# Analysis of Relevant Canadian Legislation

Prepared for

The Canadian Biotechnology Advisory Committee
Project Steering Committee on the Regulation of
Genetically Modified Foods

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**Executive Summary**

The twin issues of transparency and public participation have given rise to legitimate criticisms of Canada's regulatory decision-making process for products of biotechnology. Current legal limitations on the disclosure of third party information by the government have often been cited as reasons for not disclosing more product testing data particularly as it relates to the human health and environmental safety testing of new biotechnology products. A second criticism is that unlike comparable systems in countries like Australia and the US, Canada's regulatory regime generally makes no provision for public input or comment throughout the risk assessment process leading to a regulatory decision.

This report examines both of these issues from a perspective outside of the narrow context of biotechnology product regulation and concludes that there are feasible policy options worthy of further investigation.

Evident from the existing jurisprudence around access to information are the ideas that in order to be exempted from disclosure, third party information must constitute a trade secret, or meet objective criteria for confidentiality, or its disclosure must have a reasonable probability, not just a possibility, of causing measurable harm to a third party. It is highly likely that government could be more transparent with respect to releasing product safety related information without jeopardizing trade secrets or competitive advantage. A number of options exist, including: not exempting certain information under subsection 20(1) of the *Access to Information Act* and dealing with whatever court challenges may arise; performance of environmental and human health safety testing of biotech products by government and releasing relevant information; releasing relevant information by invoking Ministerial discretion "in the public interest"; and securing third party agreement.

The last of these options presents benefits for both industry and government, and a model exists in the practice by the Pest Management Regulatory Agency of publishing Proposed Regulatory Decision Documents that contain summarized product safety data approved by the proponent. This example also serves as a model for incorporating public participation in the regulatory decision making process. Particularly in the area of genetically modified crops and foods, companies are becoming increasingly convinced that broader disclosure of environmental and human health related product safety information is in their interest.

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## 1 Introduction

Canada has a robust and scientifically sound system for regulating agricultural products of biotechnology. The existing system has been effective in ensuring that the application of these products in agriculture and food production has not resulted in additional negative environmental consequences or any additional adverse effects on livestock or human health.

Nonetheless, there are legitimate criticisms of the Canadian regulatory system that relate to the transparency and openness of the regulatory decision-making process. The first is that there is a lack of adequate disclosure of third party information particularly as it relates to the human health and environmental safety testing of new biotechnology products. Current legal limitations have often been cited by regulators as "an impediment to more closely linking federal research and monitoring capacity with the regulatory functions"[1] and as reasons for not publicly disclosing product testing data. Second, unlike comparable systems in countries like Australia and the United States, Canada's regulatory regime generally makes no provision for public input or comment throughout the risk assessment process leading to a regulatory decision.

This report will examine both of these points from a perspective outside of the narrow context of regulating agricultural biotechnology products. The existing legislative limitations on the disclosure of third party information will be explored by examining the *Access to Information Act* (ATIA) and other acts, such as the *Canadian Environmental Protection Act*, 1999 (CEPA 1999), that contain specific provisions for third party information. Additionally, the role of public involvement in some selected Canadian regulatory processes will be highlighted. The intent is not to present an exhaustive survey of all federal government activities incorporating public participation but only some representative examples that may have relevance to the Canadian Biotechnology Advisory Committee's special project on the regulation of genetically modified foods in Canada.

## 2 Access to Information Act

In the absence of overriding provisions contained in the Act under which an activity or product is regulated, the federal government's ability to disclose third party information is proscribed by Section 20 of the *Access to Information Act*. Section 20(1) defines the classes of information that are protected (exempted) from disclosure

[1] Government response to the report of the House of Commons Standing Committee on the Environment and Sustainable Development, *Pesticides: Making the right choice for the protection of health and the environment*. Pp. 18.

as well as the particular circumstances that allow for the disclosure of exempted information (subsections 2-6). These provisions are explored in some detail in the following discussion.

### *2.1 Third Party Information*

Subsection 20(1) of the Act protects from disclosure, on a mandatory basis, financial, commercial, scientific and technical information received from, pertaining to or affecting third parties. As referenced in this and following subsections, the head of a government institution refers to the Minister in the case of a department, who may designate person(s) within the institution to exercise or perform any of the duties or functions of the head of the institution under the Act. Paragraphs (a) through (d) delineate the nature of information that may qualify for exemption.

**20. (1)** Subject to this section, the head of a government institution shall refuse to disclose any record requested under this Act that contains

(*a*) trade secrets of a third party;

(*b*) financial, commercial, scientific or technical information that is confidential information supplied to a government institution by a third party and is treated consistently in a confidential manner by the third party;

(*c*) information the disclosure of which could reasonably be expected to result in material financial loss or gain to, or could reasonably be expected to prejudice the competitive position of, a third party; or

(*d*) information the disclosure of which could reasonably be expected to interfere with contractual or other negotiations of a third party.

#### 2.1.1 Trade Secrets

A trade secret is a recognized legal concept, which is chiefly the product of case law, and must satisfy all of the following conditions:

- it consists of information;
- the information must be secret in an absolute or relative sense (*i.e.*, known only to one or a relatively small number of persons);
- the possessor of the information must demonstrate that s/he has acted with the intention to treat the information as secret;
- the information must be capable of industrial or commercial application; and
- the possessor must have an interest (*e.g.*, an economic interest) worthy of legal protection.

Research data or abstract ideas not capable of being used industrially or commercially cannot qualify for an exemption as a trade secret, nor can information that has already been made public by means such as a product monograph[2].

### 2.1.2 Confidential Information

Paragraph 20(1)(b) provides a mandatory class exemption for any financial, commercial, scientific or technical information of a confidential nature that is consistently treated in a confidential manner. This exemption is intended to protect confidential information provided to the government by a business or commercial interest, regardless of whether it was provided pursuant to a statutory obligation or on a voluntary basis.

To meet the test of 20(1)(b), the information must be truly confidential, and consistently treated as such by the third party, and must have been supplied to the government by a third party. The legal concept of confidential information is that it is information which is of value to the possessor and which has been entrusted to another person in circumstances which create an obligation on that person to maintain the information in confidence. This obligation may be based in contract, expressed or implied, or may arise by virtue of the relationship of the parties and the circumstances under which the information was provided.

Information must be determined to be confidential by some objective standard rather than based on the subjective considerations of a third party[3]. Justice MacKay, in the decision of *Air Atonabee, c.o.b. under the firm name and style of City Express v. Minister of Transport* (1989) 27 F.T.R. 194, identified three requirements for information to qualify as confidential:

1. the information must not be available from sources otherwise accessible by the public nor obtainable by observation or independent study by a member of the public acting on his own;

2. the information must originate and be communicated in circumstances giving rise to a reasonable expectation of confidence that it will not be disclosed; and

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[2] *Cyanamid Canada Inc. v. Canada (Minister of Health and Welfare)* (1992), 41 C.P.R. (3d) 512 (F.C.T.D.); aff'd (1992), 45 C.P.R. (3d) 390 (F.C.A).

[3] *Maislin Industries Limited v. Honourable Minister of Industry, Trade and Commerce et al.,* [1984] 1 F.C. 939, (1984) 10 D.L.R. (4th) 417.

3. the information, whether required by law or supplied gratuitously, must be communicated in the context of a relationship which is either fiduciary or not contrary to the public interest and which will be fostered "for public benefit by confidential communication".

In order to be considered confidential, information submitted to the government must be done so under circumstances in which there is an expectation by both parties that it will be treated confidentially. "Regarding information that must be reported to the Department, such as information regarding land transfers, there is no presumption of confidentiality. The applicant's mere expectation that the communications would remain confidential when submitted to the Department is not enough. The case law on the issue of confidentiality is clear that the test to be met is an objective, and not purely subjective one. The Department did not treat the information as confidential, and provided no assurances that it would not be disclosed."[4]

As previously stated, paragraph 20(1)(b) relates only to confidential information supplied to the government by a third party and does not include information such as audit reports prepared by government inspectors[5].

### 2.1.3 Financial Loss or Gain, or Loss of Competitive Position

In Paragraph 20(1)(c), the Act exempts the disclosure of information in which there is a reasonable expectation of (1) material financial loss to a third party, (2) material financial gain to a third party or (3) prejudice to the competitive position of a third party. In this context, material is taken to mean substantial or important.

The key consideration of whether disclosure of the subject information would meet the injury test of 20(1)(c) is the interpretation of the phrase "could reasonably be expected to". In *Piller Sausages & Delicatessens Ltd. v. Canada (Minister of Agriculture),* [1988] 1 F.C. 446 (T.D.), the court concluded that "the evidence of harm must be detailed, convincing and describe a direct causation between disclosure and harm and must not merely provide grounds for speculation as to possible harm". However, the Court of Appeal in *Canada Packers v. Canada (Minister of Agriculture)* [1989] 1 F.C. 47 (C.A.), rejected the test in *Piller* and concluded that paragraphs 20(1)(c) and (d) required a "reasonable expectation of probable harm". The Court of Appeal also noted that the words "could reasonably be expected to" did not imply a distinction between direct and indirect causality but only of what is reasonably to be expected and what is not.

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[4] *Timiskaming Indian Band v. Canada (Minister of Indian and Northern Affairs)* (1997), 132 F.T.R. 106 (F.C.T.D.); aff'd [1999] F.C.J. No. 1822 (QL) (F.C.A.), A-721-96, judgment dated November 23, 1999.

[5] *Canada Packers Inc. v. Canada (Minister of Agriculture),* [1989] 1 F.C. 47 (C.A.).

The following are some examples of types of information that might qualify for an exemption under this paragraph if the injuries specified in the exemption could reasonably be expected to result in harm:

- information relating to the resource potential of a particular corporation;
- confidential economic evaluations of a corporation such as those which are filed with regulatory bodies;
- reports required to be filed with the government by manufacturers, for example those relating to design problems leading to automobile recalls.

### 2.1.4 Contractual or Other Negotiations

Paragraph 20(1)(d) provides that information that could reasonably be expected to impair the ability of any third party likely to be affected by the disclosure to negotiate in a non-prejudicial manner, be exempted from disclosure. As with the previous provision, what is required from 20(1)(d) is the probability and not mere possibility or speculation that disclosure of the information might interfere with contractual or other negotiations[6].

## *2.2 Product or Environmental Testing*

**(2)** The head of a government institution shall not, pursuant to subsection (1), refuse to disclose a part of a record if that part contains the results of product or environmental testing carried out by or on behalf of a government institution unless the testing was done as a service to a person, a group of persons or an organization other than a government institution and for a fee.

**(3)** Where the head of a government institution discloses a record requested under this Act, or a part thereof, that contains the results of product or environmental testing, the head of the institution shall at the same time as the record or part thereof is disclosed provide the person who requested the record with a written explanation of the methods used in conducting the tests.

**(4)** For the purposes of this section, the results of product or environmental testing do not include the results of preliminary testing conducted for the purpose of developing methods of testing.

Even information that would be exempt from disclosure under 20(1) may be disclosed if it contains the results of product or environmental testing carried out by or on behalf of a government institution. However, if the testing was done as a service to a person, a group of persons or an organization other than a government

[6] *Saint John Shipbuilding Limited v. Canada (Minister of Supply and Services)* (1990), 67 D.L.R. (4th) 315; 107 N.R. 89 (F.C.A.).

institution and for a fee, subsection 20(2) does not apply. Thus, for example, the provision does not apply to product testing done by the National Research Council on a commercial basis.

The provision also does not apply to testing done by a third party and submitted to a government institution, either on a voluntary or mandatory basis. It is this latter point that has been put forward by various regulatory authorities as one of the reasons for not publishing more detailed information related to the environmental and human health safety assessments of plants with novel traits and novel foods.

When the results of product and environmental testing are disclosed pursuant to subsection 20(2), under subsection 20(3), the government institution is required to provide the applicant with a written explanation of the methods used in conducting the tests. The intent of this requirement is to provide contextual information about test results, which could be misleading if released on their own.

Subsection 20(4) provides that the results of product or environmental testing do not include the results of preliminary testing conducted for the purpose of developing test methods.

### *2.3 Permissive Disclosure*

**(5)** The head of a government institution may disclose any record that contains information described in subsection (1) with the consent of the third party to whom the information relates.

Information that would otherwise be exempted from disclosure under section 20(1) may be disclosed if consent is obtained in writing from the third party. This provision is intended to prevent situations where the institution would be under an obligation not to disclose information even if the third party agreed to disclosure. Consent of the third party may be obtained at the time of submission, during informal consultation or in response to the notification of the intent to disclose by the government institution (Section 27 of the *Access to Information Act*).

### *2.4 Disclosure in the Public Interest*

**(6)** The head of a government institution may disclose any record requested under this Act, or any part thereof, that contains information described in paragraph (1)(b), (c) or (d) if that disclosure would be in the public interest as it relates to public health, public safety or protection of the environment and, if the public interest in disclosure clearly outweighs in importance any financial loss or gain to, prejudice to the competitive position of or interference with contractual or other negotiations of a third party.

This subsection provides that information that would normally be exempted under subsections 20(1)(b), (c) or (d) may be disclosed if such disclosure would be in the public interest. In such a case, the information must relate to public health, public safety or protection of the environment, and the public interest in disclosure must clearly outweigh any financial or business losses, or gains, of a third party. This "public interest" override does not apply to trade secrets as set out in 20(1)(a), nor does it apply for information which is not exempted under 20(1)(b), (c) or (d).

Subsection 20(6) is one of the most difficult provisions to apply. The difficulty derives from the discretion it bestows on heads of government institutions to disclose third party information that must otherwise be exempt on a mandatory basis by invoking a public interest "override". It makes heads of institutions responsible to form an opinion about the possibility of disclosing in the public interest information relating to public health, public safety or protection of the environment. In exercising this discretion, consideration must be given to the purpose of the Act, as laid down in section (2), below:

**2. (1)** The purpose of this Act is to extend the present laws of Canada to provide a right of access to information in records under the control of a government institution in accordance with the principles that government information should be available to the public, that necessary exceptions to the right of access should be limited and specific and that decisions on the disclosure of government information should be reviewed independently of government.

Since the basic principle of the Act is to codify the public's right of access to government information, there is an onus on heads of institutions to consider seriously whether disclosure in the public interest clearly outweighs in importance the injury involved when exemptible third party information relates to public health, public safety or protection of the environment. For disclosure under 20(6), the information must be more than simply "of interest to the public". A specifically identifiable and substantial danger must exist that the continued protection of the information will directly result in some harmful short- or long-term effect on public health, public safety or the environment.

### *2.5 Third Party Notification*

Section 27(1) of the Act provides that in the event an institution intends to disclose information under the environmental or product testing provisions of 20(2) or under the public interest "override" in 20(6), it must notify the third party.

**27.** (1) Where the head of a government institution intends to disclose any record requested under this Act, or any part thereof, that contains or that the head of the institution has reason to believe might contain

(*a*) trade secrets of a third party,

(*b*) information described in paragraph 20(1)(*b*) that was supplied by a third party, or

(c) information the disclosure of which the head of the institution could reasonably foresee might effect a result described in paragraph 20(1)(c) or (*d*) in respect of a third party,

the head of the institution shall, subject to subsection (2), if the third party can reasonably be located, within thirty days after the request is received, give written notice to the third party of the request and of the fact that the head of the institution intends to disclose the record or part thereof.

This notification procedure will not be discussed in detail here, other than to point out that notification must be given within 30 days of receipt of a request for the information and that 20 days must be allowed for third party representations. The final decision must be rendered by the institution within 30 days following the notification.

## 3 CEPA 1999

On September 14, 1999, the *Canadian Environmental Protection Act*, 1999, (CEPA 1999) received Royal Assent. The primary purpose of the Act is to contribute to sustainable development through pollution prevention. Additional guiding values of CEPA 1999 include the precautionary principle; the polluter pays principle; and removing threats to biological diversity. Both the Minister of the Environment and the Minister of Health have responsibilities under this legislation.

Sections 46-53 of CEPA 1999 provide the authority, and proscribe the limitations, on gathering information by government for the purposes of environmental monitoring, research, state of the environment reporting, creating inventories and for the development of objectives, guidelines and codes of practice. The intent is that publishing this material promotes public participation and gives Canadians access to environmental information that relates to their own communities. Information that can be requested from a company is limited to what is in their possession, or is reasonably accessible.

Under section 51, a person providing information may request that it be treated in confidence based on the following criteria, which are equivalent to those described in paragraphs 20(1)(a), (c) and (d) of the *Access to Information Act*:

**52**. Despite Part II, a request under section 51 may only be based on any of the following reasons:

(a) the information constitutes a trade secret;

(b) the disclosure of the information would likely cause material financial loss to, or prejudice to the competitive position of, the person providing the information or on whose behalf it is provided; and

(c) the disclosure of the information would likely interfere with contractual or other negotiations being conducted by the person providing the information or on whose behalf it is provided.

Noteworthy from section 52 is the elimination of the mandatory class exemption for confidential information that was contained in subsection of 29(1)(b) of the *Access to Information Act*. In order to be exempted, information either must be a trade secret or must meet the injury tests of financial loss or impairment of contractual or other negotiations.

Section 53 provides that the Minister may seek additional justification for a request of confidentiality, and describes the recourse available should the Minister not be satisfied with the justification. The public interest "override" in 53(3) of CEPA 1999 differs from that of the *Access to Information Act* in that in exercising discretion, the Minister must also consider damage to "privacy, reputation or human dignity".

Additional justification

**53. (1)** The Minister may, after studying the reasons provided under section 52, require the person in question to provide, within 20 days and in writing, additional justification for the request for confidentiality.

Extension of time

**(2)** The Minister may extend the period mentioned in subsection (1) by up to 10 days if the extension is necessary to permit adequate preparation of the additional justification.

Minister's decision

**(3)** In determining whether to accept or reject the request, the Minister shall consider whether the reasons are well-founded and, if they are, the Minister may nevertheless reject the request if

(a) the disclosure is in the interest of the protection of the environment, public health or public safety; and

(b) the public interest in the disclosure outweighs in importance

(i) any material financial loss or prejudice to the competitive position of the person who provided the information or on whose behalf it was provided, and

(ii) any damage to the privacy, reputation or human dignity of any individual that may result from the disclosure.

Acceptance of request

**(4)** If the Minister accepts the request, the information shall not be published.

Publication

**(5)** If the Minister rejects the request,

(a) the person has the right to ask the Federal Court to review the matter within 30 days after the person is notified that the request has been rejected or within any further time that the Court may, before the expiry of those 30 days, fix or allow; and

(b) the Minister shall advise the person in question of the Minister's intention to publish the information and of the person's right to ask the Federal Court to review the matter.

Applicable provisions

**(6)** Where a person asks the Federal Court to review the matter under paragraph (5)(a), sections 45, 46 and 47 of the Access to Information Act apply, with any modifications that the circumstances require, in respect of a request for a review under that paragraph as if it were an application made under section 44 of that Act.

## 4 Opportunities for Public Involvement in Regulatory Decision Making

Canadian law requires that the process of rule making, whether as new or amended legislation, statutes, or regulations, be transparent and open to public input. This is accomplished through the advertisement of proposed new or amended rules in the *Canada Gazette*. Similar provisions do not generally exist with respect to the institutional policy decisions that generally govern the approval of new products of biotechnology. The purpose of this section is to highlight specific practices in other areas of regulation that increase the public's opportunity to participate in the decision making process or that provide enhanced public information.

### *4.1 Pest Management Regulatory Agency: Issuance of Proposed Regulatory Decision Documents*

The Pest Management Regulatory Agency (PMRA), reporting to the Minister of Health, was created in 1995 as part of the government's response to the Pesticide Registration Review (PRR) team's 1990 report on *Recommendations for a Revised Federal Pest Management Regulatory System*. The mandate of PMRA under the *Pest Control Products Act* includes protecting public health and the environment by prohibiting the registration for use in Canada of any pest control product that may pose an unacceptable risk. The legislation also requires that the registrant show that the pest control product is efficacious before it can be registered. A product that poses unacceptable health or environmental risks or is without pest control value cannot be registered.

As part of the reform of pesticide registration, the 1990 report recommended that the system incorporate extensive public access to information relating to all aspects of the regulatory system. The intent was to increase opportunities for public involvement in the development of new aspects of the regulatory system and to create conditions that would allow for pre- and post-decision access to health, safety and environmental data. Integral to this was the recommendation that Proposed Regulatory Decision Documents (PRDDs) be prepared for all proposed registrations of new active ingredients, and for registrations that may result in substantially increased use or exposure.

The recommendation to issue PRDDs has been implemented by PMRA as part of its policy to consult on proposed decisions to register new active ingredients if the application was received after April 1, 1995. PRDDs outline such matters as the characteristics of the candidate pesticides, the results of the PMRA's health risk, environmental risk and value assessments, proposed uses, application rates, label information and the Agency's rationale for its proposed decision[7].

The topics covered in the PRDD generally include, but may not be limited to, a discussion of:

- the properties and characteristics of the active substance;
- methods of analysis;
- impact on human and animal health including exposure, acute toxicity, acceptable daily intake, and worker safety;
- residue effects and maximum residue limits;
- environmental fate including microbial decomposition in soil and water;
- effects on terrestrial and aquatic non-target species; and
- efficacy of the product including the potential for the selection of resistant populations.

[7] For an example of a proposed regulatory decision document, see: PRDD99-05(Hexaconazole) accessible from the Internet at: http://www.hc-sc.gc.ca/pmra-arla/english/pdf/PRDD9905e.pdf.

PMRA accepts written comments on the proposal up to 45 days[8] from the date of publication of the PRDD.

Third party information contained within a PRDD is released subject to approval by the applicant. To date, since April 1995, PMRA has published 9 PRDDs and a refusal by the applicant to allow information to be released "has happened on a couple of occasions where there was a decision to not register a product" (personal communication, J.D. Smith, PMRA). On these occasions, companies were concerned about the potential market impact that publication of the negative decision would have in other countries. In these cases of a negative decision, the PRDD was not published.

Following the close of the public comment period and the analysis and consideration of comments received, PMRA publishes the final Regulatory Decision Document (RDD)[9]. The purpose of the RDD is to communicate the final decision and to summarize and/or address the comments received in response to the PRDD. On occasion, the comments received are significant enough to warrant requesting additional testing and/or information from the applicant.

### *4.2 Canadian Food Inspection Agency: Variety Registration*

With few exceptions, all grains, oilseeds, forage crops, pulse crops, and lentils[10] are subject to national variety registration prior to sale or advertisement for sale in Canada or import into Canada[11]. The application process and variety registration system are specified in Part III of the *Seeds Regulations* (sections 63 – 77), which are administered by the Canadian Food Inspection Agency who acts as the Registrar of new varieties.

In Canada, varieties are currently registered based on merit in order to ensure:

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[8] The publication of the first PRDD in 1995 allowed for a 60 day comment period as was recommended in the 1990 PRR. Since 1996, this period has been reduced to 45 days.

[9] A copy of the regulatory decision document related to PRDD99-05 for hexaconazole fungicide can be accessed at http://www.hc-sc.gc.ca/pmra-arla/english/pdf/RDD2000-04-e.pdf.

[10] The complete list of crops that are required to be registered is contained in Appendix I of "Procedures for the Registration of Crop Varieties in Canada" (March 24, 2000). CFIA. Accessible on the Internet at http://www.cfia-acia.agr.ca/english/plaveg/variet/regenr_promode.shtml.

[11] Section 3(1)(b) of the *Seeds Act* states that no person shall: "sell or advertise for sale in Canada or import into Canada seed of a variety that is not registered in the prescribed manner."

- that agronomically inferior or unadapted varieties are excluded from the Canadian marketplace;

- that new varieties meet current requirements for resistance to economically important disease; and

- high quality products for processors and for consumers.

Two characteristics of the variety registration process are of interest within the context of this report. The first of these is the appeal process (excerpted from *Procedures for the Registration of Crop Varieties in Canada*, CFIA, below), which provides a mechanism whereby applicants may seek a review of the Registrar's decision.

## 8. Review of Registration Decisions:

### 8.1 Process

Where the Registrar refuses to register a variety, or grants the variety a registration that is restricted regionally or in duration, or where the registration restricts the manner in which seed or commodity crop is produced (contract registration), the applicant may request that the Registrar review the decision. Similar procedures may be used for the review of the suspension or cancellation of registration.

If there is a valid objection to a registration decision, the Registrar may consult with an expert or group of experts knowledgeable in the area of concern who have no interest in the outcome of the review.

The selected expert(s) will recommend a course of action to the Registrar. The recommendations are not binding on the Registrar.

### 8.2 Procedures for Application for Appeal of a Registration Decision

a) The appellant must make a written request to the Registrar within 30 days of receipt of notice that the decision was made.

b) The appellant must include the reasons for requesting the review along with substantiating information or documentation.

The variety registration system also provides for limited public input through recommending committees, whose role is to recommend varieties for registration. Only varieties that have been recommended by one of the recommending committees may be submitted for registration. These committees must be formally recognized by the Minister of Agriculture and Agri-Food Canada and their membership generally consist of university and government research scientists, specialists from provincial departments of agriculture, and industry or producer group representatives.

The recommending committees are responsible for:

- formulating testing procedures that are appropriate for their crop(s) including a mechanism for verification of trials/validation of data;
- regularly reviewing the testing procedures to ensure that they reflect acceptable scientific practices; and
- ensuring that reference varieties are current and fairly represent the requirements of Canadian agriculture.

As neither the *Seeds Act* nor *Seeds Regulations* contain specific provisions relating to third party information, the disclosure of such information of a confidential nature (*e.g.*, pedigree information) is governed by the *Access to Information Act*.

### *4.3 CEPA: Environmental Registry*

CEPA 1999 requires the establishment of an Environmental Registry[12] of information published under, or related to, the Act. The goal of the Registry is to make it easier to access public documents such as:

- proposed administrative and equivalency agreements;
- regulations;
- Ministerial notices; and
- inventories such as the National Pollutants Release Inventory.

In addition to advertisement in *Canada Gazette Part I*, notification via the Environmental Registry serves as another means of alerting the public of the opportunity to provide input into the CEPA Priority Substances Assessment Program[13]. The Environmental Registry is not a forum for public consultations *per se*

[12] The Registry is electronic and accessible through the Internet at http://www.ec.gc.ca/CEPARegistry.

[13] Subsection 76(1) of CEPA 1999 requires the Minister of the Environment and the Minister of Health to compile a list, "to be known as the Priority Substances List" (PSL), which may be amended from time to time, and which identifies substances (including chemicals, groups of chemicals, effluents and wastes) that may be harmful to the environment or constitute a danger to human health. The Act also requires both Ministers to assess these substances to determine whether they are "toxic" or capable of becoming toxic as defined under section 64 of the Act. If, following assessment, a substance on the PSL is judged "toxic", it may be added to the List of Toxic Substances in Schedule 1 of CEPA 1999, which then allows

but rather a means of providing pertinent information regarding ongoing consultations, and as such does not directly accept public comments.

Upon completion of the scientific assessment for each substance on the Priority Substances List, a draft assessment report is prepared and made available to the public. In addition, the following must be published in the *Canada Gazette*:

- a summary of the scientific results of the assessment; and

- a statement as to whether government proposes to recommend:
  (a) that the substance be added to the List of Toxic Substances in Schedule 1; or
  (b) in the alternative, that no further action be taken in respect of the substance.

The notice in the *Canada Gazette* provides for a 60-day public comment period during which interested parties can file written comments on the recommendations and their scientific basis. After taking into consideration any comments received, revisions to the draft assessment report may be made, and the final decision published in the *Canada Gazette*.

The process described above is typical of the general case in which a list of regulated articles, as specified within a regulation, must be amended through addition, deletion, or modification.

### *4.4 Canadian Environmental Assessment Act: Public Registry*

Environmental assessment has been applied by the Canadian government since 1974 as a planning tool to predict the likely environmental effects of proposals requiring a federal involvement or decision. The process was updated in 1977 and reinforced in 1984 when the Environmental Assessment and Review Process guidelines were issued by order-in-council. Further reforms announced by the federal Minister of Environment in 1990 led to the passage of the Canadian Environmental Assessment Act (CEAA), which received royal assent in June 1992.

CEAA sets out in legislation, the responsibilities and procedures for the environmental assessment of projects involving the federal government. The Act establishes a clear and balanced process that brings a degree of certainty to the

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government to regulate the substance or enact instruments respecting preventative or control actions.

environmental assessment process and helps responsible authorities[14] determine the environmental effects of projects[15] early in their planning stage. The Act applies to projects for which the federal government holds decision-making authority -- whether as proponent, land administrator, source of funding, or regulator. The Canadian Environmental Assessment Agency was established to administer CEAA and replaces the Federal Environmental Assessment Review Office. The new Agency reports to the Minister of the Environment, but operates independently of any federal department, including Environment Canada, or any other agency.

Of relevance to the current discussion is the requirement under CEAA for every responsible authority to establish a public registry for the purpose of facilitating public access to records related to environmental assessments (subsections 55(1), (2), (3) and (4) of CEAA have been excerpted, below).

Public registry

**55. (1)** For the purpose of facilitating public access to records relating to environmental assessments, a public registry shall be established and operated in a manner to ensure convenient public access to the registry and in accordance with this Act and the regulations in respect of every project for which an environmental assessment is conducted.

Public registry established

**(2)** The public registry in respect of a project shall be maintained

(a) by the responsible authority from the commencement of the environmental assessment until any follow-up program in respect of the project is completed; and

(b) where the project is referred to a mediator or a review panel, by the Agency from the appointment of the mediator or the members of the review panel until the report of the mediator or review panel is submitted to the Minister.

[14] The federal authority that either has proposed the project or has been asked to provide support or approval in the form of funding, land, or a permit, licence, or other approval specified by regulation.

[15] Under the Act, a project can be either an undertaking in relation to a physical work, such as any proposed construction, operation, modification, decommissioning, abandonment or other undertaking; or any proposed physical activity not relating to a physical work that is listed in the regulations to the Act. Examples include: dredging as part of constructing a bridge; construction of a fish ladder; the movement of CFCs out of Canada; the harvesting of marine plants in coastal waters; low-level flying over the back country of a National Park; or ocean dumping of substances prescribed by the Canadian Environmental Protection Act.

Contents of public registry

**(3)** Subject to subsection (4), a public registry shall contain all records produced, collected, or submitted with respect to the environmental assessment of the project, including

(a) any report relating to the assessment;

(b) any comments filed by the public in relation to the assessment;

(c) any records prepared by the responsible authority for the purposes of section 38;

(d) any records produced as the result of the implementation of any follow-up program;

(e) any terms of reference for a mediation or a panel review; and

(f) any documents requiring mitigation measures to be implemented.

Categories of information to be made publicly available

**(4)** A public registry shall contain a record referred to in subsection (3) if the record falls within one of the following categories:

(a) records that have otherwise been made available to the public in carrying out the assessment pursuant to this Act and any additional records that have otherwise been made publicly available;

(b) any record or part of a record that the responsible authority, in the case of a record under its control, or the Minister, in the case of a record under the Agency's control, determines would have been disclosed to the public in accordance with the Access to Information Act if a request had been made in respect of that record under that Act at the time the record comes under its control, including any record that would be disclosed in the public interest pursuant to subsection 20(6) of that Act; and

(c) any record or part of a record, except a record or part containing third party information, if the responsible authority, in the case of a record under the responsible authority's control, or the Minister, in the case of a record under the Agency's control, believes on reasonable grounds that its disclosure would be in the public interest because it is required in order for the public to participate effectively in the assessment.

Among the 14 categories of information that may be exempted from publication in the registry, are certain types of third party information. For the purposes of CEAA, exemptible third party information must meet the same criteria as established under subsection 20(1) of the ATIA. Subsection 55(4)(b) of CEAA incorporates by reference the public interest "override" provision described in subsection 20(6) of the ATIA and the same notification requirements must be met if exercising this discretion.

The Canadian Environmental Assessment Agency has established a public registry framework within which all responsible authorities can function. In addition to providing single-window access to information on environmental assessments, the

framework seeks to ensure consistency across the federal government and assist other federal departments and agencies in meeting their public registry obligations under the Act.

Environmental assessments may be of three types: screenings, comprehensive studies and panel reviews. Screenings are generally for small projects and account for about 99% of the more than 25,000 assessments performed under the Act since 1992. There is limited public involvement in the screening process.

Public participation in comprehensive studies[16] is mandatory only after the study report has been completed, when the Agency invites the public to review and comment on the report. An independent background study commissioned in 1999 concluded that public participation activities, before the review-and-comment period, have been included as part of all comprehensive studies conducted to date. This participation has taken the form of public meetings, open houses, advisory committees, workshops, and community liaison office and site visits. The study concluded that most comprehensive studies have involved the public early in the process.

The Canadian Environmental Assessment Agency is responsible for managing the review-and-comment period after the submission of the comprehensive study report. The Agency typically has provided a comment period for a minimum of 30 days, though the period has been as long as 60 days, and as low as 15 days (following a previous 30-day review and comment period already held as part of the assessment by the provincial government). The number of public comments received during this review period has ranged from nil (a decommissioning of a Canadian Forces base) to nearly 200 (a proposed used fuel storage facility at a nuclear generating station).

Since January 2000, the Canadian Environmental Assessment Agency has been overseeing a multi-stakeholder review of CEAA, which was scheduled to culminate in a report to Parliament by the Minister of Environment in December 2000. Three challenges facing the review include: making the process more predictable, consistent

[16] As of mid-1999, 46 proposed projects required a more thorough form of assessment called a comprehensive study; 23 of these studies were still under way as of mid-year. Since the introduction of the Act, five projects have undergone full review by a panel, with another four panel reviews under way as of mid-1999. The majority of these reviews were performed co-operatively, either combining the federal process with that of a provincial jurisdiction, or by combining with another federal review process, such as that of the National Energy Board. To date, a formal mediation process, as defined in the Act, has not been used in an environmental assessment. *[Review of the Canadian Environmental Assessment Act: A discussion paper for public consultation, December 1999]*

and timely; improving the quality of environmental assessments; and strengthening opportunities for public involvement.

With respect to public involvement, concerns have been expressed about the scope and timing of opportunities for early, meaningful public participation in screenings and comprehensive studies; the application of more judicial, adversarial procedures in joint panel reviews; the involvement of Aboriginal people in environmental assessments; and the lack of a reliable, user-friendly system to ensure public access to up-to-date, useful information on environmental assessments.

## 5 Conclusions

In Canada, openness, transparency and public involvement are mandated by law when even small changes are contemplated to statutes and/or regulations. Publication of the proposed change in the official Parliamentary journal, *Canada Gazette*, is the mechanism for alerting the public and soliciting comment. In contrast, the opportunity for public input in advance of policy decisions that do not involve a change in a regulation is very limited. This is exemplified by policy decisions that result in product approvals (*e.g.*, drugs and therapeutic products, novel foods, environmental release of plants with novel traits) in which there is no opportunity of public input during the risk assessment or product review processes.

The existing pieces of legislation under which agricultural products of biotechnology are regulated (*e.g.*, *Food and Drugs Act, Seeds Act, Feeds Act, Fertilizers Act*) do not contain specific provisions regarding the disclosure of third party information. In this case, the *Access to Information Act* (ATIA) prevails. Although not extensive, the existing case law dealing with protecting the confidentiality of third party information (section 20 of the ATIA) is instructive. Within the jurisprudence are the ideas that in order to be exempted from disclosure, third party information must constitute a trade secret, or meet objective criteria for confidentiality, or its disclosure must have a reasonable probability, not just a possibility, of causing measurable harm to a third party.

CEPA 1999, which also explicitly deals with third party information, differs from ATIA in that it removes the mandatory class exemption for confidential information. Exempted information either must be a trade secret or must meet the injury tests of financial loss or impairment of contractual or other negotiations.

With respect to agricultural products of biotechnology, there is a perceived need for greater public accessibility to the relevant human health and environmental safety information. It is highly likely that progress could be made in this area without

jeopardizing trade secrets or competitive advantage. The following options illustrate at least four ways that enhanced safety information could be provided by regulatory authorities within existing legislation:

- **Not exempting certain information under subsection 20(1) of the ATIA and dealing with whatever court challenges may arise.** Information that would be in the public interest generally comprises experimental data derived from examining the interaction of the novel plant with managed or unmanaged ecosystems, effects on non-target organisms, tendency to weediness and the potential for outcrossing; or the compositional, toxicological, and nutritional analyses, and allergenic potential of novel food products. This type of information would not generally be regarded as a trade secret. Moreover, since many of the products seeking approval in Canada are also being evaluated, or have already been approved, by the U.S. or other countries that practice broader disclosure than Canada, there is a legitimate question as to the confidentiality of such information. As to the injury tests required to exempt such information from disclosure, appellants would have to demonstrate that such disclosure during the process of a product approval was more injurious than not approving the product. This would be a difficult case to make with certainty. In addition to providing enhanced public information, one advantage of this option is that it would provide some sorely needed legal precedent.

- **Government could perform its own environmental and human health safety testing of plants with novel traits and novel foods.** The information generated from such testing meets the criterion of subsection 20(2) of the ATIA and there would be nothing to preclude government publication. This option would also address a main criticism of the existing regulatory framework, which is that government currently does no independent testing to ensure the safety of products of biotechnology. However, this approach is contrary to the principle that it is the responsibility of developers to undertake the research and testing required to demonstrate product "safety". This approach would also add significantly to the public cost and duration of the approval process.

- **Invoking the public interest "override".** Notwithstanding the fact that government agrees certain information is subject to mandatory exemption under section 20(1) of the ATIA, disclosure could be "in the public interest". However, it is unlikely that exercising such Ministerial discretion would be judged as protecting the public from a specific and substantial danger in the case of genetically engineered crops and foods.

- **Securing third party (*i.e.*, applicant) agreement.** This option has benefits for both industry and government. As demonstrated by PMRA, the policy of publishing Proposed Regulatory Decision Documents (PRDDs) and soliciting public input based on disclosure of safety data as agreed by the applicant is possible. Generally, industry is supportive of PMRA's policy in this area. The few objections that have arisen around published PRDDs were generally over particular wording within the PRDD, and negotiations resolved these issues. Undoubtedly, one of the reasons for industry acceptance of this process lies in the consultation that government undertook in 1994 as it prepared its response to the 1990 Pesticide Registration Review.

Even in the absence of disclosing more detailed safety data, providing an opportunity for public input during the assessment and evaluation phase is possible. Currently, both the Canadian Food Inspection Agency and Health Canada publish regulatory decision documents that respectively summarize the environmental or human health safety concerns that were assessed prior to approving the environmental release of a plant with novel trait or a novel food. Nothing within the existing legislation or regulations would preclude the publication of a similar document just prior to the final decision and providing a period of public comment.