PETITION UNDER THE AUDITOR GENERAL ACT, R.S.C., c.A-17

Date: May 9, 2000

To: Auditor General of Canada
Minister of Agriculture and Agri-Food
Minister of Environment
Minister of Fisheries and Oceans Canada
Minister of Health
Minister of Industry
Minister of Natural Resources

Petitioners: Canadian Institute for Environmental Law and Policy
Council of Canadians
Dr. E. Ann Clark
Dr. Bert Christie

Solicitors: Sierra Legal Defence Fund

PETITION UNDER THE AUDITOR GENERAL ACT

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Auditor General Act Petition – Regulation of GMOs

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PETITION TO THE AUDITOR GENERAL

1. NATURE OF THE PETITION

This petition is being submitted by Sierra Legal Defence Fund on behalf of the Canadian Institute for Environmental Law and Policy (CIELAP), Council of Canadians, Dr. E. Ann Clark and Dr. Bert Christie pursuant to section 22 of the *Auditor General Act*, R.S.C., c.A-17, as amended concerning an environmental matter in the context of sustainable development. In particular, the petition is being submitted in relation to the federal laws, regulations and policies concerning genetically modified organisms. This includes all foods derived from plants, animals or microorganisms that have been genetically modified, as well as genetically modified animal feed, fish, trees and insects. The particular concerns and relief sought vis-a-vis this Petition are referenced in detail below.

2. CONFORMANCE WITH THE *AUDITOR GENERAL ACT*

It is respectfully submitted that this petition falls within the requirements of section 22 of the *Auditor General Act* (the "Act"). Specifically, it is submitted that the following requirements are met:

(a) Receipt of a Petition in Writing From a Resident of Canada

The Canadian Institute for Environmental Law and Policy (CIELAP) is an independent, not-for-profit environmental law and policy research and education organization, founded in 1970 as the Canadian Environmental Law Research Foundation. CIELAP was incorporated pursuant to the laws of Ontario and is a resident of Canada. The Institute is a registered charity, and has a long history of environmental law and policy research and publication on the environmental and health regulation of products of biotechnology.

The Institute hosted the first conference in Canada on the environmental regulation of biotechnology products in 1984, has participated in all major consultations on the issue with the Government of Ontario, and the federal departments of Environment, Health, and Agriculture and Agri-Food since then. The Institute's Director of Research, Dr. Mark Winfield served as an advisor to the Canadian delegations to the recent negotiations on the Protocol on Biosafety under the United Nations Convention on Biological Diversity.

The Institute's recent publications on biotechnology include *Regulation of Agricultural Biotechnology in Canada* and *The Citizen's Guide to Biotechnology.* Copies of both of these publications are attached to this Petition as Tab 1 and 2 respectively.

Council of Canadians is an independent, non-partisan citizens' interest group providing a voice on key national issues. It is incorporated pursuant to the laws of the Dominion of Canada and is a resident of Canada. Council of Canadians, founded in 1985, is comprised of over 100,000 members and 50 chapters across the country.

One of the Council's principal active campaigns is on GM foods. Its mandate includes lobbying Members of Parliament, conducting research, disseminating information and educating consumers. The Council of Canadians is a pre-eminent citizens' watchdog organization and an important information source on GMOs.

Dr. E. Ann Clark is an individual who is a resident of Canada. She holds a B.S. in Biological Sciences, an M.S. in Agronomy and a Ph.D. in Crop Production and Physiology. Dr. Clark is an Associate Professor at the University of Guelph, with twenty years experience in pasture and grazing management and sustainable agriculture. She is a critic of genetically modified foods and has authored several influential and compelling reports on the issue.

Dr. Bert Christie is an individual who is a resident of Canada. He holds a B.S.A. in Agronomy, and an M.S.A. and Ph.D. in Plant Breeding. For many years, Dr. Christie served as Professor, Department of Crop Science at the University of Guelph. From 1989 to 1998, he was a research scientist with Agriculture and Agri-Foods Canada. He is an expert in plant breeding and genetics and is a critic of genetically modified foods. Dr. Christie is now retired but continues to consult.

(b) An Environmental Matter in the Context of Sustainable Development

The subject matter of this petition concerns the release into the environment and/or presence of genetically modified organisms (GMOs) that may have, and in some instances already have had adverse and/or unknown effects on the environment. More generally, the dramatic impact that GMOs may have on public health, food safety, and food security is, in our submission, a vitally important environmental issue in the context of sustainable development.

The well accepted definition of sustainable development is: 'development that meets the needs of the present, without compromising the ability of future generations to meet their own needs.'[1] Parliament has adopted the achievement of sustainable development as a central purpose of the *Canadian Environmental Protection Act*, Canada's principal environmental protection statute.[2]

The Government of Canada has confirmed in its Guide to Green Government ('Guide') that there are three dimensions to sustainable development that must be integrated to ensure that this principle is complied with: social, economic and environmental.[3] The Office of the Auditor General agrees that 'reconciling economic development, social equity and environmental quality is at the core of sustainable development.'[4] The Guide points out that such an integrated approach must be based on sound science, including recognition of the precautionary principle, which underscores the importance of taking

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[1] World Commission on Environment and Development, Our Common Future (Toronto: Oxford University Press, 1987), at 8.
[2] *Canadian Environmental Protection Act, 1999*, declaration.
[3] 'A Guide to Green Government,' Environment Canada, 1995. See web site: http://www.ec.gc.ca/grngvt.
[4] See web site: http://www.oag-bgv.gc.ca/domino/cesd_cedd.nsf/html/sd_e.html.

early action in the face of scientific uncertainty. The Guide further recognizes that to achieve an integrated approach, environmental policy can no longer be reactive, responding to problems after they have developed. These principles lie at the very core of biotechnology regulation.

The issue of how to regulate GMOs presents unique concerns in terms of all three dimensions of the sustainable development concept.

Environmental Impacts

In environmental terms, GMOs have the potential to cause dramatic and irreversible adverse environmental effects. These include the creation of new pests, the enhancement of the effects of existing pests, harm to beneficial non-target species (see 'Environmental Risks' section, infra), species extinction, and disruptive effects on ecosystem processes and functions. Examples of such disruptive effects include horizontal gene transfer[5] and the potential for accumulation of active *Bacillus thuringiensis* (Bt) endotoxin in the soil where it could persist for hundreds of days, retaining active insectisidal properties.[6]

The potential impacts of GMOs on the conservation and sustainable use of biological diversity were recognized by the international community in 1992 through the *United Nation's Convention on Biological Diversity*[7] and, more recently through the adoption of *Cartagena Protocol on Biosafety*[8] under the Convention.

Significant potential for adverse effects on human health, such as toxicity or allergenicity has also been identified. Health Canada, in its Sustainable Development Strategy, has admitted that 'concern for health and well-being is at the very heart of sustainable development.'[9]

Economic Impacts

Economically, the emergence of agricultural biotechnology has been associated with major consolidations within the agricultural supply industry. Many of the products which had been commercialized, such as corn, canola and soya seeds modified for resistance to specific brands of herbicide, are designed to secure market share for seed and herbicide suppliers and reinforce the dependency of farmers on these firms for inputs.

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[5] This refers to the unplanned transfer of the live Bt transgene to unrelated wild organisms, i.e.: through the soil. Thus, genetically engineered genes may disrupt and modify other organisms in unwanted and unanticipated ways. This is a unique threat posed by GMOs. See the work of Mae Wan Ho, Genetic Engineering Dream or Nightmare? Gateway Books, Bath, U.K., 1998.

[6] See the work of Guenter Stotzky out of New York University, showing that active Bt endotoxins (different from the original inactive Bt protoxin carried by Bt which degrades quickly under UV radiation) can persist in the soil for at least 234 days.

[7] *United Nations Convention on Biological Diversity*, 1992, reprinted in (1982) 31 ILM 822, Art. 8(g).

[8] Agreed to: Montreal, 29 January 2000. See web site: www.biodiv.org for the final text.

[9] 'Sustaining our Health: Health Canada's Sustainable Development Strategy,' Health Canada, November 1997, executive summary.

Little or no investment is occurring in the development of more sustainable forms of agricultural production which do not rely on capital intensive inputs, such as integrated pest management and organic farming. In fact, certain applications of agricultural biotechnology, such as pesticidal plants using the B*acillus thuringiensis* (Bt) toxin gene, may actually undermine the viability of these alternatives.

In addition, there is the problem of 'genetic pollution,' meaning that transgenes from genetically modified crops may be transferred to neighbouring farms. This threatens the livelihood of organic farmers (who may lose their certification) and others who want to charge a premium for non-GM products. It also compromises agronomic practices.

These approaches are in stark contrast to the objectives set out in Industry Canada's Sustainable Development Strategy. The Strategy includes the objectives of fostering a marketplace climate that promotes sustainable development, as well as enhancing the ability of Canadian firms to develop tools which contribute to sustainable development.[10]

Social Impacts

From a social perspective, biotechnology raises a host of issues. Many Canadians question the acceptability of the deliberate movement of genetic material across the species barrier for religious and ethical reasons. The patenting of genetic material raises a range of additional questions. The availability of genetic testing touches on issues of the security of the person. Furthermore, the highly-capital intensive forms of agriculture with which modern biotechnology is associated are undermining the economic and social viability of rural communities. The replacement of human skills and labour with capital inputs results in dramatic reductions in their populations.

We submit that a review of the federal regulatory framework for GMOs fits directly within the mandate of section 22 of the Act, for these environmental, economic and social reasons. In particular, it is our submission that *the current framework fails to evaluate products of biotechnology from a sustainable development perspective*, and that this failure has significant negative implications for the environmental, social and economic well-being of Canadians.

(c) Category I Department

This petition is directed, where applicable, to the following Category I departments:

- Agriculture and Agri-Food Canada
- Health Canada
- Environment Canada
- Industry Canada
- Natural Resources Canada
- Fisheries and Oceans Canada

[10] Industry Canada, 'Sustainable Development Strategy,' December 1997.

3. BACKGROUND

Over the past few years, there has been a rapid commercialization of agricultural biotechnology in Canada. Examples of genetically modified (GM) food products and crops include herbicide tolerant corn, canola, and soya, and corn and potatoes modified to produce their own pesticides. Other products approved for commercialization include GM tomatoes and flax. Modern biotechnology research is rapidly expanding into new areas, and the commercialization of GM fish, animals and trees is on the horizon.

Concern over the regulatory treatment of GMOs has been mounting worldwide, prompting many countries to endorse the precautionary principle and to take action to ensure public health.[11] International bodies are also undertaking work in this area, recognizing that the current standards and assessments for food safety are deficient.[12] Biotechnology regulation has clearly moved from being a domestic problem, to being a pressing international issue.

Canada has pledged in the Guide to Green Government to meet its international obligations in order to help resolve sustainable development issues. One such obligation is laid out in the Convention on Biological Diversity (CBD), which mandates parties to regulate, manage or control the risks associated with the use and release of living modified organisms associated with biotechnology.[13] This requirement includes taking into account adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, as well as human health. Unless a more integrated approach to decision-making is taken, the requirements under the CBD – among others - will not be met.

International concern over GMOs was highlighted by the recent biosafety negotiations in Montreal that culminated in the adoption of a new Protocol under the CBD. The Protocol presents clear evidence of the global acknowledgement that GMOs can have potential adverse effects, and that safeguards are therefore required. It is clear from both the preamble and the body of the agreement[14] that the precautionary principle is endorsed. Countries have agreed to implement measures that will ensure adequate levels of protection in their treatment of GMOs (in a transboundary context) even in the event of scientific uncertainty. This includes the requirement to label shipments of commodities

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[11] For instance, the British government has endorsed a moratorium (to 2003) on the introduction of new GM crops. Furthermore, a recently agreed 'Common Position' in the European Union on the amendment to its Novel Foods Directive will substantially tighten the regulation of GM foods throughout Europe. Also, the Hong Kong Legislative Council recently voted in favour of the introduction of a mandatory labelling regime for GM foods.

[12] The Codex Alimentarius Commission - the international food standardizing body - at its 23rd Session, agreed to undertake new work in the area of foods derived from biotechnology. The Organization for Economic Cooperation and Development (OECD) is also looking into the issue, including holding several government and stakeholder meetings, and mandating a Task Force to assess the implications of biotechnology and other aspects of food safety.

[13] Supra n. 7 above.

[14] See Articles 1 (Objective) and 11 (Procedure for LMO-Food, Feed and Processing) re: the Precautionary Approach; Articles 4 (Scope), 7 (Application of the AIA Procedure), 12 (Review of Decision), and 15 (Risk Assessment) as examples of references to effects on human health.

that may contain living modified organisms that are bound for transport,[15] which begs the question of why equivalent safety measures are not being implemented domestically.

Canada needs to live up to its pledge to take an integrated approach to decision-making in order to achieve sustainable development. It also needs to take measures to meet its obligations under the CBD. The industry-friendly regulatory regime currently in effect is allowing GM products to be moved to market prematurely, putting the health of Canadians, and the environment, at risk.

4. RISKS ASSOCIATED WITH GENETICALLY MODIFIED ORGANISMS

The release of GMOs into the environment and the introduction of GM foods into the global food chain have created a new generation of unprecedented environmental, health, ethical and social concerns. These concerns require a new breed of laws and regulations to respond to the associated risks. This section synopsizes these concerns.

Environmental Risks

Various studies have been conducted indicating at the least, a lack of knowledge regarding the long term effects of GM foods or at the worst, actual harm. A study conducted by Dr. Arpad Pusztai and Dr. Stanley Ewen, published in the British medical journal *The Lancet* in 1999 found that rats fed with genetically modified potatoes that were toxic to insects had 'variable effects' on different parts of the rat gastrointestinal tract.[16] This study drew conclusions about the unpredictability and safety of GM foods based upon animal testing. The publication of this study garnered a great deal of publicity, and even resulted in the suspension – and subsequent retirement - of Dr. Pusztai from the Rowett Research Institute in Scotland. The study methods used have since been criticized, although no follow-up studies have been carried out that establish otherwise than what was reported by the study.

Harm to the environment is no longer mere supposition. Both Hilbeck (in Switzerland) and Birch (in Scotland), eminent scientists, have conducted studies demonstrating environmental effects of GMOs on ladybugs, green lacewings and other beneficials.[17] Another study conducted on the monarch butterfly[18] demonstrated that a high percentage of this species that fed on Bt corn pollen died prematurely.

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[15] Article 18 (Handling, Transport, Packaging and Identification) sets procedures for the packaging and identification of LMOs destined for transport.

[16] 'Effect of Diets Containing Genetically Modified Potatoes Expressing *Galanthus nivalis* Lectin on Rat Small Intestine,' The Lancet, Vol. 354, No. 9187 16 October 1999.

[17] See 'Tri-trophic Interactions Involving Pest Aphids, Predatory 2-Spot Ladybirds and Transgenic Potatoes Expressing Snowdrop Lectin for Aphid Resistance,' Birch, A.N.E., I.E. Geoghegan, M.E.N. Majerus et. al., Molecular Breeding, 5:75-83, 1999, and 'Effects of Transgenic *Bacillus thuringiensis* Corn-fed Prey on Mortality and Development Time of Immature *Chrysoperla carnea*,' Hilbeck, A., M. Baumgartner, P.M. Fried and F. Bigler, Environmental Entomology, 276:480-487.

[18] 'Transgenic Pollen Harms Monarch Larvae,' J. Losey, L. Raynor, and M. Carter, 399:214, May 20, 1999; or see 'Non-target Effects of Bt Corn Pollen on the Monarch Butterfly (Lepidoptera: Danaidae),' L. Hansen and J. Obrycki, abstract of a poster presented at the North Central Branch Meeting of the Entomological Society of America. 29 March 1999, at web site: www.pme.iastate.edu/info/monarch.htm.

Furthermore, there is evidence of gene flow (known as 'outcrossing' or 'cross-contamination') via wind or other natural means from GM crops to non-GM crops. This can be seen as a new form of 'trespass' that creates similar problems as with the introduction of exotic or alien species into an ecosystem. The phenomenon of cross-contamination, or 'genetic pollution' is problematic in the context of sustainable development for a number of reasons. These range from economic problems such as affecting the eligibility for organic certification, or denying farmers the ability to obtain a 'GMO-free' premium on products, to environmental effects like increased weediness. This can create unwanted effects such as reducing crop yield and compromising agronomic and weed control practices on neighbouring farms and inadvertently affecting natural biodiversity.

Outcrossing has also been known to unintentionally create multiple herbicide tolerant crop plants. For instance, canola crop growing in a field in northern Alberta was recently found to be tolerant to three different herbicides.[19] This is the first official case of 'natural gene stacking' resulting from multiple gene crossings. The unfortunate upshot may be increased use of herbicides to compensate for the creation of new resistant strains of crops.

Other potential harms include: loss of useful pest resistance genes, harm to beneficial non-target species, the unleashing of secondary pest problems, the creation of new or worse viruses, and other unknown harms.[20] Unconfined release of GMOs into the environment can have different effects depending on ecosystem attributes, in different years, with different crops, and on different scales of introduction. This means that unintended or unexpected (untested) effects may occur after commercial release, since confined release testing can only elaborate data on those issues that were actually *contemplated.* Further, the rapid move to commercialize GM trees and fish presents an entirely new subset of environmental risks, which as at the moment are not subject to regulation.

A recent report from the World Wildlife Fund Canada, providing an overview of the environmental impacts of the commercialization of agricultural biotechnology is attached hereto at Tab 3.

Human Health Threats

In terms of human health issues, concerns abound as well. On January 18, 2000, an independent group of Canadian scientists and academics released a study disputing the evidence used by the federal government to conclude that genetically engineered foods are safe to eat.[21] Among some of the more alarming statistics presented was the fact that

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[19] 'Triple Resistant Canola Weeds Found in Alta.,' Western Producer, February 19, 2000. See web site: www.producer.com/articles/20000210/news/20000210news01.html.

[20] See 'Risks of Genetic Engineering' fact sheet, Union of Concerned Scientists for more information, at web site: www.ucsusa.org/agriculture/gen.risks.html.

[21] 'Food Safety of GM Crops in Canada: Toxicity and Allergenicity,' E. Ann Clark on behalf of GE Alert, January 2000.

toxicity was not actually tested or measured in 70% (28 of 40) of the available crops approved in Canada.[22] Furthermore, 'no measure of allergenicity was provided for any of the 40 available crops.'[23] One of the deficiencies cited in the report was that most of the conclusions on food safety in Canada have been based on 'inferences and assumptions' rather than on actual testing.

The problem of unanticipated allergic reactions is specific to GM products, because this kind of technology alone 'can transfer proteins across species boundaries into completely unrelated organisms' on a commercial scale.[24] Also, GM products may create novel toxins or elevate currently innocuous compounds to toxic levels by activating previously dormant pathways.

Yet another concern is the possible creation of antibiotic resistant pathogens. This is caused by placing what are called 'marker genes' in GMOs for antibiotic resistance. The presence of these genes can have two key negative effects:

> eating these foods could reduce the effectiveness of antibiotics to fight disease when these antibiotics are taken with meals...Second, the resistance genes could be transferred to human or animal pathogens, making them impervious to antibiotics. If transfer were to occur, it could aggravate the already serious health problem of antibiotic-resistant disease organisms.[25]

A lawsuit launched in 1998 against the U.S. Food and Drug Administration (FDA)[26] resulted in the release of government documents that demonstrated the concern that internal FDA scientists themselves have about the safety of GM foods. Despite the FDA's public declaration that GM foods are 'substantially equivalent' to traditional crops (see a discussion of substantial equivalence, infra), scientists within government were not convinced about their safety.

These risks urgently need to be addressed by the federal government. Ultimately, there is a need for *new and enhanced risk assessment parameters*, coupled with *effective, long-term monitoring* in both field trials and market releases of GM crops. The Canadian regulatory regime - which does not take into account the potential for accidental or unintended effects across a range of circumstances - is poorly structured, and inadequate in terms of ensuring public health and environmental safety. The potential for public health threats are sufficient enough to warrant action that errs on the side of caution.

A recent report drafted by Professor E. Ann Clark of the University of Guelph regarding the regulation of the human health aspects of genetically modified foods is attached to this submission at Tab 4.

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[22] Ibid, at p. 1.
[23] Ibid, at p. 2.
[24] Supra note 20 above, at 1. Note the University of Nebraska scientific study of soybeans engineered to contain brazil nut proteins, which caused an allergic reaction in individuals allergic to brazil nuts.
[25] ibid, at 2.
[26] Alliance for Bio-Integrity et. al. v. Shalala (1998); still pending. See web site: www.bio-integrity.org for particulars.

Social and Ethical Concerns

New ethical issues have been created by modern biotechnology. The patentability of living organisms, the question of ownership of genetic material, and the manipulation of plants and animals for human use are but a few of the new issues. From an ethical perspective, individuals are being denied the right to choose what food they eat because of the lack of labelling and information-sharing. This obvious and calculated information gap means that citizens, by omission, may be buying products that they *do not* want. This problem is underscored by recent polling, which demonstrates that Canadians familiar with the GMO issue are worried about their safety and are in favour of labelling.[27]

A report drafted by John Fagan, Professor of Molecular Biology (in the U.S.) regarding a precautionary approach to labelling, is attached to this petition at Tab 5.

Insertion of animal matter into other GM products raises other religious and ethical concerns. Without a proper mandatory labelling and segregation scheme, individuals who do not eat meat based on religious dietary laws are at risk of having their constitutional right to religious freedom infringed.[28]

Furthermore, the highly-capital intensive forms of agriculture with which modern biotechnology is associated are undermining the economic and social viability of rural communities. The replacement of human skills and labour with capital inputs results in dramatic reductions in their populations.

Impacts on Sustainable Agriculture

Socially and economically, GM crops may not be consistent with the concept of sustainable agriculture and may even undermine such practices. The commercialization of corn and potato crops modified to contain the Bt (*Bacillus thuringiensis*) gene, may, for example, result in the rapid emergence of Bt resistant pest populations. This would have a major adverse effect on the viability of organic agriculture as well as integrated pest management farmers, both of whom rely on Bt as an important pest control strategy.

Furthermore, evidence suggests that GM crops do not offer sustainable reductions in use and reliance on pesticides or insecticides. Recent evidence has shown that 'the pesticide reduction benefits have been overstated, the ecological risks under researched and

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[27] 'National Poll and Cross-Country Protest Demonstrate Consumers Won't be Fooled by GE Foods,' Media Release, Council of Canadians, March 31, 2000.

[28] Supra n. 26 above. The Shalala case challenged US Food and Drug Administration policy on GM foods on four principal grounds. One of these grounds asserted that GM foods are a breach of freedom of religion. Various religious Plaintiffs joined suit, claiming that GM foods that could contain animal matter violate some people's religious dietary laws. Failure to label such food burdens their free exercise of religion. John Fagan's Article (attached hereto), 'A Science-Based, Precautionary Approach to the Labeling of Genetically Engineered Foods,' (p. 4) points out that 'the commercialization of foods and food ingredients derived from plants that carry animal genetic information has not yet commenced. However, this is inevitable within the next few years.'

reported, and the economic costs and benefits miscalculated.'[29] For instance, a recent study commissioned by the ERS-USDA demonstrated that use of Bt crops did not provide either a yield benefit or any clear insecticide use reduction.[30]

GM farming may also pose a threat to traditional agricultural practices by becoming unaffordable to smaller farmers.[31]

There is no evidence that the Government of Canada has considered these impacts on the viability of more environmentally, socially and economically sustainable forms of agriculture in its assessments of agricultural biotechnology products.

5. FEDERAL REGULATORY REGIME FOR BIOTECHNOLOGY AND FOOD SAFETY – OVERVIEW AND ASSESSMENT

(i) Institutional Structure

There are a number of federal departments that have input into the regulation of GM products. Environment Canada and Health Canada (along with the Canadian Food Inspection Agency, or CFIA) are the key players, with other departments such as Industry Canada and the Department of Fisheries and Oceans influencing government law and policy, as well as acting as funding mechanisms for new biotechnology research and development.

The CFIA began operations in April, 1997 and has since assumed responsibility for the regulation of agricultural products from Agriculture and Agri-Food Canada. The purported purpose of this shift was to rectify Agriculture Canada's apparent conflict of interest as being the lead developer, promoter as well as regulator of agricultural biotechnology products in Canada. Nevertheless, the mandate of the CFIA is also to regulate and promote biotechnology products, meaning that this conflict of interest has not been removed but merely duplicated in another forum.

A restructuring of the institutional set-up for pre-market safety assessments of biotechnology products is clearly required. This means shifting the responsibility for risk assessment to a single body with no industry-related mandate. It means ensuring that a *comprehensive*, *independent* and *transparent* assessment of the potential risks associated with GM products is conducted for each and every product. Public health and environmental safety cannot be guaranteed without functionally separating the

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[29] WWF Canada, 'Do Genetically-Engineered (GE) Crops Reduce Pesticides? The Emerging Evidence Says Not Likely,' relying on reports such as Lethbridge Research Centre Report, 2000. 'Benefits of Herbicide-tolerant Canola Systems Vary, Study Shows'. January 13, 2000.

[30] Genetically Engineered Crops for Pest Management, see web site: www.econ.ag.gov/new-at-ers.

[31] See 'The Regulation of Agricultural Biotechnology in Canada,' Sarah Bjorquist (Canadian Institute for Environmental Law and Policy), 1999 for a greater discussion of these issues.

department that deals with promotion of trade from the department that regulates the product.[32]

Professor William Leiss formerly, the Eco-Research Chair at Queen's University School of Policy Studies has stated that 'credible regulation requires the clear and unambiguous separation of a regulatory decision-maker from the economic interests under its jurisdiction.'[33] The fear that industry may influence the assessment process is not unfounded. In 1998, for example, 'Health Canada scientists told an internal labour board that they were being pushed to approve the [genetically engineered bovine] growth hormone despite their concerns that it is not safe.'[34] Dr. Shiv Chopra of Health Canada admitted that 'we have been pressured and coerced to pass drugs of questionable safety, including rBST [recombinant bovine somatotropin].'[35] This kind of pressure must be removed from the system in order to ensure credibility and consumer trust.

The problems created by this inadequate institutional framework are exacerbated by the fact that manufacturers are empowered to self-test their own products. No testing is conducted independently by government, whose role is limited to a review of the information provided by the proponent of the product. This formulation, coupled with a regime that assumes that novel foods are no more dangerous than their natural counterparts, means that the threshold that industry has to meet in providing safety information to the government is exceptionally low. This shifts the burden of evidence to farmers and consumers to show harm, rather than placing the onus on the proponent to adequately demonstrate safety - an inherently anti-precautionary approach.

(ii) Regulatory Regime

Canadian Environmental Protection Act

The recently amended Canadian Environmental Protection Act (CEPA) has as its overarching objective the protection of public health and the environment from the effect of potentially 'toxic' substances. These include substances that:

> (a) have or may have an immediate or long-term harmful effect on the environment or its biological diversity;
> (b) constitute or may constitute a danger to the environment on which life depends; or

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[32] An approach more like that proposed by the Commission of the European Communities in its recent 'White Paper on Food Safety' is warranted. It contains information on the establishment of an independent European Food Authority that will 'be guided by the best science, **be independent of industrial and political interests**, be open to rigorous public scrutiny, be scientifically authoritative, and work closely with national scientific bodies.'

[33] 'Biotechnology in Canada Today: Not More Regulation, but More Credible Regulation,' William Leiss, a presentation to the House of Commons Standing Committee on Environment and Sustainable Development, June 11, 1996, at 5.

[34] Supra n. 31 above, at 48.

[35] 'Cover-up Alleged at Health Canada,' quoted in Anne McIlroy, the Globe and Mail, September 17, 1998.

(c) constitute or may constitute a danger in Canada to human life or health.[36]

Part 6 of the amended CEPA deals exclusively with the regulation of animate products of biotechnology. As such, it is the only existing piece of legislation dealing directly with this issue from a health and environmental perspective and can therefore be seen as the 'driver' in terms of setting regulations for biotechnology. In particular, Part 6 requires all products of biotechnology that are new to Canada be subject to an assessment of their potential 'toxicity' as defined by the Act, prior to their import of manufacture. This assessment may occur under Acts of Parliament other than CEPA provided that notice is before the manufacture, import or sale of the living organism and an assessment of whether it is 'toxic' or capable of becoming toxic is carried out.

In other words, through CEPA, Parliament has mandated that all products of biotechnology undergo assessments of their potential toxicity (as defined by CEPA) before they can be manufactured, imported or sold in Canada, either under CEPA or under another Act of Parliament. Part 5 of the Act provides for similar assessments for any other new substances which is not a living product of biotechnology.

The Seeds, Feeds and Fertilizers Act

These acts are administered by the CFIA, which has the authority to make regulations dealing with issues such as seed quality (grades), inspection, and packaging and labelling. However, these statutes that regulate agricultural biotechnology 'contain no clear legislative authority for the evaluation of genetically engineered products from an environmental or human health perspective.'[37]

The assessment procedure used to determine safety pursuant to these acts is based on the standard of 'substantial equivalence.' Crops that meet this threshold are not required to undergo a risk assessment. Those that are found not to be so equivalent must meet certain basic criteria under Regulatory Directive Dir94-08 (the environmental assessment directive).[38] All data under this Directive is provided by the industry petitioner (manufacturer of the product), who has only to meet the weak burden of showing that the risks are the same as between the traditional and GM product. Further, Directive 94.08 allows the government to waive the information requirements for novel crops based on a 'sound scientific rationale,' an undefined concept that can therefore become a massive loophole.

Utilization of the concept of substantial equivalence in this context is problematic, as it is a standard derived from health assessments, not environmental ones. Its use as a safety baseline for environmental evaluation does not necessarily follow, in that it does not contemplate alternative systems of agriculture being harmed by biotechnology. This ignores problems such as pollen spread and out-crossing and consequential harm to

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[36] CEPA, as amended, s. 64.
[37] Supra n. 31 above, at 34.
[38] AAFC, *Assessment Criteria for Determining Environmental Safety of Plants with Novel Traits*, December 16, 1994.

neighbouring farmers. It does not adequately assess harm to non-target organisms, such as insects. GM crops cleared by the CFIA are not adequately addressing potential risks, leaving it up to chance how large-scale release in varied ecosystems will play out. Precaution demands a more intensive assessment process.

Food and Drugs Act and Regulations

In October of 1999, a new Regulation Amending the Food and Drug Regulations (948 – Novel Foods) was adopted. This new Regulation has created a new Division under the federal Food and Drugs Act (FDA), Division 28, regarding Novel Foods.[39] Pursuant to the Regulation, novel food means:

> (a) a substance, including a microorganism, that does not have a history of safe use as a food;
>
> (b) a food that has been manufactured, prepared, preserved or packaged by a process that
>
> > (i) has not been previously applied to that food, and
> > (ii) causes the food to undergo a major change; and
>
> (c) a food that is derived from a plant, animal or microorganism that has been genetically modified such that
>
> > (i) the plant, animal or microorganism exhibits characteristics that were not previously observed in that plant, animal or microorganism,
> > (ii) the plant, animal or microorganism no longer exhibits characteristics that were previously observed in hat plant, animal or microorganism, or
> > (iii) one or more characteristics of the plant, animal or microorganism no longer fall within the anticipated range for that plant, animal or microorganism.

Any substance that falls within this definition must now pass through a prescribed process, known as 'Pre-market Notification.' A Pre-market approval procedure was rejected in favour of this much more limited approach. Pre-market notification merely requires that the manufacturer or importer of the novel food notify the Director of his or her intention to sell or advertise for sale the novel food. Within 45 days after receiving a notification referred to in paragraph B.28.002(1) (a) of Regulation 948, the Director is obliged to review the information included in the notification and, if the information establishes that the novel food is safe for consumption, notify the manufacturer or importer of the sufficiency of the information. If the information is not sufficient, and additional information of a scientific nature is necessary in order to assess the safety of the novel food, the Director then requests submission of same. Within 90 days, the Director must assess the new information and determine whether it establishes that the novel food is safe for consumption.

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[39] Regulations Amending the Food and Drug Regulations (948 – Novel Foods) – Division 28.

The FDA Novel Foods Regulations is founded on an entirely illogical premise. It holds novel foods to a lower standard of assessment than innocuous food additives such as common table salt or sweeteners. A comparative analysis of the treatment of novel foods with food additives demonstrates that regulation of the former is substantially less rigorous than the latter. For instance, food additives, which are governed by Division 16 of the Food and Drug Regulations, require that all food additives as prescribed in the Regulations be labelled. Furthermore, the procedure for adding to or changing the Table of food additives in Division 16 requires the provision of a whole list of prescribed information, including intended use, concentration and effect on food, as well as reports and tests establishing the safety of the food additive.

This divergence in regulatory treatment as between food additives and novel foods cannot be reconciled. The requirement to label items such as preservatives, sweeteners and food enzymes and not foods that have been manipulated at the genetic level makes no sense. Genetically modified foods present unique health risks, such as the presence of unknown allergens or toxins in food. The inadequacy of the risk assessment process in Canada is exacerbated by the failure to label, precluding any possibility of future epidemiological monitoring to interpret and respond to potential health problems.[40]

Furthermore, the FDA contains major gaps. No regulations have been adopted to provide for the environmental evaluation of products regulated under it, nor does it address issues such as the protection of the environment and conservation of biological diversity. Both types of assessments are mandated by Part 6 of CEPA with respect to living products of biotechnology, and by Part 5 of CEPA with respect to any other product.

The critical problem area in the treatment of novel foods is the federal government's regime for safety testing. The method of determining whether a GM product needs to undergo an assessment rises and falls on the definition of 'familiarity' and 'substantial equivalence.' Familiarity means that once a particular crop or product has been approved, this will then serve as the safety baseline for the next crop that comes along. Too many assumptions are built into this process. Substantial equivalence sets another baseline that assumes that novel foods are the same as their conventional comparators, an assumption that is a barrier to understanding the real risks posed by GMOs. For instance, if a novel food is determined to be substantially equivalent to its natural counterpart, then no risk assessment will be conducted by the federal government. This determination is made exclusively by information provided to the government by industry, giving the petitioner an inappropriate amount of input into the safety evaluation process. It is a regime lacking in *accountability*, *transparency*, and *independence*, as it relies on the notifier/petitioner to identify any potential risks. This approach constitutes such a fundamental flaw that the entire assessment procedure for novel foods is necessarily thrown into question.

Another concern is the application of the standard of substantial equivalence itself. According to this principle, only selected characteristics are compared as between the GM product and any variety within the same species. If the two are grossly similar, then

[40] It is important to stress here the complete absence of any post-release monitoring program requirements, particularly for food safety. This is a glaring omission in the system.

the GM food does not then need to be rigorously tested, on the assumption that it is no more dangerous than the non-GM equivalent. Substantial equivalence is a vague concept that is subject to *abuse*, *misinterpretation* and *inconsistency* in application.

The federal government designates a product as being substantially equivalent 'if the product *traits, use, safety and effect* on the environment are known to be equivalent to those of products that have already been approved by the Canadian Food Inspection Agency or are generally regarded as safe for that use.'[41] However, a product may be not only substantially equivalent but actually 'identical' to its natural counterpart and still contain a single harmful compound. Consequently, any claim of substantial equivalence is only as good as the series of tests upon which that claim is based. Any potential risk will only be identified if tests are carried out that are 'capable of quantitating the characteristic which happens to be different in the genetically engineered food compared to its non-genetically engineered counterpart.'[42] As a risk parameter, substantial equivalence is incapable of taking into account *unanticipated*, or *accidental* effects.

Furthermore, this standard does not require that any long-term, clinical field trials be conducted. In fact, 'no feeding trials are reported dealing with longer term exposures representative of the risks expected from chronic consumption of GM foodstuffs. Conclusions derived from acute toxicity studies are not predictive of chronic risks.'[43] The CFIA Office of Biotechnology, conversely, has made a blanket declaration that 'the potential for long-term effects from novel foods is no different than that from traditional foods which have been safely part of the Canadian diet for a long time.'[44] This statement is – and can only be - an assumption, since no testing has been, or is *required* to be conducted for long-term or chronic exposure to GM foods. The *hope* is that in the long term, exposure to GM foods will produce no negative effects. If this assumption proves false, there will unfortunately be 'no chance of remediation with GMOs that have gone wrong.[45] This approach violates the precautionary principle, as codified in the Canadian Environmental Protection Act, the recent Biosafety Protocol, and endorsed by Environment Canada in its Sustainable Development Guide.

A recent Canadian study found that in 70 per cent (28 of 40) of the available crop Decisions, *no* laboratory or feeding trial measurement of toxicity was presented.[46] The study also pointed out that for crops such as canola and cotton, the entrance into the

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[41] Supra n. 38 above, at 2

[42] 'The Failings of the Principle of Substantial Equivalence in Regulating Transgenic Foods (Also Applies to Other Novel Foods), Fagan, John, See web site: http://www.natural-law.ca/genetic/substantialequivbyJF.html at 1.

[43] Supra n. 21 above.

[44] 'Questions About Long Term Effects of Foods Derived From Biotechnology,' Office of Biotechnology, Canadian Food and Inspection Agency. See web site: http://www.cfia-acia.agr.ca/english/ppc/biotech/longterm.htm.

[45] 'GMOs – A Healthy Skepticism,' V. Howard, 55 Science in Parliament 10 (July/August 1997).

[46] Supra n. 21 above. The study found that 'the potential toxicity in all canola and cotton crops is dealt with by assuming that a) all human exposure to GM plant toxins will occur only through consumption of oil, b) toxicity risk derives solely from proteinaceous material, and because c) all proteinaceous material is removed in the process of refining the oil, therefore d) there is no risk, and hence, no need for testing. *The evidence upon which each of these assumptions is made is not presented*'[emphasis].

human food chain through *livestock feed* is not assessed for safety. Health Canada takes responsibility for assessment of GM crops only through directly human consumable products. The study concluded – as regards toxicity - that of all the available GM crops approved for commerce in Canada, *70 per cent have not been subjected to any actual lab or animal toxicity testing, either as refined oils for direct human consumption, or indirectly as feedstuffs for livestock.* The study also found that *no measure of allergenicity* was provided for any of the 40 available crops. The report concluded that

> In the absence of long term whole food feeding trials and other more integrative (less narrowly targeted) risk assessment studies, extrapolating the safety of single purified proteins to entire crops, or results of acute testing to chronic risk, is unwarranted. The analysis presented in this report suggests the need for a fundamental reassessment of the process by which the safety of GM foods is tested in Canada.[47]

Other major gaps in the regulatory regime exist as well. A number of products, such as genetically modified fish, with major environmental and biodiversity implications, are being tested now, and are rapidly approaching commercialization. However, they remain completely unregulated. A similar situation exists with respect to genetically modified animals.

These conclusions underscore the need for a complete overhaul of the governmental assessment process. The system must be revamped *to ensure protection of public health, the environment and biological diversity* as is legally required under CEPA, the FDA and the United Nations Convention on Biological Diversity.

Conclusion

As has been clarified above, the regulation of biotechnology in Canada is deficient in a number of ways. Key areas of concern can be grouped into six main areas:

- ***Conflicts of Interest with Regulatory Agencies*** – one of the key agencies responsible for the regulation of agricultural biotechnology, the Canadian Food Inspection Agency, also acts as a promoter of the technology. This is an obvious conflict of interest, which places the health, safety and environment of Canadians at risk.

- ***Inadequate Legislative Foundation*** – The legislation under which the Canadian Food Inspection Agency purports to regulate agricultural biotechnology products was never intended for this purpose and contains no clear authority regarding the assessment of the potential environmental, health or biodiversity impacts of biotechnology products.

- ***Inadequate Assessment Process*** – The procedures for assessing GM foods and most other products relies on the questionable principles of 'familiarity' and 'substantial equivalence.' The approach is less rigorous than that employed for common food

[47] Ibid.

additives, such as sweeteners, and is inconsistent with the requirements of Parts 5 and 6 of CEPA that all products of biotechnology be subject to environmental, human health and biodiversity impact assessments prior to manufacturing, import or sale. Instead, the government has chosen to regulate biotechnology using standards that are inherently incapable of measuring long-term, unanticipated or accidental side-effects. The assessment process has also failed to investigate adequately the long-term implications of biotechnology products for the viability, of other more sustainable practices, such as organic agriculture and integrated pest management farming.

- ***Gaps in the Existing System*** – Many products, with the potential for major environmental, health and biodiversity impact such as genetically engineered fish and animals, are now approaching commercialization. However, they remain completely unregulated. The environmental aspects of GM foods also remain unregulated.

- ***Lack of Accountability*** – The existing regulatory regime is almost completely lacking in transparency and public accountability. Members of the public are provided with no notice of when approvals of biotechnology products are being considered, have no opportunity to comment on proposed approvals, and have no access to the submissions of proponents to support approvals. The current process relies entirely on information submitted to government by proponents (manufacturers), providing for no independent government testing of products or the external review of data submitted by proponents.

- ***Denial of the Right to Choose*** - in the absence of mandatory labelling of GM foods, the current regulatory system provides no means for members of the public who have concerns regarding the environmental or health effects or biotechnology products, or who wish to choose not to consume such products for ethical, religious or social reasons, with a means to exercise these preferences in the marketplace. Now that biotechnology companies are creating 'specialty' GM products (such as golden rice with enhanced vitamin A), these products will *have* to be segregated in order for the manufacturer to be able to properly ask the consumer to pay a premium for them – thereby eliminating the excuse not to label.

These weaknesses and gaps require prompt and decisive action. Many of the threats posed by GMOs can be ameliorated by implementing a mandatory labelling scheme and by employing a more comprehensive safety assessment. *An enhanced safety evaluation would include changes such as initiating an independent assessment procedure, adopting a clearer, more inclusive safety standard, analyzing long-term effects, and providing the public with access to information.* These changes are essential, because people have a right to choose what they want to eat. They also have a right to know that the food on their table is safe for themselves and their families.

A recent report by the Canadian Institute for Environmental Law and Policy, outlining the weaknesses in the Government of Canada's system for the regulation of products of agricultural biotechnology, and making recommendations for its reform, is attached to this submission.

6. RELIEF SOUGHT

Based on the weaknesses and gap areas identified above, we request the following relief pursuant to section 22 of the Act:

(i) Review of the Laws, Regulations and Policies

The federal government is requested to assess whether the existing regulatory system for genetically modified organisms is consistent with the principles of sustainable development. In assessing this issue, the government is requested to review all laws, regulations and policies, as well as institutional arrangements to ascertain whether obligatory sustainable development considerations are being factored into decision-making. The review must include areas already regulated (e.g.: microorganisms, and crop plants) and those that are not (e.g: genetically modified fish).

In particular but not limiting the above, the federal government is requested to review the following:

- *Does the existing regulatory system provide for the evaluation and assessment of biotechnology products from a sustainable development perspective before they are introduced into Canada, including their potential immediate and long-term adverse social and economic impacts?*

- *Does the existing regulatory system for biotechnology provide for the clear separation of regulatory and promotional roles among different agencies involved in the promotion and regulation of biotechnology?*

- *Does the existing system meet the requirements as set out in Article 8(g) of the Convention on Biological Diversity? In other words, is the government adequately considering the impacts of biotechnology products on the conservation and sustainable use of biodiversity, taking also into account effects on human health?*

- *Does the existing system meet the requirements as set out by Parliament in Parts 5 and 6 of CEPA that all products of biotechnology be subject to pre-manufacturing or import notification and assessment of potential their "toxicity," as defined by the Act, before their introduction into Canada?*

(ii) Implementation of Safety Measures

The petitioners request that the federal government undertake appropriate measures in order to repair regulatory problem areas. These measures would include the following:

- The enactment of new legislation that takes into account the unique characteristics and risks of these products. Given that much of the science surrounding GMOs is new, with accompanying new risks, legislation must be enacted that incorporates appropriate safeguards and measures. With the exception of CEPA, the existing

legislative framework, including the *Seeds, Feeds and Fertilizers Acts* were not specifically intended to deal with these products, or the specific risks that they pose.

- The establishment of requirements for the independent, governmental evaluation and testing of all products of biotechnology. Assessments should take into account a range of growing environments, and include post-release monitoring of performance to test the potential for instability across growing locations and seasons.

- The establishment of clear evaluative criteria, including an improved safety standard that takes into account the potential immediate and long-term direct or indirect harmful effects on human health, the environment, and the conservation and sustainable use of biological diversity of biotechnology products. This should include consideration of impacts on sustainable agricultural practices, such as integrated pest management and organic farming.

- The clear separation of regulatory and promotional functions among agencies. In particular the promotional activities of the Canadian Food Inspection Agency must be terminated, or its regulatory functions transferred to another agency with a clear and overriding mandate to protect human health, the environment and biological diversity;

- The requirement of mandatory labelling of GM products. This will not only ensure public and environmental health and safety, but will also allow food risks to be monitored in the long term.

- The adoption of measures to ensure that the system is accountable and transparent. This requires provisions for public participation in decision-making including:
  - public notice and comment periods prior to the approval for manufacture, use, import or export of new biotechnology products;
  - public access to industry submissions for approval; and
  - making public the full records of government approval decisions of GM products.

We believe that the adoption of these measures is necessary to protect Canadians' health, safety and environment, and to ensure that the Government of Canada's policies and practices with respect to biotechnology are consistent with the principles of environmental, social and economic sustainability.

All of which is respectfully submitted,

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Per: Melanie Steiner
Solicitor for the Petitioners

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