

# *From Biotechnology to Nanotechnology: What Can We Learn From Earlier Technologies?*

**Michael D. Mehta**  
*University of Saskatchewan*

*Using Canada as a case study, this article argues that regulating biotechnology and nanotechnology is made unnecessarily complex and inherently unstable because of 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.*

**Keywords:** *nanotechnology; biotechnology; regulation; Canada*

Many developed countries are now investing heavily in a 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, and so forth. Proponents of nanotechnology suggest that the world's needs could be met by utilizing a limitless supply of atoms to manufacture valuable molecules (Duell, 1999). The potential range of applications is staggering and the cost of basic nanoscience research high. As with biotechnology, several actors are committed to developing innovations resulting from discoveries in nanoscience (Mehta, 2002). Can lessons be learned from our experiences with biotechnology? Do new technologies like nanotechnology require a different way of understanding the risks and benefits, the roles of regulation, and the changing nature of science-technology-society interactions?

## **Lesson One: Substantial Equivalence**

In Canada, Health Canada and the Canadian Food Inspection Agency (CFIA) share joint responsibility for regulating novel plants. Plants with novel traits (PNTs) are defined as follows:

Plant 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. (CFIA, 2002c, ¶ 1)

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 (CFIA, 2002a). 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, fertilizers, 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, *Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada* (2001), concluded that substantial equivalence should not be used as a decision threshold for determining whether genetically modified (GM) products should undergo rigorous scientific assessment. In section 8.1 of the report, members of the expert panel noted,

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. (Royal Society of Canada, 2001, Sect. 8.1)

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 GM products with existing products and because an assessment based on “superficial similarities” does not satisfy the burden of proof for safety.<sup>1</sup>

The concept of substantial equivalence implies that novel products (e.g., GM 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, and so forth 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, p. 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. As with many new scientific and technological applications (e.g., the Internet), regulation seems to occur as an afterthought or stems from concerns raised by a range of actors (e.g., nongovernmental organizations) (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.<sup>2</sup> 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 suggested 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 the nanoscopic level. Bottom-up approaches use synthetic chemistry, bioengineering tools, and devices like the *nanohand* to physically place individual molecules into a predetermined location.<sup>3</sup> Forrest believes that the development of assembler technology and different levels of containment for prerelease and postrelease of nanoassembling devices is key to understanding how best to regulate this technology. Forrest suggested the following phases for regulating nanotechnology:

1. Preassembler: Regulators should assist in writing standards for developers and stimulate critical public debate about nanotechnology.
2. Postassembler, preassembler 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. Postassembler lab, preactive shield: When sealed assembler labs become available, scien-

tists 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. Postactive 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 (1989) set of regulatory phases for nanotechnology and how Canada regulates GM organisms. The development of nanoassembler technology is akin to developments in recombinant DNA technology. Once recombinant DNA technology became possible, developers used isolation and sterilization techniques to ensure that newly developed organisms were contained. The development and refinement of agronomic traits in GM 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 GM foods. Additionally, GM plants have been released into the environment with few existing safeguards in place for monitoring, containing, or neutralizing plants that may harm nontarget insects and other organisms, facilitate the development of superweeds through pollen flow, and potentially damage the viability and marketability of organic farming.

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 public from participating in a meaningful way. If future regulators of nanotechnology adopt this approach, the public is likely to be excluded systematically under the guise of science-based assessment.

### **Lesson Two: Labeling**

The issue of labeling GM foods has become complex and divisive. In the past several years, many countries around the world have moved toward either vol-

untary or mandatory labeling regimes. In general, countries of the European Union and several countries in Asia and Oceania have adopted mandatory labeling laws. Although there are differences (e.g., percent of GM ingredients, store-bought vs. 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 GM foods, ethical and religious concerns, and consumer rights and sovereignty arguments by requiring some form of labeling. By contrast, two of the world's largest producers of GM foods (e.g., Canada and the United States) have adopted voluntary guidelines for labeling. In Canada, very few products are actually labeled in a positive (e.g., "this product contains GM ingredients") or negative (e.g., "this product does *not* contain GM ingredients") way. In fact, strong pressure from food processors and retailers to pull from grocery shelves products with any reference to genetic modification exists.<sup>4</sup> A range of consultative exercises has 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. In 2002, CBAC published an article dealing with the topic of labeling. In this article, CBAC explained how they are balancing the different issues associated with adopting a mandatory versus voluntary system in Canada.

After examining economic issues (e.g., costs of labeling, segregation, identity preservation, and the need to comply with international trading agreements), CBAC concluded that not enough support in Canada exists to recommend either a mandatory or voluntary labeling system at this time. Because other bodies, including the Canadian General Standards Council and Codex Alimentarius Commission, are currently working on this issue, CBAC concluded that adopting a mandatory labeling system is premature.<sup>5</sup> They underscored 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, p. 6). In other words, science-based assessment has deemed these products safe. Anyone who asks for mandatory

labeling must be opposed to science-based assessment and therefore must be responding illogically and irrationally to science and technology.

One of the main arguments given for not requiring mandatory labeling of GM foods is based on the process versus 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 (2002b) asserted that “[all PNTs] have undergone a full, comprehensive, and rigorous safety assessment prior to release into the environment” (§ 5). Once approved, PNTs may be sold as food. If the novel food does not contain any allergens, no labeling is required. Presumably, if a novel food contains a protein known to trigger allergic reactions in some individuals (e.g., nuts, gluten, dairy), labeling for the allergen is required but not for the process by which the food was produced.<sup>6</sup> In other words, Canadian regulators prohibit labeling that 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.<sup>7</sup>

The lesson for future technologies like nanotechnology is that labeling is likely to be a complex regulatory and public relations nightmare. It is likely that debates over mandatory and voluntary labeling and process versus product will emerge when consumers are exposed to more products produced by nanotechnology.

### **Lesson Three: Precautionary Principle**

In recent years, the precautionary principle, also known as the 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 (United Nations, 1992), the Maastricht Treaty (European Union, 1992), the Cartagena Protocol on Biodiversity (United Nations, 2000), and at least 10 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. (United Nations, 1992, Principle 15)

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 GM organisms. 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.<sup>8</sup> 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 GM organisms. The expert panel recommended that more attention be paid to the reproductive biology of modified plants, their toxicological properties, and potential impacts on ecosystems.

Some organizations like the Canadian Chamber of Commerce (2002) 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 stated,

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. (Canadian Chamber of Commerce, 2002, ¶ 1)

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 modeling tools for comparing nonmarket 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 that is based on experimentally generated data (International Food Biotechnology Council & ILSI Allergy & Immunology Institute, 1996). 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 the overall strength of evidence.<sup>9</sup>

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 recognizing and curtailing serious risks (e.g., runaway replication) comes with serious costs, too.

### Conclusion

Examples of how Canada has failed to include the public 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 labeling laws for GM foods, and reconceptualization of the spirit of the precautionary principle erodes trust and makes governance more complex.

### Notes

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

2. 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 preconstructed segments of DNA (Hubert, 2001).

3. 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>.

4. In August 2001, a large Canadian grocery chain known as Loblaw's pulled products from their shelves with genetically engineered-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 labeling like genetically engineered-free labels as long as such labels are truthful (Section 5.1) and do not promise unsubstantiated health benefits (Section 3.1).

5. 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.

6. Some Canadian organizations like the Consumers Association of Canada (CAC) believe that it is inappropriate to distinguish with labeling between different kinds of food modifications. For instance, the CAC points out that novel foods have been made over the years with advanced hybridization and accelerated mutagenesis. Like with recombinant DNA technology, these techniques produce plants with characteristics that are unlikely to occur naturally.

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

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

9. See [www.emcom.ca](http://www.emcom.ca) for a discussion on how a weight-of-evidence approach can be used for assessing the risks of endocrine modulating substances.

### References

- Canadian Biotechnology Advisory Committee. (2002). *Improving the regulation of genetically modified foods and other novel foods in Canada*. Ottawa, Canada: Report to the Government of Canada, Biotechnology Ministerial Coordinating Committee.

- Canadian Chamber of Commerce. (2002). Science, the precautionary principle and public policy development. Retrieved March 29, 2002, from <http://www.chamber.ca/newpages/polP8.html#Anchor4>
- Canadian Food Inspection Agency. (2002a). *Frequently asked questions*. Retrieved March 25, 2002, from <http://www.inspection.gc.ca/english/index/faqs.shtml>
- Canadian Food Inspection Agency. (2002b). *Long term testing/substantial equivalence*. Retrieved March 25, 2002, from <http://www.inspection.gc.ca/english/ppc/biotech/reg/equive.shtml>
- Canadian Food Inspection Agency. (2002c). *Plant biosafety office*. Retrieved March 25, 2002, from <http://www.inspection.gc.ca/english/plaveg/pbo/pbobbve.shtml>
- Duell, C. H. (1999). Technological transformation: The increase in power and complexity is coming just as the raw materials are eroding. *Development Dialogue*, 1-2, 25-73.
- European Union. (1992). *The Maastricht Treaty: Treaty on European Union*. Paris: Author.
- Food and Drugs Act (R.S. 1985, c. F-27). Available at <http://www.canadians.org/campaigns/campaigns-genfoodmedia010830.html>.
- Forrest, D. (1989). *Regulating nanotechnology development*. Retrieved March 5, 2002, from [www.foresight.com/NanoRev/Forrest1989.html](http://www.foresight.com/NanoRev/Forrest1989.html)
- Health Canada. (1994). *Guidelines for the safety assessment of novel foods*. Food Directorate, Health Protection Branch, Volume 2: Genetically modified microorganisms and plants. Ottawa, Canada: Food Directorate, Health Protection Branch, Health Canada.
- Hubert, B. (2001, April 3). *Building DNA with the nanoassembler*. Retrieved March 29, 2002, from [www.techtv.com/screensavers/showtell/jump/0,24331,3320067,00.html](http://www.techtv.com/screensavers/showtell/jump/0,24331,3320067,00.html)
- International Food Biotechnology Council & ILSI Allergy & Immunology Institute. (1996). Allergenicity of foods produced by genetic modification. In E. Clydesdale (Ed.), *Critical reviews of food science and nutrition* (p. 36). New York: CRC Press.
- Mehta, M. D. (1998). Sex on the net: Regulation and control of pornography in the new wired world. In L. Pal & C. Alexander (Eds.), *Digital democracy: Politics and policy in the wired world* (pp. 164-179). Toronto, Canada: Oxford University Press.
- Mehta, M. D. (2002). Nanoscience and nanotechnology: Assessing the nature of innovation in these fields. *Bulletin of Science, Technology & Society*, 22(4), 269-273.
- Royal Society of Canada. (2001). *Elements of precaution: Recommendations for the regulation of food biotechnology in Canada*. Ottawa, Canada: Author.
- United Nations. (1992). *Rio Declaration on Environment and Development*. Geneva: Author.
- United Nations. (2000). *Cartegena Protocol on Biosafety. Convention of Biological Diversity*. Geneva: Author.

*Michael D. Mehta, associate professor and director of the Sociology of Biotechnology Program at the University of Saskatchewan, is the author of more than 30 publications. He has helped make risk analysis and public consultation a more formally recognized area of research in the discipline of sociology. He has presented his work in scholarly conferences and workshops across Canada, the United Kingdom, the United States, South Korea, and Singapore. He studies public perceptions of blood safety, endocrine modulating chemicals, and nanotechnology.*