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Government of Canada Defends Biotechnology Against Sierra Legal Defence Fund 2000

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Report Highlights:

On May 9, 2000 the Sierra Legal Defence Fund filed a petition under the *Auditor General Act*, which contained a series of four questions and six suggested measures relating to genetically modified organisms, specifically as this issue relates to sustainable development in Canada. This report contains a summary of the questions, suggested measures, and the Government of Canada response is outlined in this fact sheet

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Review of Canadian Federal Laws, Regulations, and Policies on Genetically Modified Organisms, Specifically Relating to Sustainable Development: Summary of the Response of Federal Departments to the Petition from the Sierra Legal Defence Fund

The following is based on a September 7, 2000 Canadian Food Inspection Agency release.

Background to the Petition

On May 9, 2000 the Sierra Legal Defence Fund filed a petition under the *Auditor General Act*, which contained a series of four questions and six suggested measures relating to genetically modified organisms, specifically as this issue relates to sustainable development in Canada. A summary of the questions, suggested measures, and the government response is outlined in this report.

Background to the Government Response

On September 7, 2000, the Canadian Ministers of Agriculture and Agri-Food, Environment, Fisheries and Oceans, Health, Industry, and Natural Resources provided a joint response to the petition. The departments worked together to contribute their expertise to this response hoping that, by doing so, interested Canadians would have available to them a considered, integrated response on these important issues.

Federal Role on Sustainable Development in Canada

In December 1995 amendments to the *Auditor General Act* established an Office of the Commissioner of the Environment and Sustainable Development (for more information, check the Web site of the Office of the Auditor General at http://www.oag-bvg.gc.ca and follow the links to the Commissioner of the Environment and Sustainable Development). These amendments required Ministers to table sustainable development strategies in the House of Commons and to update them every three years. These strategies are required to be comprehensive, results-oriented, and developed in consultation with a department's clients and other stakeholders. By December 1997, twenty eight federal departments had developed their first sustainable
development strategies - most departments publish specific information on sustainable development, as it relates to their work, on their Web sites.

These amendments also authorized the Auditor General to receive petitions on environment and sustainable development matters, and require that Ministers respond to them within 120 days. To date, the Commissioner of the Environment and Sustainable Development has received over 20 petitions on a number of environmental topics.

Federal Regulatory Framework for Biotechnology

In 1993, the Government of Canada established the *Federal Regulatory Framework for Biotechnology*. This framework resulted from an agreement among federal regulatory departments on principles for an efficient, effective approach for regulating biotechnology products. These principles assure that the practical benefits of biotechnology products and processes are balanced with the need to protect human health, animal health, and the environment. Both traditionally developed products and those developed through the newer molecular techniques, such as genetic engineering, are included under this framework.

Canadian Government Response to Questions in the Petition

Question 1: 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?

GOC Response: The government agrees that new products should be regulated from a sustainable development perspective before they are introduced into Canada. Canada's existing regulatory system clearly provides for the risk management and risk assessment of biotechnology products from a sustainable development perspective. We also have a comprehensive approach to developing or amending regulation that addresses health, social, economic, or environmental risk, undertaken through Risk Impact Analysis Statements, which consider immediate and long-term socio-economic impacts, including impacts on the environment and sustainable development. These Statements are available to the public, and interested Canadians are invited to review and comment on these regulatory proposals.

Question 2: 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?

GOC Response: The government fully recognizes the requirement to separate its regulatory and promotional functions. Therefore, different mandates have been assigned to each department and agency. In relation to biotechnology products, a clear distinction has been made for health and environmental assessment responsibilities as they relate to the mandates of the following departments: Health Canada and its Pest Management Regulatory Agency, the Canadian Food Inspection Agency, Fisheries and Oceans Canada, and Environment Canada. While the government does not play a promotional role relating to their regulatory responsibilities, it does have the clear mandate to provide straightforward, accessible, and science-based information to Canadians on issues of public interest.

Question 3: Does the existing system meet the requirements as set out in Article 8(g) of the Convention on Biological Diversity?

GOC Response: Article 8(g) of the *Convention on Biological Diversity* states that each Contracting Party shall: "Establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity,

taking also into account the risks to human health."

The Government considers that by vigorously protecting humans and the environment it is, in fact, also protecting and preserving biodiversity as intended in Article 8(g). Maintaining Canada's high standards for the protection of human health and the environment is fundamental to the regulation of products of biotechnology. It is the first principle of the 1993 *Federal Regulatory Framework for Biotechnology*.

Question 4: 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 "toxicity" as defined by the Act, before their introduction into Canada?

GOC Response: The *Canadian Environmental Protection Act*, 1999 (*CEPA*, 1999) came into force on March 31, 2000, with the exception of a provision relevant to the regulation of biotechnology products (ss. 106 (7)) that will come into force on September 13, 2001. When this provision comes into force, *CEPA*, 1999 will be fully implemented. In the interim, provisions similar to those in *CEPA*, 1988 remain in effect.

Canadian Government Response to Suggested Measures in the Petition

Suggested Measure 1: The enactment of new legislation that takes into account the unique characteristics and risks of these products.

GOC Response: Rather than introducing new legislation, Canada has taken the approach of amending existing legislation to assure continuous improvement, particularly when dealing with dynamic technologies such as biotechnology. For example, in 1996 significant amendments were made to regulations under the *Feeds Act*, the *Health of Animals Act*, and the *Seeds Act*. With regard to food, the *Novel Foods Regulation* was designed to allow Health Canada to conduct a safety assessment of novel foods including those derived from biotechnology. A new regulatory framework is being developed for all transgenic aquatic organisms, including fish, that will meet the criteria set out in the *CEPA, 1999*.

Suggested Measure 2: The establishment of requirements for the independent, governmental evaluation and testing of all products of biotechnology.

GOC Response: The federal government does conduct an independent evaluation of the products of biotechnology. During the course of a safety assessment, regulators may determine that additional testing or verification is required, for example, to provide information that takes into account a range of growing environments. This additional work may be carried out by the government or by product proponents under the direction of the government.

Suggested Measure 3: 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.

GOC Response: By "evaluative criteria," the government understands that the petitioners are referring to the criteria by which regulators process the information provided by a product proponents or otherwise obtained, to arrive at an assessment conclusion. In this context, clear evaluative criteria are used in assessments by the regulatory departments and agencies. In addition to the provision of information requirements set out in federal regulations, a series of corresponding federal guidelines specifies the detailed information requirements needed to conduct the various product safety assessments.

Risk assessment decisions take into account the best available science as well as the knowledge base in Canada and abroad. Specific evaluation criteria are determined and provided in various formats to the public, industry, and other stakeholders. These evaluation criteria are presented in pre-submission consultations with the product proponents and in consultations for the preparation of draft guidelines and assistance documents, and are published on departmental Web sites.

Suggested Measure 4: 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.

GOC Response: The Canadian Food Inspection Agency (CFIA) was created in 1997 to consolidate the delivery of all federally mandated food inspection and quarantine services, as well as plant protection and animal health programs—delivery that was previously provided by four federal government departments (Agriculture and Agri-Food Canada, Fisheries and Oceans Canada, Health Canada, and Industry Canada). The CFIA reports administratively to the Minister of Agriculture and Agri-Food and is not involved in economic promotional activities related to products of biotechnology.

Suggested Measure 5: The requirement of mandatory labeling of GM products.

GOC Response: Work is currently underway both in Canada and abroad to address the complex issues of the labeling of genetically modified products. The Government of Canada is committed to giving due consideration to these initiatives. They include the project to develop a Canadian standard (through the auspices of the Canadian General Standards Board) for the voluntary labeling of foods obtained or not obtained through genetic modification; the study being undertaken by the Standing Committee on Agriculture and Agri-Food on mandatory labeling of genetically modified foods; and deliberations under the Codex Committee on Food Labeling, the key international forum addressing this topic, on "foods and food ingredients obtained through
certain techniques of genetic modification/genetic engineering." Health Canada and the Canadian Food Inspection Agency share the responsibility for food labeling policies under the *Food and Drugs Act*. Health Canada's responsibilities are related to health and safety issues. As such, mandatory labeling is required for genetically modified foods where safety concerns such as allergenicity and compositional or nutritional changes are identified.

Suggested Measure 6: 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.

GOC Response: In ensuring that the federal approach is accountable and transparent, the public has the opportunity to fully participate in the development and implementation of the regulatory system for products of biotechnology, including being involved at the policy formulation level. The level of public participation and government accountability in the regulatory system is described in the *Government of Canada Regulatory Policy 1999*. This policy reflects Canadians' views that health, safety, the quality of the environment, and economic and social well-being are important concerns. The policy further elaborates the requirement to fully consult with Canadians and consider their views in developing or modifying regulations.

On the topic of biotechnology regulation, the Government of Canada has carried out consultations on this issue, and input has been provided through individual Departments' and Agencies' regulatory and guideline proposals, the Canadian Biotechnology Strategy (CBS) renewal project, Parliamentary Committee hearings, and federal public opinion research (such as the February 2000 CBS poll).

With regard to the communication of individual regulatory decisions to the public, federal regulatory authorities such as Health Canada and the Canadian Food Inspection Agency already prepare and publish decision documents relating to safety assessments of novel products, including those obtained through biotechnology. These decision documents can be accessed through the websites for Health Canada at www.hc-sc.gc.ca, and CFIA at www.cfia-acia.agr.ca.

Looking Ahead...

Science is not static-- new types of novel and biotechnology-derived products are expected to become available, and the federal government is already looking ahead. For example, in December 1999, the Ministers of Health, Agriculture and Agri-Food, and the Environment announced their intention to establish an Expert Scientific Panel to advise them on the scientific regulatory capacity and capabilities needed to meet the challenges of the next generation of food biotechnology products.

On February 17, 2000, the Royal Society of Canada established the Expert Scientific Panel and tasked them to identify:

- the types of foods from biotechnology that could be submitted for regulatory safety reviews over the next 10 years
- the science likely to be used to develop these products
- any potential risks, short- or long-term, to human health, animal health and the environment

As part of the renewal of Canadian Biotechnology Strategy, the Canadian Biotechnology Advisory

Committee (CBAC) was created in 1999 . CBAC provides advice to Federal Ministers on social, economic, regulatory, scientific, ethical, regulatory, environmental and health aspects related to biotechnology. The Committee is giving regulatory issues a priority in their Work Plan for 2000 and has announced a special initiative entitled *The Regulation of Genetically Modified Foods*.

The recommendations of these expert advisory bodies and the other international initiatives underway will provide critical guidance to Ministers and the Canadian public regarding future evaluation criteria and information requirements needed to keep the regulatory system evolving with the pace of new biotechnology applications.

For Your Information

Canada believes it has one of the safest and most effective regulatory systems in the world. In its renewal of the Canadian Biotechnology Strategy, which followed extensive public consultations, the Government of Canada put forward a vision of being a world leader in the responsible development of biotechnology. This means that we must continue to apply rigorous standards to the manner in which we regulate and monitor products of biotechnology, particularly as they relate to human health and the environment. Canada must continue to assure that the products and processes of biotechnology are subject to the highest standards of scientific testing for health, safety, and environmental impact.

For more information on sustainable development and departmental strategies, please consult the following Web sites:

Health Canada
www.hc-sc.gc.ca/susdevdur/intro_e.htm

Agriculture and Agri-Food Canada
www.agr.ca/policy/environment/sustainability/

Environment Canada
www.ec.gc.ca/sd-dd_consult/final/SDGES_E.HTM

Industry Canada
http://strategis.ic.gc.ca/SSG/sd00051e.html

Natural Resources Canada
www.nrcan.gc.ca/dmo/susdev/part1e.htm

Fisheries and Oceans Canada
www.dfo-mpo.gc.ca/sustdev/sust_e.htm
Canadian Food Inspection Agency
www.cfia-acia.agr.ca/english/ppc/biotech/bioteche.shtml

End text.

To see the actual CFIA news release or to view a wide range of related links regarding Canadian biotechnology and labeling, please visit:
http://www.cfia-acia.agr.ca/english/ppc/biotech/enviro/sierrafse.shtml

Reaction

The following is in response to the above Government of Canada release from the President of the Canadian Organic Growers, Eleanor Heise, dated September 11, 2000. Begin text.

GOVERNMENT ADMITS TO GAPS IN BIOTECH SAFETY REGULATION

In its response to a petition filed through the Auditor General's Act last May, the federal government acknowledges weaknesses in its regulation of genetically altered foods.

The petition was submitted by the Sierra Legal Defense Fund on behalf of the Canadian Institute for Environmental Law and Policy (CIELAP), the Council of Canadians and Drs. Ann Clark and Bert Christie.

"This report confirms many of the concerns we have about the gross inadequacy of the existing rules," said Jennifer Story, Health Protection Campaigner for the Council of Canadians. "The government refuses to ask and answer the hard questions about the safety of genetic engineering."

"The government does not adequately address the question of sustainable development," said Anne Mitchell, Executive Director of CIELAP. "They remain silent on the crucial question: Do GMOs contribute to an environmentally and socially sustainable agriculture and food system? Their risk assessment is narrow and does not adequately assess any potential long-term risks involved."

According to its written response, the federal government:

- acknowledges the lack of regulations for research on GE fish, research that is being currently conducted with government funds, and in government facilities (p. 17)
- admits the complete reliance on data provided by proponents to understand the potential impacts of GMOs (p. 22)
- admits it does not require long-term safety studies (p. 28), and
- acknowledges that they are doing no post-release monitoring, relying instead on the biotech companies to report any problems (p. 23).

At the same time, the government firmly denies other criticisms contained in the petition. They provide a very robust claim that the Canadian Food Inspection Agency (CFIA) isn't in a conflict of interest and that it doesn't participate in promotional activities. A quick visit to the CFIA Web site, however, provides access to documents with titles like "The benefits of food biotechnology."

"Instead of soliciting the input of the citizens they claim to serve, government continues to deny the public the opportunity - any opportunity - to contribute to the approval process," says Dr. E. Ann Clark, Associate Professor, University of Guelph. "It is not difficult to see who benefits, and who is disenfranchised, by the systematical refusal to allow citizens to access the data that forms the basis of the approval - even after the approval has been granted." End text.

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