

The Regulation of Biotechnology Risk (Or, Why We Need a Gene Law?)

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I. REGULATION OF BIOTECHNOLOGY RISK: PRODUCT OR PROCESS?

The current regulatory regime for biotechnology products in Canada uses a network of existing legislation and departmental mandates to assess health and environmental risks and to align its evaluation methods with those of its international trading partners.¹ The primary federal departments and agencies involved are Health Canada, Environment Canada, and the Canadian Food Inspection Agency, operating under eight different Acts of Parliament. The rationale for this approach is explained as follows:

“Biotechnology uses living organisms, or parts of living organisms, to make new products or provide new methods of production. This broad description covers all organisms, their parts and products, whether developed traditionally or through the newer molecular techniques such as genetic engineering [...] [D]epartments and agencies now regulating products developed using traditional techniques and processes are responsible for regulating products developed using biotechnology techniques and processes.”

This approach is also used, entirely or in large part, by many of Canada’s trading partners.²

¹ This presentation is the concluding sections in “Some Aspects of the ‘New Biotechnology’ and its Regulation in Canada”, by William Leiss and Michael Tyshenko, forthcoming as Chapter 16 in D.L. Van Nijnatten and R. Boardman, eds., *Canadian Environmental Policy : Ecosystems, Politics and Process*, 2d ed. (Toronto: Oxford University Press).

² A useful summary can be found in the “Factsheet: The Federal Regulatory System”, included in the information site on the National Biotechnology Strategy <http://www.ic.gc.ca>.

The scientific rationale for the approach was enunciated by an expert panel appointed by the U.S. National Academy of Sciences (NAS), in a report published in 1987, and it was re-affirmed by a similar group in 2000.³ The rationale takes the form of three statements:

1. “There is no evidence that unique hazards exist either in the use of rDNA techniques or in the movement of genes between unrelated organisms.”
2. “The risks associated with the introduction of rDNA-engineered organisms are the same in kind as those associated with the introduction of unmodified organisms and organisms modified by other methods.”
3. “Assessment of the risks of introducing rDNA-engineered organisms into the environment should be based on the nature of the organism and the environment into which it is introduced, not on the method by which it was produced.”

As mentioned earlier, humans have been doing genetic modification in domesticated plants and animals through selective breeding for millennia; and in this century, before the advent of molecular biology, other modern techniques (such as radiation) have been used as a way of selecting for desired traits. All this may properly be called indirect genetic manipulation, because genetic structures carried within cells could not be accessed as such and the manipulation occurred at the level of the whole plant or animal, in earlier times, or at the cellular level more recently. On the other hand, genetic manipulation using molecular biology accesses genes directly, which was possible only after the discovery of the structure of DNA; the applications resulting from this new direction are only about twenty years old. We could refer to these as the “pre-molecular” and “molecular” phases of plant genetics.⁴

³ U.S. National Academy of Sciences, *Introduction of Recombinant DNA-Engineered Organisms into the Environment: Key Issues* (Washington, D.C.: National Academy Press, 1987); U.S. National Research Council, *Genetically Modified Pest-Protected Plants: Science and Regulation* (Washington, D.C.: National Academy Press, 2000) at 44.

⁴ Cf. the distinction made by David Dennis, who writes on his Website: “[B]iotechnology is defined as the transfer of genes using the techniques of molecular biology to generate transgenic plants. It does not refer to methods used by modern plant breeders.” <http://www.performanceplants.com/FAQ.htm>.

In Canada the lead federal regulators for plant biotechnology applications, Agriculture and Agri-Food Canada and now the Canadian Food Inspection Agency, have argued that there is a strong element of continuity from “traditional practices” (*i.e.*, selective breeding) to the “new biotechnology” (*i.e.*, modern genetic engineering).⁵ During hearings on biotechnology regulation held by the House of Commons Standing Committee on Environment and Sustainable Development in mid-1996, a senior AAFC official provided a general perspective along these lines, where the single phrase “new or traditional biotechnology” was said to cover a process of continuous evolution that has proceeded through four stages: (1) plant cultivation and animal husbandry; (2) selective breeding of plants and animals; (3) gene transfer within the same species; (4) gene transfer among different species.⁶

This perspective reinforces the rationale for the current regulatory approach: “Under the regulatory framework, Agriculture and Agri-Food Canada assesses the traits of the final products rather than the actual processes of biotechnology, with the belief that genetically engineered organisms are not fundamentally different from traditionally bred organisms.”⁷ But a slightly different note is struck by the following passage from the same document:

“Through new biotechnology techniques, scientists can modify the characteristics of organisms for our benefit in a more controlled way than with traditional practices [...] These techniques allow the transfer of genes to be carried out in a very controlled way, so that only one or a few desirable traits are transferred at a time. Furthermore, these technologies can be used to introduce desirable traits from outside the species, something that is not possible with traditional breeding methods.”

⁵ Contrast the definition given by David Dennis (*supra* note 4) with the following statement from material (dated August 1997) posted on the CFIA Website: “Biotechnology involves using biological processes to produce substances beneficial to agriculture, the environment, industry, and medicine. In fact, we have used biotechnology to make everyday products for thousands of years.” <http://www.cfia-acia.agr.ca>

⁶ Standing Committee, transcript of hearing, meeting N° 19 (May 16, 1996), testimony of Dr Brian Morrissey, AAFC. The current wording on the traditional *versus* new biotechnology distinction is on the CFIA Website at <http://www.cfia-acia.agr.ca> (last updated August 1997).

⁷ AAFC, *Biotechnology in Agriculture: General Information*, Ottawa 1995.

The first quotation says that “genetically engineered organisms are not fundamentally different from traditionally bred organisms”, whereas the second says that the new technology does something “that is not possible with traditional breeding methods.” The first suggests that no new authority is needed; the second at least puts the question we have raised on the table for discussion, and we shall return to it in our concluding section.

Another prominent feature of the regulatory stance taken by Canadian federal departments is what may be called a highly restrictive perspective on risk.⁸ For the regulators, as expressed in their slogan of “science-based risk assessment”, risk is restricted only to those hazards that may be characterized with precision by scientific practice, such as the ones described above (herbicide and insect tolerance). It is indeed very important for the public to be protected against such risks through the existence of regulatory oversight. However, it has also been known for some time now that among the public, which is not generally expert in the science of molecular biology, or in other sciences, there is a quite different perspective on risk, one that is much broader in scope than that of the regulators and that is permeated by values different from those which govern scientific practice. This differing value structure is revealed in the comprehensive public attitude surveys on biotechnology done in Europe.⁹ The main conclusions are: First, perceived usefulness of the biotechnology product is a pre-condition of citizen support. Second, people seem prepared to accept some risk as long as there is a perception of usefulness and no moral or ethical concern. Third, and most importantly, moral doubts (that is, a sense that something is “wrong”) can act as a *veto* on people’s willingness to accept specific biotechnology applications. In other words, the regulator’s concept of “safety” (acceptable risk) is not the final or overriding consideration; rather, a looser but also deeply-held sense of “right and wrong” is the decisive criterion for public acceptance.

This is where the “process” *versus* “product” distinction becomes relevant. As shown earlier, biotechnology regulators maintain that, since there are no unique risks associated with genetic modification, there is no need for a unique form of regulatory oversight for GM applications of any

⁸ For a valuable discussion of this point see K.J. Barrett, *Canadian Agricultural Biotechnology: Risk Assessment and the Precautionary Principle* (Ph.D. Thesis, Department of Botany, University of British Columbia, 1999).

⁹ Eurobarometer. *Nature*. June 26, 1997.

kind. In other words, the regulators say that it would make no sense to regulate the process of biotechnology (that is, directly moving genes themselves among different organisms), as opposed to the various products (for example, herbicide-tolerant canola or insect-resistant corn plants), because the relevant risks are in the end products, not in the process that created them. Moreover, these risks are similar to most of those with which we are already familiar, as a result of conducting regulatory oversight over food products made from “conventional” (non-GM) crops—risk factors such as toxicity (for example, from pesticide residues), bacteria and other pathogens, allergenicity, digestibility, nutritional deficiencies, and so on. Again, this list contains important risks against which the public needs to be protected through competent and diligent regulatory supervision. But it is not a complete list of risks that are of interest to the public.

The intense and still growing public controversies over biotechnology are, in our opinion, a strong indication that many among the public do indeed wish the process of so-called “new” biotechnology itself (the engineering of new organisms through molecular biology) to be the subject of specific regulatory oversight. This is what is implicit in the now-famous term “Frankenfood” and its cousins (when Japanese scientists first cloned a pig in the summer of 2000, it was immediately baptized “Frankenpig”)—namely, a perceived concern about what may be the ultimate type of creations that emerge from the science of modern molecular biology, and whether or not those creations will be consistent with our moral sense of right and wrong, or instead give rise to a new and troubling dimension of “moral risks.”¹⁰ What the public senses, albeit unclearly, that is different about the “new biotechnology” (as opposed to the farmers’ conventional and age-old practices of selective breeding) is its inherently unlimited character, the fact that every new stage of understanding leads to an enhanced capacity to manipulate more thoroughly the genomes of all plants and animals, including humans. There are some manipulations that can be imagined that are so repugnant to our moral sensibility that they must be forbidden: are we supposed to wait until we are confronted with those actually existing products, along with their makers’ assurances that they are “safe”, and only then express our repugnance?

¹⁰ See the section entitled “Cloning: Down the road towards moral risks”, in W. Leiss, Inaugural Lecture for the Research Chair in Risk Communication and Public Policy, University of Calgary (March 1999: text and illustrations files): <http://www.ucalgary.ca>.

On the contrary, what we must have is an anticipatory public oversight that looks broadly at the general features of all the genetic manipulations that are proceeding along the way from laboratory science to new product development, and that applies not only scientific criteria, but also a range of ethical judgments, to those intended manipulations. This requires the creation of a unique, specialized regulatory body at a national level, working in parallel (but entirely independent of) the existing departmental regulatory agencies that are charged with assuring product safety. Such a proposed agency was described in the 1998 Royal Society statement on genetically modified plants for food use as an “over-arching body” or “super-regulator” that would have responsibility for the “wider issues” surrounding genetic modification. This idea is further elaborated in our concluding section.

II. WHY WE NEED A GENE LAW?

Looming in the future are applications of biotechnology far more complex than the ones we have seen so far: genetically engineered food crops involving multiple transgenic insertions, eugenics using genetic screening (modification of inherited human traits), and gene therapy (elimination of undesirable inherited human traits and single gene diseases). Science will make possible, should we wish to have them, the construction of human-animal chimeras for organ harvesting or of quasi-human living entities.¹¹ Some of these futuristic biotechnology applications may never come to pass (although it would be unwise to take this for granted), but of some things we can be certain—that scientific research on such things as genetic markers for human disease, aging, and intelligence will continue; that the methods of moving genetic materials between species will be explored and refined; and that the potential commercial applications of any such research that promises attractive medical benefits will be well-funded by the biotechnology industry.

¹¹ A frightful application of biotechnology which we do not have time to deal with here is the bioengineering of virulent bacteria and viruses for warfare, in the form of “biological weapons” such as microorganisms and viruses that have been genetically modified to make them more deadly. One is described as a recombinant Ebola-smallpox chimera called “Ebolapox”, in which the infection possesses the characteristic of severe internal hemorrhaging of the Ebola virus but also the contagiousness of smallpox. At present, about eighteen countries are reportedly known to have, or are suspected of having, a capacity to develop such biological weapons: R. Lewis, “Bioweapons Research Proliferates” (1998) 12 *The Scientist* 1; R. Preston, “Annals of Warfare, The Bioweaponeers” (1998) *The New Yorker* 52.

Our society and others missed a golden opportunity to “do the right thing” when the need for the regulation of the new biotechnology appeared during the 1980s, namely, to apply an appropriate risk management approach to this task, one that had learned from the mistakes of previous epochs. When the first versions of a new approach to health and environmental risk management appeared on the scene, in the 1970s, they had to be applied retrospectively to major industries, such as chemicals and nuclear power, which had grown up and prospered in the absence of society’s having proper regulatory structures in place. Much was learned in the battles to impose a new structure on those industries—for example, the differences between “expert” and “public” assessments of risk, and the need to encompass both (the nuclear industry never did learn to appreciate this important point). But like other nations, Canada failed to seize the opportunity, when the new biotechnology came along, to apply these lessons.

This failing had two aspects, both of which are explored well in Katherine Barrett’s recent doctoral thesis. First, governments everywhere, ever anxious to prove themselves as good economic managers by “picking winners” among new technologies, became obsessed with acting as aggressive promoters of the new biotechnology. Their promotional orientation inevitably dictated the way in which they would approach their responsibilities for assessing and regulating this new industrial sector. Their desire to find an approach which would encourage a fledging sector to develop quickly is illustrated well in the fact that their regulatory rationale, based on the process/product distinction, only appeared after the first generation of product development in industrial laboratories was well under way. Moreover, the chosen regulatory framework was constructed virtually in a secret dialogue between industry and government officials; the public was invited in, and introduced to the subject, only after the fact, after governments were already committed to its basic structure.¹² These self-imposed limitations on regulatory responsibility also inhibited Canadian federal departments from freely engaging the public in discussions on a wider range of issues: no communications program from these departments to date, dealing with products of the new

¹² Perhaps the most powerful constraint on the Canadian regulators was their perceived need to conform (for trade harmonization reasons) to the U.S. model, which first made the choice on how to approach the regulation of the new biotechnology. So far as excluding the public is concerned, it is likely that this was not at all an explicit decision; rather, it is the “normal” procedure for governments to first make policy choices and then to design a public consultation process that leaves out the most basic issues from consideration.

biotechnology, has included a balanced account of risks and benefits, and controversial issues often elicit a response from “official spokespersons” that is either confrontational or merely inarticulate.¹³

Second, the core concept in that basic structure was an excessively narrow construction of the concept of risk: only risks characterized by the science of plant biology itself would be admitted into the calculus, and all of them were confined by definition to product-based risks. The structure of regulatory discourse about the new biotechnology had decided, before the public was ever invited into the debate, to rule out *a priori* any considerations having to do with the process of using molecular biology to create new organisms. The discussion would be about product safety, and nothing else. This apparently clever strategy allowed industry to get its first-generation products into the marketplace with a minimum of fuss, but it overlooked the fact that, these days, there is no guarantee that the public will passively accept a “definition of the situation” that institutions seek to impose arbitrarily on public discourse.¹⁴

There is a certain lack of public confidence in the new biotechnology that, in our opinion, will not be easily repaired. In our view, a new public institutional structure is required, one which acts truly independently of industrial interests and which is charged with taking the widest possible purview on all the relevant aspects, especially moral and ethical aspects, of the potential social consequences of applications of the new biotechnology.¹⁵

¹³ Asked to respond to a newspaper story about the invasion of GM canola plants into neighbouring fields, a spokesperson for CFIA stated: “That is a question that has been raised. That is my response.” H. Scoffield, “Canola farmer fights seed invasion”, *The Globe and Mail*, Toronto, August 14, 2000, at B4.

¹⁴ Monsanto Inc. Was awarded U.S. Patent Number 5, 723, 765, entitled: “Control of Plant Gene Expression.” (M. Oliver, J. Quisenberry, N. Trolinder, G. Lee & D. Keim, “Control of Plant Gene Expression”, March 3, 1998). The patent’s main invention is to genetically engineer crops that produce seeds that are reproductively sterile in the second generation. This would make it impossible for farmers to save and replant seeds, making them dependent on the seed suppliers. Over 1.4 billion people, mostly living in third world countries, depend on farm-saved seeds. The public backlash associated with Monsanto’s terminator gene patent and its potential impact has been nothing less than incredible. Genetic engineering of plants to produce sterile seeds has been renounced as a “morally offensive application of agricultural biotechnology.” Intense hostility world-wide towards this developing technology has been a public relations disaster for Monsanto. <http://www.rafi.org/web/>.

¹⁵ Some of the broader issues involving the international context are briefly noted in the report, *Transgenic Plants and World Agriculture*, issued in July 2000 by the National

In the new biotechnology (the “molecular” phase of biotechnology) there is a marked qualitative increase in the human capacity to manipulate genomes of all organisms, plant and animal, including the transfer of genetic material across greatly different species. It seems to us that there is a sufficiently important qualitative difference between these two pre-molecular and molecular phases of genetic manipulation to justify the introduction of a generic oversight mechanism for the latter. In other words, we need a designated “gene regulator” to oversee the processes of molecular biology, with respect to the suitability of specific genetic manipulations intended to be introduced into the environment.¹⁶ That is, an agency which would be a regulatory authority separate from, and superior to, the multi-departmental apparatus for the assessment of product safety previously described.

It is at least possible to see in the present achievements and future promises of molecular biology the prospect of a qualitative change in human technology which also opens up for human societies qualitatively different issues of ethics and sensibility, because there is almost no limit to the genetic manipulations that can take place when science can operate directly on DNA. In this sense, the process that is at stake here—namely, the creation of transgenic entities through the direct manipulation of DNA using molecular biology—may be sufficiently unique, and moreover may have ethical implications for human societies sufficiently profound in nature, that it ought to be the subject of unique form of oversight.¹⁷

Finally, whether or not there is any warrant for a new level of oversight based on considerations of health and environmental safety, there is another reason entirely to consider this, namely, as a response to what we earlier referred to as the poorly-articulated public concerns about the present and future of genetic manipulation. In other words, given what is thought and imagined about this technology and its ultimate operational capacities, it is advisable to provide another level of regulatory oversight for no other reason than as a means of additional reassurance to the

Academies of seven countries and regions (Washington, D.C.: National Academy Press, 2000).

¹⁶ This section draws upon the concluding section in William Leiss, “The Trouble with Science: Public Controversy over GM Foods” (January 1999): <http://www.ucalgary.ca>.

¹⁷ The great majority of current genetic manipulations in plant biology are confined to plant genes.

public.¹⁸ This need not be seen as pandering to the lowest common denominator of understanding, or as “giving in” to the current critics of GM technologies, especially those who do not share the basic tenets and values of the modern scientific community.¹⁹ It also need not be envisioned as a heavy regulatory burden, duplicating unnecessarily what already exists, but rather—to use the words of The Royal Society report referred to earlier—as a body with “an ongoing role to monitor the wider issues associated with the development of GM plants.”²⁰ Obviously, the mandate and operational authority of such a body would require clear description and clear differentiation from the product-based safety reviews which now exist. But in the end, as a practical matter, it may be more efficient to provide this additional layer of public reassurance than to fight an endless rearguard action against the dark shadows conjured up in imagination by fears of what a newly-potent science of genetics might bring.

¹⁸ Regular news about new stages of completion in the Human Genome Project will produce, among other things, an enormous increase in public concerns about genetic manipulation.

¹⁹ One of the most active groups in the Internet traffic on GM foods is the Natural Law Party.

²⁰ The purview of such a body should extend to the full range of expected manipulations (plant, animal, human).