

The Biopolitics of Genetically Modified Organisms in Canada

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In recent years we have witnessed the rise of considerable resistance to genetically modified (GM) food and crops around the world. This has led to a moratorium on the planting of new GM crops in Europe, and regimes for the mandatory labelling of GM foods in more than 30 countries, including Japan and Australia. By contrast, the Canadian regulatory system has approved 51 "plants with novel traits" and "novel foods" since 1995, almost all of which are GM, and any demands to require labelling of these products have been resisted by the federal government. Working with theoretical concepts developed by Michel Foucault, this essay examines this situation in Canada. The author traces the way in which facts and values have together given shape to a *biopolitical* struggle between those scientists who would frame genetically modified organisms (GMOs) as a manageable risk and those who have adopted a more precautionary framing. Three specific terms used in Canadian "science-based" regulation – "novelty," "familiarity" and "substantial equivalence" – can be seen to represent ambiguous compromises in these ongoing struggles at the international level. In Canada these concepts have been mobilized to narrow the horizon of what can be expected to be risky about genetic engineering, allowing swift approval of many GM crops. High-level scientific critiques of this system, however, buoyed by public concern, point towards the need for a more open-ended regulatory process in Canada, one that would acknowledge that decision making in this field is inevitably both technical and political.

Au cours des dernières années, nous avons observé une résistance de plus en plus importante aux aliments et cultures génétiquement modifiés un peu partout dans le monde. Ceci a entraîné l'imposition d'un moratoire sur la plantation de nouvelles cultures comprenant des organismes génétiquement modifiés en Europe et de régimes sur l'étiquetage obligatoire d'aliments génétiquement modifiés dans plus de 30 pays, y compris le Japon et l'Australie. En comparaison, le système de réglementation canadien a approuvé 51 « végétaux à caractères nouveaux » et « nouveaux aliments » depuis 1995 – la plupart étant génétiquement modifiés – et toutes les demandes concernant l'étiquetage de ces produits ont été résistées par le gouvernement fédéral. S'inspirant de concepts théoriques formulés par Michel Foucault, le présent article examine la situation au Canada. L'auteur retrace comment les données et les valeurs ont entraîné des conflits biopolitiques entre les scientifiques qui jugent que les organismes génétiquement modifiés posent des risques contrôlables et ceux qui insistent sur une plus grande prudence. Trois expressions précises utilisées au Canada dans la réglementation « à vocation scientifique » – « nouveauté », « familiarité » et « équivalence essentielle » – peuvent

être perçues comme représentant des compromis ambigus dans le cadre de ces conflits continus à l'échelle internationale. Au Canada, ces concepts ont été mobilisés pour mieux prévoir ce qui pourrait entraîner des risques dans le domaine du génie génétique, favorisant une approbation rapide de plusieurs cultures génétiquement modifiées. Toutefois, des critiques de ce système à l'échelon scientifique supérieur – alimentées par les inquiétudes du public – semblent indiquer qu'on a besoin d'un processus de réglementation moins limité au Canada, ce processus tenant compte du fait que la prise de décisions en la matière comprend inévitablement des composantes techniques et politiques.

Introduction

For millennia, man [*sic*] remained what he was for Aristotle: a living animal with the additional capacity for a political existence; modern man is an animal whose politics place his existence as a living being in question. (Foucault, *The History of Sexuality* 143)

The advent in the mid-1990s of commercial production of the first generation of genetically engineered crops, as well as the Canadian government's approval of food ingredients derived from these crops, has prompted the highest level of public debate since these techniques were first developed in the early 1970s about how and whether the products of genetic engineering should be applied. Proponents argue that genetic engineering harbours enormous potential benefits to farming and the food supply around the world (Avery). But critics see genetically modified organisms (GMOs) as a troubling development. Concerns range from questions about food and environmental safety, to moral concerns about playing God, to criticism of the way in which genetic engineering, along with new interpretations of intellectual property law, reinforce the trend towards oligopolies in the global seed and agri-chemical industries (Kloppenburg; Rifkin).

This debate centres around the perceived uniqueness of GMOs; however, at the level of public policy, the Canadian government has taken few steps to act on many of the concerns raised. The official view in government is that transgenic organisms are not really all that different from non-GM food and crops. This fact, it is argued, is a purely scientific assessment, backed by international expert consultations, and it should set the context for any policies dealing with GMOs.

An important example of this dynamic is the ongoing debate in Canada over the labelling of GM foods. Polls consistently show that more than 90% of Canadians support the mandatory labelling of genetically engineered foods (Environics).¹ The argument for labelling is strong, based on the liberal tenet that consumers have a right to information on products in order to make choices. The

issue has come up for a vote on several occasions in Canada's parliament, most recently brought forward by members of the governing Liberal party.² Yet the federal Cabinet's position is that requiring such labelling is simply unacceptable. This is not based on a direct challenge to the idea of consumer choice. It is based on the view that there is no scientifically justifiable reason for singling out GMOs from their non-modified counterparts. In the case of labelling policy, then, what many perceive to be an important *political* issue is ostensibly decided on the basis of the *scientific* judgement that GMOs and non-GMOs should be "treated the same" (Health Canada).

In terms of environmental safety and consumer health, the two areas of public concern where the government has taken an active regulatory role, we can see a similar response. In a regulatory system that officially subjects GMOs to a "comprehensive scientific review ... that emphasizes human, animal, and environmental safety" (Vanclief) the uniqueness of these organisms is downplayed by treating them as part of larger classes of "plants with novel traits" (PNTs) and "novel foods," which are evaluated for their "familiarity" and "substantial equivalence" to conventional foods and crops (Plant Biosafety Office, *Regulatory Directive Dir 94-08*).

What is happening here? What does the case of food biotechnology reveal about the relationship between science and politics in Canada? In this essay I argue that we are witnessing a public debate rooted in divergent value framings being dealt with in policy as a question to be settled by *truth*. At first glance, it appears as if science is being drawn upon to silence the concerns of the public. Rather than silence the debate, however, I believe that the turn to science produces a different kind of political struggle – a *discursive* struggle that fits within what Foucault terms *biopolitics* (*The History of Sexuality* 141).³ Biopolitics refers to the particularly modern relations of power, rooted in specific expert truth-claims and material practices, that enable the regulation and efficient production of "life" by scientists, governments and industries, as well as the forms of resistance that emerge in this context. In this work I draw on the genealogical method Foucault brought to the study of biopolitics. Genealogy involves an examination of truth claims and theories that claim objectivity. What is their source and what are the effects of the striving for autonomy and objectivity; how is resistance enabled in this particular biopolitical field?

The arrival of GMOs involves a variety of material and discursive practices that normalize the manipulation of organisms at the genetic level. The regulatory practices for novel foods and PNTs, as undertaken by the Canadian government, are important aspects of this normalization in Canada. The concepts that anchor this system, particularly novelty, familiarity and substantial equivalence, can be seen as critical nodal points within the biopolitics of GMOs. These are discursive objects of "truth" as well as practices of power. As with other examples of biopolitics, however, I argue here that there are cracks in the foundational discourses and practices

of genetic engineering. These are places where truth claims can be seen to “over-extend” their domains by “claiming universality” and within these cracks resistance has taken root (Foucault, *Power/Knowledge* 85). The growing strength of these “discourses of resistance” are appropriate, I believe, for they point the way towards more democratic approaches for dealing with the inherently political issue of genetic engineering.

There is a small but growing Canadian literature that uses Foucault's methods to examine environmental politics (Darier; Richardson, Sherman and Gismondi), but little analysis of biotechnology has been undertaken drawing on this approach. Wright's comparative work on the American and British approaches to regulating genetic engineering up to the early 1980s offers a seminal account of the early discourses in the field of biotechnology regulation (Wright), but there is a need to document the considerable shifts that have taken place since then. I aim to help fill this gap by presenting a small part of the story of regulation in Canada. While some important works describe and critique the Canadian experience with biotechnology (Abergel; Barrett et al.; Boyens; Doern; Kneen), none undertake a Foucauldian analysis.

The quotation from Foucault's *History of Sexuality*, with which I preface this piece, suggests the thrust of my examination. Foucault did not see himself as an environmentalist, so this should not be read as a statement on the dangers inherent in modern technologies. Rather, the “existence” Foucault suggests modernity places “in question” is the view we have of ourselves as living and as social beings. Today this is “politics” in the sense that the ways we come to understand life are increasingly constituted through scientific truths. And these truths are more than “facts”; they are value-laden in their framing. In the case of the biopolitics of genetic engineering, the regulatory “facts” have mainly been framed by bodies firmly committed to an industrial reshaping of the living world and the ever-expanding management practices this assumes are possible.

Theorizing Science and Politics

In this essay I work with the concepts of “discourses” and “biopower/biopolitics” as developed by Foucault. A discourse is a system of interwoven truth claims embedded in social relations and material practices. Truth claims entail, but are not reducible to, interpretations (Litfin, “Framing Science” 252). Discourses can only be understood within their historical contexts, and there are often radical ruptures between one era and the next. For example, in *The Order of Things* Foucault shows how during the Classical Age knowledge of plants and animals was based on constructions of categories around “resemblance” such as Linnaeus's classification scheme. Shortly thereafter a very different discourse for organizing life emerged based on the hidden dynamic mechanisms of life now called “biology” (Darier 11).

For Foucault, discourses are politically significant as a form of power (*power/knowledge*), because they shape the horizon of what makes sense and what does not. This is to say that discourses have both a productive as well as a disciplinary character. Central to the productive character of discourses are the innumerable points of resistance that exist within those discourses and that interact with them in unpredictable ways. A key example for Foucault is the way in which the appearance within nineteenth-century psychiatry, jurisprudence and literature of a whole series of discourses on homosexuality made possible a strong advance of disciplinary social controls in this area of perversity; but it also made possible the formation of a *reverse discourse*: "Homosexuality began to speak on its own behalf, to demand that its legitimacy or naturality be acknowledged, often in the same vocabulary, using the same categories by which it was medically disqualified" (*The History of Sexuality* 101).

In his later works Foucault emphasizes the social networks necessary for the production, defence and performance of discourses. In the case of the human sciences, the "will to knowledge" was spurred on by the perceived need to foster and manage a growing population for the demands of industrial capitalism, as well as by the emergence of liberalism with its preference for government "at a distance" rather than overt control by the state (Rose and Miller 175). Foucault is careful not to assume that the way discourses are shaped is readily reducible to class relations (as many Marxists suggest), national interests (as Realists might argue), or the instrumental rationality of the state (as Adorno or Habermas contend). This is because power, he argues, is not something that is wielded by particular groups in society. As the example of homosexuality illustrates, power is relational. It can be thought of as a *web* or *field*, which is sustained by the participants within it. As a political terrain it is in a constant state of flux.

Litfin illustrates the way an understanding of discursive power is applicable to controversies involving the interface between policy and the natural sciences (*Ozone Discourses*). In such controversies scientific knowledge is not simply a body of concrete and objective facts. Accepted knowledge is deeply implicated in questions of framing and interpretation, and these are shaped in relation to perceived interests. This is not to say that scientific knowledge is not empirically based, nor that it is a mere product of power. In most cases what is understood as "fact" by scientists has withstood the tests of self-consistency, replicability and peer-review, which are key to the validation of scientific knowledge. Yet even when two sides in a scientific controversy accept the same empirical data, differences in how they frame those data can be crucial to determining what they are understood to mean. Such differences can be the result of a number of possible factors, including, but not limited to, extra-scientific political or economic interests. This includes differences in rules of acceptable evidence within scientific disciplinary cultures (an intra-scientific

bias). It also includes the possibility of fundamentally different normative perspectives regarding, for example, the consequences of making errors in judgement. Scientific discourses are thus both empirical and irrevocably political.

Biopower/biopolitics refers to the emergence in the eighteenth and nineteenth centuries of new forms of knowledge/power concerned with fostering and administering life (including "biology"). Biopower reconstituted sovereign power, which Foucault characterizes as power over death, into a new power over life focussed on the shaping of the individual and the care of populations (Rutherford, "Entry" 38). In terms of social relations, biopolitics is bound up with the aspirations of industrial capital: "The investment of the body, its valorization, and the distributive management of its forces were at the time indispensable" (Foucault, *The History of Sexuality* 141).

Foucault refers to biopolitics as the "entry of life into history," that is, the arrival of "life" as a distinct object of concern with a wide range of accompanying knowledges and practices. Biopower involves expertise, administration and "practices of the self" to further the production and supervision of life across "two poles of development linked together by a whole intermediary cluster of relations" (Foucault, *The History of Sexuality* 140). On the one hand, the disciplines of medicine and psychiatry, among others, focussed on shaping the body of the individual – the production of a particular kind of human subject – to increase its utility and manageability. On the other hand, the emergence of studies of population, agricultural productivity, living conditions and biology focussed on the supervision of what Foucault calls the *species* body. Sex and reproduction sit at the pivot of the biopower axis.

Furthering this analytical thread, we can use the term *ecopower* to encapsulate the extension of biopower to the living world as a whole. To describe this phenomenon, Rutherford uses the term *ecopolitics* (Foucault's concept of *biopower*) while Luke uses *geopower* (57). *Ecopower* is also driven by the joint interests of capital (to colonize and commodify) and the state (to manage for the sake of the perceived public good). Through the practices of "sustainable" forest management, for example, *ecopower* involves a recasting of the discourses of nature into biological, chemical and physical terms that are thought to be fully amenable to management, intervention and increases in productivity.

It is important to note that Foucault explicitly dismisses any suggestion that biopower results in the total integration of all aspects of life into the techniques that administer it. Indeed, "life constantly escapes them" (Foucault, *The History of Sexuality* 143). This enables resistance and the articulation of "reverse discourses" within the scope of biopolitics. In the context of *ecopower*, this is exemplified by the way many environmentalists use the scientific tools designed to understand the dynamics of the natural world in order to critique forms of industrial intervention into nature. This results in questions like "How sustainable are these forest practices,

really?" While these critical voices are enabled within ecopower, however, they can also be constrained by its implicit acceptance that the "management" of all living things is both possible and desirable. This can be a frustrating realization for environmentalists who use the tools of science to criticize, but whose political concerns are not fully addressed by the possibility of simply more "scientific" management of nature. This point will be returned to as I explore the biopolitics of genetic engineering.

The Biopolitics of the *Gene*

Canadian government policy documents define *biotechnology* as "the applied use of living organisms, or their parts, to produce new products" (Agriculture Canada 1). In the case of plant biotechnology, considerable developments took place in the twentieth century. Whereas historically plant breeders worked with the natural variability of traits within a species or among closely related species to develop new plant varieties, in the 1950s this was supplemented by the techniques of mutagenesis. Mutagenesis involves subjecting plant cells to radiation or chemicals to encourage random genetic mutations that might lead to beneficial plant traits. In 1973, the first successful genetic engineering (or recombinant DNA) experiments with micro-organisms ushered in a new era of possibility. Since the 1980s, genetic engineering has essentially meant that species is no longer a barrier to crop developers. In principle, a strand of DNA can be extracted from the cells of any living organism and be inserted into the genome of a plant cell, from which a new line of transgenic plants can be propagated.

In terms of crop development, biotechnology includes conventional breeding, mutagenesis and genetic engineering. This term did not emerge in widespread usage, however, until after the more controversial techniques of genetic engineering became possible. The concept of biotechnology itself is therefore an illustration of the normalization process of biopolitics in the area of genetics.

This new field of biopower involves a constellation of material and discursive practices that have come to recast biology in engineering terms. At the one pole of the new biopower axis we find the production of *enhanced* traits within individual organisms (and their progeny) through *modifications* to their genetic *blueprints*. At the other pole we see the emergence of new approaches to the *assessment* and *management* of the *risks* of recombinant organisms to consumers, agriculture and the environment. Foucault saw the goal of producing docile, useful bodies through a technique of overlapping objectification and subjectification as critical to making the human sciences historically possible (Dreyfus and Rabinow 160). Today the goal of creating a docile, productive nature, and consumers as condoning subjects of GM food, has enabled particular discourses extolling the safety and

benefits of transgenic organisms to flourish. Whereas biopower has sex at its axis, this is now supplemented with the non-sexual, laboratory-based recombination of genes.

All these discursive and material practices are centred around the idea of bringing the gene into the realm over which humans are thought to have predictable control and administration. But what are *genes*?

Since the 1860s Mendelian genetics has recognized that many phenotypic traits are related to functional units of heredity. These were called genes, though for a long time little was understood about what these units were composed of or how they worked and interacted. By the 1950s the molecular gene made its entry into history. With the discovery that many aspects of heredity could be linked to the deoxyribonucleic acid (DNA) found in each cell, the gene became defined as "a specific sequence of nucleotide bases, whose sequences carry the information required for constructing proteins, which provide the structural components of cells and tissues as well as enzymes for essential biochemical reactions" (Campbell 308). Based in such scientific definitions, the gene has come to be seen as the specific segment of the genetic code or blueprint, written in DNA, which carries the information necessary for a given trait.

Reflecting on this, a number of biologists and historians of biology have noted that the idea of the gene as a code or blueprint is a very limited and reductionist construction of organismic life. For example, a particular strand of DNA is not necessarily the sole determinant of a trait. In some cases, the position of the gene on a chromosome can affect the phenotypic outcome. In other cases the same gene does very different things in different organisms. A single gene can also be responsible for more than one trait. These are known as *pleiotropic* effects (Holdrege 51).

The notion that DNA can actually be thought of as a functional code is also highly problematic. Kay shows how efforts by scientists using computer analyses, information theory, linguistics and cryptanalysis to break the genetic code in the 1950s yielded no results. This is because the genetic code is not a code at all:

Rather, [the genetic code] is a powerful metaphor for the correlation between nucleic and amino acids.... Despite the acknowledged pitfalls of applying information theory to biology ... these information and scriptural representations of heredity set root and proliferated. They did so mainly as a result of their transdisciplinary and cultural resonances and because of their efficacy as models and analogies in the process of biological meaning making. (Kay 11)

The resonances of the genetic code to which Kay refers were a combination of the centuries-old theistic discourse of the "book of life," which many scientists still see themselves as engaged in deciphering, and the more immediate historical context in the early 1950s of the nexus between genetics research, military funding and the

emerging computer age. This combination fostered a command-and-control view of genetics (Kay 12).

This discussion is not meant to suggest that genes are not real. In fact, it is important to recognize the efficacy of the genetic code metaphor for many of the experiments that work within its scope. The point here is to understand that the construction and deployment of the gene as a scientific problem of truth is also a practice of power. Since the 1950s, what Keller terms "gene talk" has widely circulated the view of the gene as an independent, manipulable, transferable molecular entity at the root of all (or most) organismic traits (Keller 143).⁴ When coupled with the commercial drive that has come to dominate the biotechnology industry, this linear discourse has become a key rhetorical force in the normalization of genetic engineering (Keller 143).

To understand this normalization of GMOs in the Canadian context better, and the particular role of regulation, it is important first to trace the discursive content of the genetic engineering controversy from the 1970s to the early 1990s.

Defining the Biotechnology Problem

The first key discursive moment in biotechnology regulation came in the early 1970s when genetic engineering was a research science based in American universities. At that time, the scientists working in this field managed to channel considerable public controversy over genetic engineering, encompassing social, health, economic, security and environmental concerns into a much narrower debate about the *hazards* of genetic engineering research (Wright). Since the early recombinant DNA experiments were targeted at micro-organisms, the hazards being discussed involved the possibility of unwittingly introducing modified pathogens to the environment. Wright argues that the move to focus on hazards was accepted by a skeptical public because the scientists involved appeared to exhibit a healthy degree of caution towards the new engineering techniques. This included a short-lived, self-imposed moratorium.

Having defined the problem as an issue of laboratory hazards, the first generation of genetic engineers proposed and brought into place *guidelines* primarily designed to *execute safely* and *contain* genetic engineering research.⁵ Aside from its focus on hazards, this initial effort at regulation is significant for three reasons. First, it established the dominance of a technical discourse – one that excluded broader social considerations about the implications of the science – in defining the genetic engineering problem. Second, in North America at least, it placed the genetic engineering research community in the driver's seat in terms of defining and finding solutions to the genetic engineering problem. Third, it allowed the research to continue, as long as the products remained contained in the laboratory.

A second key discursive moment in the politics of biotechnology came in the early 1980s in the United States. At that time, a variety of factors came together to displace the discourse of genetically modified organisms as an inherent hazard by a *manageable risk* discourse. A decade of experience with genetically modified micro-organisms had been gained, as well as several years with modified plants, and many of the molecular biologists working in this field were becoming convinced that the dangers of genetically modified organisms were not as significant as had first been imagined. Mobilizing “gene talk” – the view that specific DNA sequences can be associated with specific traits, and only those traits – they argued that rDNA techniques provide for far more precise, and thus predictable, changes in an organism than any other technique (Krimsky 143).

Organizing genetic engineering in terms of a discourse of risk rather than hazard introduced a number of new dimensions to the biopolitics of GMOs. First, the overall risk/benefit calculation shifted. The burden of proof was placed on critics of the technology to prove its dangers, rather than on proponents to prove its innocuity and benefits. Second, the risk framing assumed there was sufficient baseline data and scientific understanding to characterize and calculate the real risks of a new product. This can result in an emphasis being placed on known variables rather than those that are unknown or uncertain. Third, ongoing discussions of GMO risks could be framed in terms of their manageability rather than their avoidance, because the practice of risk assessment was seen as the precursor to risk *management*. Fourth, within the risk discourse, even unanticipated hazards were implicitly considered manageable, should they be missed beforehand but emerge at a future time. Finally, the risk framing implied that risks and benefits of GMOs could and would be fairly traded and that no distinction need be made between benefits and risks to the producer of the technology and those that befall the consumer.⁶

The regulatory adoption of this manageable risk discourse in the United States was made possible for several reasons. Many of the scientists with genetic engineering expertise had become employed by the emerging American biotechnology industry by the late 1970s, and they had set their sights on commercialization rather than just laboratory research. Across North America politicians were thinking of genetic engineering as a tool for gaining a competitive advantage in foreign agricultural and pharmaceutical markets; in the United States in particular, the Reagan administration was strongly anti-regulatory. This resulted in “deliberate release” policies, predicated on the manageability of GMO risks, which allowed for movement of GMOs out of the lab and into the field (Wright 337-382).

The adoption of the manageable risk discourse was important because genetic engineers were not actually able to pinpoint where in the host's DNA an introduced genetic construct had taken hold. (This is still true in most cases today.) Rather than focus on the possibility of unintentional, but unknowable, effects resulting from

transgenesis, most molecular biologists chose to view the lack of major problems as sufficient indication that transgenic organisms, when viable, were truly the sum of their parts and nothing more.

When it came to the environmental release of genetically modified organisms, however, molecular biologists were not the only scientists to speak with authority. Krimsky documents an important “paradigm conflict” between ecologists and molecular biologists in North America throughout the 1980s and into the 1990s on the subject of genetic engineering risks (133-151). Many ecologists argued that there was no simple framework for predicting the effects of genetically engineered organisms. For example, an influential 1989 report by seven scientists for the Ecological Society of America cited cases of secondary phenotypic effects resulting from a single genetic alteration. Some of these effects were expressed only in certain environments (Tiedje). These scientists were part of shaping the early iterations of a reverse discourse which, by the 1990s, would be centred around the notion of *precaution*.

I term this the *precautionary* framing because the issue of GMOs and their possible effects has become central to the increase in calls for applying the *precautionary principle* in environmental and health policies. This policy principle has its origins in the German *vorsorgeprinzip*, which expresses the belief that society should seek to avoid environmental problems by careful “forward-looking” planning and blocking the flow of potentially harmful activities (Jordan and O’Riordan 4). Over the past 10 years, the precautionary principle has found its way into numerous international environmental agreements, including the 1992 Rio Declaration.

Enabled by scientific uncertainty – the Achilles heel of science-based regulation – the precautionary framing rejects the assumption that the potential risks of genetic engineering can be assumed to be insignificant and/or manageable. Instead, its proponents argue – on scientific grounds, and within the broader risk framing – against the release of GMOs until uncertainties are better understood and accounted for. Still, it is notable that within the networks that deployed precaution to counter the release of GMOs in the late 1980s there was a wide range of underlying positions on genetic engineering. These included those who were against genetic engineering on moral or religious grounds but who employed the authoritative language of science to back up their position. There were also many ecologists who worked to characterize and study the nature of the specific risks of genetically engineered organisms. In the case of modified crops, these risks include the possibility of increased weediness of GM crops, of gene flow to relatives of modified crops and effects to overall crop-plant genetic diversity (Rissler and Mellon). These scientists argued that although some possible negative effects were foreseeable, the longer-term environmental implications were not. This emphasis upon long-term uncertainties can best be seen as a value judgement based on ecologists’ past experience with other technologies

(including hazardous chemicals). It was clearly not based on experimental evidence regarding GMOs, since there was no such long-term research to date. A key regulatory fault line in the biopolitical struggles over GMOs during this period was between those policy makers and scientists directly involved in developing the regulatory systems for GMOs in the United States and those in European countries. This difference has been widely characterized as being about "product-based" versus "process-based" regulation of GMOs (Jasanoff; Dunlop), although it can be seen to mirror the disciplinary based struggle between molecular biologists and ecologists.

The product-based approach, which evolved in the United States in the 1980s, was strongly influenced by the participation of molecular biologists and the reductionist discourse that framed GMOs as manageable risks. Translated into regulatory policy, this framing meant that "all organisms carry equivalent safety considerations," so the focus would be on the end use of the product and not on how it was developed (Dunlop 150). In contrast to the American regulatory system of the late 1980s, European process-based regulation, formalized in the 1990 *EC Regulatory Directive 90/220 on the Deliberate Release of GMOs*, was strongly influenced by reports that suggested genetic engineering carried "special risks" not easily predictable (Dunlop 152).⁷ As a result, those plants that were the result of genetic engineering were subjected to a significantly higher degree of regulatory oversight than non-engineered organisms.

The international debates over how to define the GMO problem came to a head in various efforts, many of which continue to this day, to develop an international scientific consensus on these issues. The first such talks were initiated in 1983 when a Group of National Experts (GNE) on Safety in Biotechnology was co-ordinated through the Organization for Economic Cooperation and Development (OECD) to help harmonize international regulatory systems (Levidow et al. 140). Similar discussions took place under the auspices of the United Nations Environment Program as well as the Food and Agricultural Organization and the World Health Organization (UNEP; FAO/WHO, *Strategies for Assessing the Safety of Foods Produced through Biotechnology and Biotechnology and Food Safety*). Southern countries, from which much of the germ plasm of interest to genetic engineers originates, also managed to convince northern countries wanting to pursue biotechnology to place the issue of biosafety into the 1992 Convention on Biological Diversity (CBD) (Munson 502). This eventually resulted in further negotiations on an international *Biosafety Protocol*.

Each forum brought together scientists and policy-makers working with widely divergent framings of the biotechnology issue, often from within the same countries, in an attempt to define common international approaches. They are of enormous relevance to Canadian biotechnology policy because it is in relation to concepts that emerged from international expert meetings that Canada justifies its approach to biotechnology regulation. Before examining how the discourses of GMO regulation were shaped within international fora in the early 1990s, and how

Canada has developed them since, I provide an overview of the way in which Canadian regulators review the products of biotechnology.

Regulating Agricultural Biotechnology in Canada

In Canada there are four federal agencies and departments that have legislative authority over products of biotechnology: Health Canada for genetically modified drugs, cosmetics and foods; Fisheries and Oceans Canada for modified aquatic organisms; the Canadian Food Inspection Agency (CFIA) for modified seeds, animals, veterinary biologics, feed and feed supplements; and Environment Canada for new substances not regulated by other departments, such as micro-organisms to be used in industrial processes (BSCO; Doern 5). In this essay I restrict my attention to the environmental safety-based model for the regulation of plants, as undertaken by the CFIA, and on the safety assessments of GM foods undertaken by Health Canada scientists. These are the final two stages of review and assessment of the potential risks of a new modified crop variety destined for food use. The initial two stages of review are the self-assessment for laboratory biosafety, followed by confined field trials, as regulated by the CFIA under Regulatory Directive 2000-07. The confined trials permit seed developers to evaluate the crop's performance under various growing conditions while allowing them to gather data to be used in the environmental safety assessment (PBO, *Regulatory Directive 2000-07*).

The Canadian regulatory system does not single out transgenic organisms for review. Rather, it is a product-based system in which *plants with novel traits (PNTs)* are the objects of regulatory attention by the CFIA, while *novel foods* are regulated by Health Canada for their safety as foods. Plants with novel traits are defined as plant varieties/genotypes 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, cultivated or introduced into a population of that species through a specific genetic change. PNTs include those derived from both recombinant DNA technology and plants derived through traditional breeding. (PBO, *Regulatory Directive Dir 94-08*; emphasis mine)

This definition of PNTs clearly depends on the definitions of two other concepts: familiarity and substantial equivalence. Familiarity is defined as "the knowledge of the characteristic of a plant species and experience with the use of that plant species in Canada" (PBO, *Regulatory Directive Dir 94-08* 2). Substantial equivalence is defined as "the equivalence of a novel trait within a particular 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 safe in Canada, based

on valid scientific rationale." (PBO, *Regulatory Directive Dir 94-08*). To date, all GM crops approved by the CFIA have been classified as PNTs and subjected to an environmental review; however, the principle underlying this system is that "the notion of what is novel could regularly change based on new scientific information" (BSCO 11).

Familiarity and *substantial equivalence* are more than simply useful aids for clarifying the definition of PNTs. These concepts, when elaborated with reference to specific variables that can be empirically observed and tested, are in most cases designed to be the triggers as well as the end-points of the environmental assessment process. The concepts are triggers in that a lack of knowledge about a plant's familiarity or substantial equivalence, as determined by the applicant (usually the plant developer or importing company), is what sets a more in-depth data review in motion. The concepts are also end-points in the sense that once a PNT has been determined to be familiar and substantially equivalent to crops already in use in Canada, with any new traits falling within acceptable boundaries or not posing unmanageable risks, then the PNT and any other lines derived from it are considered "safe" and needing no further environmental assessment (PBO, *Decision Document DD 95-01 1*). In cases where the PNTs are not considered substantially equivalent and familiar, more detailed testing is expected to take place, but this situation has yet to arise.

As regulatory triggers and safety thresholds, familiarity and substantial equivalency refer to specific sets of characteristics of the plants in question. The familiarity regulators are looking for includes previous experience with *the plant species*; *the new trait*; *the trait introduction method*; and *the cultivation practices* that will be used for the plant species (PBO, *Regulatory Directive Dir 94-08*, Appendix 3). When there is familiarity with the species possessing the new trait, then the next test, that of substantial equivalency, involves the comparison between information about the PNT and data representing accepted ranges for the species in question. This information about the PNT's counterpart is found in species-specific *companion documents*, which are publicly available on the CFIA's Plant Biosafety Office web site (PBO, *Regulatory Directive Dir 94-08*).⁸ Specifically, substantial equivalency of a PNT to its counterpart involves the comparison of five qualities: altered weediness potential; gene flow to related species; altered plant pest potential; potential impact on non-target organisms; and potential effect on biodiversity. It is significant that these specific indicators are the more tangible risks ecologists articulated in the 1980s and early 1990s. The regulation of GMOs has incorporated some of the concerns raised by more precautionary scientists; however, this does not mean the Canadian regulatory system has adopted these ecologists' emphasis on a long-term, experimental approach to gauging the effects of genetic engineering, as I discuss below.

The CFIA's environmental assessment of PNTs involves a team of approximately 10 scientists who review information and raw field test data about the PNTs (Doern 10). The reviewers do not carry out their own testing of the PNTs. They draw on data supplied by the applicant and published scientific and technical literatures and international reports. They also have access to 20 or so experts within the government science establishment (Doern 10). The applicant presents sufficient information to demonstrate both familiarity and substantial equivalency of the PNTs to a conventional counterpart. If any risks are detected through this process, the applicant shows they can be mitigated with risk management strategies that control the product's usage and growing conditions. Then the CFIA approves the environmental safety of the PNT. The CFIA does not monitor to see if assessment judgements were accurate or to uncover unanticipated effects, nor are there research programs in place to evaluate cumulative effects of a variety of GMOs.

Health Canada's process for assessing the safety of genetically modified foods follows a similar pattern. The process is described in the 1994 *Guidelines for the Safety Assessment of Novel Foods*.⁹ According to the definition included in these guidelines, novel foods, like PNTs, are not specifically limited to genetically modified products (Food Directorate, *A Bureau of Food Policy Integration*). For example, fruits not previously imported into Canada are also considered novel foods.

The safety assessment of novel foods begins with a review of how the food was developed, including, if relevant, the molecular biological data that characterize a genetic change (Doern 8). As with the safety-based model for the regulation of PNTs, in all cases of GM foods that have come before Health Canada to date, the food safety assessment process hinges on the idea of demonstrating the substantial equivalence of the novel food. Health Canada has taken its definition of substantial equivalence from the OECD; it is published in Volume II of *Guidelines*.

Substantial equivalence embodies the idea that existing organisms used as food or as a source of food can be used as the basis of comparison when assessing the safety of the human consumption of a food or food component that has been modified or is new. If one considers a modified traditional food about which there is extensive knowledge on the range of possible toxicants, critical nutrients or other relevant characteristics, the new products can be compared with the old in simple ways. (Food Directorate 7)

Health Canada determines the substantial equivalency of a novel food to a conventional counterpart by comparing a set of molecular, compositional and nutritional data for the modified organism to its traditional counterpart, where such exists. Once substantial equivalence can be established based on these criteria, no additional safety testing is required (Doern 4). In cases where the new organism is considered to be equivalent to its counterpart with the exception of the presence of

novel gene products, such as proteins, associated with the introduced trait, the focus is then placed on these new components (Food Program 3). Depending on the perceived risk associated with them, these components may then be assessed using a range of traditional testing methods such as toxicological testing (Food Directorate, *Guidelines for the Safety Assessment of Novel Foods: Volume II*). In cases where a novel food is so different that it cannot be compared in any way to a traditional food, extensive testing may be necessary, but this situation has yet to arise.

Health Canada has approximately 10 scientists who review data provided by the applicant to determine the safety of a novel food (Doern 13). In terms of the overall standards of the assessment, a Health Canada Training Module states that "the evaluation of an application for a novel food safety assessment is comparable to the peer review of a manuscript for publication in a scientific journal" (Doern 16). Given this statement, it is notable that there is no requirement for a peer review of these assessments themselves within the extended scientific community, nor is it even easy for external scientists to access the environmental or health assessment data because much of it is confidential business information (Clark 3). Although extensive ongoing consultations are undertaken with key stakeholders in the development of the Canadian regulatory system for novel foods and with novel traits, there is also no provision for public involvement in the individual product assessment processes (Doern 13).

A Genealogy of Novelty, Familiarity and Substantial Equivalence

Given the international and interdisciplinary scientific controversy that existed around how to define the GMO problem when Canada developed its regulatory framework, what does this Canadian system for assessing GMOs, with its language of novelty, substantial equivalence and familiarity, really mean? How do these concepts fit in with the biopolitics of genetic engineering?

The Canadian government states that its regulatory system is "internationally recognized and endorsed as a rational scientific approach" by the FAO/WHO as well as by expert consultations organized under the auspices of the OECD and the United Nations Environment Program. The terms *novelty*, *substantial equivalence* and *familiarity*, however, are more than internationally accepted "science-based" standards for evaluating genetically modified organisms. They are also key discursive nodes within biopolitics. On the one hand, this language is the product of compromise within the conflicts over how to define the GMO problem – struggles that have yet to be fully resolved. On the other hand, these terms appear to function discursively to shape the horizon of expectation for Canadian regulators and the public regarding what may or may not be risky about GMOs.

In the context of the OECD, a Group of National Experts met from 1983 to 1993 to develop a common understanding on how to regulate GMOs. Terminological disputes were a significant impediment to progress during the meetings. For example, some delegates refused to discuss hazards on the grounds that they linked GMOs with harmful effects, while others used the term only to denote the potential for harm (Levidow et al. 140). In an attempt to find a broad conceptualization of hazards, the term *familiarity* first came to be adopted by the OECD – but only after it was redefined.

In the United States, the term *familiarity* was already in use as a regulatory concept rooted in the manageable risk discourse. In that context, familiarity with the host plant, and the assumption that molecular genetic methods involve manipulation of not more than a few genes and their associated regulatory elements, which are usually “well characterized,” meant that “crops modified by molecular and cellular methods should pose no risks different from those modified by classical genetics methods for similar traits” (NRC 66-72).

This American usage was not acceptable to many members of the Group of National Experts. “Familiarity breeds contempt” was the view of at least one of the European Community regulators (Levidow et al. 140). None the less, familiarity was eventually adopted in a bid to avoid an impasse, but only after it was given a definition designed to distance the word from its American usage. According to the OECD, familiarity “is not synonymous with safety.” It means “having enough information to be able to judge the safety of the introduction” (OECD, *Safety Considerations for Biotechnology Scale-Up of Crop Plants* 7-10, 28-31).

At the time, familiarity was praised as a “flexible concept” (Levidow et al.). In hindsight, we can see that this has indeed been the case. On the one hand, becoming familiar with a GMO could be interpreted as the demand for a significant knowledge base regarding the implications of the new organism before it is released to the environment, as the *precautionary* framing expects. On the other hand, the language itself, with its origins in the permissive American regulatory system, could be mobilized to suggest that familiarity with the species and the new trait before their recombination does indeed imply that the new transgenic organism can be assumed to be safe. This is exactly how the term has come to be used in the CFIA’s environmental review, with the only caveat being that an organism also has to demonstrate substantial equivalence to a traditional counterpart with regards to five specific ecological criteria.¹⁰ But substantial equivalence is another loaded term, however.

Substantial equivalence has its roots in assumptions embedded in the conventional breeding process (Barrett et al. 177-80). Conventional breeding is also the direct origin of the idea of *novelty* and *plants with novel traits*, so I discuss these two concepts in tandem.

Through years of crossing and selecting plants with specific characteristics, traditional breeders develop lines that are distinguished by novel traits such as

increased disease resistance or an altered oil profile. Field trials are then undertaken with these plants to verify the *validity* and *stability* of the specific trait that characterizes the new variety (Barrett et al. 179). Within these breeding programs the relative genetic uniformity of the material used means that interactions of the breeding-derived trait with other parts of the genome are assumed to be of no functional significance. Should a negative effect be created, this is expected to be discovered during the breeding process, and these plants are simply weeded out of the new line. Thus within traditional plant breeding, the assumption is that the *novelty* is *entirely* located in the new trait, and the rest of the plant can be thought of as generally the same as other plants of the species.

Because genetic engineering also focusses on the movement of genetic elements thought to be associated with a particular trait (although often between unrelated species), it is not difficult to see why the term *plants with novel traits* came to be associated with the products of biotechnology in the 1980s (OECD, *Recombinant DNA Safety Considerations* 28). But if the term were to be adopted with its traditional breeding assumptions, then the idea of *novelty* could allow one to sidestep the possibility that the unanticipated (including pleiotropic) effects of the genetic engineering process itself could also harbour new hazards. This is consistent with "gene talk" and its assumptions of rDNA precision, but not with a precautionary view of GMOs.

Because of the strength of the more precautionary framing in Europe, novelty came to be redefined in some international discussions dealing with environmental risks associated with GMOs. In the United Nations Environment Program (UNEP) International Technical Guidelines for Safety in Biotechnology, for example, organisms with novel traits are defined as "organisms produced by genetic modification and whose resultant genetic make-up is unlikely to occur in nature. *These do not include organisms obtained by conventional techniques and traditional breeding methods*" (UNEP 17; emphasis mine).

Canada has justified its use of the concept of novelty as a regulatory trigger with reference to this very document (BSCO 16). The Canadian definition of PNTs contradicts this definition, however; it was designed to avoid focussing specifically on the uniqueness of the rDNA techniques. Instead, Canadian regulators appear to have reintroduced the assumptions implicit in the traditional breeding process from which the term originated. Implicit in the phrase *plants with novel traits* is the idea that it is primarily the traits that should be the objects of regulatory concern.

Substantial equivalence, like familiarity and novelty, is also amenable to both the precautionary and manageable risk framings of GMOs. In early OECD documents, where the concept was first articulated internationally, no criteria were given of what should be measured to establish equivalency (OECD, *Safety Evaluation*). Scientists who favoured an in-depth examination of the GMO and those who assumed a GMO could be considered safe as a non-engineered novel

organism were able to find common ground in a terminology that suggested the need for a comparative assessment methodology.

While its meaning and implications remain ambiguous at the international level, in Canada, substantial equivalence has become key to normalizing genetic engineering. Defenders of Canada's regulatory system argue that the process of determining equivalence subjects GMOs to a "comprehensive" assessment (Vanclief). The actual practices used to determine this equivalence, however, embody the assumptions that the risks of GMOs are minimal and entirely manageable.

How is this possible? As implemented by Health Canada, the first stage of the test of substantial equivalence for food safety involves a basic review of molecular, compositional and nutritional data. This can be expected to reveal the proteins produced by the inserted transgene and its associated elements, such as marker genes. It may also demonstrate unanticipated effects of the genetic engineering process, but these are not necessarily visible in such crude compositional overviews (Kuiper, *Food Safety Evaluation*). In fact, unintended phenotypic alterations may not appear until the plants from which the foods are derived are subjected to particular environmental conditions (Barrett et al. 185). If unexpected effects are not immediately apparent but the anticipated change, attributable to the introduced construct, is apparent, then substantial equivalency for the GMO is accepted. Further attention is then given exclusively to the anticipated gene products of the novel trait, their expected risks (based on past experience with the trait in other organisms), and the manageability of these risks.

In the case of substantial equivalence in the environmental assessment of PNTs, we can also see how this test, with its implicit assumptions, simplifies the work of CFIA in several important ways. First, the assessment allows assessors to focus specifically on whether or not the novel protein expressed by the PNT will result in environmental risks rather than on the whole plant and its varied characteristics in multiple environments. Second, where experimental studies of effects of the novel protein are undertaken, the linear "gene talk" assumptions mean that many of these studies are based on samples of the protein produced in bacteria cultures (known as "bridging studies") rather than on the proteins produced by the modified plants. Finally, in many cases the assessment is based on judgements regarding whether or not specific environmental risks might be *expected* to be caused by the genetic transformation, rather than on actual experiments. Whether a modified canola line will affect non-target organisms, as one example found in a CFIA decision document, was based on a "detailed characterization of the novel gene and novel protein" (PBO, *Decision Document DD 98-28*). The conclusion from this assessment was that the "gene and protein ... *should* not possess altered toxic

or allergenic properties" (emphasis mine). This is important information, but precautionary scientists point out that such "toxicity and allergenicity profiles do not exhaust the range of ways that a GMO could affect non-target organisms" (Clark 4).

The degree to which unanticipated effects are considered a non-issue in the current regulatory framework is revealed by the fact that no long-term monitoring is undertaken by the CFIA or Health Canada to see if products work as anticipated, if risk assessment predictions are accurate or if GMOs produce unanticipated outcomes. From the perspective of a study of biopolitics, this is particularly revealing, given that in-depth monitoring is usually a central practice of biopower in other spheres. The reason we have yet to see monitoring of PNTs in Canada is that it is difficult for the government to justify monitoring genetically engineered PNTs when it never monitored new crop plants before. Regulators are quite aware that undertaking such monitoring could be construed as an admission that there is something different about GMOs that requires increased vigilance.

There are two further ways in which the current regulatory system appears to embed "gene talk" assumptions while it would be difficult to show that existing scientific knowledge substantiates them. First, within the CFIA and Health Canada, regulators admit that their experience of undertaking the comparative practice of assessing substantial equivalence has brought to light how little the baseline of conventional agricultural practices and their environmental effects (for example on soil communities) are understood.¹¹ Apparently, the assumption that there is little difference between PNTs and established crop varieties has been guiding the determination of safety, rather than ecological science. Second, there is currently a move within the CFIA and Health Canada to use data on previously approved novel foods and PNTs as part of the baseline data against which to assess the next generation of PNTs, since in many cases the previously approved PNT is the closest comparator for evaluating equivalence. Although I would not contest the fact that an earlier approved PNT may indeed be a good comparator, such a move only makes sense if one assumes that the limited evaluations undertaken by the CFIA and Health Canada give us as much experience with the recently introduced novel plants and foods as we have with traditional crop plants and foods. Yet this is something that can only be substantiated after long-term study and monitoring, neither of which the current regulatory system undertakes.

From this overview, it is clear that there is a specific normative bias to the regulatory model developed through the 1990s in Canada, rooted in the assumptions of "gene talk" and the manageable risk discourse. It is difficult not to see the connection between this bias and the decision made by successive Canadian governments, beginning in the early 1980s, to invest heavily in the emerging agricultural biotechnology sector.

The Contemporary Precautionary Critique

The release of GM foods onto domestic and global markets in the mid-1990s resulted in a strong public backlash towards GMOs, especially in Europe. Within the context of biopolitics, this resistance should come as no surprise. Struggles within the relations of biopower are often “immediate struggles” in which “people criticize instances of power which are closest to them, those which exercise their action on individuals” (Foucault, *The History of Sexuality* 211). On one level, GMOs are targeted towards the management of nature at the genetic level, but through the medium of modified food, people also become visceral subjects of this new extension of biopower.

The consumer resistance to GM foods has invigorated the precautionary critique of biotechnology and the way it is currently regulated in Canada. Although the scientific arguments against GMOs have no solid evidence of significant harm caused by GMOs to date, a number of examples point to holes in the manageable risk framing. These include cases of risks to endangered species that were missed by the regulatory process, such as the widely discussed issue of monarch butterflies harmed by corn designed to express a pesticidal protein.¹² There are also a number of documented cases of unexpected secondary effects of genetic modification affecting agricultural ecosystems (Tappeser et al.). Finally, the uncertainties in genetic engineering were highlighted by a recent case in which Monsanto informed Health Canada that a variety of modified soybean had “extra” pieces of DNA that were not reported, and thus not specifically assessed, in its initial submission for safety approvals in 1994 (Office of Food Biotechnology). Each of these examples illustrates the way in which life “escapes” the degree of predictability and manageability espoused by biopower (Foucault, *The History of Sexuality* 143), thereby providing footings for reverse discourses. Such discourses, as exemplified in a recent report prepared by a panel of the Royal Society of Canada, have come to target (and reinterpret) the concept of substantial equivalence.

This report was commissioned by the government of Canada in response to the wave of criticism it faced in 1999 and 2000 from prominent environmentalists and environmental non-governmental organizations. Although government had hoped for an independent scientific vindication of its regulatory system, the Royal Society of Canada’s Expert Panel offered a more critical perspective (Barrett et al.).

Among the issues raised in the report is the ambiguous use of the concept of substantial equivalence in Canadian regulatory practice (Barrett et al. 36). The panel provides what it thinks would be a scientifically justifiable interpretation of substantial equivalence, which “should require *rigorous scientific analysis* which establishes that, despite *all* changes introduced into an organism as a result of the introduction of novel genes, the organism poses *no more risk* to health or the environment than does its

conventional counterpart" (Barrett et al. 183; emphasis mine). The expert panel argues that government regulators do not appear to be consistently applying this high standard of equivalence. Instead, there are cases where "substantial equivalence is determined based on the assumption that no changes have been introduced into the organism other than those directly attributable to the novel gene," thereby disregarding the possibility of pleiotropic impacts of the transgene (182; Brunk and Ellis). This situation is particularly problematic from the panel's point of view because risk assessments are "based solely on data and information provided by the petitioner, and decision documents describing and validating outcomes are ... not readily available to either the scientific community or general public" (Barrett et al. 182).

In a private response to the Royal Society report, regulators at Health Canada argue that "there are never assumptions of Substantial Equivalence" in the regulatory process (Green 1). The letter lists the variables looked at to evaluate a new food for safety, including compositional and nutritional information. Health Canada notes that they do "consider the potential for secondary or unexpected impacts" although there is no mention of any experimental protocol designed to reveal such effects.¹³

The focus of the Royal Society report's criticism, and the urgency with which the regulators jump to the defense of current regulatory practices in Canada, shows how the question of a GMO's similarity or difference to a non-modified organism remains the scientific heart of the normative controversy over GMOs – as it was when these issues first erupted 30 years ago. Yet we can never expect a purely *scientific* answer to this question. The issue of how much knowledge one needs to determine equivalency and how confident one could be about such a determination are ultimately judgement calls. Those who espouse the manageable risk frame believe that basic compositional and nutritional data and a check for obvious allergens and toxins are sufficient for a safety evaluation. After facing the kinds of arguments made by the Royal Society, regulators may look more closely for unanticipated secondary effects of genetic changes in the data sets they receive, but such a search has its limits – circumscribed by a lack of baseline data, for starters.¹⁴ Critics will continue to be able to show that one could take the risk analysis one step further in an attempt to reveal more fully the effects of genetic engineering. What about data from crops grown in a wider variety of environments, or subjected to different kinds of selection pressures? In Europe, the intensity of public pressure has triggered scientific efforts to characterize many of the minute differences between GE and non-GE foods using more detailed profiling techniques, although it is acknowledged that these need "further development and validation" before they can be used routinely for screening of unintended effects in transgenic plants and foods (Kuiper, *Profiling Techniques 2*). The encouragement of these new sciences of proteomics and metabolomics is one of the productive effects of the scale achieved by the GMO

risk/precaution controversy, and even more assessment science will likely follow.

Internationally, the possibility for more precautionary regulatory approaches to GMOs was entrenched in early 2000 in the draft Cartagena Protocol on Biosafety – the final end product of the biosafety clause in the Convention on Biological Diversity in 1992. This international agreement on the trade of *living* genetically modified organisms (LMOs) states that in cases where countries believe they do not have sufficient scientific information to make a firm regulatory decision about the environmental safety of an LMO, they may still decide to restrict import of that LMO on the basis of precaution (CBD). The Cartagena Protocol will have considerable implications for the politics of Canadian regulation, since Canada's appeal to international fora as a way to legitimate its biotech regulatory policies will be used as a basis for critiquing those policies. The Canadian Environmental Institute for Law and Policy (CEILAP), for example, has recently argued that there is a contradiction between Canada's regulatory framework and the precautionary approach embedded in the Cartagena Protocol – a protocol that Canada has signed but has yet to pass into domestic law (MacRae).

Opening Up the Process

At first glance, it appears as if the narrow focus of the risk discourse is not curtailed but entrenched by the renewed precautionary critique. This is because manageable risk and precaution are poles within the same discourse, a discourse that emphasizes the technical similarities and differences between GMOs and non-GMOs. This appears to have sidelined concerns about genetic engineering, including religious and moral questions and the socio-economic issues related to GMOs in agriculture. The question of labelling seems to be a good example; however, Foucault would suggest that we look at the ways in which, through biopolitics, a platform may be created for these other concerns to come into play.

As recently as 1997, a key part of industry and government's argument against labelling was that there was simply no way to differentiate GMOs from non-GMOs. Since that time, new developments have resulted in the technical ability to assign a unique identifier to each GMO "event," as well as the capacity to test plant products in the field, or their products in foods, to determine which particular GMO they might be. In this way the practices of biopower associated with genetic engineering have provided the tools necessary for labelling regimes for GMOs to be brought into place – tools that offer a degree of accuracy never before realized for other kinds of segregated commodities, for example kosher or organic products. Although the seed industries in Canada continue to resist labelling of all GM foods, labelling has been made possible through the sciences they have developed.

The growing attention to precaution also offers the opportunity to challenge the idea that GMOs should be regulated on a strictly scientific basis. In its articulation, the precautionary principle is an explicit acknowledgment of the relationship between norms and science in risk decision making. This has led to considerable rethinking among academics and policy analysts of the closed nature of the processes through which these norms are usually determined – often as tacit judgements made by particular groups of scientific experts (Wynne). The arguments for more precautionary regulation have been accompanied by demands for more openly democratic decision-making processes around risk issues, rather than simply a reversal of dominant norms. (For an excellent overview see Raffensperger and Tickner.)

The need to open up risk-based decisions in the context of a precautionary perspective also comes through in the Royal Society of Canada Panel's report. The panel expresses concern about the very narrow mandate it was given by the federal government. It was specifically asked to review the preparedness of the regulatory system for the kinds of risks that will be posed by the products of biotechnology over the coming 10 years. The panel notes that even though people often articulate concerns in terms of risk, there is a much wider group of issues people associate with genetic engineering. It reframes the notion of risk by discussing the socio-economic, philosophical and metaphysical risks associated with GMOs (Barrett et al. 1-9). The panel suggests that each of these kinds of risks is part of the larger public debate over genetic engineering and that the government should not lose sight of them in an effort to define a purely technical solution to the genetic engineering controversy.

The idea of opening up GM crop and food regulation to more than its particular version of science-based decisions is still strongly resisted by the Canadian government; however, growing resistance to the varieties of GM crops about to come down the regulatory pipe may yet force a rethinking of the current model. The most significant upcoming case is that of herbicide-tolerant wheat, varieties of which are now at the field trial stage in Canada and due to hit markets in 2003.

Canadian wheat farmers currently export significant quantities of wheat to countries that have moratoria on GMO imports or strong labelling regimes that effectively limit GMO markets. Most Canadian wheat growers, in an effort to protect these markets, would choose not to use engineered wheat varieties. The choice to export non-modified wheat, however, may not be available once engineered seed arrives on Canadian markets. This has already happened with canola. Canadian farmers who have chosen to grow non-modified canola have found their crops to be significantly contaminated with engineered genes that came from neighbouring fields through pollen in the wind. For organic canola farmers, whose consumers want GMO-free products, this genetic contamination has effectively spelled an end to their markets. A coalition of farmers in Saskatchewan is pursuing lawsuits against

Monsanto and Aventis, two of the largest biotech companies (SOD). Wheat farmers may face a similar situation if modified wheat varieties pass the regulatory approvals process.¹⁵ In such cases a regulatory decision supposedly based on science becomes a *de facto* political decision about which markets all Canadian farmers can grow for – not just those who choose to adopt the new engineered varieties.

This situation has led the Canadian Wheat Board, among others, to demand that market considerations and the status of segregation capability be part of regulatory decisions on whether Canada will register new engineered crops (CWB). Such demands add weight to the argument for a regulatory system that would explicitly acknowledge its decisions are political as well as technical, and that open debate over the values implicit in regulation (including judgements about standards of scientific evidence and proof or judgements about the importance of certain markets or the ethical acceptability of certain species crosses, for example) ought to be part of regulatory determinations for engineered crops and foods. This would be a marked improvement over the current Canadian regulatory system – a system that hides behind the guise of being science-based in order to further only one particular set of value judgements regarding GMOs.

Notes

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1. It is important to draw a distinction here between the mandatory labelling of GM foods, called for by many public interest organizations, and the voluntary labelling of such products, guidelines for which are being developed by the Canadian food industry.
2. In October 2001, Liberal Member of Parliament Charles Caccia brought forward bill C-287, which would require mandatory labelling of GM foods. It was voted down 126 to 91 only after the ministers of Health, Agriculture, Industry and Trade sent a letter to MPs stating that the Cabinet would be developing a plan for dealing with public concerns over GM foods (Adam).
3. Foucault uses the term *biopolitics* and *biopower* interchangeably in *The History of Sexuality: An Introduction*. I tend to use the term *biopolitics* in this essay because I think it better encapsulates the relational nature of power stressed by Foucault.
4. Haraway refers to this phenomena as “genetic fetishism” (91), while Lewontin calls it “the doctrine of DNA” (35).
5. The Canadian manifestation of these efforts can be found in the *Guidelines for the Handling of Recombinant DNA Molecules and Animal Viruses and Cells*, brought in by the Medical Research Council of Canada in 1977 (LCDC). An updated version, Health

Canada's *Laboratory Biosafety Guidelines*, continues to govern genetic engineering laboratory and greenhouse-based research in this country.

6. For further discussion of the value judgements implicit in risk analysis, see Shrader-Frechette.
7. This has since been replaced with an even more precautionary policy, "Directive 2001/18/EC" (European Parliament).
8. The CFIA's Plant Biosafety Office web site can be found at www.inspection.gc.ca/english/plaveg/pbo/pbobbve.shtml
9. At the time of this writing, these guidelines were being reviewed and updated, but the basic principles for evaluation will remain the same.
10. Among OECD countries, this particular use of substantial equivalence in environmental reviews is unique to Canada. Most only apply the concept in food safety assessments.
11. This theme was clearly apparent at multi-stakeholder consultations on the GMO regulatory system held in Aymer, Quebec, 29-31 May 2002, at which the author represented the Canadian Environment Network.
12. For a good overview of the controversy around this issue, see Pew Initiative 17.
13. Obtained through an Access to Information request submitted by Brad Duplisea of the Canadian Health Coalition.
14. The official response to the Royal Society's report is that the CFIA and Health Canada will implement every one of the panel's 53 recommendations.
15. Canola is an open-pollinated crop, whereas wheat is not, so it would take much longer to see significant genetic contamination of wheat through pollen flow. Such contamination would eventually appear through a variety of mechanisms including volunteer plant survival and seed mixing.

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