CANADIAN INSTITUTE FOR ENVIRONMENTAL LAW AND POLICY
L'INSTITUT CANADIEN DU DROIT ET DE LA POLITIQUE DE L'ENVIRONNEMENT

A 2008 FACT SHEET ON BIOTECHNOLOGY

A Perspective and Recommendations on Biotechnology Policy

This article was written by Susan Holtz, Senior Policy Analyst with the Canadian Institute for Environmental Law and Policy (CIELAP) after discussion with Anne Mitchell, the Institute's Executive Director. It has been developed to help Canadians reflect and act on concerns about biotechnology. CIELAP has been raising questions about the need for a policy framework for biotechnology since it held its first workshop on the subject in 1984.

Introduction: A Still Contentious Policy Area

In the early 1980s, CIELAP became involved in attempting to promote a responsible, open and transparent approach to managing what was then the emerging field of biotechnology. Over the years since then, the organization has held workshops and published a number of legal and policy documents with recommendations on the topic, as well as participating in many forums, conferences and advisory bodies.

Enormous strides have been made in both the science and the technology related to genetics and molecular biology during this span of time. These have undoubtedly resulted in new benefits, particularly in the increase of scientific knowledge and in diagnostics and medicine. However, some ongoing scientific research in this field and certain contemporary biotechnology applications, both in use and proposed, continue to raise a variety of ethical, moral, social, ecological, and even theological issues. Just what the hazards and risks are, as well as the potential opportunities and benefits, and whether their distribution is equitable, have been and in many cases still are highly contentious matters. Moreover, in many countries, including Canada, a number of environmental and other civil society groups consider the existing regime for oversight and regulation of biotechnology inadequate, along with the lack of avenues for effective public engagement.

This present document is intended to provide CIELAP's broad policy perspective on contemporary biotechnology issues. It does not review or propose specific legislation or detailed institutional arrangements. Rather, it briefly discusses ongoing concerns related to different biotechnology applications; presents CIELAP's overall policy approach; and recommends new institutional developments to address six specific weaknesses or gaps in government and institutional oversight.

Not A Single Issue: Biotechnology's Different Applications

Biotechnology today includes a huge spectrum of research and technological applications. These bring up very different sets of issues and possible responses. For purposes of discussion, then, we suggest grouping biotechnology applications and science into the following six categories:

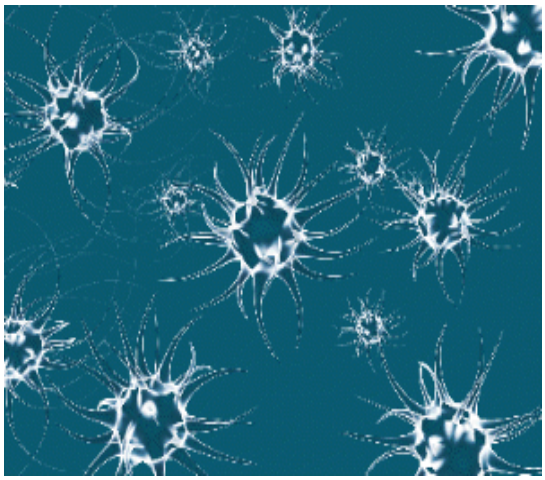
Basic research

Some avenues of research raise questions that are really more about spiritual or moral unease concerning the implications and directions of this research than about specific ethical issues. An example is the recent synthesizing from scratch of the entire genome of the bacterium *Mycoplasma genitalium* (announced in the January 24/08 online edition of *Science*). Some may believe that such research, which in this case is a major step leading toward the creation of synthetic organisms, along with other similarly extraordinary extensions of human technological

capability, are morally or spiritually wrong, regardless of any practical risks or benefits. Others may disagree.

Medical research and reproductive technology

These generally involve issues related to individual privacy, the ethics and morality of cloning of humans and other animals for use, and decisions about "designing" certain human characteristics. Sometimes there are definite moral dimensions to these questions; the Canadian Supreme Court decision disallowing the patenting of the "Onco-mouse," for instance, was argued in part on the felt sense of inappropriateness about owning patent rights to a higher life form. Much conflict, though, centres on common types of ethical dilemmas within historical and evolving medical practice, where the rights, risks and benefits for individuals interact with public policy. Another dimension of these applications is the use of traditional knowledge about medicinal plants and remedies and their genetic manipulation for corporate profit. These issues mainly concern public policy matters such as patent rights and compensation for the appropriation of traditional knowledge.



"Indoor" biotechnology applications

There are many different applications here, in fields such as renewable energy (e.g., genetically modifying yeasts to produce renewable transportation fuels like ethanol, biodiesel, or even gasoline from biomass sources like waste wood). The research and development concerning such things as genomics, gene therapy, diagnostics, and related work in the field of human health and medicine is a huge area of activity. Another, more problematic example is plant molecular farming (PMF), that is, the use of genetically modified plants to produce pharmaceutical products or industrial chemicals. I group together these diverse applications if they take place inside secure facilities, including factories, greenhouses, or laboratories, with the intention of strictly containing modified organisms. This is because the risks are primarily ecological or related to human or animal health. Whether strict containment is possible and the severity of the consequences if it's breached are critical questions. Depending on the specifics, environmental and health benefits from these applications are generally considered significant, though with various reservations.

"Outdoor" biotechnology applications

These include applications involving genetically modified seeds, crops, and trees for commercial use in agriculture and forestry, outdoors in the open environment. Such applications have been highly contentious, involving ethical objections related to ecological risks, unknowns regarding health risks, and social justice issues about the increasing concentration of corporate control in agriculture, along with negative economic impacts on small farmers in the developing world and in the organic agriculture sector elsewhere. The claims of economic benefits, along with the suggested need for genetically modified crops to provide higher yields and reduced environmental damage from tillage and pests, are also very contentious.

Military applications

Secular pacifists, peace activists and members of traditional "peace churches" such as Quakers and Mennonites will obviously have objections to such applications. Particularly if there are risks to civilians and the environment, others may also oppose various developments in this area.

Hybrid bio-nanotechnology, sometimes referred to as next-generation nanotechnology

Biotechnology does not actually include nanotechnology, which latter is about the manipulation of ma-

terials at the molecular scale. Nanotechnology poses its own set of risks, since materials at this extraordinarily small scale have novel physical, optical, electrical and other characteristics. Little is known about the toxicity and other biological and ecological effects of nano-scale materials, but because of their various special properties, such as electrical conductivity or great tensile strength, they are already being used in upwards of 600 commercial products.

However, next-generation nanotechnology is about marrying genetically modified organisms – yeasts or bacteria, for instance – with nano-scale materials in order to make self-assembling products, such as solar arrays, battery components or even batteries. There are many concerns about ecological, worker health, and other risks, mainly because to date, regulation of nanotechnology is not in place and many would argue that regulation of biotechnology is inadequate. (It should be noted that in the summer of 2007, Environment Canada posted notification that nanomaterials having novel molecular structures would be subject to the Canadian Environmental Protection Act [CEPA] regulations, an important step in the right direction. Nevertheless, that still excludes from regulatory oversight many nanomaterials now in use, though there is ongoing discussion about further developments in nanotechnology regulation and policy.) So far, putting in place a regime for managing and regulating hybrid bio-nanotechnology has received virtually no public or political attention at all.

CIELAP'S OVERALL POLICY RECOMMENDATIONS

As a non-profit environmental research organization, CIELAP's work is focused on providing analysis and promoting the development of law, policy, and public practice from a sustainability and public interest perspective. The fundamental values of sustainability or sustainable development are about supporting simultaneously both environmental integrity and human well-being. This is the broad normative context for CIELAP's positions and recommendations.

Because of the large number of different issues involved in the many applications of biotechnology, CIELAP has only two overall policy recommendations. These are:

1. Because there are so many different ethical and moral perspectives concerning such a wide variety of applications, governments should actively seek and support regular input from a broad cross-section of individuals and civil society organizations. Advice should formally be sought about Canada's biotechnology research priorities, international trade positions, legislation including possible product and research bans, labeling, liability, intellectual property issues, and environmental and social equity concerns, among other topics.

2. For reasons of ecological risk and because of social and economic equity considerations, CIELAP supports a comprehensive ban on "outdoor" biotechnology applications.

RECOMMENDATIONS FOR BETTER MANAGING BIOTECHNOLOGY

Managing technology is never a completely successful enterprise for governments. Still, public policy has a number of institutional means to try to do this in order to achieve important social or economic goals. What is striking about biotechnology in Canada is how narrow these goals have been (commercial success, primarily) and how limited public input into policy decisions about its goals, research and financial support, and regulation.

The following are six important areas where CIELAP believes institutional change is needed in managing biotechnology:

1. <u>Public research funding</u>

CIELAP supports the institution of new formal avenues for public input and review.

2. <u>Policy review and advice</u>

Here also ongoing formal avenues for public input and adequate support for public participation are lacking and should be created.

3. <u>Labeling</u>

An alternative to outright legislated bans on certain products or activities is labeling. Currently and for many years past, the Canadian government has refused to require labeling of food and other products involving genetically modified organisms (GMOs). This decision deprives citizens of the ability to make

informed personal choices about these products. Especially in a contentious political climate regarding GMOs, and where a ban on GMOs in food is not allowable under existing trade rules (see the later section on trade issues), labeling allows market signals to influence choices made by food producers and retailers, and directly rewards those giving customers what they want to buy. In the absence of outright bans on GMO food products, CIELAP supports their mandatory labeling.

4. <u>The regulatory regime</u>.

The present regulatory regime is a confusing patchwork of existing legislation that may or may not be adequate to manage the specific challenges of biotechnology. **CIELAP supports a thorough review of existing legislation, and possibly major change to consolidate, streamline, and make it more transparent and effective.**

5. <u>Liability</u>.

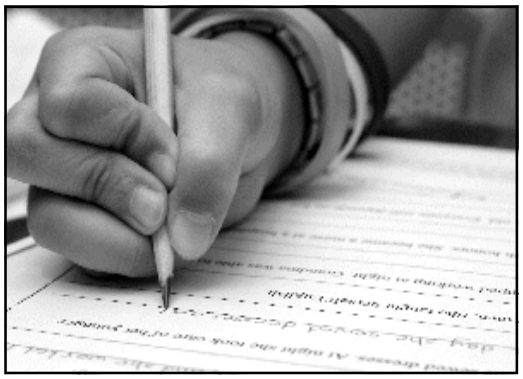
Currently, there is no legislative direction in Canada concerning civil liability for biotechnology. For those who might be affected (for example, an organic grower whose crop is contaminated by neighbouring genetically modified crops and who loses organic certification because of this), the only choice is a civil suit with the burden of proof on the complainant.

Unlike a number of other countries, Canada has no legislation apportioning responsibility and costs to either the neighbouring farmer or the commercial producer of the GMO product. The result is legal uncertainty and financial exposure for those adversely affected. As well, farmers with GMO-contaminated crops are liable to civil action against themselves for patent infringement, despite the fact that it is now known that genetic contamination of nearby plants from GMOs can and does take place.

CIELAP supports a public review and adoption of a strict liability regime, possibly modeled on Germany or other EU legislation.

6. <u>World Trade Organization (WTO) rules and trade-related issues</u>.

Current international trade rules constrain national initiatives and international treaties from broadly employing some approaches to environmental legislation and related economic and trade sanctions. This is not entirely unreasonable, as some countries have used "environmental" legislation as a protectionist mechanism for unfairly restricting international trade. However, right now, trade measures are one of the key points of conflict both within the EU and between the EU and North America regarding the acceptability of genetically modified food crops, with an individual country's ability to restrict GM crops at question.



CIELAP, along with many other environmentalists, supports a new round of WTO negotiations aimed at finding a more acceptable approach to environmental matters in both international treaties and in environment-related trade disputes.

Most, including CIELAP, would agree in principle with rules that disallow arbitrary "environmental" trade restrictions, but that would permit countries more latitude in their environmental restrictions involving legitimate environmental goals and considerations, especially in disputes where there is scientific uncertainty and the precautionary principle is invoked.

Because "the devil is in the details," creating such modifications in trade rules would require a committed negotiating effort.

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