

**Regulating Biotechnology and Nanotechnology in Canada:
A Post-Normal Science Approach for Inclusion of the Fourth Helix¹**

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Abstract

The triple helix of state, university and industry is missing an essential fourth helix, the public. Advances in biotechnology and nanotechnology are jeopardised by the virtual absence of this helix. Using Canada as a case study, this paper argues that regulating biotechnology and nanotechnology is made unnecessarily complex and inherently unstable due to a failure to consult the public early and often enough. Furthermore, it is argued that future regulators (and promoters) of nanotechnology may learn valuable lessons from the mistakes made in regulating biotechnology, and may appreciate the value of adopting a post-normal approach to science.

Introduction

In 1994, Canadians were introduced to genetically modified food. Early commercial applications of recombinant DNA technology concentrated primarily on agronomic traits like herbicide tolerance (e.g., Roundup Ready canola) and insecticidal properties (e.g., Bt corn and potatoes). Without advanced notification, fanfare or

mandatory labelling, the public was exposed to this technology. A few years later, this failure to include the Canadian public began to backfire. Many Canadians became aware that a significant amount (approximately 70%) of processed foods in grocery stores contained ingredients derived from genetically modified organisms. In 2000, Greenpeace Canada and other non-governmental organisations held protest rallies to heighten public awareness. In 2001, Charles Caccia (MP, Davenport, Ontario) put forward in the House of Commons an amendment to the Food and Drugs Act (Bill C-287) that required all food produced with the assistance of recombinant DNA technology to be labelled. Although Bill C-287 was subsequently defeated, and the debate over mandatory labelling appears to be losing momentum, the Canadian public continues to express low levels of trust in regulators of gene technology. Clearly, the massive investments in biotechnology made by universities, industry and state require some degree of social acceptance.

Many countries, including Canada, are now investing heavily in another transformative technology known as nanotechnology. Nanotechnology involves creating and manipulating organic and inorganic matter at the nanoscale. Nanoscientists are developing techniques for atom-by-atom construction of objects that have potential applications in medicine, electronics, information technology, environmental monitoring and remediation, military equipment and weapons, etc. Proponents of nanotechnology suggest that the world's needs could be met by utilising a limitless supply of atoms to manufacture valuable molecules (Duell, 1999). The potential range of applications is staggering and cost of basic nanoscience research high. As with biotechnology, universities, industry and the state are committed to developing innovations resulting

from discoveries in nanoscience (Mehta, 2002). Additionally, few efforts have been made to include the public, or the so-called “fourth helix,” in these plans.²

To understand how triple helix relations generate barriers to innovation by excluding the fourth helix (Bunders et al., 1999), this paper will consider the difficulties associated with regulating the products of biotechnology and nanotechnology in Canada. Although nanotechnology is in its infancy, and few understand it, a set of lessons can be gleaned from the experience of regulating and promoting biotechnology. In short, this paper demonstrates how triple helix relations come under greater scrutiny when innovations generate both scientific and social uncertainty, and erode trust (DeMarchi and Ravetz, 1999). To overcome these obstacles and to minimise the challenges they pose to governance, it is suggested that triple helix institutions accept that post-normal science has arrived and welcome fourth helix participants.

Setting the stage

In the first half of the 20th century, large industrial players like General Electric, Westinghouse and Ford had the resources and desire to support internal research that bolstered innovative capacity and provided competitive advantage. Teams of company scientists conducted research to improve products and manufacturing techniques. For example, Ford scientists worked on improving the internal combustion engine and its power characteristics, new braking and suspension systems, developed alloys and polymers, and explored the aerodynamic properties of different designs. In this era of

company-led science, a distinct separation existed between industrial, academic and government science.

With the coming revolution in microelectronics the boundaries between these three arenas became less demarcated. The development of the transistor and later the microchip not only revolutionised how many products were designed and constructed, but stimulated a convergence of industrial, academic and government science. In many parts of the Western world, new partnerships were forged between these actors. The so-called “triple helix” would eventually blur the boundary between basic and applied research, and provide social scientists and others with a valuable theoretical approach for understanding how various categories of actors in the science/technology interface interact and produce new forms of knowledge.

The revolution in biotechnology and other life sciences is an illustration of how triple helix relations produce large amounts of technically and commercially exploitable knowledge. However, triple helix relations generate a range of challenges and bring into question fundamental issues like how best to regulate new technologies and ensure democratic accountability. These problems are likely to be magnified with the forthcoming revolution in nanotechnology.

Post-normal science

In recent years, social scientists and others have shown an increased level of interest in analysing the enterprise of science. Since the 1950s, developments in science have stimulated major innovations in nuclear technology, information and

communication technology, biotechnology and nanotechnology. In addition to stimulating innovation and convergence, these technologies have generated also a pressing social need to understand the risks and benefits that flow from such innovations, and have brought into question the enterprise of science and the adequacy of regulations.

The relationship between science and technology has undergone a range of transformations since World War II. Vannevar Bush (1945) proposed with his “endless frontier” thesis that a distinction should be maintained between basic and applied research. Basic discoveries in science occurred in universities while industry translated these discoveries into commercially viable applications on a case-by-case basis. For Bush, this split in responsibilities allowed university researchers the opportunity to explore ideas and test theories without the guidance or interference of industry. Bush assumed that some research conducted in universities would inevitably show commercial promise, and that there was significant value in ensuring autonomy and independence at the basic research stage. As a presidential advisor, Bush’s vision was accepted uncritically and became the basis for outlining a linear relationship between knowledge generation and future commercial applications.

The endless frontier thesis was an attempt to explain how science in the United States could continue to grow following a successful relationship between university research and military applications during World War II. During the war, many American universities benefited significantly from an infusion of grants to conduct research in nuclear physics, radar and sonar, aerodynamics, ballistics, and so on.³ The eventual success of the United States and her allies is attributed, in part, by their ability to develop

and deploy military applications of technology. It became apparent to many, including Bush, that this pattern of success could be emulated to forge a new relationship between industry and universities.

This linear model of technological diffusion is related to what Thomas Kuhn referred to as “normal science.” In the *Structure of Scientific Revolutions* (1962), Kuhn proposed that advances in scientific knowledge resulted from sudden, “intellectually violent revolutions” known as “paradigm shifts.” Instead of science being a steady accumulation of knowledge, Kuhn suggested that during periods of normal science the main task of scientists is to help reconcile fact with theory. This involves using accepted scientific techniques, tools, and analysis to solve puzzles and build on the base of knowledge. Many of the innovations that flowed from normal science involved steadily building on this base of knowledge, and came from puzzle-solving activity. The puzzle-solving activity that occurred during periods of normal science would sometimes reach an impasse where standard scientific modes of inquiry generated strong conflict and vocal disagreement amongst scientists. For Kuhn, a paradigm shift was likely to occur at this point and the tradition-bound activity of science would be shattered.

For industry, the shattering of scientific tradition creates a range of challenges and opportunities. Karl Popper viewed Kuhn’s explanation of normal science as a threat to civilisation since it acts as an institutional barrier to innovation (Popper, 1970; see also Agassi, 1998; Pinter and Pinter, 1998). Popper believed that the concept of paradigm shift stifled innovation by demarcating acceptable from unacceptable areas of inquiry and by creating institutional mechanisms (e.g., peer review) for punishing novel and unorthodox

approaches to knowledge discovery. Paradigms also constrain scientific research by placing a premium on discipline-based science. For Popper, paradigms hold back scientific discovery by narrowing inquiry and channelling research into areas that may not have the greatest social utility or commercial value.

The debate between Kuhn and Popper over normal science has become moot in recent years. Many recent discoveries in science have resulted from a convergence of disciplines and a shattering of scientific traditions. These discoveries have also resulted from a non-linear relationship between basic and applied science, and awareness that normal science is being replaced by what Functowicz and Ravetz (1992, 1993) called “post-normal science.” Post-normal science recognises that science is always tentative in its conclusions, and therefore subject to revision or reversal. Funtowicz and Ravetz claim that a post-normal approach is needed when uncertainty is high, values in dispute and stakes important. When traditional science has difficulties dealing with an issue, a post-normal approach offers access to a new perspective that values heuristics, trends, and extended communities of interest. As such, post-normal science aims at producing knowledge for addressing “real-world” problems like global climate change, stratospheric ozone depletion, water quality, and the sustainability of agriculture.

A post-normal approach changes relationships between a wide range of actors (e.g., triple helix institutions) by creating a set of feedback mechanisms that encourage science to find novel ways of handling the world’s pressing social and environmental problems. By its very nature, post-normal science is used for dealing with post-normal hazards (e.g., genetically modified foods, BSE) that pose serious challenges to

governance due to low levels of trust (De Marchi and Ravetz, 1999), and a growing gap between science and policy (Funtowicz and Ravetz, 1990). Incidentally, post-normal hazards are also post-modern since demonstrating actual harm is difficult and because a range of new actors (e.g., transnational activist groups like Greenpeace International) have some legitimacy at the bargaining table. Post-normal science leads to post-normal decision-making and the development of a “new political epistemology for science” (Funtowicz and Ravetz, 1992: 254).

A post-normal approach to science attempts to deal with uncertainty and complexity, and their associated negative impacts on innovation, by focusing on how science can be democratised, and how basic research can be translated into strategic research. Post-normal science is used when risks are non-quantifiable (e.g., bioterrorism) and when no one scientific approach or discipline can reasonably claim privileged access to the “truth.” This approach to knowledge production is very different from the traditional one. Although science is accorded some status in a post-normal world, it does not dominate. In order to address post-normal hazards, and to stimulate innovation that springs from the interstices of disciplines, post-normal science incorporates a range of perspectives in the form of “extended peer communities.” An extended peer community includes a variety of actors from triple helix institutions and individuals from the fourth helix. As such, an extended peer community is more than simply an expansion of democratic participation (e.g., consensus conferences, citizen juries, focus groups), it is a community that broadens the knowledge base and helps identify underlying values and potential conflicts. How can a post-normal science approach help us understand the value

of the fourth helix in crafting a new regulatory regime for dealing with innovations in nanotechnology? What lessons can we learn from biotechnology?

Lessons learned

Baber (2001) notes that the growth of certain scientific and technical areas (e.g., biotechnology and nanotechnology) is due primarily to transdisciplinarity, and that such growth is contributing to a reconfiguration of triple helix institutions. As a result, such developments continue to blur the distinction between basic and applied research, and pose challenges to regulators. As with many technologies, regulation lags significantly behind the pace of innovation. During periods of normal science, triple helix institutions could adjust incrementally to changing regulatory environments, and promote the value of co-operation and co-ordination of interests. With the emergence of post-modern hazards, and the rise of post-normal science, the configuration of triple helix institutions is changing. The importance of the fourth helix, and “extended peer communities,” is increasing. Additionally, it is probable that new technologies will stimulate a convergence of what Limoges (1993) describes as the traditional divide between scientific and public controversies. For Limoges, scientific controversies are different from public controversies because they focus on debates over accepted “truths,” whereas the public responds to questions of urgency, prudence and expediency. In a post-normal science era, scientific and public controversies eventually converge, and sometimes collide.

In some ways, developments in biotechnology helped push the western world into a post-normal science era. In particular, the creation and subsequent sale of transgenic foods ignited controversy in many parts of the world that signalled the decline of normal science. The use of recombinant DNA technology to cross what was called the “species barrier” ushered in a general awareness that science needs re-conceptualising (Nowotny et al., 2001), and an appreciation for hybridity (Gibbons et al., 1994). Disciplinarity is no longer the dominant system for creating and organising knowledge. Knowledge creation is now more reflexive, non-linear, complex and hybridised. Furthermore, inclusion of the fourth helix becomes critical since scientific knowledge is increasingly evaluated by its social robustness and inclusivity. Biotechnology exists in the space between normal and post-normal science, and therefore oscillates between the old and the new, linear and non-linear, and triple helix and fourth helix modes. By contrast, developments in nanotechnology are unfolding in a post-normal science era. Several lessons emerge with this transition.

Lesson one: substantial equivalence

In Canada, Health Canada and the Canadian Food Inspection Agency (CFIA) share joint responsibility for regulating novel plants. The use of recombinant DNA technology to create novel plants places these regulators squarely into a post-normal realm, even if they do not acknowledge this. Plants with novel traits (PNTs) are defined as:

[P]lant varieties/genotypes that are not considered substantially equivalent, in terms of their specific use and safety both for environment and for human health, to plants of the same species in Canada, having regard to weediness potential, gene flow, plant pest potential, impact on non-target organisms and impact on biodiversity. PNTs may be produced by conventional breeding, mutagenesis, or more commonly, by recombinant DNA techniques. Safety assessments are required for all PNTs intended for importation and for environmental release in Canada.⁴

Novel foods do not have a history of safe human consumption and are produced by techniques that have not been used previously. Before reaching the marketplace, all novel plants and plant products are assessed for environmental, animal and human health safety. Health Canada considers how novel foods compare to traditional counterparts, examines nutritional characteristics, checks for the presence of toxins or anti-nutrients, and looks for potential allergens.⁵ The CFIA's role is to assess potential environmental risks associated with introducing novel crops and to oversee confined trials, unconfined release and variety registration. The CFIA is also involved in regulating products of biotechnology for animal feeds, fertilisers and veterinary biologics.

In spite of the efforts made by Health Canada and the CFIA to ensure the safety of novel foods, considerable debate over the use of substantial equivalence as a comparative approach exists. A recent report by the Royal Society of Canada entitled *Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada* (2001) concludes that substantial equivalence should not be used as a decision threshold

for determining whether or not GM-products should undergo rigorous scientific assessment. In section 8.1 of the report, members of the expert panel note:

In general, those who are responsible for the regulation of new technologies should not presume its safety unless there is reliable scientific basis for considering it safe. This approach is especially appropriate for those who are responsible for the protection of health and environment on behalf of the Canadian public.

Additionally, the expert panel rejected the use of substantial equivalence as a decision threshold because this approach is inconsistent with a precautionary approach for comparing new genetically modified products with existing products, and since an assessment based on “superficial similarities” does not satisfy the burden of proof for safety.⁶

The concept of substantial equivalence implies that novel products (e.g., genetically modified foods) can be compared systematically to counterparts that have a history of safe usage. For example, corn with a Bt gene for insect resistance can be compared metabolically, nutritionally, etc. to other kinds of corn. With the exception of the Bt event, it is assumed that Bt corn and non-Bt corn are highly similar. Although regulators consider data on how these modifications are made, assessing the safety of novel foods is based on “the product and not the process used to develop it” (Health Canada, 1994: 4). The use of substantial equivalence and a process-product model for regulating products of biotechnology is likely to find acceptance among future regulators of nanotechnology.

In Canada, no regulatory agency has jurisdiction presently over products of nanotechnology. Although Canada is investing heavily in nanotechnology (e.g., in 2001, the National Research Council provided funding for the National Institute for Nanotechnology), little work on assessing the regulatory or social impacts of nanotechnology is being funded. Like with many new scientific and technological applications (e.g., internet), regulation seems to occur as an afterthought or stems from concerns raised by a range of actors (e.g., NGOs) (Mehta, 1998). In Canada, it is likely that existing regulatory authorities will share responsibility for regulating the environmental and human health impacts resulting from nano products. Additionally, it is likely that nanotechnology will converge with other technologies like biotechnology.⁷ In this instance, the split of responsibility between Health Canada and the CFIA is likely to be maintained for nanotechnology.

An examination of the literature reveals David Forrest (1989) to be one of the earliest writers on the challenges of regulating nanotechnology. Forrest suggests that regulation of this technology should occur in four distinct phases based on the development of assemblers. Assemblers are machines that manufacture objects on an atom-by-atom or molecule-by-molecule basis. The development of assemblers will accelerate bottom-up, rather than top-down, approaches to manufacturing and machining. Top-down refers to precision machining that strips away material from the macroscopic to nanoscopic level. Bottom-up approaches use synthetic chemistry, bioengineering tools, and devices like the “nanohand” to physically place individual molecules into a pre-determined location.⁸ Forrest believes that the development of assembler technology, and

different levels of containment for pre- and post-release of nanoassembling devices, is key to understanding how best to regulate this technology. He suggests the following phases for regulating nanotechnology:

- (1) Pre-assembler: Regulators should assist in writing standards for developers and stimulate critical public debate about nanotechnology.
- (2) Post-assembler, pre-assembler lab: Once assemblers are developed, regulators should help developers create safe ways to contain this technology. At this stage, the use of assemblers is confined to laboratory conditions.
- (3) Post-assembler lab, Pre-active shield: When sealed assembler labs become available, scientists can begin developing advanced assemblers and new materials. At this stage, assemblers are still used for experiments and development work, and have limited commercial application.
- (4) Post-active shield: Assemblers can now be used in a wide range of applications and settings. Malfunctioning nanomachines can be monitored, contained or decommissioned. In theory, measures should be in place to prevent runaway replication and the uncontrolled release of nanomachines that could damage ecosystems and human health.

There are several similarities, and notable differences, between Forrest's set of regulatory phases for nanotechnology and how Canada regulates genetically modified organisms. The development of nanoassembler technology is akin to developments in recombinant DNA technology. Once recombinant DNA technology became possible, developers used isolation and sterilisation techniques to ensure that newly developed

organisms were contained. The development and refinement of agronomic traits in genetically modified plants (e.g., herbicide resistance) led to commercial applications for this technology. Regulators assess the safety of these new organisms prior to release into the environment and marketplace. However, unlike Forrest's phases, little or no public consultation occurred in any of these phases for genetically modified foods. Additionally, genetically modified plants have been released into the environment with few existing safeguards in place for monitoring, containing or neutralising plants that may harm non-target insects and other organisms, facilitate the development of "superweeds" through pollen flow, and potentially damage the viability and marketability of organic farming (Mehta, under review).

With biotechnology, the use of substantial equivalence and reliance upon an artificial distinction between product and process has fostered a regulatory approach that excludes the fourth helix from participating in a meaningful way. If future regulators of nanotechnology adopt this approach, the fourth helix is likely to be excluded systematically under the guise of "science-based assessment." Such an approach to regulating nanotechnology will be profoundly inconsistent with the post-normal nature of the risks generated by this technology, and with the profound social and economic transformations that nanotechnology is likely to usher in.

Lesson two: labelling

The issue of labelling genetically modified foods has become complex and divisive. In the past several years, many countries around the world have moved towards

either voluntary or mandatory labelling regimes. In general, countries of the EU and several countries in Asia and Oceania have adopted mandatory labelling laws. Although there are differences (e.g., percent of genetically modified ingredients, store-bought v. restaurant food, finished products like oils, etc.) in the application of these laws, many of these countries have responded to consumer concerns about the safety of genetically modified foods, ethical and religious concerns, and consumer rights and sovereignty arguments by requiring some form of labelling. By contrast, two of world's largest producers of genetically modified foods (e.g., Canada and the United States) have adopted voluntary guidelines for labelling. In Canada, very few products are actually labelled in a positive (e.g., this product contains genetically modified ingredients) or negative (e.g., this product does not contain genetically modified ingredients) way. In fact, strong pressure from food processors and retailers to pull from grocery shelves products with any reference to genetic modification exists.⁹

A range of consultative exercises have taken place in Canada to address some aspects of this debate. The Canadian Biotechnology Advisory Committee (CBAC) was created by the Canadian government to provide independent advice to the seven ministers of the Biotechnology Ministerial Coordinating Committee on a wide range of social, ethical and economic dimensions associated with developments in biotechnology. On 12 March 2002, CBAC presented a position paper to the Standing Committee on Health on the labelling of genetically modified foods. In this paper, CBAC explains how they are balancing the different issues associated with adopting a mandatory v. voluntary system in Canada. CBAC (2002: 2) writes:

Consumers believe they have the right to know whether the food they eat is derived from genetically modified plants. This may be for a number of reasons including perceived and potential health risks, perceived and potential risks to the environment, a fundamental ethical objection to genetic modification of any kind, religious beliefs, broader societal concerns...or a view that full realization of the precautionary principle requires labelling.

After going through these concerns, as well as examining economic issues (e.g., costs of labelling, segregation, identity preservation and the need to comply with international trading agreements), CBAC concludes that not enough support in Canada exists to recommend either a mandatory or voluntary labelling system at this time. Since other bodies including the Canadian General Standards Council and Codex Alimentarius Commission are currently working on this issue, CBAC concludes that adopting a mandatory labelling system is premature.¹⁰ They underscore this observation by pointing out that “All GM products on the market have been approved as safe for health and the environment by the responsible regulatory authorities” (CBAC, 2002: 6). In other words, science-based assessment has deemed these products safe. Anyone who asks for mandatory labelling must be opposed to science-based assessment, and therefore be responding illogically and irrationally to science and technology. This is the expected normal science response.

One of the main arguments given for not requiring mandatory labelling of genetically modified foods is based on the process v. product distinction referred to in the

discussion on substantial equivalence. In Canada, approximately 50 novel foods have been approved by Health Canada and the CFIA. To date, all plants produced through recombinant DNA technology have been defined as plants with novel traits. The CFIA asserts that “[all PNTs] have undergone a full, comprehensive, and rigorous safety assessment prior to release into the environment.”¹¹ Once approved, PNTs may be sold as food. If the novel food does not contain any allergens, no labelling is required. Presumably, if a novel food contains a protein known to trigger allergic reactions in some individuals (e.g., nuts, gluten, dairy), labelling for the allergen is required but not for the process by which the food was produced.¹² In other words, Canadian regulators prohibit labelling which gives consumers an opportunity to discriminate against approved foods based on process rather than product distinctions. In reality, many consumers see process and product as important to decisions they make on a wide range of items.¹³

The lesson for future technologies like nanotechnology is that labelling is likely to be a complex regulatory and public relations nightmare. It is likely that debates over mandatory and voluntary labelling and process v. product will emerge when consumers are exposed to products of nanotechnology. The relationships between traditional triple helix institutions will be challenged by these debates. Since most of these debates are likely to occur within a post-normal science context, an appreciation for how the fourth helix can be incorporated early is key.

Lesson three: precautionary principle

In recent years, the precautionary principle, also known as precautionary approach, has become a central feature of many national and international laws and treaties. Various articulations of this principle can be found in Principle 15 of the Rio Declaration on Environment and Development (1992), Maastricht Treaty (1992), Cartagena Protocol on Biodiversity (2000), and at least ten other environmental treaties. Principle 15 defines the precautionary principle as:

...in order to protect the environment, the precautionary approach shall be widely applied by States according to their capability. 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.

Known as a “better safe than sorry” approach, the precautionary principle is playing a strong role in debates on nuclear safety, greenhouse gas emissions and global climate change, and the safety of genetically modified organisms. The rise of the precautionary principle is due to the creation of post-modern hazards and the increasing importance of post-normal science. It is likely that proponents and regulators of nanotechnology will have to deal with the precautionary principle in explicit ways. The social and scientific uncertainty resulting from innovations in nanotechnology will be significant, and identifying lessons from how the precautionary principle is being applied to biotechnology, may be valuable.

In Canada, the Canadian Environmental Protection Act (1999) mandates use of a precautionary approach. Chapter 33 of the Act states: “Whereas the Government of Canada recognises the integral role of science...social, economic and technical matters are to be included in that [assessment] process.” From the perspective of regulators like Health Canada, application of the precautionary principle is a distinctive part of science-based risk management. In other words, risk assessment is done first and the precautionary principle is applied later when developing options that are guided by values and priorities.¹⁴ The Royal Society of Canada’s report (2001) on the regulation of food biotechnology also refers to the importance of using a precautionary approach for assessing the safety of genetically modified organisms. The expert panel recommends that more attention be paid to the reproductive biology of modified plants, their toxicological properties, and potential impacts on ecosystems.

Some organisations like the Canadian Chamber of Commerce have been quite critical of the use of a precautionary approach by the Government of Canada. The Chamber is a national and international advocacy group representing the interests of business. With respect to the precautionary principle, the Chamber states:

There has been an apparent shift in certain parts of the federal government, particularly Health Canada and Environment Canada, away from risk-based assessment of environmental and health risks which considered many factors to a more hazard-based approach where, in cases where the science is not sufficiently strong to be indicative of action, the

precautionary principle is invoked and precipitous and costly action is called for.¹⁵

The Chamber also recommends that precautionary measures be cost-effective and based on risk management principles and current science, and that the use of socio-economic modelling tools for comparing non-market benefits with “real dollar” costs be discontinued. In other words, science-based assessment should be used exclusively in the regulation of products that may generate environmental and human health risks. If science fails to demonstrate significant risk, and risk management can be used to control exposure to hazards, then application of the precautionary principle is unfounded.

If a precautionary approach is used as a risk management tool, then how do regulators of biotechnology assess complex and uncertain topics like allergenicity and toxicity? Health Canada applies a “weight of evidence” approach which is based on experimentally generated data.¹⁶ In the case of allergens in food, Health Canada compares characteristics of proteins from novel foods with known allergens. The molecular weight, rate of digestion and amino acid sequence are used to predict allergenicity. A weight of evidence approach also considers consistency of the data, biological plausibility and overall strength of evidence.¹⁷

It is likely that developments in nanotechnology will require new approaches for addressing uncertainty and heightened understanding of how risks and benefits should be balanced. Strong application of the precautionary principle during early stages of risk management may negate the benefits of pursuing this kind of science. Conversely, not recognising and curtailing serious risks (e.g., runaway replication) comes with serious

costs too. Can a weight of evidence approach be used for understanding the risks posed by very different kinds of constructs and potentially new life forms made by nanotechnology? This question, and others like it, illustrates the shortcomings associated with using a normal science approach for dealing with new technologies like nanotechnology. It also demonstrates the importance of creating mechanisms for including the fourth helix in discussions on how nanotechnology should be regulated. Without these mechanisms, public opposition to nanotechnology is likely to be strong and international in scope.

Conclusion

The regulation of nanotechnology is likely to occur within a post-normal science era where uncertainty is high, values in dispute, stakes significant and public concern elevated. Traditional triple helix relations between state, university and industry are being transformed by the nature of post-modern hazards and the ascendancy of post-normal science. An essential ingredient for ensuring the smooth functioning of post-normal regulation is full inclusion of the fourth helix, the public. The fourth helix is the “extended peer community” referred to in work on post-normal science.

Examples of how Canada has failed to include the fourth helix in discussions on how to regulate biotechnology are instrumental for understanding the possible pitfalls associated with future regulation of nanotechnology. Confusion over the use of substantial equivalence, a failure to put in place mandatory labelling laws for genetically modified foods, and re-conceptualisation of the “spirit” of the precautionary principle,

erode trust and make governance more complex. This paper argues that these mistakes will make the transition to a nano economy more difficult, and may generate unnecessary risks and social conflict.

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Notes

¹ The fourth helix is not necessarily the end user. With nanotechnology, it is likely that end users will be industry, at least for the first several decades.

² The fourth helix referred to in this paper is different than the quadruple helix referred to in Baber (2001). With specific reference to Singapore, Baber describes the quadruple helix as composed of external scientific experts consulted by the Singaporean government during the early 1980s to set science and industrial policy.

³ The so-called “War on Terrorism” following September 11, 2001, had a similar impact on boosting research. Agres (2002) notes that U.S. President George W. Bush has requested from Congress a 15.7% increase in the budget for the National Institutes of Health. Most of this increase is directed towards building better capacity for dealing with threats of bioterrorism.

⁴ Canadian Food Inspection Agency, Plant Biosafety Office

<http://www.inspection.gc.ca/english/plaveg/pbo/pbobbve.shtml> Downloaded on 25 March 2002.

⁵ Canadian Food Inspection Agency, Frequently Asked Questions.

<http://www.inspection.gc.ca/english/index/faqs.shtml> Downloaded 25 March 2002.

⁶ On 23 November 2001, several governmental agencies including Health Canada, CFIA, Agriculture and Agri-Food Canada and Department of Fisheries and Ocean released an action plan for addressing the conclusions of the Royal Society of Canada report. In this plan, these agencies indicate that substantial equivalence represents a safety standard approach and not a decision threshold.

⁷ A typical strand of DNA is only two nanometers wide. Nanotechnology could be used for building DNA one base pair at a time. Additionally, nanoassemblers could be used for placing or repositioning pre-constructed segments of DNA. Source: “Building DNA with the nanoassembler.” Downloaded on 29 March 2002 from www.techtv.com/screensavers/showtell/jump/0,24331,3320067,00.html

⁸ Scientists at Denmark Technical University are working on the nanohand. The nanohand uses a microcantilever system for manipulating nanostructures. See <http://www.mic.dtu.dk/research/Nanohand/Nanohand.htm#about>

⁹ In August 2001, a large Canadian grocery chain known as Loblaws, pulled products from their shelves with GE-free labels. This outraged many Canadians and prompted groups like the Council of Canadians to picket and boycott their stores. Incidentally, the Food and Drugs Act (1985) explicitly allows positive and negative labelling, like GE-free labels, as long as such labels are truthful (Section 5.1) and do not promise unsubstantiated health benefits (Section 3.1). Source: <http://www.canadians.org/campaigns/campaigns-genfoodmedia010830.html>

¹⁰ Codex develops voluntary food standards for protecting health and promoting fair practices in the international trade of food. Canada chairs the Committee on Food Labelling.

¹¹ Source: <http://www.inspection.gc.ca/english/ppc/biotech/reg/equive.shtml>

¹² Some Canadian organisations like the Consumers Association of Canada (CAC) believe that it is inappropriate to distinguish with labelling between different kinds of food modifications. For instance, the CAC point out that novel foods have been made

over the years with advanced hybridisation and accelerated mutagenesis. Like with recombinant DNA technology, these techniques produce plants with characteristics that are unlikely to occur naturally.

¹³ Consumers have boycotted products manufactured by non-unionised workers, child labourers, and those made with questionable environmental practices. An increase in the sale of organic produce illustrates that distinguishing between process and product is untenable.

¹⁴ Source: <http://www.hc-sc.gc.ca/english/protection/precaution.html>

¹⁵ Canadian Chamber of Commerce, “Science, the precautionary principle and public policy development.” Downloaded on 29 March 2002 from <http://www.chamber.ca/newpages/polP8.html#Anchor4>

¹⁶ See International Food Biotechnology Council and ILSI Allergy and Immunology Institute (1996). “Allergenicity of foods produced by genetic modification” in E. Clydesdale (ed.) *Critical Reviews of Food Science and Nutrition*, 36. New York: CRC Press.

¹⁷ See www.emcom.ca for a discussion on how a weight of evidence approach can be used for assessing the risks of endocrine modulating substances.