predict the impact of large-scale release. For example, Seidler and Levin (1994) suggest that the cumulative effects of many small scale releases are unlikely to reflect the impact of larger scale introductions; Dale and Irwin (1995) and Brown et al. (1996) note that widespread commercialisation of rDNA crops in a variety of habitats will increase the likelihood of hybridisation among crops and wild relatives; and Gliddon (1994) argues that the scale of commercial plantings may be sufficient to overcome slightly lower fitness levels of crop-wild hybrids (see also Kareiva and Parker 1995; Regal 1994; Ruesink et al. 1995; Wrubel et al. 1992).

The temporal scale of Monsanto’s field trials seems an equally poor indicator of the potential impact of commercial-scale HTC release. Monsanto collected data on HTC over two field seasons, the usual time period for variety trials. Additional data for the check variety was gathered from one previous year, and Monsanto claimed to have conducted private trials over a total six year period with no "untoward" environmental effects. Had these six years of trials been specifically designed to observe and evaluate environmental hazards—and had data been provided to support these evaluations—we might be more confident that no "untoward" effects will occur in the future. However, the only direct tests for environmental impacts were reported for the two year period covered in the risk assessment. Some tests, for example invasiveness in non-agricultural settings, were conducted during a single field season only.
The limited time frames for rDNA crop risk assessments have been criticised both within and outside the scientific community, with many calls for long term studies (e.g. Gates 1995; Lefol et al. 1996; Tiedje et al. 1989). For example, in modelling experiments conducted by Kareiva et al. (1996), “any sampling effort of less than 3 years (regardless of the number of sites) provided a poor estimate of canola rate of increase.” The authors state that “[i]f this example portends a general trend, then experimental assessment of GEO [genetically engineered organisms] risks will require several years of data, with shortcuts to speed up the process coming at a high cost in terms of predictive power.”

Even if we include the three years of commercial-scale release subsequent to Monsanto’s field trials (1995-1998), the time frame for many physical, ecological or evolutionary impacts to occur and be detected remains inadequate (Fredshavn and Poulsen 1996; Snow and Palma 1997). Studies of invasive species have shown, in some cases, a significant time lag between the initial introduction to a new ecosystem and the eventual spread and establishment of “invasive” populations. Due to interactions among a number of ecological and genetic factors, initial effects may therefore be a poor indicator of longer term impacts (Cronk 1995; Kareiva and Parker 1995). For example, Rasmussen et al. (1998) review the significance of ongoing “long term agroecosystem experiments” (LTAEs) in determining the sustainability of agricultural practices and trends. The study revealed that, though few in number, LTAEs of longer than 50 years can provide better indicators of soil changes than studies of 10-20 years. Monsanto’s experimental time frame of 1-2 years pales in comparison to the temporal scale of LTAEs, and casts doubt on Monsanto’s definitive conclusion that HTC will have positive effects on sustainability and “overall environmental quality”, and no negative environmental impacts.
In addition to the problems of limited temporal and spatial scale, Monsanto’s field trials represent a narrow range of relevant ecological situations. Variety trials must be conducted in a total of 24 sites including short, long and mid-season growing zones across Western Canada (WCCRRRC 1998). This range aims to provide a representative sample canola performance in agronomically important ecosystems (the intention of the variety trials). Monsanto reported experiments and observations in up to 24 sites in Alberta, Saskatchewan and Manitoba. However, only variety trial criteria (e.g. vegetative vigour; time from seed to maturity) and observations recorded during these trials (e.g. for “effects on beneficial insects”) were documented in all or most of these sites. Tests specific to the risk assessment were conducted in far fewer sites. For example, shattering and seed dormancy were tested at 3-5 sites. The test for invasiveness, measured by growth in a roadside ditch, was conducted at one site only. The requirement to test agronomic performance across a broad range of growing conditions is inconsistent with testing invasiveness, dormancy and shattering in far fewer (or one only) ecological settings. Furthermore, none of these tests or observations accounted for other geographic areas, ecosystems and growing conditions where HTC or hybrids among HTC and wild relatives may be purposefully or inadvertently grown in the future. Canola is a notoriously weedy species and studies have shown that populations are common along roadways and field margins, and are particularly high along regular routes of seed trucks (Crawley and Brown 1995). Repeated introductions through spillage and pollen flow can establish persistent feral populations (Crawley 1995 and Brown; Weiss 1999). It is, moreover, the explicit intent of both Monsanto and AAFC to introduce HTC to other countries (and hence ecosystems) through marketing strategies and trade policies. Canada is reliant on the foreign canola market, currently exporting almost 3000 tonnes of seeds annually (CCC nd). As Clark (1998) notes, Canadian risk assessments are “parochial”
in that they only consider local environmental contexts and do not consider risk of spreading to other environments and countries.

Finally, Monsanto's field trials were restricted in the most literal sense: both private and variety trials were "confined" to ensure "reproductive isolation" (AAFC 1994b). AAFC's guidelines for confined field testing recommend isolation distances, post-harvest land use to destroy all plant material, and other methods of reproductive control" (AAFC 1994b). Canola variety trials are semi-confined, with a minimum of two border rows on either side of the test plot (WCCRRC 1998). Variety trials are also "managed" with herbicides, pesticides and fertilisers to reflect normal industrial agricultural practices in Western Canada. But are these conditions relevant for testing the environmental hazards of HTC? Confined trials, by definition, prevent gene flow and interactions with non-target organisms or environments, and therefore cannot be used to observe or accurately evaluate these impacts. Use of chemicals and other management "tools" will likely represent standard growing conditions (again, the purpose of the variety trials) but may be less relevant for feral or hybrid populations outside canola fields, or agricultural settings outside Canada. As Seidler and Levin (1994) note, "lack of evidence of harm" based on small-scale, confined and managed field trials is often used to argue the safety of rDNA crops, but this reasoning is invalid because "virtually all releases [referring to the US] have been on small plots of land conducted under conditions that minimise ecological response to transgenic plants and genes" (emphasis added).

Whether the results of controlled small-scale trials can be meaningfully extrapolated to commercial releases remains a crucial, open question—and a paradox for all technologies with potential large-scale hazards. On one hand, small-scale tests seem a prudent, if incomplete, pilot study for (implied) future expansion. On the other hand, the ultimate and
only truly representative experiment is full-scale release, a process tantamount to using "society as a laboratory" (Krohn and Weyer 1994). Issues of scale are therefore critical to effective environmental risk assessment yet are contentious and complex enough to truly challenge the boundary between "scientific" and "ethical" questions. Neither Monsanto nor AAFC fully acknowledged or addressed this complexity in their study of HTC. I will return to this point in Chapter 4.

**Experimental Design**

Perhaps a more straight-forward methodological question concerns experimental design. Were Monsanto's experiments "valid" according to generally accepted norms of the scientific method? In fact, many of the reported experiments were simply poor scientific method even at the most basic level of design, controls, replications and observation procedures. Variability of data and loss of some experimental replications was attributed, in part, to adverse or "atypical" weather conditions. Granted, these conditions "reflect the realities of conducting field trials" (M. MacLean personal communication, 1999). However, other sources of variability are less easily dismissed, such as planting control and test plots in different geographic or topographical areas (shattering, dormancy and herbicide efficacy tests); using older control seeds than tests seeds (germination tests) and test seeds from "a poor seed source" (seed production); using different sized plots within a single experiment (allelopathy; volunteer counts); or "inadvertently" harvesting seven test plots with a large combine (allelopathy). Sources of variability for each test are described in more detail in Section 3.3. The effects of such contingencies were exacerbated by the low (or unspecified) number of replications or trials for many of the test parameters. For example, samples for compositional tests were taken from non-replicated plots; the invasiveness test had 2
replicates within a single trial; and volunteer counts and allelopathy studies were conducted on 2-4 sites only. In the latter case, sites were divided into a number of plots for counting purposes, but the sizes of these plots were variable and apparently arbitrary. An additional concern in the volunteer test, is the apparent lack of standardisation of the original plant population; only the number of volunteers were counted but it is not clear that original canola populations were comparable. At best, these problems suggest that increased replications and longer testing times would contribute to more accurate data. At worst, such inconsistencies invalidate Monsanto’s and AAFC’s broad conclusion that HTC will have no additional environment impact.

The appropriateness of controls for assessing HTC has been a controversial question since rDNA herbicide tolerant lines were first proposed for variety registration. Some members of the WCCRRC (including representatives from Monsanto) felt that Westar was not an appropriate “check” variety for HT lines mainly due to yield differences between the two varieties, as well as the added cost of herbicide application. It was originally proposed that HT lines should constitute a new and separate assessment class, but later decided that, for consistency, Westar should be maintained as a check variety\(^\text{10}\) (WCCRRC 1993a; WCCRRC 1993b). Similar doubts have been expressed in the scientific literature regarding the use of parental lines as controls in environmental risk assessments, and several researchers have stressed the need for additional and/or alternative controls depending on the question being addressed. For example, Linder and Schmitt (1994) argue that in most cases, the most appropriate controls for rDNA crops are null segregants, \textit{i.e.} rDNA crops that have lost the transgene through segregation. When testing for invasiveness, Crawley et al. (1993) and Fredshavn et al. (1995) further emphasise the need to include an external control (a weedy species known to be a better competitor than canola) to better reflect natural situations.
where competition has a significant effect on invasiveness, and to account for the high degree of variability within canola populations.

Variability within canola populations is indeed a significant problem (Darmency 1994; Fredshavn et al. 1995; Lefol et al. 1996). Monsanto stated that the HTC line GT73 was selected from single seed of the parental variety and therefore “inherited only a portion of the genetic variability of the parental variety”. Letters from plant breeders regarding the variability of canola were the only documents related to environmental safety that were withheld by Monsanto as confidential. However, through personal communication, one of these plant breeders stated that due to variability and high levels of outcrossing in canola, any observed phenotypic differences between an rDNA plant and a parental variety could not be conclusively attributed to the presence of the new genes, unless all other genetic differences between the two experimental lines were controlled, i.e. the test varieties were isogenic (K. Downey personal communication, 1999; see also Kumar et al. 1998). There is no indication in the Monsanto data that genetic backgrounds of the HTC and Westar were controlled. Therefore, it is not clear from the data presented in the report that the experiments were capable of detecting differences between the HTC and parental populations. As noted by Fredshavn et al (1995), “it is always possible to show lack of significant difference between populations provided that data are sufficiently poor, i.e. that the variation within populations is larger than the variation between two effectively distinct populations”.

Finally, many risk assessment criteria, such as adaptation to abiotic stress factors, overwintering capacity, flowering period and effects on non-target organisms and biodiversity, were addressed through “observations” of variety trials. While reliance on observations is not, in itself, a flawed approach, no record of findings for these parameters were provided and no systematic procedures were outlined. As mentioned earlier, monitoring
checklists did not include a space for effects on non-target organism or biodiversity, and these effects are unlikely to be simply “observed” over the course of two field seasons. If observations are to be a significant source of data, explicit means of detecting and recording effects must be established.

Monsanto’s experimental design casts serious doubt on the validity of their overall conclusions. Details of experimental or observational procedures were often vague or absent; number of complete replications for several tests was low; many parameters were not controlled and variability was not accounted for. Nonetheless, as we will see in the following section, Monsanto and AAFC relied on these methods to draw very broad conclusions about the environmental effects of HTC.

3.4.4 Data and Reasoning

Having established the above framework of questions and research design, what kind of data did Monsanto and AAFC generate or cite and how were these data used to support their conclusions? Two general types of data and styles of reasoning were used: (1) Monsanto attempted to show that there was no statistically significant difference between HTC and Westar as measured by parameters such as volunteer counts (weediness) and germination in a roadside ditch (invasiveness). These conclusions were supported by quantitative, experimental data and generally conform to “strict” standards of evidence as discussed in Chapter 1. (2) For other parameters such as gene flow and effects on biodiversity, Monsanto relied on a “balance of evidence”, drawing on qualitative data, observations and published literature. Some parameters, such as plant pest potential, were addressed through a combination of these approaches. Were these data and styles of

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reasoning adequate to test parameters in question and support overall conclusions? Let us first examine more closely the “statistical validity” of Monsanto’s data and conclusions.

As I noted in the section above, several experiments suffered from low replication number and high variability. The test for invasiveness into non-agricultural settings is perhaps the most questionable in terms of statistically validity. This experiment aimed to assess the invasiveness potential of HTC relative to Westar by growing 4 plots (2 mowed; 2 not mowed) each with 50 seeds of HTC and Westar. The trial was conducted once and no selective pressure (via Roundup) was applied. Average germination counts were 1 for the control and 2.3 for HTC. Based on this data Monsanto concluded that Westar and GT73 “do not significantly differ” and cited an error rate of p=0.05. More generally, Monsanto stated that “GTC will not become invasive of natural habitats”. AAFC agreed: “Data showed that GT73 was neither more invasive nor more persistent than ‘Westar’” (AAFC 1995a). Similar reasoning was used in the volunteer counts and allelopathy studies. There are several serious problems with these conclusions beyond the methodological problems discussed above.

First, both Monsanto and AAFC used the finding of no significant difference to conclusively accept the null hypothesis of “no effect” with an error rate of 5%. These are overconfident and statistically invalid conclusions. One can only reject the null hypothesis with the calculated error rate, i.e. the chances that the effect occurred by chance are 1 in 20. One can support the null hypothesis, in this case with an unknown margin of error, but not unconditionally accept the conclusion of “no effect”. Monsanto’s statistical analyses do not “prove” that HTC is no more invasive than the parental line.

A second problem with the conclusions based on statistics is that, given the small sample sizes and large degree of variability, we cannot be sure that the experiments were rigorous enough to detect differences. Statistical power measures the ability of a statistical
test to detect true differences between populations and can be used to determine the sample size required for a valid test. This calculation is particularly important if inferences are drawn from a finding of "no difference" (Helberg 1995)—as in the HTC case—for it may reveal a high probability of erroneously concluding no effect. Thus "rigorous statistical power calculations can be used to determine what confidence to put in analyses of data that fail to reject the [null hypothesis] of no effect" (Peterman and M'Gonigle 1992). The power of a particular test is a function of sample size, experimental design, variability, and sampling methods: failure to reject the null hypothesis may indicate a "true" lack of effect, or it may indicate that the tests were simply not robust enough to detect effects. Given the stakes of the HTC risk assessment (to release or not release HTC), and the small sample sizes for many of the tests reported by Monsanto, it seems reasonable, if not imperative, to include a measure of statistical power. Conner (1997) notes that the "power of the statistical analysis...can be the single best indicator of how much public credibility the study's findings deserve" and therefore should be included in every discussion on environmental hazards and public safety.

Other tests in the HTC assessment were supported by a variety of information sources and types of data, rather than statistical analyses of experimental data alone. For example, analysis of gene flow drew on published literature, field observations and one experiment. While a diversity of methods and information sources is undoubtedly a model of "good science" in many cases, this approach can also be problematic, particularly if scientific principles are underdeveloped or if the body of research and published literature is small. As in the statistical analyses described above, lack of data can be a powerful tool: it requires considerable effort to tip the balance of evidence and demonstrate that hazards can indeed occur. I will illustrate my point by examining in detail one potential hazard, gene flow.
Gene flow and introduction of a new trait into a population involves many steps: pollen flow from the source plant, pollination of the recipient, hybrid formation, establishment of a hybrid population, and successive backcrossing with the parent type leading to introgression of the trait into the recipient population. In the case of HTC, “gene flow” entails all of these steps as well as expression of the HT gene and resultant increased weediness or invasiveness of the wild population. While it was not always clear which of these events was under assessment in the HTC study, the general argument can be summarised as follows:

(1) Neither Monsanto nor AAFC claimed that pollen flow from unconfined fields would not occur, as it seems generally accepted that total pollen containment is not possible (Kareiva and Parker 1995; Timmons et al. 1996; Timmons et al. 1995; Wilkinson et al. 1995).

(2) Monsanto argued that hybridisation could occur between *B. napus* and related species but at “low”, “very low” or “essentially zero” frequency. AAFC stated the “potential” for hybrid formation with seven related species (AAFC 1995a) (See Section 3.3.5).

(3) Despite this probability, both parties argued that the consequences of gene flow were not significant because crop-wild hybrids would not be more weedy or invasive than non-hybrid will plants.

Let us examine points (2) and (3) more closely.

In the HTC assessment, evidence for low probability of hybrid formation was drawn primarily from specific literature on Brassica outcrossing, and was supported by a single field experiment. Categorical statements of low probability are problematic however because the hazard, gene flow, is a moving target: knowledge of hybridisation potential and community ecology is constantly changing with new research; boundaries among wild and domesticated species are porous and dynamic, and the scale of unconfined HTC release has increased from zero in the early 1990s to over 2 million hectares in 1998 (James 1998). Each of these factors contribute to the accuracy of overall probability ratings, and are discussed in turn below.
Scheffler and Dale (1994) review outcrossing studies to 1994 (the date of the Monsanto assessment), and list 17 species capable of forming hybrids with *B. napus*. Only four of these crosses were documented under open pollination; the remainder were facilitated through hand pollination or embryo rescue. Most of these crosses were cited in the AAFC companion document (AAFC 1994c). Monsanto included some of the published data, but limited their review to data “relevant to natural field conditions”, and did not consider facilitated crosses to be indicative of gene flow potential.

Research published since the Monsanto report has added to the list of potential *B. napus* hybridisation partners. For example, Lefol et al. (1996) report the spontaneous hybridisation of herbicide tolerant rDNA *B. napus* to *Hirschfeldia incana* (hoary mustard; syn. *Brassica adpressa*) and Vyas et al. (1995) obtained hybrids and backcross progeny between *B. napus* or *B. juncea* and *Diplotaxis erocoides* through embryo rescue. Furthermore, studies of outcrossing between Brassica and *Erucastrum gallicum* (dog mustard) that were “underway” at the time of the Monsanto assessment concluded that gene flow and introgression between *B. napus* or *B. rapa* and *E. gallicum*, as well as *Raphanus raphanistrum* (wild radish) is indeed possible. In fact vigorous hybrids that “could successfully compete with the Brassica parent” were formed between *B. napus* and *R. raphanistrum*, and between *B. rapa* and *E. gallicum* (Lefol et al. 1997). Monsanto’s assertion of “no reports” of hybridisation between *E. gallicum* and canola, was therefore short-lived.

Other relevant outcrossing events have recently been documented. For example, Mikkelsen et al. (1996a) and Brown et al. (1996) demonstrated the spontaneous hybridisation of herbicide tolerant *B. napus* with *B. rapa* under field conditions. Hybrids were backcrossed to *B. rapa* plants and produced offspring that were herbicide tolerant but otherwise displayed
weedy characteristics such as seed dormancy and high pollen fertility. According to the authors, these results suggest “a possible rapid spread of genes from oilseed rape to the weedy relative *B. campestris* [*rapa*]”. More recently, Bergelson et al. (1998) reported that an rDNA plant (Arabidopsis) was approximately 20 times more likely to outcross than similar mutagenised or conventional plants. Previous studies have indicated that chromosomal location of the transgene may affect rate of hybridisation (Mikkelsen et al. 1996b). These results suggest that rDNA techniques may, in some cases, confer unique hazard potential to crops. If so, the risk of gene flow should be evaluated for rDNA crops and not simply inferred from research (or lack of) on parental types (see Section 3.4.3 on experimental design above).

The complexity of gene flow is further illustrated by recent work on “bridge species” as a viable mechanism for gene escape. Brown et al. (1996) reviewed hybridisation potential among *B. napus* relatives (*i.e.* crosses not involving napus) and noted that many Brassica hybrids have sterile pollen. While this may appear a convenient safety feature, “[male] sterile plants have a greater tendency to be cross pollinated by other plants or species...and a second cycle of hybridisation may occur....” This process may allow for bridge crosses where hybrids between two weedy species more easily cross with HTC and thereby function as a conduit for gene flow from *B. napus* to weedy relatives. For example, these authors suggest that *B. rapa-S. arvensis* (birdseed-wild mustard) hybrids may provide a viable bridge for gene escape from *B. napus*, a significant hazard particularly if the “danger” of direct gene flow from *B. napus* to wild mustard “does not exist in nature” (Bing et al. 1996; but see Lefol et al. 1996).

Neither Monsanto nor AAFC considered seriously the hazard of horizontal gene flow, transfer of genes through non-sexual mechanisms. Monsanto states that “there is no
documented horizontal transfer of genes from Brassica species”; AAFC does not raise the issue at all. However, at least two studies have demonstrated uptake of genes from rDNA plants by fungi (Hoffmann et al. 1994) and bacteria (Gebhard and Smalla 1998). In the latter case the plant gene was expressed in the bacterium and was transferred with some additional DNA sequences. These studies were conducted in the laboratory and therefore may not reflect natural conditions, but do suggest the possibility of horizontal gene flow.

The above review highlights the evolving knowledge of gene flow and outcrossing potential. Not only is scientific literature and research effort constantly changing, however, but the plants themselves are dynamic. Weed classifications, populations and habitats are affected by a host of related factors such as agricultural practices, environment, physical disturbance and land development, food preferences, and geographic location (Burnside 1996; Knobloch 1996). The claim that gene flow is unlikely because a wild species is not present in Canada, is present in low numbers, or is not listed in the compendium *Weeds in Canada* (as claimed for *B. adpressa, B. carinata, D. erucoides,* and *B. nigra*) may also be short-lived. For example, AAFC stated that the weed *B. carinata* was “not reported as present in Canada” (AAFC 1994c). Yet, by 1996 *B. carinata* was under study as a potential oilseed crop in Saskatchewan (Getinet et al. 1996). Changes in the distribution and abundance of wild relatives may also affect outcrossing rates. Application of post-emergent, broad spectrum herbicides such as glyphosate reduces the number of weeds in agricultural fields but does not eliminate all weeds. The few isolated weeds that are left are more likely to be pollinated by HTC than are plants in high density populations (Klinger et al. 1992). It might also be noted that weed surveys and compendia (such as *Weeds in Canada*) are useful guides but are not static or encyclopaedic. The accuracy of data may vary over time and with sampling design and effort (Kareiva et al. 1994). For example, Thomas et al. (1998) note that
the recorded decrease in weed density in Alberta over the past 25 years is due in part to changes in sampling practices: early surveys were conducted before application of broad post-emergence herbicides; later surveys were conducted “after all control measures had been taken”.

A final and important criticism of the “low probability” argument is that it fails to consider the scale of HTC release in Canada, as discussed in Section 3.4.3 above. The rapid growth of the canola industry in the past 20 years, an increase in some related weedy species over the same time period (Thomas et al. 1998), and the unprecedented production of HTC, may substantially affect the rate of hybridisation and the absolute number of crop-wild hybrids. For example, Lefol et al. (1996) argue that even though the probability of hybrid formation between *B. napus* and *S. arvensis* is $10^{-10}$, this probability “is not negligible” given the scale of *B. napus* cultivation. In fact, Scheffler and Dale (1994) suggest that the scale of HTC release and hybrid formation may partially compensate for the lower fertility of some crop-wild hybrids. This is an important point particularly as Monsanto cites decreased fertility as evidence for the low probability of gene flow.

Of course, Monsanto and AAFC could not have considered the ecological changes or literature published since 1994. Yet the rapid accumulation of evidence in the past few years suggests that low observed frequency does not imply low probability of an event. Moreover, proclaimed “low probability” events are not a static category, but are bounded in part by time, effort, and the limits of knowledge. These points raise a critical question: Why were more studies not conducted by Monsanto or AAFC at the time of the risk assessment?

One way to justify acceptance of a low probability of gene flow would be to argue that, regardless of probability, the overall risk of gene flow is negligible because the final consequences are insignificant. In other words, even if gene flow did occur, at whatever
probability, the outcome would be acceptable because the consequences are thought minimal. Levidow (1996) describes this rationale as a shift from “how likely?” to “so what?” questions. This rationale is apparent in the HTC assessment: Monsanto and AAFC seemed less concerned about the low—but existing—probability of gene flow because both parties relied on the following two arguments to suggest that the overall consequences of gene flow will nonetheless be negligible.

First, both parties argued that crop-wild hybrids would be no more invasive or weedy than existing wild plants because no selective advantage will be conferred to hybrids by the herbicide tolerance trait. That is, glyphosate tolerance does not confer any competitive advantage outside managed ecosystems where Roundup is applied (AAFC 1995a) and therefore herbicide tolerant hybrids should not pose a problem. This rationale is weakened by that fact that in Canada, glyphosate is widely used by forestry, agriculture and horticulture industries for the cultivation of conifer and deciduous trees, grasses, fruit, garden flowers, legumes, cereals and grains. Roundup and other glyphosate-based herbicides are also used on non-cultivated land including rights of way, shelterbelts, fencerows, urban areas, recreational and public areas, commercial, storage and industrial sites, and on stubble and fallow land (PMRA 1999b). Selective pressure for herbicide tolerant plants exists at least in these areas, particularly if all other (non-tolerant) crops are destroyed. As stated by Radosevich et al. (1992), herbicide tolerant crops “through increased herbicide effectiveness could further reduce plant diversity, thus allowing almost unlimited growth of any weed that survives or adapts” (see also Darmency 1994; Wilkinson et al. 1993).

In any case, selective pressure through herbicide application may not always be the limiting factor in population establishment. Fitness—the ability to survive, compete and reproduce—depends on many characteristics of the organism and environment. For example,
weed and hybrid populations may be limited by factors affecting seed stages more than those affecting adult populations (Linder and Schmitt 1994). Several studies have examined the effects of seed dormancy and germination cues on persistence of crop-wild hybrids. Wild species frequently have high seed dormancy and can remain viable for several years. *B. rapa*, for example, has longer seed dormancy and longevity than *B. napus* (Linder and Schmitt 1994). Hybrids between *B. napus* and *B. rapa* display dormancy patterns similar to *rapa* (high) or *napus* (short) (Adler 1993; Landbo and Jorgensen 1997; Linder and Schmitt 1994). However, backcrossing these hybrids with either parent has produced plants with *B. rapa*-like dormancy and germination behaviour (Landbo et al. 1997). Reciprocal crosses and backcrosses could therefore result in a variety of complex scenarios. For example, HT hybrids with high dormancy that persist in the gene bank may be transported to other areas, and upon germination back-cross into wild or crop populations. This process might distribute the HT trait through both time as well as space (Linder et al. 1994) exposing hybrids to a diversity of biotic and abiotic pressures.

A related but more general component to Monsanto’s and AAFC’s argument that gene flow is of negligible consequence, is an overall presumption that any adverse events could be controlled or managed. Specifically, gene flow to wild relatives (as well as volunteers and invasive HTC) could be controlled through application of non-glyphosate herbicides. For example, AAFC states that volunteers and hybrids “should they arise, would be controlled using other available chemical means” (AAFC 1995a); and Monsanto claims that “all the weeds that present any potential risk for gene-flow with [HTC] can be effectively controlled with several herbicides other than Roundup”. As will be discussed further in Chapter 4, this rationale implies and imposes a continued dependence on chemical herbicides in agriculture: herbicide tolerant crops “represent only a refinement to the existing
technology of weed control that relies almost exclusively on herbicides” (Radosevich et al. 1992). This dependence, furthermore, will not be restricted to the allegedly “environmentally friendly” herbicide, glyphosate. Continuous application of the same herbicide selects for crops and weed resistance, a well documented phenomenon that necessitates rotation among herbicide types (see Caseley et al. 1991; WSSA nd). While it has been claimed that tolerance to non-selective herbicides such as glyphosate is unlikely (Sherman et al. 1996), recent reports of glyphosate resistant ryegrass in Australia suggest increased use of glyphosate could result in wide range of tolerant crops and weeds (Robert and Baumann 1998). These plants, as well as tolerant crop-weed hybrids, and plants that develop resistance to multiple herbicides, will require control with existing chemicals and/or the perpetual development of new herbicide controls. As critics of industrialised agriculture have noted, these practices may exacerbate weed and pest problems in the long-run. Clark (1998) for example, points out that many plant and insect species that currently infest agricultural fields were once “minor” members of the biotic community. These organisms have become major, costly “pests” through the use of broad-spectrum pesticides which have eliminated natural population controls.

Thus in several respects, Monsanto’s data and evidence are suspect. The statistical validity of the data is highly questionable given the small sample size, poor experimental design and high variability. Furthermore, none of the tests included calculation of statistical power, a critical omission when far-reaching decisions are based on failure to reject a null hypothesis of “no effect” (or in Monsanto’s case, acceptance of the null hypothesis). Evidence for low probability of gene flow was drawn mainly from existing literature and did not entail extensive experimentation. Data for other parameters such as abiotic stress factors and effects on beneficial insects were generated mainly from unstructured and unrecorded
observations. In all of these cases, "...the absence of evidence for environmental risks may well be more indicative of 'absence of looking' rather than absence of risks" (Kareiva and Parker 1995). I have suggested two reasons for "absence of looking" in the gene flow example: an inadequate argument that crop-wild hybrids will not survive due to lack of selective pressure, and a questionable assumption that adverse events can be controlled, and that this form of management is an "acceptable risk". Chapter 4 will explore these points in more detail.

3.4.5 Conclusions of the HTC Assessment

**Plausibility**

Table 3.2 summarises the "anticipated relative effects" of HTC versus Westar as submitted to AAFC by Monsanto. Table 3.3 tabulates Monsanto's final statements on the potential environmental hazards of HTC, AAFC's comments on the same hazards, and the data used to support these conclusions. Are these claims plausible? The above discussion strongly suggests that the very broad conclusions asserted by both parties cannot reasonably be extrapolated from the limited data and often flawed experiments reported in the HTC study. This discrepancy is exacerbated by a failure to acknowledge the limitations or uncertainties of the risk assessment. Three general types of uncertainty were introduced in Chapter 1 (Section 1.2.2): technical, methodological and epistemological. How did Monsanto and AAFC address these uncertainties in the HTC assessment?

**Technical Uncertainty**

Summarised as "inexactness" (Funtowicz and Ravetz 1992), technical uncertainty is inherent to scientific inquiry and is usually acknowledged in published research. This type of uncertainty derives from incomplete data, ambiguous results or variability of the
**TABLE 3.3**
FINAL CONCLUSIONS OF MONSANTO AND AAFC WITH SUPPORTING DATA

<table>
<thead>
<tr>
<th>HAZARD</th>
<th>CLAIM</th>
<th>DATA</th>
</tr>
</thead>
</table>
| Invasiveness         | •"GTC will not become invasive of natural habitats" (Monsanto)  
•"GT73 has no altered weed or invasiveness potential compared to currently commercialised canola varieties such as Westar"; "GT73 is not invasive of natural habitats" (AAFC 1995a). | Based on:  
•single study in a roadside ditch during one field season, with 2 replications with 50 seeds in each 1m² plot, no selective pressure and mean counts of 1 for control and 2.3 for test plots. |
| Plant pest potential | •"GTC is not a plant pest" (Monsanto)  
•"the plant pest potential has not been inadvertently altered"; "GT73 will not result in altered impacts on interacting organisms, including humans, compared to current varieties such as Westar" (AAFC 1995a). | Based on:  
•observations during variety trials (for effect on beneficial insects and other non-target organisms)  
•seed and/or meal analyses for amino acid, fatty acid and oil composition; proximate analysis; glucosinolate, chlorophyll and sinapine content; % protein  
•toxicity tests on novel proteins in mice and mammalian gastric juices  
•"indirect evidence that soil micro-organisms involved in maintaining soil fertility are not negatively affected" (AAFC 1995a) |
| Gene flow            | •"outcrossing of the GT genes to wild relatives can potentially generate hybrids with only B. napus, B. rapa and B. juncea at a low frequency; and these hybrids will not be weedy, or more invasive" (Monsanto)  
•"outcrossing of GT genes to B. nigra, R. raphanistrum, and E. gallicum pose no significant environmental risk due to the extremely low frequency of hybrid formations and the poor fertility of the hybrid generated" | Based on:  
•literature review (all publications used non-rDNA crops)  
•single outcrossing study using non-GT73 HTC as pollen source and Westar as recipient; 5% outcrossing for plants in contact; 0.2% at 50m; 0.1% at 225 m. No details or data provided  
•presumption that hybrids can be controlled with herbicides |
| Impact on biodiversity | •"there is no potential negative impact of unconfined release of GT canola and progenies derived from traditional breeding on biodiversity" (Monsanto)  
•"the potential impact on biodiversity of GT73 is equivalent to that of currently commercialised canola varieties such as Westar" (AAFC 1995a). | Based on:  
•no additional data provided or literature cited |
experimental system. Technical uncertainty can often be reduced through more research or improved test design. Monsanto and AAFC reported a degree of technical uncertainty in their assessment, for example by calculating statistical significance, noting effects of adverse or “atypical” weather conditions, and citing obvious human errors. While many sources of variability were acknowledged, however, the influence of this “inexactness” was not. There was little indication that technical uncertainty of experiments should qualify test results, temper overall conclusions of safety, or stimulate further investigation.¹²

**Methodological Uncertainty**

This type of uncertainty refers to the “unreliability” (Funtowicz and Ravetz 1992) of chosen methods to accurately represent the system under study: For instance, how can small-scale confined tests be extrapolated to commercial-scale, unconfined release? As discussed in Section 3.4.3 (Methods of Inquiry) above, this problem is inherent to all assessments of large-scale hazards, perhaps with the significant exception of trial-and-error approaches. Monsanto and AAFC seemed unaware of this issue but for the fact that commercial release is the effective end-point of the risk assessment process. According to CFIA officials, uncertainty is addressed by monitoring releases and if need be, revising initial decisions based on new information or unforeseen events (CFIA interviews 1998). In other words, adverse scale-dependent effects are thought manageable, and new information is fed back into the regulatory machinery to prevent similar occurrences in the future. The premise that uncertainty can be controlled was further illustrated by assessment of gene flow potential, discussed above. Low probability of outcrossing was compensated by a presumption that crop-wild hybrids could be controlled by non-glyphosate herbicides.
More glaring methodological limitations of specific experiments were similarly unacknowledged. For example, there was no suggestion that Blackleg resistance is a singular measure of biotic stress factors, that effects on biodiversity is difficult to observe, that germination in a roadside ditch may be a narrow indication of invasiveness, that toxicity in mammals may be different from that in insects, or that no baseline assessment of conventional, "familiar" agriculture has been conducted.

**Epistemological Uncertainty**

Technical and methodological uncertainties, in theory, can be reduced or eliminated through better models or more research. Epistemological uncertainty, on the other hand, signals the limits of knowledge and therefore "borders on ignorance" (Funtowicz and Ravetz 1992). This realm of so-called "great uncertainty" (Hansson 1996) has become a central issue for both the Precautionary Principle and environmental debates in general, and will be discussed more fully in Chapter 4. For the moment, we can ask if and how Monsanto and AAFC recognised the contingencies and inherent limitations of the HTC study.

While it is impossible to catalogue or calculate all variables and consequences (by the definition of epistemological uncertainty), some factors bearing on the hazards of rDNA crops can be readily identified: local and global environmental conditions (e.g. local competing species or global climate change; Gates 1995); agricultural practices such as crop and herbicide rotation; interactions among commercialised crops and the ‘next wave’ of rDNA technology (e.g. crops with multiple engineered traits); the number of farmers who choose rDNA technology and a potential consequent rise in production of, and effects on, low-input alternatives; the effects of seed and gene patents on crops diversity; and the effects of “free trade”, biosafety protocols, and other international negotiations on the scale and
distribution of rDNA crops world-wide, to name a few. Can we expect Monsanto, AAFC or any other decision-maker to predict and adequately account for all such consequences of a proposed technology? No. As van den Daele (1992) argues: “Absolute knowledge, complete control, or totally comprehensive planning cannot be the point in uncertainty arguments”.

What can be expected, however, is acknowledgement that results and conclusions are necessarily conditional (Wynne 1992b). Given the scope of the HTC claims and the ramification of AAFC’s final decision, it is remarkable that nowhere did Monsanto or AAFC qualify their conclusions. Neither party discussed the complexity of systems under study, or the relationship among ecological, agricultural and social systems. Consequently, neither acknowledged that results were drawn from, and hence contingent upon, a very restricted set of circumstances. This apparently unwavering confidence in the HTC data justified extremely broad—and I contend, unwarranted—extrapolations, which in turn supported AAFC’s final decision that unconfined release of GT73 into the environment was “safe” (AAFC 1995a).

3.5 SUMMARY OF EVALUATION

I will conclude by returning to the evaluative framework set out at the beginning of this section (3.4.1).

1. Scope of inquiry: Did Monsanto address the criteria outlined by AAFC in Regulatory Document 94-08? Are the questions and goals of the assessment relevant and appropriate to the problem of potential environmental harm from large-scale unconfined release of HTC?

Monsanto addressed all of the general assessment criteria listed in the Regulatory Document in some manner. Most of the data requirements for very specific tests (e.g. reproductive characteristics) were also fulfilled. However, Monsanto used very limited
parameters to test hazards such as stress factors, allelopathy and invasiveness, and did not address more complex issues such as effects on biodiversity, non-target populations or “overall environmental quality changes” in any meaningful way. A major part of the problem, of course, was in the framing of questions. All hazards were limited to “anticipated relative impacts” of HTC versus conventional canola varieties; only comparative differences registered as an “impact”. The scope of relevant effects was therefore restricted at the outset. At the same time however, the questions were too broad and vague to have any significance, especially summarised as “+” “0” or “-” in table form (see Table 3.2). The depth and breadth of information provided by Monsanto and accepted by AAFC suggests neither party was committed to fully examining these parameters. I have argued that the HTC risk assessment was more germane to the narrow goals of pre-commercial variety trials and food/feed safety than to understanding the interactions of HTC within agricultural and non-agricultural ecosystems. Indeed several environmental assessment criteria were addressed only within the mandate of these other policies. It appears Monsanto attempted to consolidate all regulatory hurdles and address all criteria with minimum experiments.

2. Methods of assessment: Are experiments appropriately designed to address stated questions and support final conclusions? Are experiments consistent, replicated and controlled?

Even within the limited and impractical framework set out by AAFC, Monsanto’s risk assessment was of arguable merit: Procedures were often unclear; observations were not systematic (at least no indication of a system was provided); methods and test parameters were variable; experimental controls were of questionable relevance; number of replications were minimal; temporal and spatial scales were limited. If we take peer-reviewed scientific publications as one measure of good (or at least sanctioned) science, as AAFC and Monsanto
claim to have done, it seems unlikely that Monsanto’s methods could withstand such scrutiny (all other things being equal).

3. Data and reasoning: Are the data statistically valid? How complete is the evidence relative to existing, published scientific literature? What types of data were gathered and how were data used to support conclusions?

Another—very conservative—measure of “good science” is statistical validity. As we have seen, Monsanto’s statistical methods are not only suspect, but incomplete. None of the tests included a measure of statistical power, yet very general and far-reaching conclusions were drawn from acceptance of the null hypothesis, no effect. The extent to which existing research and scientific controversy are acknowledged provides a further measure of “good science”. Monsanto and AAFC drew on published literature to support several of their conclusions. However, their review was not comprehensive and failed to represent the diversity of research and scientific opinions on the hazards of rDNA crops. More importantly, where Monsanto relied heavily on published literature, as in assessing gene flow, lack of research was frequently used to support a conclusion of “no effect” rather than a more qualified “we don’t know”.

That Monsanto and AAFC were interested in, and aimed to measure, only relative effects of HTC versus Westar, was sometimes lost in their broadly stated conclusions. However, this is an important qualifier to all of the test results. “No effect” means no greater environmental effect than existing varieties of canola. Both Monsanto and AAFC accepted—and hence imposed—this standard without adequately questioning or assessing the hazards of non-HTC canola. Therefore, to conclude that the “relative anticipated effects” of HTC are negligible or non-existent, is not to conclude that HTC will have no adverse effects overall. These assumptions were buried in a non-negotiated standard of “acceptable risk”.

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4. **Conclusions**: How are uncertainty and limitations of the study addressed? Are the conclusions plausible based on experiments and data submitted in the report?

Uncertainty did not figure largely in the HTC assessment. The categories of technical, methodological and epistemological uncertainty help to discern some of the problems and limitations of the study, but neither Monsanto and AAFC referred explicitly to "uncertainty" in the study. Nonetheless, several technical and methodological problems were acknowledged, although they did not appear to affect overall conclusions. The problem of epistemological limitations, on the other hand, was not even broached. These omissions allowed grand extrapolations of the data and produced conclusions that were neither plausible nor ultimately convincing.

In summary, does the HTC study meet AAFC’s proclaimed standard of “science-based risk assessment”? Given that “science” is a flexible term—a major premise of my dissertation—this is not a straightforward question. Indeed, it is noteworthy that AAFC never defined the term. Some documents and statements suggest that AAFC was operating under tacit assumptions about the components of “good science”, for example, that conclusions are based on empirical experiments; that data are statistically valid; that the study acknowledges relevant scientific literature; and that research could withstand the scrutiny of peer review. In this chapter, I have evaluated the HTC assessment against such standards, and found shortcomings which cast serious doubt on Monsanto’s and AAFC’s conclusion that HTC is “safe”. The working definition of science in “science-based risk assessment” seems very narrow and very weak indeed.
3.6 IS THE HTC RISK ASSESSMENT A REPRESENTATIVE CASE?

It is difficult to determine whether the HTC case study examined in this chapter is representative of rDNA crop risk assessments in Canada without reviewing all data submitted to AAFC/CFIA. As discussed under Section 1.2 (Methods) this would require detailed analysis of approximately 14,000 pages of data (as well as almost $3,000 in fees and a considerable amount of time to obtain the data). Our second, revised ATIP submission requested risk assessment data for 4 HTC varieties. Data for two varieties were withheld by AgrEvo as confidential business information. Based on discussions with AgrEvo’s Manager of Government Affairs, it is unlikely that AgrEvo would release data on any of its rDNA crops (C. Warfield personal communication, 1999).

Data for HTC variety GT73 was released in full, and included data on a fourth crop, HTC line GT200. As discussed above, GT200 was approved by AAFC for environmental release in 1996. This approval was based on the “substantial equivalence” of GT200 to GT73 and did not require data in addition to those presented in this chapter. The same standards of scientific assessment used in the GT73 case were therefore applied to at least one other rDNA crop, and, according to the regulatory framework, to all other crops deemed substantially equivalent to GT73. CFIA lists 13 varieties of HTC currently registered for commercialisation in Canada that were derived—and hence substantially equivalent to—GT73 (CFIA 1999). No Decision Documents have been published for these varieties indicating that data submitted for approval of GT73 were also used to approve derivative varieties.

A final indicator is comparison of information provided in all published HTC Decision Documents—as these are the only publicly available information on environmental risk assessments. As of April 1999, Decision Documents for 6 varieties of HTC (B. napus)
have been issued. Among these documents, descriptions of environmental assessment data reviewed by AAFC/CFIA and conclusions regarding overall safety of the crop are almost identical (mainly allowing for differences in types of herbicides). Although Decision Documents do not provide details of the data submitted by developers, there is no indication that different questions were asked or different standards of assessment imposed. Even if higher or different standards were applied in subsequent releases, these changes would not be retroactive to earlier decisions, unless all HTC currently grown in Canada was recalled.

In marked contrast to the Canadian regulatory system, risk assessment data for rDNA crops approved in the US are available upon request from the Department of Agriculture. Ecologists Parker and Kareiva (1996) and Purrington and Bergelson (1995) collectively reviewed 8 of these “petitions” for environmental release and noted shortcomings in the arguments for low risk similar to those noted in the HTC case above. For example, conclusions were more often based on existing literature (such as “Baker’s list” of weedy characteristics) than direct experiments. Uncited suppositions that experimental data were not needed, lack of published evidence, or assumptions that adverse events could be controlled (e.g. with herbicides) were frequently used to substantiate conclusions. Where experiments were performed, Purrington and Bergelson (1995) found that “a large fraction of the experimental data is obtained from experiments that are critically flawed” for example containing no control. In many cases, parameters relevant to environmental safety (such as lifetime survivorship, fitness of hybrid with other cultivars and geographic range) were not addressed in the applications.

Thus, although I cannot conclude that the HTC case analysed in this chapter is truly representative of all environmental approvals in Canada, there are several indicators that it is not unrepresentative. Lack of publicly accessible data on the risk assessment process,
however, effectively precludes comprehensive critical analysis. We must trust the claims of
government and industry that decisions are based on sound science—an issue I will explore
in the following chapter.
Endnotes: Chapter 3

1. The AgrEvo representative responsible for this decision stated that all information submitted to the federal government by private companies regarding a product is considered CBI. If the government determines that no health hazard is related to the product, it is the decision of the company whether or not to release information to the public (C. Warfield, personal communication, 1999).

2. enolpyruvylshikimatephosphatase synthase

3. aminomethylphosphonic acid

4. A potential health hazard associated with antibiotic resistance marker genes is transfer of the genes to microorganisms possibly leading to antibiotic resistant populations of pathogens.

5. Livestock feed assessments were also overseen by AAFC; proposed guidelines were made official in 1995 (AAFC 1995b).

6. Proximate analysis includes: seed moisture, oil, protein, ash, crude fibre, and calorie levels.


8. As noted in Chapter 2, draft regulations were available early in 1994 but discussion among WCCRC members in February 1994 indicated concern that lack of regulations “continues to delay Canada from exploiting opportunities inherent to transgenic canola”. WCCRC members requested assurance that regulations would be in place within 12 months (WCCRC 1994a; WCCRC 1994b).

9. The directive implied this was ensure confined trials were not used to increase seed stocks (CFIA 1996).

10. Discrepancies were eventually resolved by adding 8 extra merit point to HT varieties, in effect assuring their registration approval (Chapter 2; Griffiths 1997).


12. A single exception was the potential to overestimate seed shattering through volunteer counts.
CHAPTER FOUR

Analysis:
Boundaries of Science, Risk and Precaution

4.1 IDEAS, INTERESTS, INSTITUTIONS

4.1.1 Boundary Work

In Chapter 1, I introduced four theories of risk: technical, economic, social and precautionary. I further suggested that operative concepts of risk shape decision-making in critical ways, namely by embodying powerful assumptions about the “reality” of hazards, the capabilities and limits of scientific knowledge, the appropriate goals of risk analysis, and the most effective means to meet those goals. In the same chapter, I outlined an analytical framework centered on ideas, interests and institutions, and briefly discussed how such social and political phenomena can be used to construct boundaries around “science”, and hence around science-based policies. Chapter 2 traced the evolution of biotechnology policy in Canada, identifying the major influences which have shaped current regulations. Here we saw how concepts of risk and boundaries of science are intricately linked through AAFC’s commitment to “science-based risk assessment”. Finally, Chapter 3 illustrated the kind of scientific methods, data and reasoning used to assess the environmental safety of herbicide tolerant canola. Through this case study, I argued that while neither AAFC nor Monsanto explicitly defined “science”, both parties employed a very narrow interpretation of scientific principles in their assessment of HTC, and further that both parties were more concerned with regulatory efficiency than environmental protection. Such a limited conception of science need not, however, imply careless omission nor purposeful deceit. Rather, definitions are necessarily bounded by entrenched and sanctioned ideas, interests and
institutions. In this chapter, I will explore more fully the concept of "boundary work" and how this process has shaped risk assessment and decision-making for rDNA crops.

While construction and dismantling of boundaries has been a recent focus of several political scientists and sociologists (e.g. Benhabib 1996; Jasanoff 1987; Levidow and Carr 1997; Levidow et al. 1996; Nigge 1996), with regard to science, the practice of "boundary work" has been most fully developed by Thomas Gieryn (1983; 1995; 1999). Gieryn's central concern is the authority granted to scientific knowledge: "Why is science conferred the legitimate power to define and explain nature and other realities?" (Gieryn 1999). He contends that such "epistemic authority" derives not from any universal or essential qualities of the scientific method, nor from any special insight these methods may provide. Rather, the authority of science derives primarily from the various ways in which science is represented and subsequently from the acceptance of these representations among a wider audience. "Boundary work" is the process through which these representations of science are constructed and convincingly portrayed. If Gieryn is right, "science" is a conveniently flexible concept, which is contingent upon particular circumstances, and adaptable to particular interests. Boundary work is therefore an effective tool for understanding the role of science in a larger social and political arena.

There is nothing special about the term "boundary" in this context. As in most instances, boundaries establish limits of viable ideas or courses of action; sanctioning some and ruling out others. This is the "screening effect" discussed in Chapter 1. As Gieryn notes, "epistemic authority exists only to the extent that it is claimed by some people... but denied to others (which is exactly what boundary-work does)" (Gieryn 1999). In this sense, boundary work is closely tied to ideas, interests and institutions: ideas form the outlines of boundaries which are reinforced by institutions and advanced by and for a particular community of
interests. In the following sections, I use this analytical framework to examine how boundaries were established around Canadian risk assessment policies in general, and the HTC assessment in particular. This analysis will clarify the relationship among science, risk and precaution in current biotechnology policies, and thereby identify barriers to effective implementation of the Precautionary Principle.

4.1.2 Ideas

Idea and Dominant Ideas

In various forms, liberalism has historically been the dominant political ideology in Canada. One particular form of liberalism which has gained prevalence since the early 1980s is known as “economic liberalism” or “neo-liberalism”. The dominant ideas of economic liberalism are familiar: market responsiveness, individual self-reliance, competitiveness, and efficiency (Skogstad 1996). Strong reliance on market forces and belief in individual choice means that, under a liberal agenda, government intervention or constraints must be well justified. For example, government may adopt a more assertive role in order to ensure security and safety, to prevent infringement of basic human rights, or in cases of clear market failure (as in monopolies, failure to provide public goods or production of public “bads” such as pollution).

The primary focus of economic liberalism can be thus distinguished from other forms such as “ethical” or “political” liberalism. The latter advocate greater constraint on the free market and if necessary redistribution of resources, both in the name of a priori principles of equal opportunity and individual liberty. Economic liberalism, on the other hand, is more aligned with utilitarian goals of maximising overall (aggregate) welfare through relatively unrestricted market forces (Manzer 1994). By this reasoning, social well-being or the
“greater good” will be achieved through increased overall economic prosperity—and economic prosperity will be achieved through a competitive and responsive marketplace. Broadly speaking then, the “conception of justice” for economic liberals is “descriptive of the rules that govern trade” (Barry 1996).

According to Manzer (1994), a new brand of economic liberalism, dubbed “technological liberalism”, has dominated Canadian public policy since the late 1980s:

For technological liberals, the overriding determinant of political, economic and social life...is the emergence of a global economy. The new global economy is ruthlessly competitive, not just among individuals and firms, but also among nations. Material well-being, political freedom and cultural development are already strongly determined by, and in the future will be overwhelmingly dependent on, superior capacity for scientific creativity, technological innovation and economic productivity (Manzer 1994).

Moore (1998) has argued that a discourse of technological liberalism has permeated Canadian agricultural research policy since the late 1980s, and concluded that the “apparent link between innovation and competitiveness in a globalised economy, and subsequently, prosperity, is now portrayed as a fundamental economic truth”.

While economic and technological liberalism share several dominant ideas—such as efficiency, competitiveness and limited government intervention—technological liberalism places greater emphasis on free trade, globalisation and scientific and technological growth. These ideas are clearly illustrated in Canadian science and technology, agriculture and biotechnology policies throughout the time period covered in Chapter 2. Since the 1980s, there has been a deliberate and forceful push to develop competitive new technologies, and to bolster the scientific research foundation upon which technology is built. Biotechnology, as we have seen, was one of several high technologies emphatically promoted by the federal government. However, the government’s stated role in biotechnology research and development was “supportive” rather than interventionist. It fostered greater alliance and
technology transfer between the public and private sector, and provided the infrastructure, financial incentives and legal mechanisms to develop a strong biotechnology industry and market. At the same time, the government ‘downsized’ its own research branch, effectively privatising agricultural research in Canada (Moore 1998). In keeping with technological or economic liberal views, Canadian agricultural policies placed high priority on international trade. Canada’s commitment to several free trade agendas throughout this period, coupled with a mandate to significantly increase agricultural exports by 2000 only heightened the pressure to develop a competitive agri-food sector and innovative, value-added products.

Also consistent with a non-interventionist, market-based approach, the government only reluctantly implemented safety regulations for the burgeoning biotechnology industry and was careful to do so in ways that would encourage rather than dissuade further investment. This meant “harmonisation” of biotechnology policies with trading partners via the OECD and WTO and introducing least coercive policy instruments first (i.e. guidelines), moving to stricter forms (regulations and legislation) only as external pressures and potential threats to the industry mounted (for example through CEPA). This move was rendered conveniently consistent with the growing (and otherwise challenging) idea of sustainable development which demanded a balance between existing growth imperatives and more ‘green’ government policies. To this end, agricultural biotechnology was characterised as a technological solution to chemically intensive agriculture, and potential hazards were viewed in light of assumed benefits and portrayed as manageable through “scientifically sound” assessment policies.

Indeed, loosely defined, “science-based risk assessment” provided the perfect vehicle for minimal government intervention and internationally harmonised regulations. The legitimacy of such global policies however, implies and depends upon a representation of
science as universal and value-neutral. Yearley (1996) describes such a representation as a "universalising discourse" and provides an explanation for its power in environmental policies:

Universalising discourses have held out the prospect of resolving apparently intractable global problems in objective and authoritative ways. The hope has been that these universalistic discourses would supply insights that transcend national difference and political interests, and thus offer binding interpretations of the environmental problems confronting the globe (Yearley 1996).

In this sense, science provided a "common currency" (Yearley 1996) that could be recognised and accepted internationally, a requisite feature of harmonised regulations. Equally important under a liberal agenda, government intervention based on value-free science could be justified by appeal to "the facts" rather than imposition of moral values. The government could therefore rationalise regulatory action as an objective balance of "real" environmental hazards with a legitimate concern for economic welfare.

How did these dominant ideas translate into the "paradigms" and "specific objectives" of risk assessment? In contrast to the above representation of science-based risk assessment as value-neutral, I will argue that, in practice, AAFC and Monsanto did in fact impose a very binding set of values by unilaterally constructing measures of "acceptable risk".

**Paradigms and Specific Objectives**

As discussed in Chapter 1, paradigms are a series of assumptions, usually specific to a policy field, which guide action and suggest solutions (Doern and Phidd 1992). Subsequent chapters revealed at least three operative paradigms in Canadian biotechnology policies: product-based regulation; the inherent benefits of biotechnology; and the ability to control adverse consequences. The following discussion considers each of these points in order.
Product-based regulation: Perhaps most central to biotechnology regulatory policy has been the assertion that rDNA organisms should be assessed according to the characteristics of the final product, and not according to the process of development: “The approach taken under the regulatory framework is that genetically engineered organisms are not fundamentally different from traditionally bred organisms” (AAFC 1996b). Underlying this approach is a further assumption that rDNA techniques do not, in themselves, pose new or significantly greater hazards than other methods of genetic manipulation. Rather, biotechnology is merely a more precise, innovative and efficient application of earlier “conventional” technologies. According to AAFC: “...because of the precise nature of the new [rDNA] techniques of biotechnology, we may actually have more knowledge about genetically engineered organisms than those that occur naturally” (AAFC 1996b).

This incremental view of biotechnology fostered an incremental approach to regulation. The Canadian government has consistently and effectively rejected the notion of comprehensive new legislation for biotechnology in favour of flexible guidelines and successive amendments to the Seeds Act. Even as guidelines and regulations for “plants with novel traits” were formulated in the early 1990s, the principles of familiarity and substantial equivalence further entrenched the notion that rDNA crops were in fact not “novel” at all. As Lindblom (1959) first pointed out, incrementalism may be the most expeditious route to policy change—and one consistent with a minimalist approach to government intervention—but important empirical and value considerations may be overlooked or overridden in the process. AAFC’s decision to use product-based regulation narrowed the scope of risk assessment to “anticipated relative effects” of rDNA crops versus the presumably acceptable effects of conventional crops.
However, several arguments against product-based regulation, and for the inherent novelty of rDNA crops have been well-articulated. For example, Regal (1994) lists “phylogenetic leapfrogging” (the ability to recombine genes from widely divergent species with no coevolutionary history or agricultural precedent) and the addition of new, dominant single-gene traits as significant differences between rDNA and hybrid crops. More specific to the HTC case discussed in Chapter 3, even if we accept the product-based regulations of the federal government, no “product” similar to HTC was commercialised in Canada prior to 1995. While some varieties of herbicide tolerant canola had been released in Canada\(^2\), these were not glyphosate tolerant (the herbicide was in a different chemical class), and were grown on a commercial scale in Ontario only. In other words, even disregarding the rDNA process, HTC was a novel product. As Karieva and Parker (1995) point out, the argument that “nothing bad has happened” in conventional agriculture cannot be extrapolated to rDNA crops because no similar conventional crops have been commercialised; this is not a valid comparison. To take the argument one step further, even if existing herbicide tolerant hybrid crops or other conventional varieties of crops were sufficiently “familiar” to HTC, they cannot provide an accurate baseline for comparison of environmental effects because no similar environmental assessment of conventional canola has been conducted (Torgersen 1996).

**Expected Benefits:** While both the federal government and Monsanto claimed rDNA crops were not inherently novel, somewhat incongruously, both parties have asserted that agricultural biotechnology will provide unprecedented economic and environmental benefits. For example, in the HTC assessment, Monsanto made the following claims:

- “there are environmental and cost benefits to farmers who will chose to use Roundup in canola production as a result of glyphosate tolerance”
- HTC allows “more environmentally sound practices” and “superior weed control”
• "the use of Roundup tolerant cultivars by canola growers offers additional benefits like a reduced total herbicide load on the environment and considerable cost savings to the farmer. These benefits will add to Canada’s international competitiveness."

No data are provided in the HTC assessment to substantiate these claims. Elsewhere, Monsanto makes more comprehensive claims about benefits of agricultural biotechnology, namely that it will contribute to global food security and sustainable development (Monsanto nd).

AAFC makes no mention of benefits in their Decision Document for HTC (AAFC 1995a) or in the Regulatory Document for environmental release (AAFC 1994a). CFIA has in fact fervently denied both the intention and responsibility for assessing the benefits of rDNA crops. For example, during the regulatory review of the Seeds Act, one stakeholder suggested that rDNA crops “should be shown to have clearly defined benefits to the environment, consumers and farmers before the products are evaluated”. In response, CFIA stated that “[o]nce any product is approved for commercial release, it is the responsibility of companies involved in selling their product to explain the benefits to consumers so that they can make decisions as to whether or not they will purchase the product” (Canada 1996a). A similar market-based approach governs assessment of the overall need for agricultural biotechnology: CFIA maintains it is “not responsible for evaluating need. The issue of whether or not these products are ‘necessary’ is left to the market place to determine” (CFIA 1998a). During interviews, CFIA regulators explicitly stated that potential benefits of rDNA crops do not influence environmental risk assessments (CFIA interviews, 1998).

Despite denial that the benefits of rDNA crops do, or should, influence risk assessments, it is clear that market imperatives and expected benefits of biotechnology have underpinned Canadian policy and regulations since the early 1980s (Chapter 2). Elsewhere, AAFC/CFIA have been quite candid about promoting the benefits of biotechnology:
Some of the benefits of biotechnology to Canadians are the production of newer and better products that may be lower in price than their traditional counterparts.... In the agricultural sector, there will be superior food products and healthier agricultural plants and animals.... (AAFC 1996c).

CFIA also maintains that biotechnology will “have major payoffs for Canada’s economy. It is creating opportunities for farmers, food processors and distributors, to sell new or improved goods in Canada and around the world. It is enabling farmers to achieve greater yields, assuring higher level of food production to meet increasing world demand for food” (CFIA 1997a). Industry Canada holds similar confidence in the benefits of biotechnology, stating that with rDNA crops “farmers can manage their crops more effectively and improve yields while applying fewer chemical pesticides and herbicides” (BIB 1998).

None of these claims are substantiated by primary research or secondary sources. In other words, while there has been no calculation or analysis of the environmental, economic or social benefits of rDNA crops by the federal government, the expected benefits of agricultural biotechnology remain a pervasive assumption against which all costs, risks and uncertainties must be unofficially balanced. As Levidow and Carr (1997) note, “logically speaking, risk assessment presupposes general benefits from biotechnology even if these remain implicit.”

**Control of Adverse Effects:** Although both Monsanto and the Canadian government heralded the benefits of rDNA crops, and neither recognised inherent risks, both parties nonetheless acknowledged some potential for adverse environmental effects, most notably persistence of herbicide tolerant weeds (volunteers) and gene flow to related wild species. As noted in Chapter 3, however, these risks were effectively minimised through the assumption that events could be controlled by “sound crop management practices” (AAFC 1995a), i.e. continuous application of several different types of herbicide. This regulatory strategy rests on several further assumptions. First, agricultural fields and surrounding areas must be
diligently monitored to detect and arrest adverse impacts once they have occurred. According to the Seeds Act, this responsibility lies not with the government but with developers and growers: “Where at any time after...receiving authorisation [to release an rDNA crop]...a person becomes aware of any new information regarding risk to the environment...that could result from the release, the person shall immediately provide the new information to the Minister” (Canada 1996a). Regulators at Industry Canada also confirmed that, once a crop is approved as “safe”, management of adverse events (for example gene flow from rDNA to organic crops) is a private responsibility, governed strictly by market forces (Industry Canada interviews, 1998).

Second, this approach assumes not only that effective management and control of hazards by the private sector are feasible, but perhaps more importantly that control through continuous herbicide application is acceptable. Of course, this presumption is linked to broader paradigms discussed above which assert that agricultural biotechnology is, overall, beneficial, and that existing agricultural practices are a suitable standard by which to measure the effects of rDNA crops. Herbicides are an integral part of intensive large-scale agriculture; the risks of these practices were therefore not in the realm of “anticipated relative impacts” of rDNA crops, but were considered an acceptable baseline against which to judge any new hazards introduced by agricultural biotechnology. Monsanto summarised this rationale in the HTC assessment: “potential effect on biodiversity from the use of herbicides has been accepted due to the benefit afforded by weed control on increased yields and an ensured supply of food.” While this regulatory strategy may be well-suited to the interests of some parties (such as herbicide/seed developers), ex post facto control measures are clearly unacceptable to others (such as advocates of low-input farming) who claim chemical
controls are undesirable, often unnecessary, and more frequently a source of the problem rather than a potential solution (Altieri nd; Clark 1998; Matson et al. 1997).

Nevertheless, attaining an "acceptable" level of risk was clearly outlined as the overall goal of regulation in the Regulatory Document on unconfined release (see Figure 2.1; AAFC 1994a). A subsequent AAFC publication stated that "safety is defined, not as the complete absence of risk, but as the level of 'acceptable risk'" (AAFC 1996c). In keeping with the framework of ideas set out in Chapter 1, we might therefore posit that the three paradigms of product-based regulation, inherent benefits, and control strategies constitute underlying premises for AAFC's "specific objective" of determining acceptable risk. How did AAFC achieve this objective? Once again, clear definitions of terms and official statements of decision-making rationale are lacking. Nowhere, for example, are criteria for "acceptability" made explicit. However, based on the foregoing discussion (including Chapter 2 and 3) it is evident that both Monsanto and AAFC sought to maximise the benefits of agricultural biotechnology while minimising or managing the risks. Acceptability was therefore implicitly defined as a trade-off between risks and benefits—a decision-making strategy grounded in broad economic and utilitarian principles. Rationale for this approach was expressed (albeit obtusely) in early background studies on regulatory options: "the advantage of risk benefit analysis is that if in a 'worse case' estimate benefits outweigh risks, then in lower estimates the same results will be reached" (Kalouas and Duke 1989). AAFC later made their risk-benefit strategy more explicit in a 'factsheet' on biotechnology regulation:

The purpose of regulation is to assure the protection of human, animal and environmental health, in addition to protecting the agricultural and forestry sectors of the Canadian economy.... The role of the regulator is to balance public concerns for safety with those of industries that wish to use technology to create national prosperity" (AAFC 1996c).
The benefits side of the equation, as discussed above, was largely presupposed under a liberal agenda that fully endorsed science and technology development as a means to greater economic prosperity. The conspicuous lack of benefits assessment by the federal government—who at the same time supported biotechnology through financial and other incentives—attests to a deep conviction in, and commitment to the expected pay-offs of investment in rDNA crops.

The risk side of the risk-benefit equation, however, demanded more direct attention, not only to justify government-imposed curbs on technological development, but also to accommodate the requirements of international trade and to address the growing ideas of sustainability and environmentalism. According to several AAFC documents, environmental risk is a function of the probability of an event, and the exposure or consequences of that event, for example: “Risk is defined in terms of probability of the occurrence of an effect, multiplied by the hazard” (AAFC 1994a); risk assessment “involves the well known steps of hazard and exposure identification, quantification of probability of effect and characterisation of risk (hazard X exposure)” (Hollebone 1993b); and risk assessment is “an estimation of hazards and the probability of human and environmental exposure to them” (AC et al. 1993). Such an approach is fully consistent with a technical concept of risk described in Chapter 1, and with “science-based” regulations sanctioned by the dominant political ideas discussed above. As illustrated in the HTC assessment, a “probability x consequences” formula sets convenient boundaries around the parameters of risk assessment: rDNA crops were ‘proven’ safe if the probability of a hazard was low or if the consequences were deemed insignificant. This task was further simplified by a priori assumptions that the probability of unexpected or novel hazards of rDNA crops relative to parental varieties was inherently low, and that the consequences of adverse events could nevertheless be controlled.
Later in this chapter, I will suggest some of the important parameters that were excluded by such a narrowly circumscribed risk assessment. First, however, let us examine how the dominant ideas of biotechnology policy were reinforced and further legitimised by key interests and institutions.

4.1.3 Interests

As discussed in Chapter 1, the range of interests which bear on policy-making can be succinctly illustrated by mapping the “policy community” and “networks” among interests within this community (Pross 1992). Similar approaches used in science and technology studies, most notably actor-network-theory (Latour 1987), attempt to account for the success of particular scientific ideas by examining relationships among various entities (“actants”) of a network, and by demonstrating how the interests of one party are represented and subsequently translated into the interests of another party. Both of these analytical techniques employ the concept of “boundary work” to explain how some interests are legitimised while others are effectively screened-out. In this section, I will briefly map the policy community for Canadian agricultural biotechnology, outlining key actors and interests. This overview will provide a necessary background for examining institutions of decision-making in the following section.

Recall from Chapter 1 that Pross (1992) distinguished two levels of involvement within the policy community: the “sub-government”, consisting of government agencies and institutionalised interest groups; and the more dynamic but less sanctioned “attentive public”. AAFC was the lead government agency for agricultural biotechnology and hence the foremost player in the policy community. CFIA has now replaced AAFC, but espouses a similar mandate on rDNA crops and enjoys a similar central role in their regulation. Several
other government agencies have played various roles in shaping biotechnology policy. Industry Canada (formerly MOSST) has sustained a strong promotional force and financial backing for the Canadian biotechnology industry, starting with the first National Biotechnology Strategy in 1983 and continuing with the renewed Strategy of 1998. Health Canada holds jurisdiction over human safety issues (such as allergen and toxicity testing) and employs a regulatory framework based on the principle of substantial equivalence, as developed by AAFC. Finally, Environment Canada maintains a significant, but subordinate role in biotechnology regulation. Under CEPA, Environment Canada is responsible only for those biotechnology products not covered by other Acts, primarily micro-organisms used for bioremediation. United States counterparts to these federal agencies (such as the Department of Agriculture and the Environmental Protection Agency) were also included in the Canadian biotechnology policy community through regular, direct consultations and continued efforts to harmonise national policies.

Policy direction of the above government departments was informed by several advisory committees. The National Biotechnology Advisory Committee (NBAC) has played an extremely influential role since its inception in 1983. NBAC not only established broad policy priorities for biotechnology R&D, but formulated key principles for environmental risk assessment (NBAC 1987-88). The Science Council of Canada (SCC) also held an advisory role within the policy community, although its mandate was broader than that of NBAC, and the SCC asserted a much more critical position on biotechnology. Several standing committees contributed further advice during periods of policy review, for example the National Advisory Board on Science and Technology examined federal science policy, and the Standing Committee on Environment and Sustainable Development proposed options for CEPA renewal. Although the advice of these committees was not binding on the
government, it is notable that recommendations of NBAC, whose membership was
consistently weighted in favour of industry interests (former NBAC member, confidential
communication, 1999), were often incorporated directly into emerging biotechnology
policies. In contrast, advice of the standing committees (particularly on CEPA) was largely
ignored by the government, and there is little evidence that the SCC made any lasting
impression on biotechnology initiatives or regulations (see following section).

In addition to federal departments and select advisory bodies, several non-government
organisations have exerted considerable influence within the biotechnology policy
community. Since the early 1980s, the OECD has maintained an influential role in policy
development, both through publications on general regulatory principles, and more directly
through consultations and workshops on safety and trade-related issues. Similar
consultations between the Canadian government and the Codex Alimentarius Commission
and various committees of the WTO are ongoing. Industry organisations and representatives
have also enjoyed direct participation in the biotechnology policy community. For example,
the WCCRRC worked closely with the federal government to establish testing procedures for
rDNA canola. The resulting system granted extra “merit points” to herbicide tolerant
varieties, and thereby provided an initial boost to the commercialisation of agricultural
biotechnology (Griffiths 1997). Industry interests were also well-represented during
amendments to the Seeds Acts (Canada 1996a). In addition to shaping the content and
direction of biotechnology policy, as we have seen, industry plays a continued and critical
role in policy implementation. All but one variety of rDNA crops commercialised in Canada
have been developed and are owned by the private sector. These developers are responsible
for conducting all risk assessment experiments and fulfilling all data requirements stipulated
The “attentive public”, according to Pross (1992), comprises a variety of interest groups and individuals who, in contrast to sub-government, are not accorded direct access to policy-making, but who nevertheless attempt to shape policy direction by exerting pressure through less direct or formal means. While public interest groups are often the most “attentive” constituents of the attentive public, until recently these groups have been conspicuously absent from the Canadian biotechnology policy community. Among the few exceptions were the Canadian Environmental Network (CEN) and the Consumers’ Association of Canada (CAC) who responded to regulatory proposals in the *Canada Gazette*, and the professional law association, Canadian Institute for Environmental Law and Policy (CIELAP) who published policy analyses on biotechnology and CEPA (CIELAP 1994). These specific organisations were also represented at the 1993 stakeholder consultation (AC et al. 1993). Not until the late 1990s, however, did more established public interest groups such as Greenpeace, Oxfam, Sierra Club and the Council of Canadians adopt a clear position and agenda on biotechnology in Canada. These groups might now be considered members of the “attentive public” but were largely absent during crucial policy-making phases in the late 1980s and early 1990s.

Perhaps a more prominent member of the attentive public during this time was the academic scientific community. Scientists in several disciplines had an obvious stake in the formulation of biotechnology policies, and the resulting tension was frequently revealed in editorials and commentaries (see Krimsky 1991; Regal 1996). As discussed in Chapter 2, the US National Academy of Sciences also expressed a keen interest and an unequivocal position on biotechnology policy, namely that rDNA organisms should be assessed according to the “familiarity” of the final product rather than the process of development. Research, opinions and policy statements published by the scientific community have clearly influenced
Canadian biotechnology policy: the NAS framework was incorporated into Canadian regulations, scientists were directly consulted during early drafts of risk assessment procedures (Caldwell and Duke 1988), and CFIA currently supplements risk assessments with data from the scientific literature (CFIA interviews, 1998). In 1993, regulators stated that “to date, consultation on draft guidelines has focused primarily on receiving technical and scientific input from the scientific community” (AC et al. 1993).

As this “map” reveals, since the early 1980s, the Canadian biotechnology policy community has primarily comprised government, industry, trade and scientific perspectives. While seemingly diverse, this community in fact represents a very narrow range of interests. All of the major players in the formation and implementation of biotechnology policy had stakes in, and/or commitments to, promoting biotechnology R&D. Other interests, for example those of environmental and consumer organisations were, at best, expressed in the role of an attentive public, but were not entertained at the level of sub-government. In this respect, the policy “network” for agricultural biotechnology has been particularly insulated and exclusive, and heavily weighted toward economic and scientific priorities. The following section examines the dominant institutional structures that have supported pro-biotechnology interests and effectively excluded critical or opposing voices.

4.1.4 Institutions

Remarkably, in terms of institutional influences on biotechnology policy, it is difficult to improve on Science Council’s critiques of the early 1980s (see Section 2.2.2). The federal government was perhaps all-too aware of institutional barriers to more effective, comprehensive and inclusive decision-making, but failed to act on the Science Council reports for at least 15 years, and has yet to fully acknowledge the scope of recommended
changes. Foremost among the Science Council’s criticisms was the government’s limited notion of public process. Fifteen years later, NBAC mounted similar criticism, pointing to the complete lack of mechanisms for holding a “non-partisan national conversation about biotechnology” (NBAC 1998). As Atkinson (1993b) has noted, defining “access points” to policy-making is one of the key functions of government institutions. What access points were made available to whom during the development of Canadian agricultural biotechnology policies?

A tradition of closed decision-making within the Canadian government has been recognised by several policy analysts, and has often been contrasted with a more open and adversarial tradition in the United States (Harrison and Hoberg 1994; Jasanoff 1986; SCC 1982). For example, through case studies of Canadian and US decision-making on hazardous substances, Harrison and Hoberg (1994) concluded that the “US approach is more pluralistic in relying upon interest group participation in risk management and even risk assessment. The Canadian approach is more paternalistic, entrusting the task of risk regulation to politicians and government experts with far less input from the public”.

While such broad comparisons are useful, as we have seen, policy-making for Canadian biotechnology was not completely restricted to government actors but was conducted in concert with industry and trade interests. Hoberg (1993) also supports this view, stating that “co-operative negotiations between government departments and industry” has been the norm in Canadian politics at least until the late 1980s. Far from “pluralistic” however, this style of policy-making might best be described as a “concertation network” (Coleman and Skogstad 1990). As briefly outlined in Chapter 1, policy networks are institutionalised associations between various interests in a policy community. Pluralist networks are characterised by a relatively weak or diffused state authority which is subject,
and open to, the influence of several contending interest groups. By contrast, concertation networks entail closed negotiations between a strong state authority and a single (or homogeneous) interest group. In concertation networks, these parties function as equal partners in shaping long-term policy goals, effectively precluding other interests from attaining an influential position in the policy community (Coleman and Skogstad 1990; Pal 1992). In terms of biotechnology policy, AAFC maintained a strong, central role in establishing environmental regulations for rDNA crops, rejecting the idea of comprehensive new legislation and disputing the regulatory expertise of Environment Canada. Pro-biotechnology interests have held an equally instrumental role in shaping regulations from the early 1980s to the present. Indeed the neo-liberal agenda of the 1980s and 1990s actively encouraged "partnerships" between government and industry, and an active role for the private sector in policy setting and implementation. The level of "concertation" between industry and government is perhaps epitomised by the exclusive and confidential risk assessment process discussed in Chapter 3.

Pressures of the early 1990s prompted several (albeit limited) attempts by the federal government to broaden the constituency of the policy community and provide a greater number of "access points" for public participation. For example, the biotechnology regulatory framework introduced in 1993 gave a nod to more open and consultative decision-making processes (at least in the press release (Canada 1993), however such requirements were not mandated in official regulations. The "first major consultation" (Canada 1996a) on biotechnology regulations was also held in 1993, but, as previously discussed, participation in this event was heavily dominated by government and industry (outnumbering other interests by about 4:1) and discussions were explicitly restricted to scientific and regulatory issues, which effectively curbed debate on larger substantive and procedural issues at the outset (AC
et al. 1993). No further consultations of this type were held until 1998 under the new Canadian Biotechnology Strategy.

The process of regulatory amendment offers an additional potential “access point” for public participation. Proposed changes must be published in the Federal Regulatory Plans (which are submitted to Parliament) and in the Canada Gazette as a Regulatory Impact Analysis Statement. These impact statements must provide a description of the regulation, alternative regulatory options, benefits and costs of the policy, results of any consultation processes, compliance and enforcement measures and a contact address. Interested parties have between 30 and 120 days (stipulated in the proposal) to comment, and any substantive changes must be incorporated into a new proposal. This process occurred during amendments to the Seeds Act in the mid 1990s. While in theory this avenue of participation in policy-making is open to all members of the public, in practice, responding to publications in the Canada Gazette requires not only intimate knowledge of the regulatory process, but keen vigilance over developments in a specific policy field. Consequently, the process tends to target those groups with sufficient time and resources as well as an immediate stake in the policy outcome, most likely members of sub-government and highly committed members of the attentive public. Even NBAC noted in 1998, that the “real challenge is for government to reach out beyond the specialised audience of the Canada Gazette” (NBAC 1998).

To its credit, AAFC augmented this process in 1994 by sending regulatory proposals to “over 2000” stakeholders including “provincial governments, universities, environmental organisations, consumer organisations, commodity associations and companies who develop agricultural products” (Canada 1996a). Comments solicited through this mailout were published in the Gazette in 1996 (Canada 1996a) for a 60-day comment period and proposals were again mailed to stakeholders. The 38 comments received through this process were
addressed by AAFC in a further statement (CFIA 1997c) but none were incorporated into the
final regulatory amendment. While “consultation” via the Canada Gazette and mailout of
regulatory proposals did reach many previously identified stakeholders and provided an
opportunity for feedback, the extent and effectiveness of this type of communication might be
compared to “direct consultation with the agriculture and agri-food biotechnology sector and
trade organisations” (Canada 1996a; emphasis added). To cite one example of the type of
communication engendered by the regulatory amendment procedure, several consumer and
environmentalist groups noted a potential conflict of interest between the promotional and
regulatory functions of AAFC. In response, AAFC collapsed promotion of biotechnology
into the broad goal of sustainable development: there could not be a conflict of interest
because both promotion and regulation of biotechnology fostered more sustainable
agricultural practices, presumably an objective to which everyone could agree (CFIA 1997c).
Undoubtedly, AAFC’s concepts of biotechnology and sustainable development differed
profoundly from those of the concerned stakeholders. Direct, two-way dialogue might have
addressed these differences in a way that “consultation” through official Regulatory Impact
Analysis Statements could not. As one policy analyst noted at the time, the federal
government has approved biotechnology products for environmental release “without any
serious public involvement in decision making” (Isnor 1993).

A general trend away from closed negotiations toward more pluralist
“multistakeholder” meetings was precipitated by the environmental movement and legislation
of the late 1980s. In particular, the Canadian Environmental Protection Act and the Green
Plan relied heavily on the outcome of multistakeholder consultations. The recurrent threat of
CEPA’s encroachment on AAFC’s regulatory authority created greater incentive for AAFC
to establish “equivalent” regulatory procedures for rDNA crops (Canada 1996a). Indeed,
"open, transparent communication and dialogue" has been highlighted as a major component of the new Canadian Biotechnology Strategy (CBS 1998). To date, however, both the ends and means of this initiative are unconvincing for several reasons. First, while the problem of accurate representation at stakeholder meetings is well documented, the first round of CBS consultations seemed particularly fraught with accusations of industry bias. The meetings were neither advertised nor fully accessible to members of the public, and were effectively dismissed by several environmental and consumer groups. A second cause for skepticism regarding the new biotechnology strategy is that CBS documents stress the need to “improve public awareness and understanding” suggesting that an educate-and-inform campaign can substitute for direct public participation and will ultimately lead to greater acceptance of biotechnology. This approach to government-public interaction was preceded by earlier stages of policy formation. For example, in 1988, an AAFC regulator recommended that government should endeavour to “allay ‘fears’ associated with new technology by providing adequate information” because “public concerns may be expressed as a perception of risk as ‘hazard’ x ‘outrage’. The greater the outrage the greater the risk! There is a difference between real and perceived risk” (Hollebone 1988). Background studies for environmental risk assessment further suggested that greater public awareness “will avoid negative exposure from the media and allow biotechnology to remain a positive issue” (Kalous and Duke 1989). Indeed, with over 60% of Canada’s canola crop planted to rDNA seed, and an additional $55 million of federal funds poured into biotechnology research in 1999, an educate-and-inform strategy might seem the best hope for a government firmly committed to the biotechnology industry.

Despite such shortcomings, at least in theory the new Canadian Biotechnology Strategy provides a greater number of access points for public participation, both through
direct consultations and through the new Canadian Biotechnology Advisory Committee. However, several critical aspects of the decision-making process remain unchanged: Risk assessment data must still be obtained through the Access to Information and Privacy Act, and release of data into the public domain can be restricted if deemed confidential business information by the developer. Decision Documents continue to be published after crops have been approved for release and fail to provide rationale or scientific data to support the final decision.

4.2 A PRECAUTIONARY APPROACH?

While no single idea, interest or institution will likely play a decisive or causal role in policy-making, a confluence of these factors may establish sufficiently “enabling circumstances” to advance some policy options and preclude others. This type of boundary-work is particularly powerful when dominant factors are mutually supportive. As the above discussion reveals, such was the case for biotechnology policy in Canada. Key ideas, interests and institutions set firm boundaries around the types of questions required of a risk assessment, the range of interests involved in decision-making, and the extent of information needed to legitimise decisions both within and beyond the policy community. More specifically, direct influence on policy setting was limited to science, industry and trade perspectives, while policy implementation, i.e. environmental risk assessment, remained under the exclusive purview of AAFC and private sector developers of rDNA crops.

How do such constructed boundaries influence implementation of the Precautionary Principle? Let us revisit the core elements of the Precautionary Principle (Chapter 1) to examine their relation to existing biotechnology regulations. In the following section, I argue that the ideas, interests and institutions that have shaped, and currently comprise
biotechnology policy and risk assessment procedures in Canada are not only incongruent with precautionary approaches, but function as effective barriers to the adoption of the Precautionary Principle. This discussion will help to identify necessary procedural and substantive changes if precautionary measures are to be implemented in Canada.

4.2.1 Claims and Commitments

We might first ask, Why be concerned with integrating the Precautionary Principle into existing regulatory frameworks for agricultural biotechnology? I suggest there are several urgent political, environmental and ethical reasons for examining more closely the role of precaution in current regulations for rDNA crops:

(1) The Canadian government has already made broad commitments to the Precautionary Principle in international fora such as the Bergen Declaration (1990) and the Convention of Biological Diversity (CBD). Both of these agreements promulgate a precautionary approach to achieving sustainable development, and Agenda 21 of the CBD specifically addresses the environmental hazards of rDNA organisms. However, the legal standing of the Precautionary Principle in these and other international declarations remains debatable. As mentioned in Chapter 1, some commentators argue that, through widespread use, precaution has reached the status of customary law and thereby renders signatory countries liable for potentially harmful yet uncertain effects. It is perhaps more commonly accepted that international conventions such as the Rio Declaration constitute “soft law”, and therefore entail a moral rather than legal obligation to comply with and implement the terms of agreement. In other words, there exists “a strong expectation that their provisions will be respected and followed by the international community” (Posey and Dutfield 1995). At least in this sense, Canada has committed to adopting the Precautionary Principle. A more explicit legal duty will
require establishment of binding protocols (such as the Biosafety Protocol of the CBD) and/or explicit integration of the Precautionary Principle into domestic law (Toner and Conway 1996; M. M'Gonigle, personal communication, 1999). The latter situation is imminent as proposed revisions to CEPA, now before Senate, incorporate the Precautionary Principle into the preamble and text of the Act. Although CEPA does not apply directly to environmental assessment of rDNA crops, amendments to the Seeds Act in 1996 clearly stated that AAFC’s regulations “are considered equivalent to standards under the Canadian Environmental Protection Act” (Canada 1996a). Incorporation of the Precautionary Principle into a renewed CEPA will therefore place additional pressure on CFIA to adopt “equivalent” precautionary measures.

(2) The pressure to reconcile the Precautionary Principle with current policies on biotechnology safety and trade is rapidly mounting in the international arena. In July 1999, environment ministers of the European Union invoked the Precautionary Principle in revised regulations on “genetically modified” organisms. If accepted by the European Parliament, the new law will constitute an effective moratorium on commercialisation and environmental release of rDNA crops. The Codex Alimentarius Commission (as advisory to the WTO) is also considering incorporation of the Precautionary Principle into international food safety regulations. Both the EU and Codex decisions will significantly affect Canada’s agricultural markets, providing greater impetus for the Canadian government to carefully examine the “precautionary” basis of existing regulations.

(3) Although the Seeds Act does not invoke the Precautionary Principle, various statements by AAFC and CFIA officials have implied that, in practice, current regulations for rDNA crops are already consistent with the principle. For example, in response to criticism that risk assessments are presently insufficient to demonstrate the safety of rDNA crops (Powell et al.
1997), CFIA stated that a key component of the assessment process “is the incorporation of the Precautionary Principle, as adopted in the Rio Convention...” (CFIA 1997b). During interviews, CFIA regulators affirmed that current regulations were indeed “precautionary” (CFIA interviews, 1998). Clarifications to the Seeds Act published during the amendment process provide a further indication that AAFC subscribes to some version of the Precautionary Principle: The department stated that provisions of the Act reflect “two aspects of the Precautionary Principle”, namely that a product can be granted “outright” or qualified approval, or can be “refused approved” even in the “absence of a full database of information” (Canada 1996a). As it is unclear how approval based on incomplete information conforms to a precautionary approach, this quotation highlights the need to examine current regulatory activities in light of various weak and strong interpretations of the Precautionary Principle.

(4) Finally, based on the core elements of precautionary approaches identified in Chapter 1, and critique of the scientific basis of risk assessment in Chapter 3, the potential hazards of agricultural biotechnology meet at least two well-recognised conditions for invoking the Precautionary Principle. First, while research on the ecological effects of rDNA crops is still in its infancy (most studies have been published since the mid 1990s) several experiments have revealed potentially “serious” effects of large-scale unconfined release. Second, notwithstanding these studies, there remains considerable uncertainty as to scope, scale and distribution of the risks or benefits of this technology. Under these conditions, the Precautionary Principle would prescribe proactive measures to forestall adverse effects. To what extent were the core elements of the Precautionary Principle adopted in—or excluded from—Canadian biotechnology regulations?
4.2.2 Elements of the Precautionary Principle in Biotechnology Regulations

To emphasise the main points of my argument, I will review the core elements of precaution in the reverse order as previously discussed in Chapter 1.

Cost Effectiveness

In the discussion above, I suggested that AAFC employed primarily technical and economic concepts of risk in determining a level of acceptable risk for rDNA crops. Specifically, they adopted (albeit roughly) a “probability x consequences” formula for risk assessment and a risk-benefit equation for risk management. These methods, as noted in Chapter 1, are not inconsistent with weaker versions of the Precautionary Principle. For example, the Rio Declaration explicitly qualifies precautionary approaches with “cost-effectiveness”; the “proportionality rule” stipulates that precaution should be adopted only in proportion to the benefits accrued (O’Riordan and Jordan 1995); and technical analyses may be used to support precautionary measures such as environmental impact assessment.

Nonetheless, most interpretations of the Precautionary Principle hold that if such economic and technical calculations are employed, they should be heavily weighted in favour of benefits, and should account for non-monetary factors such as subjective values attached to different types and distribution of risk. Such an interpretation of the Precautionary Principle might therefore encompass a form of expected utility theory.

However, even this weaker version of precaution would require a much more sophisticated and extensive consideration of risk, uncertainty and benefits than undertaken by the Canadian government. My critique of the HTC assessment revealed that Monsanto and AAFC sought—and assumed—*objective* measures of probabilities and full knowledge of the range of potential consequences. In doing so, both parties failed to investigate subjective or
intersubjective elements of risk well documented by social and psychological theorists: e.g. distribution of risks and benefits; voluntariness and consent; signal value (what the hazard portends); and degree of familiarity, visibility and control (Otway and von Winterfeldt 1982; Slovic 1992). Public opinion studies on agricultural biotechnology have in fact identified such factors as key determinants of risk (CAGEC 1997; CRI 1996; Grove-White et al. 1997; Citizen’s Panel 1999). Yet these concerns were not simply overlooked during the regulatory and commercialisation of rDNA crops, they were effectively overridden by the assumptions of “acceptable risk” inherent to the decision-making process.

Calculations of probability and consequences for a single event, however, is only one step in a complete decision-making process using expected utility theory. The sum of all expected outcomes (good and bad) must be averaged into an estimate of overall utility, and this calculation must be performed for each course of action under consideration. The expected utility of releasing rDNA crops therefore includes the probability of both beneficial and adverse consequences, and the sum of these outcomes must be measured against other options, e.g. not releasing rDNA crops, restricting crops to confined or small scales, exploring alternative agricultural technologies. The best course of action, by this theory, has the greatest overall expected utility. While both AAFC and Monsanto employed a probability/consequence function to calculate risk, and implicitly weighed these risks against assumed benefits, neither party completed the process by evaluating the advantages or disadvantages of other options, assessing the benefits of rDNA crops, or for that matter thoroughly evaluating the potential hazards. Thus AAFC’s risk assessment practices failed to meet even weak precautionary measures prescribed by a relatively conservative economic framework.
**Shifting Prior Assumptions and Burden of Proof**

As discussed in Chapter 1, prior presumptions, burden of proof and standards of evidence are often used to distinguish the Precautionary Principle from more risk-taking approaches. How “precautionary” are Canadian risk assessment procedures for rDNA crops in this respect? On a first, rather simplistic reading (one consistent with the government’s statements of precautionary measures), one could argue that AAFC adopted a prior presumption that rDNA crops are “guilty” or hazardous: if this were not the case, no risk assessment would be conducted and rDNA crops would be released as any other crop. There was, in other words, at least some recognition of potential hazard. One could also argue that proponents (e.g. Monsanto in the HTC case) already carry the burden of proof because they must test newly developed crops, submit data to convince the government that their product is safe, and absorb the cost of this procedure. In terms of standards of evidence, as we saw in Chapter 3, Monsanto and AAFC used both statistical evidence (akin to strict standards) as well as a “balance” of qualitative evidence, observations and scientific literature to demonstrate the safety of HTC.

A deeper reading of government policies and practices, however, suggests that risk assessments for rDNA crops are in fact inconsistent with a precautionary position on burden of proof, prior assumptions and standards of evidence. The whole question of appropriate burden of proof assumes that a technology is defended by a proponent, and challenged by another opposing party (Brunk et al. 1992). Developers, quite obviously, have a direct interest in proving the safety rDNA crops. But does the federal government represent genuine opposition? The preceding analysis of policy development and implementation strongly suggests that in Canada, government and industry share similar interests and commitments in promoting biotechnology. These interests were reflected in the prior
assumption that rDNA crops are not inherently hazardous. By this argument, proponents such as Monsanto have to “prove” the safety of their crops to no one. To continue the legal analogy, the prosecutor, defendant and adjudicator were all on the same side. This is a powerful position for both government and industry. The public is granted an outward appearance of objective, “science-based risk assessment”, and assurance that safety concerns have been fully addressed. Yet as Chapter 3 revealed, standards of evidence used in the HTC assessment were very weak, partly because the questions under investigation were narrow, and partly because only minor effort was made in gathering data and weighing available information: it is easy to support a prior assumption of safety (i.e. no effect) through negative evidence. The absence of ideological opposition, the lack of independent studies or review, and the security provided by confidentiality of data, grants proponents the benefit of the doubt, rather than the burden of proof. A true challenge must come from the public—after a decision to release and commercialise rDNA crops has been made. In other words, it is the public, not proponents or government who ultimately carry the burden of proof.

**Action Despite Scientific Uncertainty**

Uncertainty is a fundamental element of the Precautionary Principle. All interpretations of the principle stipulate that precautionary measures should be taken even when scientific uncertainty regarding adverse effects persists: if we don’t know, we should err on the side of caution. Implementing the Precautionary Principle therefore implies recognition that knowledge is incomplete and that consequences are unknown. However, “scientific uncertainty” remains, in general, an ill-defined term, and no declaration of the Precautionary Principle offers further clarification. As described in Chapter 1, researchers in the fields of risk analysis and STS have identified several degrees and forms of uncertainty.
ranging from technical and methodological through to epistemological or "great" uncertainty. Due to the central yet ambiguous role of uncertainty in the Precautionary Principle, it is important in evaluating any risk assessment to determine if and how uncertainty is acknowledged, the type of uncertainty recognised, and the influence of uncertainty on decision-making.

Evaluation of the HTC risk assessment in Chapter 3 revealed that Monsanto and AAFC acknowledged some level of technical and methodological uncertainty, although not to the extent that final conclusions were qualified or stated conditionally. Rather, uncertainties were rendered manageable through the prior assumptions of "familiarity" and ability to control unforeseen events. Epistemological dimensions of uncertainty—ignorance, or the limits of knowledge—were not addressed in the HTC study. Such limitations are a function of both the complex ecological and social world in which rDNA crops are released, and the boundaries constructed within these worlds by political and value commitments, i.e. the ideas, interests and institutions discussed above. According to Wynne (1992b), such value assumptions—which are inherent to scientific research, but usually not articulated—give rise to situations of indeterminacy. There exists, in other words, a critical divide between the necessarily assumption-laden world in which science is conducted, and the open-ended world in which the products of science (be it technologies or risk assessments) are consumed. Thus indeterminate situations are not simply more uncertain than those characterised by technical or methodological uncertainty, and cannot simply be resolved through further experimentation. Rather, indeterminacy describes an essential conditionality of scientific research, a conditionality that must be articulated if conclusions are to be meaningfully applied in a particular context.
These dimensions of risk were not broached in the HTC study and are not accommodated by existing risk assessment regulations. On the contrary, by actively excluding uncertainties and failing to articulate the contingent and conditional nature of scientific knowledge, AAFC fostered and rationalised a self-serving but ultimately myopic definition of risk. This "constructed ignorance" (Proctor 1994), absolved the government of responsibility for complex, indirect, and long-term effects of rDNA crops. As Levidow and Carr (1997) point out, epistemological boundaries create convenient ethical boundaries by defining the limits of accountability. The safety of rDNA crops could thereby be presented with uncommon certainty, scientific authority and assurance that hazards had been addressed and are under control. This process created a stable and "safe" business environment—thereby evading regulatory uncertainty so detrimental to investment and commercialisation—and simultaneously obviated the need and responsibility for greater precautionary action.

**Proactive and Anticipatory Approaches**

A distinguishing feature of the Precautionary Principle is an imperative to adopt proactive measures to anticipate and forestall adverse effects. At the governmental level, compliance with this obligation requires the establishment and implementation of comparable policy goals including active investigation of potential hazards and alternative options prior to—or at the very least, simultaneously with—commitment to new technologies. As we have seen, Canadian biotechnology policies were not "precautionary" in this respect. By the time risk assessment procedures were implemented in 1993, rDNA crops were already in pre-commercial variety trials, with over ten years of government-backed R&D investment behind, and the promise of international markets ahead. Moreover,
regulations were grounded in the assumption that adverse effects could be identified, monitored and controlled once they had occurred, a fundamentally *reactionary* approach. It is significant in this respect that neither the original National Biotechnology Strategy of 1983 nor the renewed strategy of 1998 allocated funds specifically for risk research, and no similar government "strategy" has been launched to encourage low-input farming techniques, such as organic agriculture. In contrast, in 1988 the US Department of Agriculture launched the Sustainable Agriculture Research and Education Program (SAN 1999) and in 1990 established a funding program for biotechnology risk assessment research (USDA 1998).

As discussed briefly above, one could argue that the Canadian government’s decision to enact regulations for rDNA crops prior to the occurrence or demonstration of adverse environmental effects is, in some sense, a precautionary move. However, we might make a useful distinction between "cautious" and "pre-cautious" positions (Barrett and Raffensperger 1999). AAFC implemented some cautious measures *while proceeding* with biotechnology development, but the government was not disposed to a genuinely precautionary position precisely *because of* these prior commitments and vested interests. Long-term, broad-scale testing of ecological impacts was simply incongruent with expediency built into the regulatory framework. Effective implementation of the Precautionary Principle requires sufficient independence to delay, discontinue or refrain from initiating technologies, and more importantly sufficient latitude, incentive and will to fully assess potential impacts and pursue alternative courses of action. Neither Monsanto nor AAFC possessed such independence, established such incentives or displayed such will.
**Ethic of Protection**

As discussed in Chapter 1, a primary goal of the Precautionary Principle is to protect the environment against adverse effects of human activities. While the philosophical grounding for a precautionary approach has not been well articulated, the weakness or strength of precautionary measures is often derived from broader ethical principles. For example, weak precautionary measures—those advocating weighted cost- or risk-benefit assessment—are often grounded in a utilitarian ethic. Stronger versions most often cite an ecocentric philosophy which recognises an intrinsic value of the environment, and/or a more anthropocentric ethic based on principles of justice, fairness or rights. Despite such differences in goals and ethical grounding, all versions of the Precautionary Principle recognise the importance of effective environmental protection *per se*. That is, policy measures that actually safe-guard the environment will help realise other political or ethical values (*e.g.* preservation of ecosystems, sustainability, justice, best cost/benefit balance etc.). This position requires that environmental values be recognised, investigated, and deliberately incorporated into policies and regulations.

I contend that the Canadian government did not adopt such a position. As discussed in Chapter 2, implementation of environmental regulations for rDNA crops was primarily motivated by a growing need to foster confidence and investment in agricultural biotechnology. Given the quality and thoroughness of experiments described in Chapter 3, it is very difficult to conclude that protection of the environment was the primary intention of the risk assessment conducted by Monsanto and approved by AAFC. Rather, what was needed, and what was achieved, was the *appearance* of scientifically sound protective measures in order to boost the biotechnology industry. The difference between instrumental use of the environment (which to some extent all agriculture must adhere) and instrumental
use of environmental regulation is subtle but important. The first might be rationalised by a weak Precautionary Principle and utilitarian ethic prescribing complete risk-cost-benefit analysis. As we have seen, AAFC adopted a broad utilitarian language, but did not fully or publicly justify their decision by conducting a thorough analysis of the risks and benefits of rDNA crops and other options. Instrumental use of environmental regulation—especially to further an industry whose environmental merits have not been investigated—is difficult to reconcile with any version of the Precautionary Principle. Steven Yearley has aptly dubbed such rationale for environmental policy-making as the “expedient use of greenery” (Yearley 1991). As it is neither the mandate of AAFC nor the business plan of biotechnology industries to protect the environment, this conclusion provides further indication that a more diverse policy community and open decision-making process might significantly re-direct biotechnology policies toward a more precautionary approach.

4.3 CONCLUSIONS: THE POWER OF BOUNDARY-WORK

The discussion thus far has demonstrated that a confluence of ideas, interests and institutions can serve to legitimise a particular set of assumptions which thereby become unchallenged foundations of government decisions. In Canadian biotechnology policies, these assumptions pervade all stages of the regulatory process from policy setting to implementation, and have established very powerful boundaries around the concepts of “science” and “risk”, and thus around the process of “science-based risk assessment”.

Such boundary-work is a function of the decision-making process; substantive and procedural aspects of risk assessment are inextricably linked and often mutually reinforcing. Atkinson (1993b) for example, notes that “institutions that nurture technical discourse and allow policy knowledge to be concentrated, effectively close doors to outsiders and provide
uncontested terrain for those within the policy community". Harrison and Hoberg (1994) have also argued that such closed decision-making provides little incentive for government to publicly rationalise policy choices. Indeed, relative to previous studies of scientific boundary-work (e.g. Gieryn 1999; Jasanoff 1987; Latour 1987), the present case is somewhat peculiar in that the actual "science" used in environmental risk assessments was (and is) never subject to scrutiny by outside interests; there has been no peer review, no third party assessment, and no disclosure of data to the public. AAFC/CFIA and proponents of rDNA crops need not, therefore, "enrol" (Latour 1987) or otherwise convince external parties that their science is credible. Rather, all that is required is a "public face" of risk assessment as based in sound, objective and universal science. This outward representation of science-based risk assessment is well suited to the dominant interests of the policy community: investors and industry require a regulatory system that can be rationalised as empirically-grounded, thorough and efficient; trade organisations demand that policies be harmonised (universal) and non-protectionist (disinterested); and successful marketing requires consumers' confidence that agricultural biotechnology has been deemed "safe" by the most rigorous process and reliable knowledge. Such strategic use of scientific authority and regulations further legitimises closed decision-making processes and conveniently obviates the need for greater public input: "The conviction that science speaks objectively and disinterestedly means that one need have no qualms about excluding other people from decision-making since they would, in any event, have arrived at the same conclusions as oneself" (Yearley 1996).

As revealed in Chapter 3, however, the "private face" of risk assessment was neither objective (in that similar conclusions would likely be drawn by another party) nor disinterested (in that conclusions were uninfluenced by a priori values or goals). Rather, the
range of questions, methods of inquiry and final conclusions of the HTC assessment were shaped in critical ways by long-term investments in—and firm commitments to—the rapid commercialisation of agricultural biotechnology. Specifically, assumptions embedded in the risk assessment supported overly confident conclusions about the safety of HTC. By severely limiting their consideration of uncertainties that would otherwise qualify and contextualise decisions, AAFC and Monsanto could rationalise the precise calculations of technical and economic risk assessment as sufficient basis for decision-making. Under this framework, further precautionary measures appear unduly risk averse and heedless of existing scientific knowledge and authority.

Wynne (1992a) has argued that such exclusive and opaque practices of decision-making exert a form of social control over an unwitting public:

Risk is assumed to have an intrinsic, objective natural meaning that everyone should share, rather than a meaning that has been created and imposed by particular dominant social institutions with their own interests and anxieties, and that systematically conceals certain issues and questions from public attention (Wynne 1992a).

This seems an apt interpretation of Canadian biotechnology policy. The public has merely been assured that risk assessments are “science-based” but beyond this government mantra, the rationale for determining the safety of rDNA crops remains inscrutable. We must simply trust the government—and its representation of science—that rDNA crops are in fact “safe”. However, according to several social analysts of risk (see Giddens 1990; Michael 1996; Wynne 1992a), public trust is exactly what is lost when decision-makers fail to recognise, articulate and account for the assumptions that underlie policies, especially when these policies unilaterally impose a level of “acceptable” risk. In other words, public protest and ultimate rejection of rDNA technologies are as likely to signal rejection of the implicit ethics of decision-makers, as concern for specific health or environmental hazards. No doubt, this
explains (at least in part) the Canadian government’s concern of late with public awareness and confidence (CBS 1998) and Monsanto’s fervent advertising and public relations campaigns. But this growing “normative uncertainty” (Levidow 1996) around agricultural biotechnology was largely created by decision-making processes that excluded normative issues in the first place. As Wynne (1992a) further argues, the “institutionalised exaggeration of the scope and power of scientific knowledge creates a vacuum in which should exist a vital social discourse about the conditions and boundaries of scientific knowledge in relation to moral and social knowledge”. Monsanto and AAFC operated under assumptions of acceptability, but these were not negotiated, researched, challenged or mutually agreed upon by all those potentially affected by rDNA technologies.

The Canadian regulatory system for biotechnology thus failed to implement precautionary measures not only regarding the ecological hazards of rDNA crops but also in terms of potential social or political effects. In this sense, the risk assessment process functions as an effective barrier to implementing the Precautionary Principle: core elements of the principle (as it is currently interpreted) challenge the carefully constructed boundaries around the AAFC/CFIA’s “science-based” process, and are therefore unlikely to be incorporated into existing regulatory frameworks. Regulatory reform cannot occur without first examining how, and by whom, concepts such as “science”, “uncertainty” and “risk” are defined, how these definitions shape policy options, and how alternative definitions—redrawn boundaries—might affect decision-making processes and conclusions. Adoption of the Precautionary Principle will require, in other words, not only a shift in ethical principles but a concomitant shift in the institutional and epistemological basis upon which decisions are made. More specifically, “risk” must be recognised and evaluated as a fundamentally
social concept. The following final section explores some avenues that may take us in this
direction.

4.4 RECOMMENDATIONS

As I pointed out above, substantive and procedural aspects of risk assessment, or any
decision-making process, are closely and necessarily tied. Many proposed solutions to
problems that cut across science, politics and ethics focus on establishing new decision-
making procedures or institutions. The premise is that more open, fair and inclusive
procedures will yield more accurate, appropriate and widely accepted decisions. In-depth
analysis of Canadian biotechnology regulations leads me to similar conclusions: the root of
the problem is procedural. However, this suggests few easy, and no absolute solutions.
Political theorists continue to debate how representative democracy might be made more
representative, how direct democracy might be applied to large-scale issues, and what other
models of democracy (for example those centered on communication or deliberation) might
entail (e.g. see Benhabib 1996). I do not intend to resolve such complex and long-standing
issues here. Rather, I will propose a series of procedural and substantive changes more
specific to agricultural biotechnology with the hope that these recommendations are carried
forward (with appropriate modifications and through appropriate means) by those more
immersed in the broader issues.

The following discussion expands on the concepts of social and precautionary risk
outlined in Chapter 1, and draws heavily on research that I have recently published elsewhere
(Barrett and Raffensperger 1999) as well as ongoing collaborative projects among myself and
members of the Consortium for Sustainable Agriculture Research and Education (CSARE)
and the Science and Environmental Health Network (SEHN). I will therefore not present
this work in the detail available elsewhere, but will outline the main ideas and directions of future study in order to suggest how changes in the epistemological and institutional basis of decision-making may facilitate changes in the ethical principles that guide protection of the environment.

"Precautionary Science"

While some critics have condemned the Precautionary Principle as non- or anti-scientific, I have argued in contrast that the principle is fundamentally a knowledge and action based decision-making tool that is not necessarily antagonistic to scientific inquiry (Barrett and Raffensperger 1999). A precautionary approach implies a level of information about the potential hazards of an activity, and prescribes further research to improve our understanding of the range of impacts and explore feasible, less harmful alternatives. However, as this dissertation and other STS research has documented, “science” is not a homogeneous entity. Rather, the practice and content of science is shaped by the values, assumptions and goals of key ‘actors’, the ‘audience’ to which science is presented, and the institutional context in which this process takes place. I have concluded in the HTC case that such factors have conspired to produce an epistemological basis that is not only inadequate to address proposed questions of risk and safety, but that is in fact incongruent with the Precautionary Principle.

Yet, if the boundaries around science are indeed malleable, there exists the possibility of re-constructing or re-directing the norms of scientific inquiry to better suit the complexities and uncertainties of rDNA crops and similar technologies. As mentioned briefly in Chapter 1, Beck (1992a; 1992b; 1996) and Wynne (1992a; 1992b; 1993) among others have begun to lay the foundations for such a reconstruction process. For example, Beck argues that the
current breakdown in the capacity of science to predict and hence prevent “modernisation risks” may actually hold the seeds of change: As science proves “less and less sufficient” (Beck 1992b) to control the adverse effects of its production, public opposition to scientific or technocratic authority builds and eventually becomes institutionalised, particularly in the form of environmentalist organisations. Yet because scientific rationality has (despite its insufficiencies) retained significant political power, such organisations are compelled to fight science with more science. Beck argues that this criticism will be internalised by the scientific community and will thereby foster an expanded form of scientific practice which is better equipped to deal with politically- and ethically-charged risk situations. More specifically, through this process “[n]ew public-oriented scientific experts emerge”, the contested foundations of scientific arguments “are exposed with counter-scientific thoroughness, and many sciences are subjected through their applied practices to a ‘politicization test’ of a previously unknown extent” (Beck 1992b). Thus Beck holds considerable optimism for the ability of science to re-fashion itself in ways that compensate for its limitations “partly by retaining [its] formal responsibilities, partly by explicitly changing them.” (Beck 1992a).

Other writers, however, stress that we must pay closer attention to the social and political conditions that not only produce potentially hazardous technologies, but also continuously define the very concepts of “risk”, “uncertainty”, and “science” (see Bauman 1992; Levidow 1994; Wynne 1996). I have undertaken such an analysis in this dissertation. However, better decision-making will require that all parties become actively involved in a process that Wynne terms “social learning”. Rather than simply an improved method of revealing physical, pre-existing properties of risk, social learning entails negotiation among various actors (government, industry, scientists, lay-people) in order to improve
understanding of the social foundations of risk: “It is learning in the sense of recognising the conditional nature of one’s own knowledge, and the implicit assumptions and commitments that constitute it” (Wynne 1992a). This interactive learning prescribes a vital role for non-scientific expertise in technology development and assessment, not as a means to appease public unrest but in recognition that all those who use—and are affected by—technologies contribute to the construction of knowledge about risk. As such, social learning also requires that existing institutions, including the scientific community, adopt a more engaged position and critical view of their role in society: “institutions would not exclude their own structure, power, and social relations from the discourse about risk” (Wynne 1992a). Similar views have been expressed by proponents of more democratic (Sclove 1995) and/or decentralised (Martin 1994) science. These movements call for greater direct interaction between the scientific community and local non-scientific communities as part of a two-way learning process that more effectively addresses issues concerning environmental and public health. All of these views merge epistemological, ethical and institutional factors. All require critical examination of the assumptions and commitments embedded in scientific knowledge, propose increased participation of members of the non-scientific community, and prescribe a more engaged, advocatory and activist science.

A move in this direction will obviously entail greater interdisciplinary effort and team-based research in order to blend and expand current approaches of the natural and social sciences. Several fields have begun to forge these links and may lend some tools necessary for such a re-construction process. To cite a few examples:

- Agroecology and conservation biology are interdisciplinary fields of research that adopt openly advocatory positions. Agroecology integrates ecology, agronomics, environmental science, rural sociology, development studies and indigenous knowledge (among other
sources) to address agriculture as an integral part of ecological, social and political systems. An agroecological approach aims beyond the productionist paradigm of current industrialised agriculture by advocating farming practices that are sensitive to both environmental and economic sustainability as well as social justice (Hecht 1995). Conservation biology defends a similar normative and holistic approach, and investigates both social and ecological influences on environmental degradation and species extinction. According to Soule (1985), conservation biology eschews strictly “utilitarian, economic objectives” and proceeds under the assumption that “biotic diversity has intrinsic value”. Breyman (1998) has argued that such a position renders conservation biology a suitable framework for a subversive “deep ecological” science.

Environmental impact assessment (EIA) is a decision-making tool and regulatory process that differs from risk assessment in several respects. EIA entails review of environmental effects of proposed projects prior to their implementation, and aims to “promote sustainable development and thereby achieve or maintain a healthy environment and a healthy economy” (EC nd). In Canada, requirements for EIAs are stipulated by the 1992 Canadian Environmental Assessment Act (CEAA) under the jurisdiction of Environment Canada. EIAs must include impacts on human health, socio-economic conditions, physical and cultural heritage, and traditional aboriginal uses, as well as cumulative environmental effects and alternatives to the proposed project (Wood 1995). CEAA also mandates public participation in the assessment process and public review of the EIA report. However, under CEAA, impact assessments are required only for specific “projects” defined as “any proposed construction, operation, modification, decommissioning, abandonment or other undertaking in relation to that physical work”, for example dams or mining operations (Canada nd). As such, rDNA crops do not fall under CEAA and have never been subject to an EIA;
agricultural biotechnology is considered a “product” not a “project”. It is nevertheless worth comparing EIA and risk assessment processes to examine how decisions for agricultural biotechnology might be different under EIA provisions.\(^7\)

- “Participatory action research” (PAR) is a framework for research that aims specifically to investigate, intervene in and ultimately change the root causes of social and environmental problems. PAR is thus distinguished by its openly activist mandate and engaged position on a particular issue. To achieve its goals, PAR is conducted in close collaboration with communities that are affected by, or have direct experience with issue at hand. Communities participate directly in all phases of research, often initiating and setting overall goals for the study, establishing the parameters of inquiry and verifying final results. An iterative two-way learning process is thereby established between the specialised knowledge of academic researchers and the experience-based knowledge of community members (Green et al. 1997).

Interestingly, none of these fields have been incorporated into regulations for agricultural biotechnology; rDNA crops continue to be viewed as an isolated technical or engineering risk (at best) rather than part of a larger ecological and social system. However, while the above approaches set important precedents, none goes far enough in examining the underlying social and political factors that emphasise or exclude particular problems, set priorities, define key terms, and determine who is involved in decision-making processes. The framework outlined in Table 4.1 attempts to bridge this gap by outlining some general elements and guiding questions that might be used as starting points toward a more “precautionary science”—one that is consistent with the ethical foundations of the Precautionary Principle, mindful of assumptions, limitations and variable constructions of science, and yet provides a grounding for decision-making about complex, uncertain, and ethically and politically sensitive technologies.
### TABLE 4.1
**SUGGESTED ELEMENTS OF A “PRECAUTIONARY SCIENCE”**
(Adapted from Barrett and Raffensperger 1999)

<table>
<thead>
<tr>
<th>KEY ELEMENTS</th>
<th>GUIDING QUESTIONS</th>
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<td><strong>Scope of Inquiry</strong></td>
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| Intended purpose of technology | • What is the claimed need for the technology?  
• What problems does it aim to solve?  
• What is the source of these problems? How do they relate to/contribute to larger problems? *(i.e. “connectivity”, see Dovers 1995)*  
• Who advances these claims? At what point in the R&D process are these claims made?  
• What, if any, objections have been raised? By whom? At what point in the R&D process are these claims made? |
| Definitions of hazard, risk, cost | • Have direct, indirect, cumulative and synergistic effects been considered?  
• Have ecological, social, economic and political effects been considered?  
• Who has defined the scope of these effects?  
• Are adverse effects measured against an existing technology? Have the potential effects of this standard been assessed? How is ‘acceptability’ determined?  
• Does the proposed technology perpetuate potentially harmful and/or unassessed trends?  
• Does the proposed technology foreclose future options? |
| Definitions of benefits | • Have benefits been assessed to the same extent and through similar processes as risks/costs? (see criteria above) |
| Distribution of risks and benefits | • How are costs, risks and benefits distributed?  
• How, and by whom, has this distribution been determined?  
• How is the distribution determined to be acceptable?  
• Does the technology concentrate or distribute authority (empower or disempower those who may be affected)?  
• What and whose commitments are resting on decisions? |
| Alternatives | • Have a range of alternatives been actively researched and assessed?  
• Have such “alternatives assessments” included a diversity of interests? Are they open to public scrutiny and possible revision? (see O'Brien 1999)  
• What social and political factors encourage or discourage particular alternatives? (e.g. unequal allocation of R&D funding may render one alternative more attractive or viable than another) |
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<tr>
<td><strong>Methods of Inquiry</strong></td>
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| Scale | • Have micro-, meso- and macro-scale effects been assessed (across time and space)? (see Rasmussen et al. 1998)  
• Have effects at the biochemical, organism, community and population levels been assessed?  
• Have local, national and international influences been considered?  
• Have multi-scale and multi-system effects been examined?  
• Have effects at different life stages and/or generations been considered?  
• Are effects reversible? Over what time period?  
• Are observable effects delayed? Over what time period? |
| Context/Extrapolation | • How and where will the technology be applied in the future (including intended and unintended dispersal)?  
• Are effects likely to be variable across different social/ecological contexts?  
• Are experiments and conclusions context specific? Are results extrapolated to more general circumstances? How are effects of conditionality assessed and acknowledged?  
• What assumptions are needed to extrapolate from specific to general circumstances? |
| Experimental Design | • Can this technology be tested on a relevant scale without imposing potential harm?  
• Are impacts tractable? How will effects be observed, recorded and/or measured? By whom?  
• Is experimentation the most appropriate way to evaluate this technology?  
• Have alternative evaluation procedures been explored?  
• Are experiments/observation procedures designed to test relevant questions?  
• Who has assisted in designing experiments? |
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<tr>
<th><strong>Data and Evidence</strong></th>
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| **Types of evidence** | • Have the following types of evidence been actively investigated:  
  ~quantitative and qualitative data  
  ~correlation, pattern, association  
  ~experimental data  
  ~experiential information (e.g. what can be learned from past experience with similar technologies? what are the experiences of those who use the technology?)  
  ~local, context-specific information (e.g. case-studies)  
  ~general principles |
| **Sources of evidence** | • Who has provided evidence?  
  • Has a diversity of interests been represented?  
  • From what sources have data been drawn (e.g. publications, modelling, interviews, participation)? |
| **Error and bias** | • Are conclusions biased toward Type 1 or Type 2 errors?  
  • Is this bias made explicit?  
  • Who may be harmed by this bias? Who may benefit? |
| **Use of statistics** | • Are valid conclusions drawn from statistical analysis (e.g. is the null hypothesis “accepted” or “not rejected”)?  
  • Has the statistical power of the data been calculated? (see Peterman and M’Gonigle 1992) |
| **Uncertainty** |  |
| **Technical and Methodological** | • How are technical and methodological uncertainties identified? How are they acknowledged?  
  • How do these uncertainties bear on (qualify) research results? How is this influence acknowledged?  
  • Can these uncertainties be reduced? (see discussion below) |
### “Great Uncertainty”

- Have situations of certainty, risk, uncertainty and ignorance/indeterminacy been distinguished?
- Have assumptions and limitations that contribute to great uncertainty been identified and articulated? Through what processes and venues?
- Have the effects of great uncertainty on research results been investigated and acknowledged?
- Who may benefit and who may be harmed from these uncertainties (e.g. if technology proceeds or is halted due to uncertainty)?
- Have “worst-case scenarios” been identified and avoided?
- Can these uncertainties be reduced? (see discussion below)

### Conclusions/Decisions

#### Procedural issues

- Are research and decision-making processes open to all interested and affected parties?
- What avenues for participation are available (e.g. direct vs. indirect participation)? How are effects of existing power structures addressed and compensated for?
- Are processes and results reviewed by “third parties” (peer review)? How are reviewers chosen and by whom? How are reviewers renumerated?
- How are results made available to public scrutiny (e.g. venues, language, cost)?
- Are processes iterative? Are decisions reversible?
- What incentives or disincentives are provided for assessors to fully explore impacts?
- Who pays for research?
- Who pays for harm (liability)?

#### Substantive issues

- Does the weight of evidence suggest potential for harm?
- Is there a need for technology?
- Are less harmful alternatives available?
- If the technology is needed and no alternatives are available (as determined through above processes), can adverse effects be mitigated or controlled? Who will conduct control measures? Who will be affected by control measures? Who will pay for these measures?
For all of the above questions, it is important to ask: Who is setting the research agenda? Whose interests are represented? What institutional structures favour particular ideas and interests over others? And how do these factors bear on final decisions? I contend that the series of questions in Table 4.1 provides a more robust foundation for the Precautionary Principle. The process is genuinely pre-cautionary because it articulates the types, extent and effects of uncertainties inherent to research and decision-making. Confronting uncertainty 'head-on' will help to identify previously concealed sources of hazards and thereby suggest means for avoiding those hazards. For example, under situations of irreducible uncertainty, hedging—keeping a diversity of options open—seems the most prudent strategy, one that is in fact demonstrated in many biological systems (Lauck et al. 1998). Precisely the opposite strategy was adopted for agricultural biotechnology; government and industry placed unprecedented resources and faith in the development of rDNA crops to the exclusion of other options. A related strategy when confronting uncertainty is to diversify the knowledge base from which conclusions are drawn. This would require decision-making processes that are open to broad participation and public review, processes which would, as argued above, stem further hazards derived from justifiable distrust of closed, top-down systems. As we have seen, this was a route not taken by the Canadian government. Finally, the framework in Table 4.1 aims to unearth the assumptions, values and limitations of all parties, and hence make explicit the conditional nature of all conclusions. This process encourages decisions that are appropriate to particular contexts, and thereby cautions against unqualified extrapolation to broader circumstances. Once again, such an approach was not evident in the decision-making processes of the Canadian government.
One of the main conclusions of my dissertation is that technologies such as rDNA organisms raise complex, highly uncertain issues that are essentially *trans-boundary* in scope. They cut across and challenge established disciplinary, political, institutional, and geographic lines (and in the case of rDNA organisms, genetic or species boundaries as well). As such, these technologies cannot be evaluated within borders constructed by a narrow and isolated range of interests, be it the restricted agenda of a single regulatory agency, the self-interested mandate of industry, the limited resources of community groups, or the capabilities of a single discipline—or for that matter a single researcher. Consistent with this conclusion, the framework in Table 4.1 provides a useful basis for discussion, but the details might best be resolved through the institutional changes outlined below.

*Institutional Change*

My analysis of the Canadian biotechnology regulatory system suggests a number of institutional or procedural changes that may significantly improve decision-making (many of which are incorporated into Table 4.1). For example,

• Third party interdisciplinary assessment of hazards, and a broader peer review of these assessments;

• Public access to assessment data and decision-making rationale *prior to approval*;

• Investigation and comparable funding of alternative technologies;

• More open and representative decision-making procedures that are advertised, accessible and binding.

Some of these recommendations seem relatively easy to implement. For example, the US Department of Agriculture makes risk assessment data freely available to the public without disclosing confidential business information. The same should be possible for the Canadian
government, especially given efforts to harmonise US and Canadian biotechnology regulations. However, for several reasons, other reforms may prove more challenging. First, as discussed at beginning of this chapter, the ideas, interests and institutions that support ongoing development and commercialisation of biotechnology are well entrenched. More open and participatory decision-making processes (i.e. more direct democracy) would entail a significant change of face by government—including a willingness to reconsider previous decisions and policies—as well as prompt compliance by the private sector. While the new Canadian Biotechnology Strategy makes some moves in this direction (e.g. by holding stakeholder consultations and replacing NBAC), to date, the government has not demonstrated as strong a commitment to public process as it has to the biotechnology industry. Criticism of the 1998 CBS consultations highlights a second obstacle to implementing procedural reforms: accurate representation. As discussed briefly above, increased participation does not ensure fair participation. Even if public negotiation processes such as “round tables” or “consensus conferences” were institutionalised in Canada, there is no guarantee that outcomes would be more representative of “expert” or public opinion. Indeed, the UK consensus conference on biotechnology held in 1994 and a similar conference held in Canada in 1999 (a non-government initiative) met with precisely this objection (Barns 1995; Purdue 1995; invited participants of Canadian consensus conference, confidential communication, 1999). Finally, the above procedural reforms do not address the substantive question of “precautionary science”. Broader participation alone cannot ensure more appropriate, long-range decision-making about biotechnology if there is no foundation for those decisions, i.e. an insufficient research base, and inadequate resources and infrastructure to develop such a base. Again, procedural and substantive change must be carefully integrated. While I believe the above reforms are necessary, worth refining and
pursuing, I would like to raise a few additional questions and propose a slightly different
tack.

I have focused my analysis thus far on government and industry because these parties
control risk assessment and decision-making for rDNA crops in Canada. However, we might
briefly look beyond this insulated network to an institution that has, traditionally, aimed to
enrich our knowledge of the social and natural worlds while serving the public interest:
academia. What is the role of academia in regulatory science, risk assessment and the
Precautionary Principle? Canadian biotechnology regulators have claimed to draw on
scientific literature and expertise to supplement data provided by proponents (CFIA
interviews, 1998), and Monsanto cited some published research in their HTC assessment.
Thus academic science does influence decision-making, but its role is indirect and secondary
to industry-conducted experiments. Furthermore, as I have noted elsewhere in this chapter,
research on the environmental hazards posed by rDNA crops is a relatively new and limited
field. Most available studies have been conducted by a small number of research groups in
the US, UK and Europe and have been published since the mid 1990s (that is, after
commercialisation). No research to date has encompassed the range of questions outlined in
Table 4.1. How can academia contribute to a more precautionary science? Why, for that
matter, do we not already have a precautionary science? I suggest that the answers to these
questions lie partly in the reward structures of academic institutions: There are currently
significant incentives and rewards for conducting biotechnology R&D, but relatively few for
conducting the type of long-term, interdisciplinary and team-based research required for a
precautionary science. This view is supported by several studies of academic funding and
reward structures, as described below.
A recent survey conducted by members of CSARE and SEHN aimed to examine incentives and barriers to “public interest research” and “scientific public service” in academic settings (CSARE 1998). Analysis of 136 questionnaire responses suggested that basic research in the “hard sciences” was most encouraged in universities; interdisciplinary, systems-oriented, and team-based research received some encouragement; and “far less support goes to participatory research, long-term research, applied research and extension or community outreach”. Incentives and barriers to particular types of research were closely tied to criteria for promotion and tenure. Respondents indicated that the number of sole- or senior-authored papers in refereed journals and amount of grants or other financial support were the most important criteria for advancement, whereas “applied research in the public interest” or “research advancing the societal purposes of the institution” were least important. While many respondents did cite institutional incentives for public interest research, about “one quarter reported experiencing threats of sanction or withholding of benefits as a means to dissuade them or a colleague, from engaging in public interest activities”. The CSARE/SEHN survey was designed as a targeted and exploratory survey, and was meant to identify problems and trends for further research, rather than provide a representative sample of all academic scientists. Nevertheless, results indicate that, relative to discipline-based research that produces a high volume of publications and draws large grants, the type of research required for precautionary science is neither encouraged nor well rewarded in many academic institutions. This conclusion is supported by a similar study released the same year. Buttel and Goldberger (1998) examined funding sources and research activities among scientists in US land-grant universities, with particular emphasis on the relationship between biotechnology research and the public service mandate of these institutions. Over 600 responses to a mail-out questionnaire revealed that scientists perceive quantity of “scholarly”
publications and receipt of grants and contracts as the most important criteria for reappointment, promotion and tenure, while “responsiveness to needs of farmers and other clientele” was among the least important criteria. The survey also suggested that “social issues in agriculture”, such as regulatory issues (“e.g. assessment of intentional introduction of genetically engineered organisms”), preserving the family farm and addressing farm-related health issues were not “frequent” components of scientists’ research. Of the scientists responding to the Buttel survey, approximately 40% were conducting research related to biotechnology and a similar number reported receipt of some private sector funding.

Thus, reward structures for particular types of research appear more closely tied to individual and institutional sources of funding and quantity of publications, than to public service. The influence of private sector funding on university-based biotechnology research, and the role of university-corporate ties in establishing and maintaining the biotechnology industry have been well documented (Busch et al. 1991; Kenney 1986; Krimsky 1991). In an effort to quantify this trend, Krimsky et al. (1991; 1996) have undertaken several analyses of financial relationships between academic scientists and the private sector. One such study measured the “rate of commercial penetration into select university departments” by calculating the number of faculty members who had dual affiliations with private biotechnology firms.11 The authors concluded that “such ties are widespread”, and in fact “[f]aculty with university and industry affiliations in the biological sciences are becoming the rule rather than the exception in the United States and Canada” (Krimsky et al. 1991). The study further demonstrated that almost 50% of identified dual-affiliated biotechnology scientists were listed as peer reviewers for National Science Foundation grants, and over 35% of biologists and biomedical scientists who were members of the National Academy of Sciences also held formal ties to biotechnology companies. A subsequent study examined
the financial interests of authors in 14 leading journals of cell and molecular biology and medicine (Krimsky et al. 1996). Of the almost 800 articles surveyed, 34% had at least one author with a financial interest in the research, yet none of these affiliations were publicly disclosed.12

While causal links are difficult to establish, taken together the above studies suggest, at best, a relative lack of encouragement and incentives within academic institutions for the type of research required to fully address the hazards of rDNA crops. At worst, significant financial ties between biotechnology industries and academic science departments, and the link between funding, rate of publication, and promotion and tenure criteria indicate substantial disincentives to conducting research that may be critical of, or detrimental to furthering biotechnology R&D.

The data and analysis presented in this dissertation clearly indicate that responsibility for the status of agricultural biotechnology in Canada rests with government and industry. Current economic dependence on international acceptance of rDNA crops, underdeveloped research programs to investigate potential hazards or viable alternatives, and completely inadequate risk assessment and decision-making practices, are functions of collaborative, often exclusive, government and industry interests over the past twenty years. Primary responsibility for amending this situation must also rest with these parties. However, I suggest that perhaps a more tangible, effective, and overall more empowering solution may be to develop a strong precautionary science within academia, and between academic and public communities. A recent report by the Kellogg Commission (NASULGC 1999) recognised that the limited public service mandate and single-discipline focus of land-grant and other academic institutions, together with a decrease in public funding and concomitant rise in private sector influence, is proving inadequate to address the “contemporary
multidisciplinary problems of the real world". The report advocates a more “engaged institution”, one that is actively involved with local communities, and thus more responsive to community problems and needs. Toward this end, the Commission recommends redesigning teaching, research and extension functions to encourage “joint academic-community definitions of problems, solutions and definitions of success” and greater commitment to, and rewards for interdisciplinary research and teaching. I concur with these recommendations. Active support within academic institutions for long-term, multi-component, team-based research and public service could contribute significantly to decision-making on such complex issues as rDNA crops and other similar technologies. I will close by suggesting some implications of these conclusions for the development and future application of the Precautionary Principle.

Implications for the Precautionary Principle

In Chapter 1, I reviewed several ambiguities and inconsistencies in current interpretations of the Precautionary Principle. It was not the purpose of this dissertation to resolve these issues; several other researchers have taken this approach (Gullet in progress; Tickner in progress). Rather, I have addressed the problem of implementing the Precautionary Principle from the other direction, identifying institutional barriers to the general, core ideas of precaution. Nonetheless, I do recognise that inconsistent and ambiguous definitions of a principle that aims for international legal status present serious barriers to its acceptance and application. Continued research to clarify procedural and substantive aspects of the Precautionary Principle is therefore essential.

To contribute to this endeavour, I will briefly discuss two additional shortcomings of current interpretations of precaution that have been highlighted by my study of Canadian
biotechnology policies. With few exceptions, these aspects of the Precautionary Principle have not been well articulated, and thus merit further consideration.

(1) Variable constructions of “precaution”. If concepts of “science”, “risk” and “uncertainty” are variably shaped by social and political factors, so too are concepts of “precaution”. As we have seen in the Canadian case study, simply claiming that regulations are “precautionary” offers no guarantee that effects have been thoroughly investigated and potential hazards avoided. Recent studies of UK and EU regulations on “genetically modified organisms” have well-illustrated that “precautionary” measures can be variably interpreted according to different interests and goals (see Levidow 1996; Levidow et al. 1996; von Schomberg 1998). Similarly, mere recognition of “uncertainty”, as prescribed in current statements of the Precautionary Principle, not only fails to confront the depth of uncertainty implied by indeterminate situations, but fails to acknowledge that uncertainty can be a powerful rhetorical tool or delay tactic to support business-as-usual practices (Hunt 1994; Proctor 1994).

These points suggest an urgent need to examine closely the social and political factors that shape definitions and declarations of precaution, particularly as the Precautionary Principle becomes integrated into international and national policies. To date, advocates of precautionary approaches, have, on whole, failed to step back and ask what it means to call an activity “scientific”, how expertise and scientific knowledge are legitimised, how social and political commitments shape definitions of risk and “good science”, and how other forms of knowledge and experience are excluded. In other words, returning to the four concepts of risk outlined in Chapter 1, precautionary (as well as technical and economic) concepts of risk, would benefit by incorporating the perspective and methods of social concepts: attempts to
clarify and implement key elements of the Precautionary Principle must include critical examination of the way science and risk are socially constructed, and how this construction may confound, impede or oppose precautionary measures.

(2) *Shifting the burden of proof.* Clearly, shifting the burden of proof to proponents to demonstrate the safety of proposed technologies—a central tenet of the Precautionary Principle—cannot ensure the overall goal of protecting “ecological space” (O’Riordan and Jordan 1995). Given that the content and representation of scientific inquiries are critically shaped by social and political circumstance, the “burden” of proof may be easily transformed into a significant *advantage,* particularly if risk assessment and decision-making are confidential and exclusive negotiations among like interests. While shifting the burden of proof may duly re-distribute responsibility and liability for harm, the prior commitments of would-be assessors, and hence their active construction of particular risk scenarios give cause to re-think this otherwise “precautionary” move (Wynne 1992b). This is a crucial point for advocates of the Precautionary Principle. Assignment of the burden of proof must carefully consider value assumptions of all parties, as well as existing power structures that may influence the articulation of these values. Rather than “shifting” the burden of proof, perhaps *sharing* this burden would more evenly distribute power, participation and responsibility, while allowing the necessary expression of diverse values, biases and interests. While such a move presents significant procedural challenges as outlined above, it nonetheless offers an initial direction for change, namely a more open, active and engaged role for all parties committed to protection of health and the environment.
Endnotes: Chapter 4

1. We need not accept Gieryn’s hypothesis as the only explanation of scientific authority, in order to appreciate that boundaries around “science” do indeed fluctuate over time and place, and that such boundaries wield a good deal of power. Gieryn takes a particularly strong position: “Science’ is a cultural space: it has no essential or universal qualities. Rather, its characteristics are selectively and inconsistently attributed as boundaries between ‘scientific’ space and other spaces are rhetorically constructed” (Gieryn 1999). A weaker version would hold that there are some general but consistent characteristics of scientific inquiry that account for its continued authority but that the boundaries around these characteristics are subject to social and political influences.

2. Three varieties of atrazine tolerant B. napus were grown in Ontario in late 1980s. The trait was transferred from B. rapa through breeding (B. rapa is naturally resistant). Atrazine lines had significant yield reductions and were not commercially viable in Western Canada. The varieties were largely phased out in 1990s due to low quality, environmental effects of atrazine and registration of new herbicides (Hall et al. 1996; G. Coy, personal communication, 1999).

3. Such as organic, biodynamic and/or agroecological approaches.

4. Current to 1997. The exception is one variety of HT flax which is owned by University of Saskatchewan (James 1997).

5. Not-for-profit non-government organisations based in the US that aim to blend academic research with community-based knowledge, needs and goals.

6. There are, of course differences of opinion and focus within these fields. My aim is to show that, in general, agroecology and conservation biology move some distance toward a “precautionary science”.

7. This research is currently underway by A. Griffiths and K. Barrett.

8. Round tables were first established by the Canadian Task Force on Environment and Economy and have been held at national, provincial and local levels. They are essentially multi-stakeholder consultations that strive for consensus-based decisions on environmental issues. Consensus conferences were first developed in Denmark and have since been widely adopted as a decision-making tool in Europe. The conferences are structured similarly to a jury process where a ‘citizen’s panel’ formulates and directs questions to an ‘expert’ panel on a particular issue. The citizen’s panel is then charged with drafting a consensus report and recommendations.

9. This based on a literature search of Agricola and CAB databases and compilation of articles on the environmental risks of rDNA crops.

10. Public interest research and scientific public service were defined in the questionnaire as follows: “Public interest research aims at developing knowledge or technologies that are “public goods”. The direct and immediate beneficiaries are society as a whole, or specific “publics” too large, diffuse or poor to organize or advocate for research on their own behalf. Public goods are freely available (not proprietary or patented) and developed to advance the common good (not identifiable private interests). “Public good” information or technologies are often developed with collaboration or advice from members of the public. Environmental protection, community farming systems and food security are areas of substantial public interest research.”

“We define scientific public service much as lawyers define ‘pro bono publico’. That is, scientific public service is research or other scientific activity for the good of the public or the welfare of the whole, usually at the request of the public. Scientific public service is a scientist offering his or her scientific skills to the community or to groups seeking to advance the public good to solve problems within his or her expertise.”

The questionnaire used participatory and community-based research, long-term and systems-oriented studies, and team-based and interdisciplinary research as indicators of public interest research.

11. Data was collected for the period between 1985 and 1988 at 10 “elite” universities in the US.
12. The study considered academic scientists in Massachusetts cited as first or last author on papers published in 1992. Financial interest was defined as meeting one of the following criteria: “a member of a scientific advisory board of a company that develops products related to the scientist’s expertise”; “an inventor on a patent or patent application for a product or process closely related to the scientist’s publication under review”; “serves as an officer, director, or major shareholder in a for-profit corporation involved in commercial activities related to the scientist’s field of expertise.”
REFERENCES

Works Cited


CSARE, Consortium for Sustainable Agriculture Research and Education. (1998). “Incentives and Barriers to Public Interest Research and Scientific Public Service.” CSARE, Madison WI.


Hoffmann, T., Golz, C., and Schieder, O. (1994). “Foreign DNA sequences are received by a wild-type strain of Aspergillus niger after co-culture with transgenic higher plants.” Current Genetics, 27, 70-76.


WCCRRC, Western Canada Canola and Rapeseed Recommending Committee. (1994). “Minutes of WCCRRC meeting. February 20th.” , Calgary AB.

WCCRRC, Western Canada Canola and Rapeseed Recommending Committee. (1998). “Procedures of the WCCRRC Inc. for the evaluation and recommendation for registration of canola/rapeseed candidate cultivars in western Canada.”


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Interviews Cited


Personal Communication


