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Balancing Industry Confidentiality with the Public Right of Access: The Case of Biotechnology in Canada

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The CISDL is an independent legal research centre which collaborates with the McGill Law Faculty in engaging students and interested faculty members in sustainable development law research and scholarly initiatives. The CISDL also works in cooperation with a network of developing country faculties of law, and is developing closer ties with the Oxford University Faculty of Law and the Université de Montreal, as well as the Yale Law School and the Cambridge University Faculty of Law.

The CISDL is engaged in six primary areas of sustainable development law research, each of which is led by a CISDL Lead Counsel based at a developing or developed country law faculty or international organisation. These include trade, investment and competition law; sustainable developments in natural resources law; biodiversity law; climate change and vulnerability law; human rights and poverty eradication in sustainable development law; and health and hazards in sustainable development law. There are also two Lead Counsels responsible for cross-cutting sustainable development law issues. As a result of its ongoing legal scholarship and research, the CISDL publishes books, articles, working papers and legal briefs in English, Spanish and French. The CISDL hosts academic workshops, dialogue sessions, legal expert panels parallel to international negotiations, law courses and seminar series, and conferences to further its legal research agenda. It provides instructors, lecturers and capacity-building materials for developing country governments and international organisations in national and international law in the field of sustainable development, and works with countries to develop national laws to implement international treaties in these areas.

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Abstract

Access to information is a crucial means by which individuals can monitor the regulators and the regulated and come to trust the regulatory system. Access to information has also developed as a principle of sustainable development law over the past fifty years through its inclusion and use in a variety of human rights, trade, and environmental fora. As public doubt over the human and environmental safety of the products of biotechnology continues to linger, industry's desire for confidentiality runs headlong into citizen actions to ensure that they and their environment are being protected.

In Canada, the Access to Information Act creates a presumption of a right of access to records under the control of government. There are exemptions to this right with regards to third party information submitted to government as well as exceptions to the exemptions. In the context of applications for unconfined release of plants with novel traits, much of the information submitted to government by the proponent is classed as confidential and so protected by the exemptions. Different studies have recommended disclosure of the environmental risk assessment data submitted by proponents but the Canadian Food Inspection Agency (CFIA) has yet to implement these recommendations. Rather, experience demonstrates that the CFIA is leaving proponents to decide when access to information will be granted resulting in fundamental misinterpretation of the Access to Information Act.

Where access to the environmental risk assessment data has been obtained, serious shortcomings have been revealed.

The problem can be fixed through proper application of the access to information rules and/or the development of new obligations but ultimately it will require an appreciation of access to information as a key component of sustainable development.

Balancing Industry Confidentiality with the Public Right of Access: The Case of Biotechnology in Canada

I Introduction

Gone are the days of blind trust in government and public authorities. Now these figures must earn the trust of the public they serve. The reasons for this are varied: in the environmental field they include landmark publications such as Rachel Carson's *Silent Spring* and the concomitant realization that industrial products and processes can harm us and the planet and need to be regulated. As Carson herself illustrates, individual members of the public can fill an important role in this regulatory process by monitoring both the regulated and the regulator. Access to information is a crucial tool for filling this role.

Access to information has also developed as a principle of international law in the past fifty years. Public participation, access to information and justice are recognized as a principle of international sustainable development law by the International Law Association.¹ The basis of the principle in international law can be traced to human rights instruments such as the *International Covenant on Civil and Political Rights*,² the *International Covenant on Economic, Social and Cultural Rights*,³ and the *Aarhus Convention*⁴; environmental treaties such as the *Convention on Biological Diversity*⁵ and the *Framework Convention on Climate Change*⁶; and economic instruments such as the use of amicus curiae briefs in disputes at the World Trade Organization and the North American Free Trade Agreement.⁷ More integrative international law instruments – i.e. instruments that integrate the three components of sustainable development: environment, economy, and human rights – also promote the principle of public participation and access to information and justice. Examples include the Rio Declaration⁸ and the *Cartagena Protocol on Biosafety*⁹.

¹ International Law Association, Resolution 3/2002, *New Delhi Declaration of Principles of International Law Relating to Sustainable Development*, online: International Law Association <<http://www.ila-hq.org>>. See also International Law Association, Committee on the Legal Aspects of Sustainable Development, *Searching for the Contours of International Law in the Field of Sustainable Development*, Fifth and Final Report (London: ILA, 2002). Also reprinted in UN General Assembly, 57th session, UN Doc. A/57/329 (2002).

² *International Covenant on Civil and Political Rights*, 19 December 1966, 999 U.N.T.S. 171, 6 I.L.M. 368 (entered into force 23 March 1976), see, in particular, Article 25.

³ *International Covenant on Economic, Social and Cultural Rights*, 19 December 1966, 993 U.N.T.S. 3, see, in particular, Article 13.

⁴ *Aarhus Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters*, 25 June 1998, 38 I.L.M. 517 (entered into force 30 October 2001).

⁵ *Convention on Biological Diversity*, 5 June 1992, 31 I.L.M. 818 (entered into force 29 December 1993), see, in particular, preambular paragraph 13, and Articles 14(1)(a) and 23(d).

⁶ *United Nations Framework Convention on Climate Change*, 9 May 1992, 31 ILM 848 (entered into force 21 March 1994), see, in particular, Article 4.1.i.

⁷ K. Bottrill, "The Principle of Public Participation and Access to Information and Justice: Recent Developments in International Law Related to Sustainable Development" (Oxford: CISDL, forthcoming 2005).

⁸ *Rio Declaration on Environment and Development*, Report of the United Nations Conference on Environment and Development, UN Doc. A/CONF.151/6/Ref.1 (1992), 31 I.L.M. 874 (14 June 1992), see, in particular, Principle 10.

⁹ *Cartagena Protocol on Biosafety to the Convention on Biological Diversity*, 29 January 2000 (entered into force 11 September 2003), see, in particular, Article 23.

While access to information by the public is an important component of environmental protection, industry has an interest in protecting its information in order to maintain a competitive edge. The public, too, has an interest in maintaining information confidential that will encourage innovation and competition.¹⁰ The need for confidentiality is particularly true in the biotechnology sector where much of a company's value may come from its intellectual property portfolio. Much of this value, in turn, derives from keeping information secret (e.g., trade secrets and inventive information prior to filing a patent application.) For many of their products to be approved for sale in the marketplace, however, biotechnology companies must submit health and safety data to government regulators. This includes information on environmental risks in the case of genetically modified organisms (GMOs) for release into the environment. In submitting this information to government, it becomes subject to access to information rules even though it may be information that the companies desire to keep secret.

As public doubt over the human and environmental safety of the products of biotechnology continues to linger, industry's desire for confidentiality runs headlong into citizen actions to ensure that they and their environment are being protected. Canada's *Access to Information Act*¹¹ goes part way to resolve the conflict but much of the balancing is not being played out in the legislation or the interpretation and application thereof by the courts. This has serious implications for the right of access, environmental protection, and sustainable development.

Following this introduction, part II of the paper presents an overview of the Canadian regulatory process for 'plants with novel traits'. This describes the information requirements that applicants must submit to government in order to obtain approval for the release of a novel plant and thus the types of information that are available through access to information requests. Part III of the paper describes the federal Access to Information Act with a particular focus on the section 20 provisions on third party information. Part IV brings these two discussions together to see how the Act has been used to gain access to the environmental risk assessment information submitted to government by different proponents and what this accessed information says about protection of the environment. On the basis of these experiences, Part V looks at what is needed to improve the balance between corporate confidentiality and public access within the context of the Access to Information Act and to contribute to sustainable development more broadly.

II The Regulatory Process for 'Plants with Novel Traits'

In order for a new crop, food, or drug to be marketed in Canada, it must pass through different regulatory procedures. Of most interest in the environmental context is the unconfined release of new organisms into the environment. In Canada, this process is governed by the *Canadian Environmental Protection Act*¹². CEPA sets rules for the introduction of new organisms into Canada but these rules are intended to serve as a safety net to catch types of organisms not covered by other legislation. Schedule IV to CEPA lists

¹⁰ T. Murray Rankin & Kathryn Chapman, "Report 19 – Access to Information Review Task Force: Third Party Provisions" (July 2001), online: Access to Information Review Task Force <<http://www.atirtf-geai.gc.ca/paper-thirdparty1-e.html>> (date accessed: 14 September 2005).

¹¹ *Access to Information Act*, R.S.C. 1985, c. A-1.

¹² *Canadian Environmental Protection Act*, S.C. 1999, c. 33 ["CEPA"].

the acts and regulations that apply to various organisms in place of the CEPA rules. The schedule includes the *Seeds Act*¹³ which governs the introduction of new plants into Canada.

The Canadian regulatory system is also built around the regulation of the product rather than the process. This means that the products of biotechnology (including plants produced through recombinant DNA technology) are regulated according to the principle that biotechnology is not a fundamentally different process from other methods used to produce new crops, new foods or new drugs. In other words, regardless of whether different plant varieties were produced through processes of modern biotechnology or more traditional breeding methods, all are subject to the same regulatory system. This system is also governed by the principle of 'substantial equivalence' wherein recently developed crop varieties may be considered substantially equivalent to pre-existing varieties that have been determined to be safe. Under this system, only 'plants with novel traits' (PNTs) must go through the full risk assessment process.

The Canadian Food Inspection Agency (CFIA) implements the *Seeds Act* and has developed regulations and 'regulatory directives' that set out the information to be provided by a proponent seeking approval for the unconfined release of a plant with novel traits. The regulatory directive on "Assessment Criteria for Determining Environmental Safety of Plants with Novel Traits"¹⁴ states that the Plant Biosafety Office of CFIA conducts an environmental safety assessment based on the following criteria:

- potential of the PNT to become a weed of agriculture or be invasive of natural habitats,
- potential for gene-flow to wild relatives whose hybrid offspring may become more weedy or more invasive,
- potential for the PNT to become a plant pest,
- potential impact of the PNT or its gene products on non-target species, including humans,
- potential impact on biodiversity.¹⁵

These five criteria of a plant with novel traits are assessed by examining a companion biology document, "which provides baseline information for the plant species of the PNT under review",¹⁶ and the information submitted by the applicant, which "consists of appropriate data and relevant scientific information describing the environmental risk of the PNT relative to its counterpart(s) already present in the Canadian environment".¹⁷ The *Seeds Regulations*¹⁸, however, allow the applicant to omit much of the information on the PNT, including the information on environmental risks, "if the Minister determines, on the basis of a written scientific rationale provided by [the applicant], that the information or part is not relevant or cannot practicably be obtained and is not required for the Minister's decision ... and notifies the person of that determination."¹⁹

¹³ *Seeds Act*, R.S.C. 1985, c. S-8.

¹⁴ Canadian Food Inspection Agency, "Assessment Criteria for Determining Environmental Safety of Plants with Novel Traits", Directive 94-08 as revised on 29 October 2004, online: CFIA <<http://www.inspection.gc.ca/english/plaveg/bio/dir/dir9408e.pdf>> (date accessed: 14 September 2005).

¹⁵ *Ibid.* at 11.

¹⁶ *Ibid.*

¹⁷ *Ibid.*

¹⁸ *Seeds Regulations*, C.R.C., c. 1400.

¹⁹ *Ibid.* at r. 110(4).

Finally, in submitting information to the government, applicants may classify portions of their application as ‘confidential business information’ (CBI). This means that the information is protected by the exemptions to access in the Access to Information Act, as described below, and that the information may only be released through an access to information request. CFIA does release short Decisions Documents that contain summaries of the information submitted by the applicant and the grounds upon which the Agency made its decision but it does not release the actual data submitted by the proponent.

III The Access to Information Act

The federal government and all the provinces and territories have access to information legislation. We shall focus on the federal Access to Information Act as the environmental and human health and safety of biotechnology are regulated at the federal level.

A. Provisions in the Act

Section 2 of the Access to Information Act creates a presumption in favour of the disclosure of information held by government:

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.²⁰

This is important as it should place the onus on anyone wanting to keep confidential information under the control of the government to justify why this should be so.

Access to information submitted by companies to the federal government is also subject to the section 20 provisions of the Act on third party information. This includes access to the environmental risk assessment information submitted by biotechnology companies in applications for approvals for unconfined release of plants with novel traits.

Subsection 1 of section 20 creates four mandatory exemptions from disclosure, i.e. third party information that must not be disclosed if it falls into one of these four categories. The categories include two class-based exemptions – trade secrets and information supplied in confidence – and two harm-based exemptions – information that could harm the competitive position of a third party, and information that could interfere with the negotiations of a third party. The courts have created tests for determining whether information falls into one of these categories. In *Société Gamma Inc. v. Canada (Secretary of State)*²¹ the court construed the trade secret exemption quite narrowly. For something to be a trade secret, it “must be something, probably of a technical nature, which is guarded very closely and is of such peculiar value to the owner of the trade secret that harm to him would be presumed by its mere disclosure.”²² For information to fall into the section 20(1)(b) exemption of ‘information supplied in confidence’ it must meet numerous criteria including

²⁰ *Supra* note 11 at s. 2(1).

²¹ *Société Gamma Inc. v. Canada (Secretary of State)* 1994, 79 F.T.R. 42, 56 C.P.R. (3d) 58 (Fed. T.D.)

²² *Ibid.* at para. 7. This interpretation was reaffirmed more recently in *Canadian Tobacco Manufacturers’ Council v. Canada (Minister of National Revenue)*, 2003 FC 1037, 28 C.P.R. (4th) 139.

that it relate to matters of finance, commerce, science or technical matters as these terms are commonly understood; it must have been consistently treated as confidential information by the third party; and the confidentiality of the information must be determined objectively.²³ For both of the harm-based exemptions in sections 20(1)(c) and (d) it is not enough to merely speculate on the possible harm. Rather, the third party must establish a reasonable expectation of probable harm on a balance of probabilities.²⁴

Section 20 also includes exceptions to these exemptions, i.e. instances where third party information can or must be disclosed despite falling within one of the categories in section 20(1). Section 20(2) contains a mandatory exemption whereby:

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.

This provision has been construed quite narrowly and it does not include activities such as testing done by the National Research Council on a commercial basis, for example, or the testing done by companies as part of the new product approval process.²⁵

Section 20(6) contains a discretionary exception whereby:

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 paragraph could have important implications for accessing the information submitted in applications for approval of new crops although it is, in fact, little used. According to Rankin and Chapman, “[a]t the federal level, there has been a reluctance to use the public interest override because, if release is in the public interest, the information likely should have been released before receiving an access request.”²⁶

In 2000, the federal government commissioned a Task Force to review the Access to Information Act. As part of its work, the Task Force commissioned a report on the third party provisions of the Act. The report presented three options for reform related to the section 20(6) public interest override provision. These were to broaden the override to include consumer protection as one of the grounds for its application, to include trade secrets as information that can be disclosed in accordance with section 20(6), and/or to broaden the override so that it applied to all exemptions under the Act, not just the third party exemptions.²⁷

²³ Michel W. Drapeau & Marc-Aurèle Racicot, *Federal Access to Information and Privacy Legislation Annotated 2004* (Toronto: Carswell, 2003) at 1144-1145.

²⁴ *Canada Packers Inc. v. Canada (Minister of Agriculture)*, [1989] 1 F.C. 47, 26 C.P.R. (3d) 407; *ibid.* at 1148-1151.

²⁵ Rankin & Chapman, *supra* note 10.

²⁶ Rankin & Chapman, *supra* note 10.

²⁷ Rankin & Chapman, *supra* note 10.

In 2002, the report of the Task Force recommended broadening the section 20(6) override to add consumer protection to the list of elements to be considered.²⁸ In April of this year, the Justice Minister presented a comprehensive framework for reform of the Act which included a discussion paper to be considered by the Standing Committee on Access to Information, Privacy and Ethics. The discussion paper requested that the Standing Committee consider, as part of its deliberations, the possibility of broadening section 20(6) to include consumer protection.²⁹

The Information Commissioner has also weighed in on this issue over the years. In his 2003-2004 annual report, he commented that section 20(6) should allow a weighing of “the public interest in accountability and transparency of public expenditures against the competitive interests of third parties.”³⁰ Also, in his response to the Task Force’s report, he recommended that all exemptions in the Act be subject to the public interest override, or, at the very least, the existing override in section 20(6) should be broadened to include consumer protection.³¹

B. Use of the Third Party Provisions of the Act

While a full-scale review of the case law under section 20 of the Access to Information Act is beyond the bounds of this paper, it is worthwhile describing the use of this portion of the Act in more general terms.

Section 20 is one of the most heavily litigated parts of the Act.³² Court decisions on this section appear to have increased in the past five years and most of the cases involve companies trying to gain access to the information of other companies.³³ This is perhaps to be expected given the financial resources that corporations have to engage in litigation, particularly in comparison to individual members of the public, but this was not necessarily the intention behind the Act.

Most of the litigation involves section 20(1) and there have been very few cases considering the other five subsections. One notable exception in this context is the case of *Dekalb Canada Inc. v. Canada (Agriculture and Agri-Food)*³⁴. In this case, Dekalb sought a review of a decision to release test results of hybrid corn samples that were taken from Dekalb’s premises. The information had been created as a result of Agriculture Canada’s monitoring of the varietal purity of certified seeds. The requester was party to a lawsuit brought by

²⁸ Access to Information Review Task Force, *Access to Information: Making it Work for Canadians* (Ottawa: Public Works and Government Services, 2002), online: Access to Information Review Task Force <<http://www.atirtf-geai.gc.ca/accessReport-e.pdf>> (date accessed: 14 September 2005) at 61.

²⁹ Department of Justice, “A Comprehensive Framework for *Access to Information Reform*” (April 2005), online: Department of Justice <http://canada.justice.gc.ca/en/dept/pub/ati/ati_whitepaper.pdf> (date accessed: 14 September 2005) at 19.

³⁰ Information Commissioner of Canada, *Annual Report Information Commissioner 2003-2004* (Ottawa: Public Works and Government Services, 2004), online: Information Commissioner <http://www.infocom.gc.ca/reports/pdf/oic03_04E.PDF> (date accessed: 14 September 2005) at 29.

³¹ Information Commissioner of Canada, *Response to the Report of the Access to Information Review Task Force: A Special Report to Parliament* (Ottawa: The Information Commissioner of Canada, 2002), online: Information Commissioner of Canada <<http://www.infocom.gc.ca/specialreports/pdf/2002special-e.pdf>> at 64 & 67.

³² *Ibid.* at 66.

³³ The assessment of the increase in court decisions is based on a review of cases that had considered each of the section 20 subsections between 2000-2005, on the one hand, and 1990-1999 on the other as listed by Westlaw on 7 July 2005.

³⁴ *Dekalb Canada Inc. v. Canada (Agriculture and Agri-Food)* 1999, 2 C.P.R. (4th) 345.

farmers who had used the hybrid corn and were claiming damages against Dekalb. The company claimed that the information fell under both the section 20(1)(a) trade secrets exemption and the section 20(1)(c) scientific or technical confidential information. The government argued that the information was subject to the section 20(2) exception to the exemptions as it was the result of environmental testing done by or on behalf of the government. The court found that the information did not fall into either the section 20(1)(a) or (c) exemptions and was nonetheless subject to the mandatory exception in section 20(2).³⁵ The information was thus disclosed to the requester. It is important to distinguish this case from the situation at hand, however, in that the environmental risk assessment information in applications for plants with novel traits is generally prepared by the proponent and does not fall under the section 20(2) exception.

As for section 20(6), the Federal Court was asked to consider whether the public interest override was properly exercised in the case of *Rubin v. Canada (Minister of Health)*³⁶. The court found that that the override is discretionary and does not create an obligation to disclose the information even if it is in the interest of the public. As such, it is not for the court to engage in the balancing exercise prescribed by the provision. Instead, the court can consider whether the discretion was exercised in bad faith. In the absence of bad faith, the exercise of the discretion will be considered proper.³⁷

IV Access to the Environmental Information in Applications for Plants with Novel Traits

As described above, CFIA releases Decision Documents that outline the basis for their approval for the unconfined release of a plant with novel traits but the actual information or data submitted in the application for approval by the proponent is not made public. Indeed, much of the information is considered confidential business information.

At the same time, however, the Access to Information Act allows individuals to apply for access to records held by the federal government including information supplied by third parties. This includes the information submitted as part of an application for approval. How are these two sides being balanced and where do individual members of the public stand? In answering this question, there are two points to be addressed: (1) how access to information actually functions in relation to plants with novel traits; and (2) how access to information in relation to plants with novel traits could help protect the environment.

A. *The Functioning of Access to Information*

An Expert Panel of the Royal Society of Canada examined the issue of confidentiality and transparency from the perspective of maintaining the integrity of risk assessment science in the regulation of food biotechnology in its report *Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada*³⁸. As part of their discussion, the Panel

³⁵ *Ibid.* at para. 12-15.

³⁶ *Rubin v. Canada (Minister of Health)* 2001, 14 C.P.R. (4th) 1, 2001 FCT 929.

³⁷ *Ibid.* at para. 54.

³⁸ The Royal Society of Canada, *Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada* (Ottawa: The Royal Society of Canada, 2001), online: Royal Society of Canada <http://www.rsc.ca/files/publications/expert_panels/foodbiotechnology/GMreportEN.pdf> (date accessed: 15 September 2005).

addressed the issue of applicants classifying portions of their submissions as confidential business information:

The company applying for approval of a biotechnology product essentially gets to decide what counts as CBI. Presumably, the regulatory agency can, and often does, negotiate with the company applicant what test data the agency will consider confidential, and thus has the power to negotiate for relatively full disclosure.³⁹

While the Panel understood that some information such as that related to genetic transformations and gene constructs needs to remain confidential, it did not agree that information on environmental and ecological consequences should be protected.⁴⁰

The Panel goes on to describe how decisions to maintain some information as confidential are not made according to any formal process:

the amount of information the regulatory departments choose to disclose from the application and approval process is not set by any formal regulations. Rather, it is a policy judgment that seeks to balance the interests of industry against the desire for transparency in the regulatory process. Government could insist on more complete disclosure of the relevant data, but many consider that such a policy discourages industry research and development.⁴¹

The Panel goes on to recommend that the “Canadian regulatory agencies seek ways to increase the public transparency of the scientific data and the scientific rationales upon which their regulatory decisions are based.”⁴² They also recommend that “[t]he data and the rationales upon which the risk assessment and the regulatory decision are based should be available to public review.”⁴³

In November 2001, Environment Canada, Health Canada, the Department of Fisheries and Oceans, Agriculture and Agri-Food Canada, and CFIA published an action plan outlining how these organizations intended to implement the Royal Society’s recommendations. The planned actions on the issue of transparency and increasing public confidence include:

- Examine the approach taken by other countries which provide for more public and expert consultations in order to determine the best model for the Canadian regulatory process. ...
- Investigate what other countries do to increase transparency including the disclosure of information about individual submissions ... [and]
- Work with applicants to achieve greater openness regarding the disclosure of specific product information.⁴⁴

While these planned actions may “seek ways to increase the public transparency of the scientific data and the scientific rationales upon which [the] regulatory decisions are based”,

³⁹ *Ibid.* at 213.

⁴⁰ *Ibid.* at 213.

⁴¹ *Ibid.* at 213.

⁴² *Ibid.* at 218.

⁴³ *Ibid.* at 218.

⁴⁴ Canada, “Action Plan of the Government of Canada in Response to the Royal Society of Canada Expert Panel Report *Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada*” (23 November 2001), online: Health Canada <http://www.hc-sc.gc.ca/sr-sr/alt_formats/hpfb-dgpsa/pdf/pubs/RSC_response-reponse_SRC_e.pdf> (date accessed: 15 September 2005) at 5.

they don't go so far as dedicating the organizations to actually making the relevant data available to public review as recommended by the Royal Society.

Since the Action Plan was released, the government departments and agencies in question have issued regular progress reports. Progress on transparency has included all five of the departments examining the approach taken by other countries that provide for more public input and expert consultations such as Australia, New Zealand, Britain and the U.S. The departments "are now looking into developing an improved, more coordinated model for transparency and consultation in Canada. Approaches used in other countries are being considered to develop our improved model."⁴⁵ CFIA's "work with applicants to achieve greater openness regarding specific product information" has involved a 'Notices of Submission' project whereby information on applications for approvals of plants with novel traits are posted to a website for public review and comment. Applicants are not required to participate in the project, i.e. it is not mandatory for information on an application to be posted,⁴⁶ and the information that has been posted to date is short descriptions of the types of data that have been submitted without actually presenting any of the hard data itself. For example, in the "Notice of Submission for Approval of Livestock Feed, Novel Food, and Environmental Safety for Genetically Improved Maize, Lysine Maize, Event LY038, from Monsanto Canada Inc.", the Notice of Submission states that "[i]n order to assess the environmental impact of the novel plant the following has been submitted: ... Examination of the response to biotic and abiotic stressors on the PNT ... Examination of the PNT to become a potential plant pest[...] Examination of gene flow from the PNT to wild relatives".⁴⁷ This description is of little use for individuals to assess the actual quality of the data and hold the regulatory authorities to account for the decisions they are making, which is ultimately the point of access to information. These more precise descriptions of the available data may be useful in filing access to information requests in order to view the actual data but the Notice of Submissions falls well short of the Royal Society's recommendation to make the data available to the public.

This fact was highlighted in an October 2004 study by the Polaris Institute on *Genetically Modified Organisms and Precaution: Is the Canadian Government Implementing the Royal Society of Canada's Recommendations?* The study finds numerous deficiencies with the Notice of Submissions project and concludes that the government still needs to "take real action to achieve full transparency of regulatory data".⁴⁸ To date, the response by the government to the Royal Society's report has failed to meet this objective.

The Canadian Biotechnology Advisory Committee (CBAC) has also weighed-in on the issue of transparency in Canada's biotechnology regulatory system. In its August 2002 report on

⁴⁵ Canada, "Progress Report: June 2005", online: Health Canada <http://www.hc-sc.gc.ca/sr-sr/alt_formats/hpfb-dgpsa/pdf/pubs/prog-rep-rap_06_2005_e.pdf> (date accessed: 15 September 2005) at 5.

⁴⁶ Peter Andr e & Lucy Sharratt, *Genetically Modified Organisms and Precaution: Is the Canadian Government Implementing the Royal Society of Canada's Recommendations?* (Ottawa: The Polaris Institute, 2004) at 11-12.

⁴⁷ "Notice of Submission for Approval of Livestock Feed, Novel Food, and Environmental Safety for Genetically Improved Maize, Lysine Maize, Event LY038, from Monsanto Canada Inc." (14 September 2004), online: CFIA <<http://www.inspection.gc.ca/english/plaveg/bio/subs/2004/20040914e.shtml>> (date accessed: 15 September 2005).

⁴⁸ Andr e & Sharratt, *supra* note 46 at vii.

*Improving the Regulation of Genetically Modified Foods and Other Novel Foods in Canada*⁴⁹, CBAC concludes

that there are significant shortfalls in the way the government communicates with and involves the public in the regulatory process for GM foods. The federal government has not provided clear information about how these products are regulated and decisions made, the roles of the various regulatory bodies, and the data that are considered during the safety assessment process. Broader information disclosure and a clear mechanism for including public views in the decision-making process are essential confidence-building measures that should be incorporated within the GM food regulatory system. Increasing transparency and public involvement will require a major commitment on the part of those responsible for the operation of the regulatory system.⁵⁰

The report includes a number of recommendations that reinforce those of the Royal Society. In particular, CBAC recommends that “the detailed scientific and technical data pertinent to the human health and environmental safety assessments of GM foods and other novel foods be made public, except for details that could unduly jeopardize a company’s competitive position”.⁵¹ The recommendation elaborates on how this should be achieved including by not automatically classifying all scientific data relating to the safety of biotechnology products as confidential business information and developing a policy on what types of environmental and human health and safety information may be considered confidential business information.⁵²

Despite the lack of progress in making environmental risk assessment data available to the public, individual Canadians have filed access to information requests in order to gain access to the scientific information submitted by proponents and have been successful in obtaining this information. These access requests were not without difficulties, however, requiring back and forth communications with CFIA, the intervention of the Information Commissioner, and over a year of waiting.⁵³

In one instance, two doctoral students filed an access request for the environmental risk assessment information submitted by Monsanto and AgrEvo (now Bayer) as part of these companies’ applications for approval for four lines of genetically modified canola.⁵⁴ The students only received access to the Monsanto data based, according to Barrett, on agreement from the company.⁵⁵ AgrEvo refused to agree to grant access to the information it had submitted:

⁴⁹ Canadian Biotechnology Advisory Committee, *Improving the Regulation of Genetically Modified Foods and Other Novel Foods in Canada* (Ottawa: CBAC, 2002), online: CBAC <[http://cbac-cccb.ic.gc.ca/epic/internet/incbac-cccb.nsf/vwapj/cbac_report_e.pdf/\\$FILE/cbac_report_e.pdf](http://cbac-cccb.ic.gc.ca/epic/internet/incbac-cccb.nsf/vwapj/cbac_report_e.pdf/$FILE/cbac_report_e.pdf)> (date accessed: 15 September 2005).

⁵⁰ *Ibid.* at 21.

⁵¹ *Ibid.* at 22.

⁵² *Ibid.*

⁵³ Elisabeth Abergel, Assistant Professor, International Studies Program, York University (24 August 2005), pers. comm.

⁵⁴ Katherine J. Barrett, *Canadian Agricultural Biotechnology: Risk Assessment and the Precautionary Principles* (Ph.D. Thesis, University of British Columbia, Department of Botany, 1999), online: Theses Canada <http://www.collectionscanada.ca/obj/s4/f2/dsk1/tape2/PQDD_0018/NQ48601.pdf> (date accessed: 15 September 2005) at 144.

⁵⁵ *Ibid.*

The AgrEvo representative responsible for this decision stated that all information submitted to the federal government by private companies regarding a product is considered CBI. If the government determines that no health hazard is related to the product, it is the decision of the company whether or not to release information to the public.⁵⁶

This is a fundamental misinterpretation of both the allowances for confidential business information and the functioning of the Access to Information Act.

First of all, what is the relationship between confidential business information and the Access to Information Act? Confidential business information is a term of art that does not appear in the Act. Judging from the literature, there appears to be a presumption that information that is classed as CBI is considered to fall within the scope of one of the section 20(1) exemptions from disclosure in the Act without elaborating as to which one.⁵⁷

This begs the question of who determines what information falls within these exemptions and on what basis this is determined. According to the Act, it is “the head of a government institution” who will refuse to disclose information if it falls into one of the exemptions.⁵⁸ It is fair enough for the applicants to indicate to CFIA what they consider to be CBI as they are likely better placed than the regulator to know what information is commercially sensitive and needs to be kept confidential. The applicants’ assessments should not be final, however, and whether or not the information they have classed as CBI actually falls within one or more of the section 20(1) exemptions should be objectively assessed using the tests set out by the courts as described in Part III, above. Indeed, in elaborating these tests the courts have held that determining whether information falls into one of the exemptions is not simply based on the assertions of those seeking to prevent the disclosure of the information. These determinations must be made objectively, and, in accordance with the presumption of access in section 2 of the Act, the third party has the burden of showing why the information should not be disclosed. Even CFIA acknowledges that information submitted to the Plant Biosafety Office “for the purposes of obtaining an authorization for the environmental release of a PNT *may* be protected under the federal *Access to Information Act*, Section 20.”⁵⁹ Thus there is most definitely no de facto rule of law that “all information submitted to the federal government by private companies regarding a product is considered CBI.”

Secondly, whose decision is it to grant or deny access to information in an application for approval? Is it the proponent’s decision (where there is no health risk) as suggested by the representative of AgrEvo or the government’s decision? Section 20 of the Act repeatedly refers to the head of a government institution as the decision-making authority although the third party has the right to be notified of decisions to disclose its information, to respond to these decisions, and to challenge the decisions in court.⁶⁰ The requester seeking access to the information can also challenge the decision of the head of the government institution by filing a complaint with the Information Commissioner and ultimately taking the dispute to court.⁶¹ Furthermore, the head of the government institution in question has the decision-making authority not just where there is a health hazard but in all situations of access to

⁵⁶ *Ibid.* at 203, citing personal communication with C. Warfield, AgrEvo representative.

⁵⁷ See, e.g., The Royal Society of Canada, *supra* note 38 at 212; CBAC, *supra* note 49 at 20.

⁵⁸ *Supra* note 11 at s. 20(1).

⁵⁹ Canadian Food Inspection Agency, *supra* note 14 at 9, emphasis added.

⁶⁰ *Supra* note 11 at sections 27 and 44.

⁶¹ *Ibid.* at s. 41.

information. So while a proponent seeking approval for a PNT from CFIA may have the opportunity to challenge a decision to release the environmental risk assessment information, it is not, as was stated by the representative of AgrEvo, this proponent's decision as to whether or not the information will be released.

In sum, the Access to Information Act sets rules for when access will be granted and when it will be refused. The courts have further defined these rules by setting standards and clarifying the burden of proof. Unfortunately, it appears as though CFIA has abdicated its responsibility in applying these rules and left it to the proponents to decide themselves when information can be released under the Act and when it will be kept confidential. The Access to Information Act may itself do a good job itself of balancing industry confidentiality with the public right of access but this balance is not being applied in practice, at least not in the context of the environmental information in applications for unconfined release of plants with novel traits. The current system is broken and needs to be fixed if Canada is to ensure that its access rules contribute to sustainable development and allow individuals to play a role in protecting their environment.

B. Access to Information and Protection of the Environment

In the context of this colloquium – A Citizen's Right to a Clean Environment – it is interesting to note that those individuals who did gain access to the information in an application found it to be sorely lacking in terms of providing an adequate environmental risk assessment of the plant variety in question. According to Barrett, “[d]etailed evaluation of the risk assessment for herbicide tolerant canola (obtained through the Access to Information and Privacy Act [*sic*]) revealed significant shortcomings in the depth and breadth of questions, methods of inquiry, analysis of data, and plausibility of conclusions.”⁶² Subsequent experience has illustrated these shortcomings as the herbicide tolerant genes introduced into canola have spread quite easily and the ‘stacking’ of different herbicide tolerant genes in individual canola plants has created problems for farmers in the prairies.⁶³ This highlights the importance of public access to information in monitoring and evaluating the work being done by both industry and government.

Furthermore, when auditors from the Office of the Auditor General of Canada examined CFIA's procedures and files for applications for unconfined release of PNTs, they found a variety of deficiencies including incomplete and poorly organized files, and unclear and little used standards.⁶⁴ More specifically, the auditors found that while CFIA issues Decision Documents summarizing the basis for their decisions to authorize the unconfined release of different PNTs, “the Agency's internal files did not provide a comprehensive record of the analyses that supported the summary information or the conclusions in the public-decision documents.”⁶⁵ In addition, the files often lacked key documents and were poorly organized making it difficult to review the means and the rationales by which CFIA reached its

⁶² Barrett, *supra* note 54 at ii.

⁶³ Royal Society of Canada, *supra* note 38 at 122.

⁶⁴ Auditor General of Canada, *Report of the Auditor General of Canada to the House of Commons: Chapter 4 Canadian Food Inspection Agency – Regulation of Plants with Novel Traits* (Ottawa: Office of the Auditor General of Canada, 2004), online: Auditor General of Canada <[http://www.oag-bvg.gc.ca/dominio/reports.nsf/html/20040304ce.html/\\$file/20040304ce.pdf](http://www.oag-bvg.gc.ca/dominio/reports.nsf/html/20040304ce.html/$file/20040304ce.pdf)> (date accessed: 15 September 2005) at para. 4.52-4.60.

⁶⁵ *Ibid.* at para. 4.54.

decisions.⁶⁶

The auditors also questioned the standard that CFIA requires for data submitted by applicants, i.e. that the data “be produced using statistically valid experimental designs and protocols (that are equivalent to the standards required for inclusion in peer-reviewed research publications).”⁶⁷ This standard is unclear and has not been well-defined. CFIA has developed a ‘Reviewer’s Checklist’ that “outlines quality standards for the evaluation of certain analytical techniques used by proponents” but there was little evidence that it had been used. The auditors concluded that, in their opinion, “the Agency cannot demonstrate through its internal documentary evidence that it is consistently applying quality management procedures in its evaluations of applications for the unconfined release of PNTs.”⁶⁸

If CFIA is not requiring adequate environmental risk assessment data, as these accounts indicate, then the Agency is putting the environment at risk. Furthermore, without access to the information in the applications, it is impossible to know the extent to which the environmental risk assessment requirements are being waived, as permitted under the Seeds Regulations. The accounts described above reinforce the value of the role that the public can play in protecting the environment and the need for access to information to fulfill this role. Unfortunately, this role is being thwarted by CFIA which has resisted the recommendations of different organizations that have called for public disclosure of environmental risk assessment data and has left the proponents of different PNTs to decide themselves whether access to information will be granted. In effect, this has reversed the presumption of access in section 2 of the Act and placed the burden on the individual to fight for access rather than having access as a right. This is a difficult and expensive burden to bear.

V What is Needed?

There are various approaches that could be adopted to help to resolve the issue of access to the environmental risk assessment information in applications for approval of plants with novel traits. These range from proper application of the existing legislation to calls for new obligations and ultimately to an appreciation of access to information as a key component of sustainable development.

Both the Royal Society of Canada and the Canadian Biotechnology Advisory Committee have pointed to some of the principles in the existing access to information scheme that should allow for better access to the information in submissions from proponents to the CFIA. The Expert Panel of the Royal Society called for negotiation between the proponents and CFIA for better disclosure and CBAC recommended the development of a policy that better defines what is and what is not confidential business information. Ultimately, what is required under the current legislative system is a better understanding of the existing rules and standards by those who must apply them in their day to day job and those who are subject to them when submitting information to the government. This means better understanding of the tests for when information falls into one of the four exemptions in section 20(1) and how to apply these tests in specific instances. It means understanding that

⁶⁶ *Ibid.*

⁶⁷ *Ibid.* at para. 4.55. See also Canadian Food Inspection Agency, *supra* note 14 at 13.

⁶⁸ *Ibid.* at para. 4.60.

it is ultimately up to the government to decide whether information will be protected from disclosure under section 20(1) and not the proponent. And it means understanding that section 20(1) is only an exemption from the overarching rule of access.

A better understanding of these rules would be facilitated if the exemptions applied to fewer situations. Numerous other countries such as Australia and New Zealand already make the environmental risk assessment information publicly available as a matter of course in their biosafety regulatory regimes.⁶⁹ It is difficult to understand why Canada cannot do the same. It is even more difficult to understand how information that is made publicly available in other countries can be considered confidential business information here and protected from disclosure via the section 20(1) exemptions. CBAC points to a trend towards public disclosure of the information in biotechnology applications and Canada would do well to follow suit if it wants to instill confidence in the regulatory system and encourage acceptance of the products of biotechnology.⁷⁰ Greater disclosure of environmental risk assessment information is not unknown in the Canadian regulatory system and the use of publicly-released Proposed Regulatory Decision Documents (which include detailed environmental risk assessment information) by the Pest Management Regulatory Agency in the regulation of pesticides could be used as a model for better access to information in the domain of plants with novel traits.⁷¹

A recent petition by Greenpeace to the Office of the Auditor General goes further and inquires whether the federal government agrees that Canadians have a right of access to the studies that are the basis for government decision-making on GMOs and whether the government agrees that the adoption by Canada of a right of access to the full environmental assessments of GMOs “would simultaneously continue to protect genuine confidential business information while promoting full transparency, good science and enhanced trust in governmental decisions in the context of sustainable development”.⁷² The petition also asks whether the government will amend Canadian legislation to give citizens the right of access to the environmental assessments and if not, why not. The petition references both the right of access to information in Article 25 of the European Directive 2001/18/EC on the deliberate release of GMOs into the environment⁷³, and the Aarhus Convention. The government has yet to reply although it is still within the time limit for it to do so.

⁶⁹ Australian Government, Department of Health and Ageing, Office of the Gene Technology Regulatory, *Risk Analysis Framework* (Commonwealth of Australia, 2005), see, in particular, chapter 5 on risk communication. For examples of the risk assessment information made publicly available in Australia, see Office of the Gene Technology Regulator <<http://www.ogtr.gov.au>>. For New Zealand, applications to import new organisms can be viewed via the website of the Environmental Risk Management Authority, <<http://www.ermanz.govt.nz>>.

⁷⁰ CBAC, *supra* note 49 at 20.

⁷¹ Donald J. MacKenzie, “Analysis of Relevant Canadian Legislation” (Ottawa: CBAC, 2000), online: CBAC <[http://cbac-cccb.ic.gc.ca/epic/internet/incbac-cccb.nsf/vwapj/AnalysisRelevantCDNLegislation_e.pdf/\\$FILE/AnalysisRelevantCDNLegislation_e.pdf](http://cbac-cccb.ic.gc.ca/epic/internet/incbac-cccb.nsf/vwapj/AnalysisRelevantCDNLegislation_e.pdf/$FILE/AnalysisRelevantCDNLegislation_e.pdf)> (date accessed: 16 September 2005) at 10-11; Andrée & Sharratt, *supra* note 46 at 13.

⁷² Petition from Éric Darier, Greenpeace, to Johanne Gélinas, Commissioner of the Environment and Sustainable Development (7 July 2005) pursuant to Section 22 of the *Auditor General Act* Citizens’ Right to Full Access to Environmental Assessment of Genetically Engineered Organisms Transparency, Good Science and Trust in Government [on file with author].

⁷³ Article 25 holds that environmental risk assessments will not be kept confidential when submitted under various other articles of the directive, EC, *Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC* [2001] O.J. L. 106/1.

Along similar lines, Canada is a signatory but not a party to the Cartagena Protocol on Biosafety. Article 23 of the Protocol requires Parties to “[e]ndeavour to ensure that public awareness and education encompass access to information on living modified organisms ...” and to make the results of their decision-making processes regarding GMOs public while still respecting confidential information. As a signatory, Canada is bound to act in a way that will not undermine these provisions even if it is not bound by the provisions themselves. Ideally, Canada will ratify the Biosafety Protocol thus strengthening calls to improve access to information.

Finally, as discussed in the introduction, access to information is a key component of sustainable development law. The examples discussed in this paper illustrate why: without access to information, individuals cannot fulfill their role as citizens in a democratic society. They cannot monitor their governments to ensure they are following through on the commitments and statements they have made and hold them accountable when they are not. They cannot monitor industry and whether it is complying with the law. And they cannot determine for themselves whether their government is indeed acting in a manner supportive of sustainable development.

A guiding principle of the Canadian Biotechnology Strategy is that the development and use of biotechnology in the country will support sustainable development.⁷⁴ In order for the government to meet this objective, it must recognize that access to information is part and parcel of sustainable development. Without access to information, individual Canadians cannot be certain that organisms being released into the environment have been properly shown to be safe. Blind trust in the regulators and the regulated is no longer realistic and experience to date has done little to earn the trust of Canadians. Ultimately, without access to information, biotechnology will not contribute to sustainable development in Canada and its role must be reconsidered.

⁷⁴ Canada, *The 1998 Canadian Biotechnology Strategy: An Ongoing Renewal Process* (Ottawa: Industry Canada, 1998), online: Bioportal <<http://www.biostrategy.gc.ca/CMFiles/1998strategyE49RAI-8312004-5365.pdf>> (date accessed: 16 September 2005) at 8.