

# A Cause of Action for Regulatory Negligence? The Regulatory Framework for Genetically Modified Crops in Canada and the Potential for Regulator Liability

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THIS PAPER CONSIDERS WHETHER, UNDER CANADIAN LAW, a government regulatory agency could be found liable for "negligent regulation" of genetically modified (GM) crops. The paper begins with an overview of the Canadian framework for GM crop regulation and notes criticisms about the adequacy of this framework. The state of Canadian law regarding regulatory liability is then analysed. The authors conclude that litigants who wish to assert a claim of regulatory negligence face significant legal barriers, particularly since review of GM crop applications involves weighing complex scientific data and determining tolerable levels of risk, matters that would likely be non-justiciable in a negligence claim. Current jurisprudence, however, leaves open some unresolved bases of liability. The paper closes with a brief overview of recommendations to improve the Canadian regulatory framework for GM crops, focusing particularly on enhancing transparency in the decision-making process.

DANS CE TEXTE, ON EXAMINE DANS QUELLE MESURE un organisme de réglementation gouvernemental pourrait, en vertu du droit canadien, être tenu responsable d'une « réglementation négligente » des cultures transgéniques. Cet article débute par une vue d'ensemble du cadre canadien pour la réglementation des cultures d'espèces génétiquement modifiées et note l'existence de critiques à propos de la justesse de ce cadre. On analyse ensuite l'état du droit canadien au chapitre de la responsabilité réglementaire. Les auteurs concluent que les parties désireuses de déposer une plainte pour négligence réglementaire rencontrent des obstacles juridiques importants, en particulier dans la mesure où l'examen des demandes relativement à des cultures transgéniques comprend l'évaluation de données scientifiques complexes et la détermination des niveaux tolérables de risque, des questions probablement non justiciables dans le cadre d'une poursuite pour négligence. La jurisprudence actuelle laisse cependant ouverts certains arguments non résolus de la responsabilité. Le texte se termine par un bref aperçu des recommandations visant à améliorer le cadre réglementaire du Canada pour ce qui est des cultures transgéniques, en rappelant en particulier l'importance d'une transparence accrue dans le processus décisionnel.

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## 1. INTRODUCTION

GENETICALLY MODIFIED (GM) CROPS REMAIN a source of heated debate in Canada and around the world. Much of the disagreement stems from divergent views about the benefits and risks of GM crops, including environmental and human health concerns. In Canada, government officials and agencies have long stressed the safety of GM products and the economic and social benefits associated with their development and commercialization. In 1998, for example, the Canadian Minister of Agriculture and Agri-Food touted Canada's emergence as a world leader in agricultural biotechnology and emphasized the benefits of Canadian efforts in this area: "Biotechnology is a valuable resource in our ongoing commitment to provide safe, healthy foods in an environmentally sustainable manner [. . . and] also offers the Canadian agriculture and food industries new opportunities for economic prosperity."<sup>1</sup> More recently, a federal report on biotechnology in Canada stated:

The growth of the biotechnology industry requires world-class business and regulatory regimes that nurture innovation and build public trust and confidence. Industry Canada supports such a competitive business climate [... and it ...] participates in initiatives to promote the creation of optimal conditions to attract and retain biotechnology companies while also protecting the public interest.<sup>2</sup>

Opponents of GM crops, on the other hand, have cautioned about the potential for adverse health and environmental impacts and raised concerns about undue

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1. Government of Canada, "Federal Government Releases New Biotechnology Strategy," News Release, 8014-e (6 August 1998), <<http://biotech.gc.ca/archives/engdoc/bh00228e.html>>.  
 2. Government of Canada, *Biotechnology Transforming Society: Creating an Innovative Economy and a Higher Quality of Life—Report on Biotechnology, 1998-2003* (Ottawa, Government of Canada, 2003), <[http://www.biostrategy.gc.ca/CMFiles/11865\\_CAN\\_BIO\\_REP\\_Ev949SFJ-922004-3421.pdf](http://www.biostrategy.gc.ca/CMFiles/11865_CAN_BIO_REP_Ev949SFJ-922004-3421.pdf)> at p. 58.

industry influence on government policy relating to GM products.<sup>3</sup>

One of the central legal questions associated with this debate concerns responsibility for harms related to GM crop approval and production. Organic crop producers in Canada, in particular, have expressed serious concern about the potential adverse impact of GM plant contamination.<sup>4</sup> Canadian jurisdictions have not enacted statutory compensation regimes<sup>5</sup> for harms associated with GM crops, so “liability flowing from GM activities must be assessed through the common law of torts.”<sup>6</sup> Scholarly literature has explored liability issues for producers and firms that produce GM crops<sup>7</sup> and, indeed, GM crop manufacturers and producers have faced litigation, such as in the Starlink maize<sup>8</sup> and GM rice (LRICE601)<sup>9</sup> contaminations in the US.

By contrast, issues of regulator responsibility and liability for approval of GM crops have received little attention. This paper focuses specifically on GM crop regulation in Canada and on the particular issue of whether a government regulatory agency could be found liable for “negligent regulation” of GM crops. Common law jurisdictions such as Canada have long abandoned the concept of Crown immunity, with the result that the actions of public officials and private citizens are subject generally to the same rules of tortious liability.<sup>10</sup> The common law recognizes, however, that the often distant relationship between a regulator and specific individuals or groups strains the notion of a private law duty of care and that governments must have room to maneuver when making regulatory decisions without the spectre of negligence claims.

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3. For discussion, see e.g. Bradley Mandrusiak, “Playing with Fire: The Premature Release of Genetically Engineered Plants into the Canadian Environment,” (2000) 9 *Journal of Environmental Law and Practice* 259–280 (summarizing environmental and human health concerns associated with the release of GM plants) and Robert F Service, “Agbiotech: A Growing Threat Down on the Farm,” (2007) 316:5828 *Science* 1114–1117 (discussing concerns with the emergence of herbicide-resistant weeds).
  4. See e.g. Saskatchewan Organic Directorate’s Organic Agriculture Protection Fund, <<http://www.saskorganic.com/oapfi/index.html>>. This organization supported an (ultimately unsuccessful) attempt to launch a class action lawsuit against Monsanto on behalf of organic farmers in Saskatchewan: *Hoffman v Monsanto Canada Inc.*, 2007 SKCA 47, <<http://www.canlii.org/en/sk/skca/doc/2007/2007skca47/2007skca47.pdf>>, 2007:283 *Dominion Law Reports*, 4th ser. 190 (dismissal of the class certification application; leave to appeal to the Supreme Court of Canada refused: <<http://www.canlii.org/en/ca/scc-1/doc/2007/2007canlii55334/2007canlii55334.pdf>>).
  5. For a comprehensive review of liability and compensation schemes in international jurisdictions, see Bernhard A Koch, *Liability and Compensation Schemes for Damage Resulting from the Presence of Genetically Modified Organisms in Non-GM Crops* (European Centre of Tort and Insurance Law and Research Unit for European Tort Law, Austrian Academy of Sciences, 2007), <[http://ec.europa.eu/agriculture/analysis/external/liability\\_gmo/full\\_text\\_en.pdf](http://ec.europa.eu/agriculture/analysis/external/liability_gmo/full_text_en.pdf)>.
  6. Lara Khoury and Stuart Smyth, “Reasonable Foreseeability and Liability in Relation to Genetically Modified Organisms,” (2007) 27:3 *Bulletin of Science, Technology and Society* 215–232 at p. 222.
  7. See e.g. Khoury and Smyth, “Reasonable Foreseeability,” *supra* note 6; Jane Matthews Glenn, “Footloose: Civil Responsibility for GMO Gene Wandering in Canada,” (2004) 43:3 *Washburn Law Journal* 547–573, <<http://www.washburnlaw.edu/wlj/43-3/articles/glenn-jane.pdf>>; Neil Craik, Keith Culver, and Norman Siebrasse, “Genetically Modified Crops and Nuisance: Exploring the Role of Precaution in Private Law,” (2007) 27:3 *Bulletin of Science, Technology and Society* 202–214; Koch, *Liability and Compensation Schemes*, *supra* note 5.
  8. For a discussion of international customary law and US obligations as well as general liability issues posed by the Starlink incident, see Gurdial Singh Nijar, “Liability and Redress for GMO Harm: The Starlink Case Study,” Third World Network Biosafety Information Service, (8 December 2000), <<http://www.twinside.org.sg/title/service9.htm>>. For further review of the US regulatory failures involved in the Starlink contamination, see Friends of the Earth International, *GMO Contamination Around the World*, 2d ed. (2001), <<http://www.foei.org/en/publications/pdfs/contamination2eng.pdf>>.
  9. For a discussion of GM rice contamination, see Heidi Ledford, “Out of Bounds,” (2007) 445:7124 *Nature* 132–133; Rick Weiss, “Firm Blames Farmers, ‘Act of God’ for Rice Contamination,” *The Washington Post*, A5(22 November 2006), <<http://www.washingtonpost.com/wp-dyn/content/article/2006/11/21/AR2006112101265.html>>; Kerri Walsh, “USDA Declares Bayer CropScience’s Rice Safe,” (2006) 168:41 *Chemical Week* 34.
  10. For a comprehensive analysis of how the law of government liability has developed, see Karen Horsman and J Gareth Morley, *Government Liability: Law and Practice* (Cartwright Law Group, 2006), and Peter W Hogg and Patrick J Monahan, *Liability of the Crown*, 3d ed. (Carswell, 2000).

This paper begins with an overview of the Canadian framework for GM crop regulation and a discussion of criticisms about the adequacy of this framework. To highlight recent litigation over GM crop approvals, claims against regulators in other jurisdictions are summarized. The paper then turns to an analysis of the state of Canadian law regarding regulatory liability. The leading case of *Anns v Merton London Borough Council*<sup>11</sup> is presented, followed by an analysis of how Canadian courts have applied the *Anns* analysis to claims of regulatory negligence. Indeed, Canadian courts continue to grapple with the “ongoing problem of determining when a public authority can be held liable in negligence.”<sup>12</sup> The legal requirement that the relationship between government regulator and plaintiff be of sufficient proximity to establish a duty of care, and the juridical distinction between government policies and operational activities, create an umbrella of Crown immunity from negligence claims. Current jurisprudence, however, leaves open some unresolved bases of liability. After assessing potential regulator liability issues associated with Canadian GM crop regulation, we conclude with a brief overview of recommendations to improve the Canadian regulatory framework for GM crops, focusing particularly on enhancing transparency in the decision-making process.

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## 2. THE CANADIAN REGULATORY FRAMEWORK FOR GENETICALLY MODIFIED CROPS

THE CANADIAN FOOD INSPECTION AGENCY (CFIA), established under the *Canadian Food Inspection Agency Act*<sup>13</sup> (CFIA Act), has primary responsibility for regulation of GM crops. Responsible for the administration and enforcement of the *Seeds Act*,<sup>14</sup> CFIA is responsible for the assessment and regulation of all plants and crops, including products derived from biotechnology. CFIA is also responsible for evaluating new fertilizers, livestock feeds, and veterinary biologics, including those products developed using biotechnology, pursuant to the *Fertilizers Act*,<sup>15</sup> the *Feeds Act*<sup>16</sup> and the *Health of Animals Act*.<sup>17</sup> The federal Minister of Agriculture and Agri-Food maintains responsibility for the overall direction of CFIA.<sup>18</sup>

Other federal departments carry out functions related to GM products. Health Canada is responsible under the *Food and Drugs Act* (FDA) and

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11. *Anns v Merton London Borough Council* (UK HL, 1977), <<http://www.bailii.org/uk/cases/UKHL/1977/4.html>>, 1977:2 *All England Law Reports* 118, 1978 *Law Reports, Appeal Cases*, 3d ser. 728 [Anns].
  12. *Holland v Saskatchewan (Minister of Agriculture, Food & Rural Revitalization)* 2007 SKCA 18, <<http://www.canlii.org/en/sk/skca/doc/2007/2007skca18/2007skca18.pdf>>, 2007:281 *Dominion Law Reports*, 4th ser. 349, at para. 1; appeal to SCC allowed in part, 2008 SCC 42.
  13. *Canadian Food Inspection Agency Act*, 1997 *Statutes of Canada* ch. 6, <<http://laws.justice.gc.ca/en/showtdm/cs/C-16.5>> [CFIA Act].
  14. *Seeds Act*, (1985) *Revised Statutes of Canada* ch. S-8, <<http://laws.justice.gc.ca/en/showtdm/cs/S-8>>.
  15. *Fertilizers Act*, (1985) *Revised Statutes of Canada* ch. F-10, <<http://laws.justice.gc.ca/en/showtdm/cs/F-10>>.
  16. *Feeds Act*, (1985) *Revised Statutes of Canada* ch. F-9, <<http://laws.justice.gc.ca/en/showtdm/cs/F-9>>.
  17. *Health of Animals Act*, 1990 *Statutes of Canada* ch. 21, <<http://laws.justice.gc.ca/en/showtdm/cs/H-3.3>>.
  18. See CFIA Act, *supra* note 13, s. 4(1).

associated regulations<sup>19</sup> for conducting safety assessments for all new foods and drugs, including products developed using biotechnology. Environment Canada has responsibility under the *Canadian Environmental Protection Act* (CEPA) for regulating products for uses not addressed under other federal laws.

The regulatory regime under the *Seeds Act* and *Seeds Regulations* is product-based, rather than process-based, meaning that trait novelty in a plant triggers regulatory review, regardless of the process by which the trait was created (through conventional breeding, recombinant DNA technology or another process). Part V of the *Seeds Regulations* defines a “novel trait” as follows:

“novel trait”, in respect of seed, means a characteristic of the seed that

- (a) has been intentionally selected, created or introduced into a distinct, stable population of cultivated seed of the same species through a specific genetic change, and
- (b) based on valid scientific rationale, is not substantially equivalent, in terms of its specific use and safety both for the environment and for human health, to any characteristic of a distinct, stable population of cultivated seed of the same species in Canada, having regard to weediness potential, gene flow, plant pest potential, impact on non-target organisms and impact on biodiversity.<sup>20</sup>

In assessing a plant with a novel trait, the regulations require consideration of “all relevant matters, including [...] the potential impact on and risk to the environment, including the potential impact on and risk to human health, posed by the proposed release”<sup>21</sup> of a seed, including a seed with novel traits. The environmental and human health risks associated with release (ranging from minimal to unacceptable risk) must be assessed, which requires evaluation of scientific data and specialized knowledge. The regulations give authority to reject, approve and impose conditions on the release of seeds.

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### 3. CRITICISMS OF THE CANADIAN REGULATORY FRAMEWORK

ONE OF THE MOST DEBATED ASPECTS OF THE CANADIAN regulatory framework concerns the use of “substantial equivalence” as the decision threshold in the assessment

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19. *Food and Drugs Act*, (1985) *Revised Statutes of Canada* ch. F-27, <<http://laws.justice.gc.ca/en/showtdm/cs/F-27>>. In 1999, the *Food and Drug Regulations*, (1987) *Consolidated Regulations of Canada* ch. 870, <<http://laws.justice.gc.ca/en/showtdm/cr/C.R.C.-c.870>>, under the Act were amended to include Division 28 (27 October 1999) 133:22 *Canada Gazette—Part II* 948, <<http://canadagazette.gc.ca/partII/1999/19991027/html/sor392-e.html>>, which addresses novel foods.

20. *Seeds Regulations*, (19 December 1996) 131:1 *Canada Gazette—Part II*, s. 107(1).

21. *Regulations Amending the Seeds Regulations*, (15 August 2001) 135:17 *Canada Gazette—Part II* 274, s. 111(1), <<http://canadagazette.gc.ca/partII/2001/20010815/html/sor274-e.html>>.

process for agricultural GM products.<sup>22</sup> As noted above, Canada operates on a product-based model of GM regulation such that the regulatory safety evaluations focus on the characteristics of the end product rather than on the processes used to develop the novel plant or food. The assessment involves determination of the extent to which a novel plant is “substantially equivalent” to its conventional counterpart except for defined differences, and the analysis then focuses on these defined differences.<sup>23</sup> Both CFIA and Health Canada operate within this decision-making framework, each using the substantial equivalence standard for evaluating new products derived from biotechnology.

The clarity of CFIA’s application of substantial equivalence in the regulation of agricultural biotechnology has been a focus of criticism. A central concern relates to the fact that, when a GM crop proposed for commercialization is deemed substantially equivalent to a non-GM variety, in practice this designation effectively “pre-empts any requirement [...] to assess further the new variety for unanticipated characteristics.”<sup>24</sup> The 2001 Expert Panel on the Future of Food Biotechnology in Canada listed proper conceptual and practical implementation of substantial equivalence as the most critical element in the current regulatory approval process in Canada, noting that when a novel plant or food is judged to be substantially equivalent to one present in the Canadian diet, “passage of this step in the decision tree spells success for its approval.”<sup>25</sup>

While the substantial equivalence analysis factors heavily into the determination process, questions have been raised about ambiguities in its interpretation and application. The 2001 Expert Panel identified two alternative and distinct interpretations of “substantial equivalence” in relation to regulation of GM products. Under the more precautionary “safety standard” interpretation, a GM organism is “substantially equivalent” if rigorous scientific analysis establishes that the organism poses no more health or environmental risks than its conventional counterpart, despite all changes resulting from the introduction of novel genes. By contrast, under the less restrictive “decision threshold” interpretation, a GM organism (GMO)

is “substantially equivalent” if, on the basis of reasoning analogous to that used in the assessment of varieties derived through conventional breeding, it is assumed that no changes have been introduced into the organism other than those directly attributable to the novel gene. If the latter are demonstrated to be

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22. For criticisms of the substantial equivalence principle and its application in GM crop regulation in Canada, see Royal Society of Canada, *Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada*, Expert Panel Report on the Future of Food Biotechnology (The Royal Society of Canada, 2001), <[http://www.rsc.ca/files/publications/expert\\_panels/foodbiotechnology/GMreportEN.pdf](http://www.rsc.ca/files/publications/expert_panels/foodbiotechnology/GMreportEN.pdf)>; Alexander Singh, “Proceed with Precaution: The Statutory, Legal, and Consumer Influence of Genetically Modified Foods in Canada,” (2005) 4 *Canadian Journal of Law and Technology* 181–193, <[http://etc.dal.ca/cjlt/vol4\\_no3/pdfarticles/singh.pdf](http://etc.dal.ca/cjlt/vol4_no3/pdfarticles/singh.pdf)>; Peter Andr ee, “An Analysis of Efforts to Improve Genetically Modified Food Regulation in Canada,” (2006) 33:5 *Science and Public Policy* 377–389, <[http://etc.dal.ca/cjlt/vol4\\_no3/pdfarticles/singh.pdf](http://etc.dal.ca/cjlt/vol4_no3/pdfarticles/singh.pdf)>.
23. Jane Matthews Glenn, “Genetically Modified Crops in Canada: Rights and Wrongs,” (2003) 12 *Journal of Environmental Law and Practice* 281–310 at p. 307; D Pate, *Genetically Modified Feeds for Livestock* (December 2000).
24. Royal Society of Canada, *Elements of Precaution*, *supra* note 22 at p. 180.
25. Royal Society of Canada, *Elements of Precaution*, *supra* note 22 at p. 180. See also Canadian Biotechnology Advisory Committee [CBAC], *Improving the Regulation of Genetically Modified Foods and Other Novel Foods in Canada* (Canadian Biotechnology Advisory Committee, 2002), <<http://cbac-ccbc.ca/epic/site/cbac-ccbc.nsf/en/ah00186e.html>>.

harmless, the GM organism is predicted to have no greater adverse impacts upon health or environment than its traditional counterpart.<sup>26</sup>

The Panel affirmed the scientific validity of the former “safety standard” interpretation of substantial equivalence, while expressing “grave reservations” about use of the latter “decision threshold” interpretation.<sup>27</sup> Its report notes how substantial equivalence is commonly used in practice by government regulatory agencies under the “decision threshold” interpretation, while public statements by these same agencies defending substantial equivalence “often play upon its inherent ambiguity” by suggesting the “safety standard” interpretation.<sup>28</sup> In interviews with the Panel, CFIA representatives claimed that substantial equivalence “is used more as a guiding principle than as an end point (decision threshold).”<sup>29</sup> After reviewing the Canadian regulatory scheme and conducting interviews with agency representatives, however, the Panel concluded that the Canadian regulatory model is consistent with the latter, less restrictive interpretation of substantial equivalence as “decision threshold.”<sup>30</sup> This conclusion means that, in practice, CFIA designations of substantial equivalence are often based on “unsubstantiated assumptions about the equivalence of the organisms, by analogy with conventional breeding,”<sup>31</sup> rather than on a full and rigorous analysis of all of the characteristics of the GM organism in question.<sup>32</sup>

In addition to concerns about application of the substantial equivalence standard, the Canadian regulatory framework has been criticized for inadequate consideration of potential socio-economic impacts related to GM crop production.<sup>33</sup> In contrast to Canada’s GM crop policy, the European Union (EU) regulatory approach includes socio-economic and ethical issues in the evaluation process and relies on the precautionary principle as the decision threshold during the evaluative process.<sup>34</sup> Opponents, however, characterize the precautionary principle as being based on unfounded fears and suggest that it operates as an

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26. Royal Society of Canada, *Elements of Precaution*, *supra* note 22 at p. 182. The Panel noted that review of CFIA regulation of GM plants “demonstrates how initial findings of ‘familiarity’ and ‘substantial equivalence’ are used to exempt new plants from the third step, which is the full environmental safety assessment.”
27. Royal Society of Canada, *Elements of Precaution*, *supra* note 22 at p. 183.
28. Royal Society of Canada, *Elements of Precaution*, *supra* note 22 at p. 182.
29. Royal Society of Canada, *Elements of Precaution*, *supra* note 22 at pp. 36–37.
30. Royal Society of Canada, *Elements of Precaution*, *supra* note 22 at p. 182.
31. Royal Society of Canada, *Elements of Precaution*, *supra* note 22 at p. 182 (emphasis in original).
32. For further discussion of the use of substantial equivalence in Canada, see e.g. Peter Andrée, “The Biopolitics of Genetically Modified Organisms in Canada,” (2002) 37:3 *Journal of Canadian Studies* 162–191; Singh, “Proceed with Precaution,” *supra* note 22; Andrée, “Analysis of Efforts,” *supra* note 22.
33. For example, the heads of ten concerned organizations wrote to the federal Minister of Agriculture requesting that the regulatory system be adapted to include a cost-benefit analysis that incorporates issues such as market impacts and farmer revenue into the approval process, although the federal government has not acted on this suggestion. See Glenn, “Footloose,” *supra* note 7 at p. 569, footnote 81.
34. See *European Community Regulation No. 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety* (EU), O.J.L. 31/1, Article 7, <<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:031:0001:0024:EN:PDF>> (on the precautionary principle).

uncertain, unscientific hindrance on technological and economic development.<sup>35</sup>

Criticism over CFIA's scientific assessment procedure is heightened by a lack of transparency about the evaluation and approval process, as neither the scientific community nor the public can review pertinent details of the information considered during regulatory assessment. Following the approval of a new GM plant for unconfined release into the environment, CFIA makes information about the approval available on its website, explaining the conclusions reached and providing the general basis of the decision.<sup>36</sup> Arguably the most important information, at least from a public interest standpoint, is not revealed: neither the studies on which the assessment is based nor their results are included in the Decision Document. The public can only review the general conclusions of the regulatory approval and examine relevant statutes and regulations to see that companies are, in fact, required to submit extensive information and statistical data. Yet, as the Expert Panel noted, while these regulations are extensive in their required information, there is no way for the public to know "the extent to which these information requirements are actually met during the approval process, or of assessing the degree to which the approvals are founded on scientifically rigorous information."<sup>37</sup>

The narrow scope of the information disclosed in CFIA's Decision Documents highlights the agency's ongoing struggle to balance the public interest in access to regulatory information against the business interests of companies. As a result, "[c]urrent regulatory practice in Canada protects the confidentiality of [...] test[ing] data submitted" by the applicant, since "[d]ata identified by [these] companies as Confidential Business Information (CBI) is protected under federal access to information laws." CBI materials can only be released "with approval of the owner of the proprietary information."<sup>38</sup>

CFIA deals with GM crop applicants on a case-by-case basis and could insist on greater information disclosure, but this response is often difficult in a regulatory environment where the government seeks to promote industry research and development as a policy priority. As one Agriculture Canada official suggested, the objective of regulatory agencies with regard to biotechnology is to implement regulations to ensure "the products can be used without adversely affecting human and animal health, and the environment[, but are] not [...] so restrictive or time-consuming to fulfill that industry loses its competitive

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35. See e.g. John Hodgson, "Scientists Cry Foul as Europe Plays Politics with GM Crops," (2008) 26:2 *Nature Biotechnology* 139-140 at p. 139 (discussing a recommendation to the European Commission (EC) from its scientific advisory body to approve two GM maize varieties; the EC has stalled on a decision, citing new papers that question long-term environmental safety; the European Federation of Biotechnology charges the EC is "cherry-pick[ing] publications claiming possible dangers."); Richard J Mahoney, "Opportunity for Agricultural Biotechnology," (2000) 288 *Science* 615; Henry Miller and Gregory Conko, "Reply to 'Precautionary Principle,'" Letter to the Editor, (2000) 18:7 *Nature Biotechnology* 697; Florian Weighardt, "European GMO Labeling Thresholds Impractical and Unscientific," (2006) 24:1 *Nature Biotechnology* 23-25.
36. Canadian Food Inspection Agency, *Decision Documents— Determination of Environmental and Livestock Feed Safety*, <<http://www.inspection.gc.ca/english/plaveg/bio/dde.shtml>>.
37. Royal Society of Canada, *Elements of Precaution*, supra note 22 at p. 214. The Panel concluded after its reviews, including discussions with CFIA representatives, that although the biotechnology company applicants were sometimes asked to provide new data, no method existed for independent review of either the quality of the scientific data or the validity of the experimental design used. Its report noted that literature reviews appeared to comprise a significant portion of the decision-making process.
38. See Royal Society of Canada, *Elements of Precaution*, supra note 22 at p. 212.

advantage and seeks markets outside the country."<sup>39</sup>

Yet since the crucial stages of regulatory decision-making are concealed from public view—with the larger scientific community unable even to confirm or challenge the validity of the data on which the assessments are based—no mechanism exists for objective verification of claims about a particular GM product under the current regulatory structure. Independent and objective scientific verification constitutes a foundational part of the scientific method, which is characterized by full and open access to clinical methodologies and trial results (as exemplified in the academic peer review process). In one known review of data that CFIA used to assess the invasiveness of Monsanto's Roundup Ready Canola, the reviewer concluded that the data was scientifically inadequate for either a rational regulatory decision-making process or a peer-reviewed publication.<sup>40</sup> The Expert Panel on the Future of Food Biotechnology agreed with this conclusion.<sup>41</sup>

An overarching regulatory issue related to these important concerns about transparency and the use of scientific data within Canadian policy involves the perception of undue industry influence and the appearance of potential conflicts of interest arising from the organizational structure and operational practices of CFIA. The goal of the Agency is both to regulate the safety of products derived from biotechnology and to promote and facilitate the development of an internationally competitive biotechnology industry.<sup>42</sup> Agriculture and Agri-Food Canada (AAFC) invests approximately \$60 million in biotechnology research and development each year, which includes collaborating with biotechnology companies in executing field tests of GM crops under investment matching initiatives, while at the same time AAFC stands to earn between one and ten percent royalties on Monsanto's Roundup Ready wheat if it is approved.<sup>43</sup> Critics have questioned a system in which CFIA, the regulatory body that deals with the evaluation and approval of GM crops, is under the aegis of AAFC, the federal department that is invested directly in the promotional and commercialization aspects of GM crop development. The perception of conflicting interests and undue influence on government policy seems inherent in the current operational structure:

If the same government agency that is charged with the responsibility to protect the public health and environmental safety from risks posed by technologies also is charged with the promotion of that same technology, and if its safety assessments are, by official policy, balanced against the economic interests

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39. Jean Hollebhone, "An Overview of the Canadian Federal and Agricultural Regulatory Frameworks for Biotechnology," *CARC Workshop on Biotechnology Regulation* (Ottawa, 5-6 December 1988), cited in Elisabeth Abergel and Katherine Barrett, "Putting the Cart Before the Horse: A Review of Biotechnology Policy in Canada," (2002) 37:3 *Journal of Canadian Studies* 135-161 at p. 141.
  40. Katherine J. Barrett, *Canadian Agricultural Biotechnology: Risk Assessment and the Precautionary Principle* (PhD Dissertation, University of British Columbia, 1999) [unpublished], <[http://www.collectionscanada.gc.ca/obj/s4/f2/dsk1/tape2/PQDD\\_0018/NQ48601.pdf](http://www.collectionscanada.gc.ca/obj/s4/f2/dsk1/tape2/PQDD_0018/NQ48601.pdf)>.
  41. Royal Society of Canada, *Elements of Precaution*, supra note 22 at p. 215.
  42. Canadian Food Inspection Agency, "Agency Overview," <<http://www.inspection.gc.ca/english/agen/broch/broche.shtml>>. CFIA states that it strives to implement a "fair and effective food, animal and plant regulatory regime that supports competitive domestic and international markets."
  43. Jason Warick, "Lining Up Against GM Wheat," *Saskatoon Star Phoenix* (9 August 2003), available at *Saskatchewan Organic Directorate's website*, <<http://www.saskorganic.com/oapf/snn-09aug03.html>>.

of the industries that develop them, this represents, from the point of view of both the public and the industrial stakeholders, a significant conflict of interest. Each stakeholder is placed in the position of having to ask, with respect to each regulatory decision, whether its own interests have been unduly compromised by the interests of the other.<sup>44</sup>

Concerns about lack of transparency in the regulatory process, application of the substantial equivalence concept, and the treatment of scientific data during safety assessments have been central to policy discussions and reform recommendations.<sup>45</sup> Issues around the perception of conflicting interests or undue industry influence on government policy go to the heart of the integrity of the regulatory system in Canada. Such concerns are intimately connected with the public's confidence in government regulation, as well as the desire for environmental, health and safety evaluation procedures and government oversight practices to keep pace with technological developments in the rapidly expanding biotechnology sector.

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#### 4. OVERVIEW OF RECENT GM CROP LAWSUITS AGAINST REGULATORS

TO DATE, CANADIAN FEDERAL REGULATORS HAVE NOT BEEN sued in negligence for their GM crop approval decisions, though such action was briefly threatened in Saskatchewan.<sup>46</sup> Legal challenges have arisen in other jurisdictions, primarily alleging that regulatory agencies failed to comply with statutory environmental assessment requirements in their GM crop approval decisions. While these claims are not directly analogous to a private law claim of negligence, they do illustrate scenarios where GM crop opponents sought legal recourse against regulatory decisions, and similar circumstances in Canada could instigate claims of regulatory negligence.

In the United States, there were several successful legal actions against the US Department of Agriculture (USDA) in 2006 and 2007, each concerning regulatory approvals that took place without adequate completion of the legally mandated environmental assessments. In three suits led by the Center for Food Safety (CFS), federal judges found that the USDA had either inadequately performed, or not conducted at all, the environmental evaluations that must be

44. Royal Society of Canada, *Elements of Precaution*, *supra* note 22 at p. 212.

45. See e.g. Royal Society of Canada, *Elements of Precaution*, *supra* note 22; CBAC, *Improving the Regulation*, *supra* note 25; Anne Clark, "Regulation of Genetically Modified Crops in Canada: Science-Based or...?" (Paper presented to the *Safe Food Conference*, Salt Spring Island, British Columbia, August 2003) [unpublished]; Andr ee, "Analysis of Efforts," *supra* note 22.

46. In a 2001 news article in the *Western Producer* regarding the then-pending Saskatchewan Organic Directorate lawsuit against Monsanto Canada Inc., reporter Sean Pratt summarized comments from Dale Adolphe, president of the Canola Council of Canada, that "growers and creators of GM canola have done nothing illegal because the products have passed food, feed, environmental and safety regulations and have made it through the variety registration system." Pratt quotes Adolphe as stating: "If the class action should be targeted at anybody, it would be targeted at the regulatory systems that allowed that." Pratt also states that "Saskatchewan Organic Directorate officials said the federal government and other parties may be included in legal action, but the main target will be Monsanto." See Sean Pratt, "Proposed GM Lawsuit May Stir Major Waves," *Western Producer* (18 October 2001), available at <<http://www.mindfully.org/GE3/Lawsuit-Major-Waves.htm>>.

conducted prior to testing or commercialization.<sup>47</sup> In *Geertson Seed Farms, et al. v Johanns*,<sup>48</sup> a case concerning the USDA's approval of Monsanto's "Round Up Ready" GM alfalfa for commercial sale, a Federal Court found that the USDA had violated environmental protection regulations pursuant to the *National Environmental Policy Act* (NEPA) by approving a GM crop for commercialization without completing a proper Environmental Impact Statement (EIS). Noting the USDA's failure to address various environmental risks, including the risk of GM crop contamination and potentially the eventual destruction of organic alfalfa in the region,<sup>49</sup> Judge Breyer of the Federal District Court of the Northern District of California halted the GM alfalfa production by granting a permanent injunction. The Court's ruling requires the USDA to conduct a full EIS containing a thorough evaluation of the environmental risks involved before commercialization of GM alfalfa can resume.<sup>50</sup>

During the same month, Judge Kennedy of the Federal District Court of the District of Columbia also found that the USDA acted unlawfully in approving field trials of GM Creeping Bentgrass and Kentucky Bluegrass.<sup>51</sup> The USDA bypassed environmental review during the approval process by claiming that the trials were "categorically excluded" from the federally required environmental risk assessments. Judge Kennedy ruled that the USDA had wrongfully exempted GM Bentgrass from the NEPA's environmental review requirements, noting that there is "substantial evidence that the field tests may have had the potential to affect significantly the quality of the human environment."<sup>52</sup> The Court ordered the USDA to halt approval of all new field trials until full environmental reviews are completed for each specific trial.<sup>53</sup> This decision has significant implications in the United States since the USDA had commonly used the "categorical exclusion" argument to avoid environmental assessments for field trials in recent years.<sup>54</sup>

Several months before these two landmark judgments, Judge Seabright of the Federal District Court for the District of Hawaii ruled the USDA violated the *Endangered Species Act* (ESA) by approving field trials of biopharmaceutical GM corn and sugarcane without considering the potential impact on endangered species. The USDA's failure to complete a full environmental safety assessment also violated the NEPA.<sup>55</sup> This case marked the first federal ruling on biopharmaceutical crops, and the Court made clear that these GM crops must be tested in a manner that complies with the environmental and species protection laws in the NEPA and ESA.

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#### Legal action over GM crop regulation has also been directed at the US

47. See Center for Food Safety, *Gaining Ground in the Courts: The Center for Food Safety's Recent Victories in the Battle over Genetically Engineered Crops*, (Center for Food Safety, 2007), <[http://www.centerforfoodsafety.org/pubs/USDA%20Violates%20Env%20Laws%20on%20GE%20Crops\\_FINAL.pdf](http://www.centerforfoodsafety.org/pubs/USDA%20Violates%20Env%20Laws%20on%20GE%20Crops_FINAL.pdf)>.
48. *Geertson Seed Farms v Johanns* (USA CA N Dist Ct, 2007). <[http://www.cand.uscourts.gov/cand/judges.nsf/ba8bc702282ba44588256d48006b732/05528e50cbd9a1c78825728200027954/\\$FILE/6-1075%20Geertson.pdf](http://www.cand.uscourts.gov/cand/judges.nsf/ba8bc702282ba44588256d48006b732/05528e50cbd9a1c78825728200027954/$FILE/6-1075%20Geertson.pdf)>, Case 3:06-cv-01075-CRB Document 83, Filed 02/12/2007.
49. *Geertson Seed Farms*, *supra* note 48 at pp. 8, 13.
50. *Geertson Seed Farms*, *supra* note 48 at p. 19.
51. *International Center for Technology Assessment v Johanns*. (USA DC Dist Ct, 2007), <[https://ecf.dcd.uscourts.gov/cgi-bin/show\\_public\\_doc?2003cv0020-94](https://ecf.dcd.uscourts.gov/cgi-bin/show_public_doc?2003cv0020-94)>, 473 *Federal Supplement 2d ser.* 9.
52. *International Center for Technology Assessment*, *supra* note 51 at p. 32.
53. *International Center for Technology Assessment*, *supra* note 51 at pp. 33–34.
54. Center for Food Safety, "Gaining Ground in the Courts," *supra* note 47 at p. 2.
55. *Center for Food Safety v Johanns* (USA HI Dist Ct, 2006), available at the CFS website, <<http://www.centerforfoodsafety.org/pubs/ORDER%208-10-06.pdf>>, 451 *Federal Supplement, 2d ser.* 1165.

Environmental Protection Agency (EPA). In 1999, Greenpeace led a coalition of environmentalists and other activists in filing a lawsuit against the EPA to force the agency to reverse its approval of Bt (*Bacillus thuringiensis*) transgenic crops.<sup>56</sup> The plaintiffs alleged that the agency violated federal law when several Bt-producing plants were approved for commercial sale. They argued there was a high likelihood that the Bt products could cause environmental harm, including the potential development of resistance to Bt insecticides. In the opening session of oral hearings, Judge Louis Oberdorder of the Federal District Court of Washington, DC, stated that he would “hold [the EPA’s] feet to the fire” on the issue of Bt crops.<sup>57</sup> After successfully opposing a preliminary application for summary dismissal of the claim, the plaintiffs later withdrew the lawsuit in July 2000, vowing to continue the challenge against EPA’s Bt crop policy. Joseph Mendelson, an attorney for CFS, one of the co-plaintiffs, explained that the suit was withdrawn in part because several of the Bt crops were up for immediate re-consideration by the EPA, meaning some elements of the lawsuit were set to be “mooted out.”<sup>58</sup>

In Indonesia, regulatory approval of Bt crops for commercialization also resulted in a contentious but ultimately unsuccessful lawsuit against the Indonesian government, again following a GM crop regulatory approval process that was heavily influenced by industry interests. A coalition of 72 non-governmental organizations (NGOs) filed legal action against a Ministry of Agriculture Decree allowing the commercial production of Monsanto’s Bt cotton in South Sulawesi.<sup>59</sup> The plaintiffs contended that none of the prerequisite biosafety tests were made public or independently reviewed, that farmers were not informed of all potential risks and effects, and that government officials had rejected outright the recommendation for an independent risk assessment. From the outset of the trial, the Indonesian subsidiary of Monsanto worked to influence its outcome, appealing for and winning the right to be added as a defendant to dispute the claim. While the suit against the government was ultimately unsuccessful, the extent to which Monsanto had influenced Indonesia’s regulatory approval of Bt cotton became clear several years later: in January 2005, Monsanto (USA) was fined USA\$1.5 million for bribing Indonesian government officials to avoid a decree requiring an environmental risk assessment for Bt cotton.<sup>60</sup>

56. *Greenpeace International, et al. v Browner* (USA DC Dist Ct, 1999), Document No. 99-cv-389 (LFO).

57. See “Greenpeace Wins First Round in EPA Lawsuit to Ban Bt Crops,” (Greenpeace International, 19 January 2000), available at Organic Consumers Association’s website, <<http://www.organicconsumers.org/ge/grnpeacesuit.cfm>>.

58. Quoted in Jeffrey L Fox, “Withdrawn Greenpeace Bt Suit Enters Spin Cycle,” (2000) 18:9 *Nature Biotechnology* 920 at p. 920.

59. “Redesigning Nature: Keeping Bt Cotton out of Indonesia,” (2001) 31 *The Ecologist* 17.

60. See e.g. “Monsanto Fined \$1.5m for bribery,” *BBC News* (7 January 2005) <<http://news.bbc.co.uk/2/hi/business/4153635.stm>>; “Former executive of Monsanto fined for bribing Indonesian official,” *The International Herald Tribune* (8 March 2007) F14, <<http://www.iht.com/articles/2007/03/07/yourmoney/monsanto.php?pass=true>>.

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## 5. A CAUSE OF ACTION FOR REGULATORY NEGLIGENCE IN CANADA?

THIS PAPER HAS SO FAR DISCUSSED THE CANADIAN GM CROP regulatory framework and summarized concerns expressed about some aspects of the GM crop regulation process, especially concerns about the way in which plants with novel traits are assessed, industry influence over decisions and inadequate opportunities for regulators to consider broader socio-economic impacts. Examples of litigation against regulators in other jurisdictions illustrate situations where critics have sought legal recourse for deficiencies in the GMO regulatory review process. The question, now, is whether a cause of action for regulatory negligence is viable in Canada for regulator decisions about approval applications for GM crops. The following section discusses the current state of Canadian law regarding government liability for negligence, summarizes recent cases involving claims of regulatory negligence, and identifies several unresolved questions that may leave open the door for future claims of liability against regulatory authorities.

Government bodies in Canada may face liability in negligence if a plaintiff can satisfy the two-step test first set out in the UK House of Lords decision in *Anns v Merton London Borough Council* and subsequently applied by the Supreme Court of Canada:

First one has to ask whether, as between the alleged wrongdoer and the person who has suffered damage there is a sufficient relationship of proximity or neighbourhood such that, in the reasonable contemplation of the former, carelessness on his part may be likely to cause damage to the latter—in which case a prima facie duty of care arises. Secondly, if the first question is answered affirmatively, it is necessary to consider whether there are any considerations which ought to negative, or to reduce or limit the scope of the duty or the class of person to whom it is owed or the damages to which a breach of it may give rise [...].<sup>61</sup>

The Supreme Court of Canada has instructed that:

At the first stage of the *Anns* test, two questions arise: (1) was the harm that occurred the reasonably foreseeable consequence of the defendant's act? and (2) are there reasons, notwithstanding the proximity between the parties established in the first part of this test, that tort liability should not be recognized here?<sup>62</sup>

In a claim of regulatory negligence, then, the analysis must focus first on the relationship between the government and the plaintiff and whether the latter's harm is a foreseeable result of the government's alleged negligent conduct. A government regulator is often not in a relationship of sufficient

61. *Anns*, supra note 11 at pp. 751–752 (cited to *Appeal Cases*). For the Supreme Court of Canada discussion and application of *Anns*, see e.g. *Kamloops (City) v Nielsen* (CAN SC, 1984), <<http://scc.lexum.umontreal.ca/en/1984/1984rcs2-2/1984rcs2-2.pdf>>, 1984:2 *Supreme Court Reports* 2; *Just v British Columbia* (CAN SC, 1989), <<http://scc.lexum.umontreal.ca/en/1989/1989rcs2-1228/1989rcs2-1228.pdf>>, 1984:2 *Supreme Court Reports* 2 [Just]; *Cooper v Hobart*, 2001 SCC 79, <<http://scc.lexum.umontreal.ca/en/2001/2001scc79/2001scc79.pdf>>, 2001:3 *Supreme Court Reports* 537 [Cooper].

62. *Cooper*, supra note 61 at para. 30.

proximity to a specific class of persons to give rise to a private law duty of care, typically because regulation is aimed at the broad public interest, rather than interests of particular individuals or groups. It has been noted that “in cases of an alleged regulatory failure, the concept of proximity has awkward application because the ‘relationship’ between the parties is one entirely based in statute.”<sup>63</sup> It is important, therefore, to consider carefully the language of the governing statute to determine if the legislative text obliges the regulator to regulate in the interests of a specific group. In such a case, members of that group may have a stronger claim that the regulator must perform its functions in a way that does not cause foreseeable harm to members of that specific group.

The second stage of the *Anns* test examines “whether there are residual policy considerations outside the relationship of the parties that may negative the imposition of a duty of care.”<sup>64</sup> These considerations focus on the undesirable consequences of imposing Crown liability, including the “spectre of unlimited liability to an unlimited class.”<sup>65</sup> An important issue at this stage is whether the impugned government activity constitutes an exercise of policy authority or the operational implementation of policy. The Supreme Court of Canada has confirmed on numerous occasions that the government is protected from negligence liability for its policy decisions, but is liable for negligence in its operational activities.<sup>66</sup> Drawing the distinction between policy and operational activity is not straightforward; as Horsman and Morley observe, “[t]he dividing line between policy and operations is less than precise. The inherent ambiguity of these concepts has resulted in decided cases that are difficult to rationalize, which in turn makes outcomes difficult to predict.”<sup>67</sup> Nonetheless, establishing the line between policy and operations is important to account for the fact that governments engage in “decision-making of a generality and complexity that a Court cannot be expected to evaluate, let alone replicate.”<sup>68</sup> In general terms, the following types of activities have been held to constitute activities that are immune from negligence liability: priority setting decisions that require governments to balance limited resources and competing social and political interests;<sup>69</sup> legislative or quasi-judicial decisions;<sup>70</sup> and decisions made under discretionary powers conferred by statute.<sup>71</sup>

In negligence claims against statutory regulators, Canadian courts have tended to focus on the first step in the *Anns* analysis to scrutinize whether a duty of care exists between the regulator and the plaintiff. Where the alleged duty does not fall into a previously accepted proximate relationship giving rise to a private law duty,<sup>72</sup> the duty may be found from the language of the statute; “[i]n novel regulatory contexts, a duty of care will be found only if the governing statutory

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63. Horsman and Morley, *Government Liability*, *supra* note 10 at pp. 5–6.

64. *Cooper*, *supra* note 61 at para. 30.

65. *Cooper*, *supra* note 61 at para. 37.

66. See e.g. *Cooper*, *supra* note 61 at para. 38; *Just*, *supra* note 61.

67. Horsman and Morley, *Government Liability* *supra* note 10 at pp 5–27.

68. Hogg and Monahan, *Liability of the Crown*, *supra* note 10 at p. 164.

69. See e.g. *Just*, *supra* note 61.

70. See e.g. *Wellbridge Holdings Ltd. v Winnipeg (City)* (CAN SC, 1971), <<http://scc.lexum.umontreal.ca/en/1970/1971rcs0-957/1971rcs0-957.pdf>>, 1971 *Supreme Court Reports* 957.

71. See e.g. *Home Office v Dorset Yacht Co.* 1970 UKHL 2, <<http://www.bailii.org/uk/cases/UKHL/1970/2.html>>, 1970:2 *All England Reports* 294.

72. For a discussion of categories of situations giving rise to a judicially recognized duty of care, see e.g. Horsman and Morley, *Government Liability* *supra* note 10 at para. 5.30.40.

scheme implies a special private duty to some subset of the community.”<sup>73</sup> As noted earlier, a major hurdle for most potential plaintiffs is that many regulatory functions are premised on a broad public interest, rather than the interests of a clearly defined group. The rationale for focusing on this first step in *Anns* is explained as follows:

The relationship between the government and the governed is not one of individual proximity. Any, perhaps most, government actions are likely to cause harm to some members of the public. That is why government is not an easy matter. Of course, the government owes a duty to the public but it is a duty owed to the public collectively and not individually. The remedy for those who think that duty has not been fulfilled is at the polls and not before the Courts.<sup>74</sup>

In considering a cause of action in negligence against GM crop regulators, the challenge is to apply existing common law principles to CFIA’s regulatory acts as mandated under the *Seeds Act* and regulations. If, for example, organic producers sought to sue regulators for negligence in their approval of a new GM crop variety, could they pass both stages of the *Anns* analysis? Could they establish a relationship of sufficient proximity that they could advance a credible claim that the regulatory authority owes them a private law duty of care to prevent foreseeable harm? Would a cause of action arise in negligence if the regulator failed to act in compliance with its governing statute? Is the manner of regulation—for example, by application of a “substantial equivalence” test—legally actionable? The following sections address these questions.

### 5.1. To Whom is a Duty Owed?

The *Seeds Act* and regulations do not stipulate that CFIA must regulate in the interest of agricultural producers broadly, or specific types of producers. Rather, the *Seeds Act* prohibits certain activities (e.g. selling seeds in Canada that have not been registered in accordance with the statute<sup>75</sup>), authorizes CFIA’s president to designate inspectors and analysts to carry out statutory functions,<sup>76</sup> sets out offences and penalties for contraventions,<sup>77</sup> and confers broad, regulation-making power on the Governor in Council.<sup>78</sup>

73. Horsman and Morley, *Government Liability*, *supra* note 10 at para. 5.30.30.

74. *A.O. Farms Inc. v Canada* (CAN Fed Ct, 2000), <[http://decisions.fct-cf.gc.ca/en/2000/t-1620-95\\_929/t-1620-95.html](http://decisions.fct-cf.gc.ca/en/2000/t-1620-95_929/t-1620-95.html)>, 28 *Administrative Law Reports*, 3d ser. 315, at para. 11.

75. *Seeds Act*, *supra* note 14 at s. 3.

76. *CFIA Act*, *supra* note 13 at s. 13(3). Section 6 of the *Seeds Act*, *supra* note 14, sets out powers of inspectors as follows:

6. (1) An inspector may at any reasonable time
  - (a) enter any place in which the inspector believes on reasonable grounds there is any seed to which this Act applies;
  - (b) open any package found in that place that the inspector believes on reasonable grounds contains any such seed;
  - (c) examine the seed and take samples thereof; and
  - (d) require any person to produce for inspection or for the purpose of obtaining copies or extracts any books, shipping bills, bills of lading or other documents or papers with respect to the administration of this Act or the regulations.

77. *Seeds Act*, *supra* note 14 at s. 9.

78. *Seeds Act*, *supra* note 14 at s. 4.

The preamble of the CFIA Act states general principles regarding CFIA's functions. It states that the establishment of the federal "food inspection agency will contribute to consumer protection and facilitate a more uniform and consistent approach to safety and quality standards and risk-based inspection systems."<sup>79</sup> The preamble is also explicit that "the Government of Canada wishes to promote trade and commerce."<sup>80</sup> These statements are relevant to all CFIA's functions and may be of minimal assistance in substantiating a claim that the regulator owes a duty of care to specific agricultural producer groups in its GM crop regulatory activities. Indeed, assessing whether particular regulatory decisions protect consumers and promote trade and commerce requires assessment of the regulator's risk analysis. As discussed in more detail below, risk analyses often involve policy dimensions that are not amenable to review in a private law negligence action.

A regulatory body that is obliged by statute to protect the interests of a defined group is more likely to owe a private law duty of care to members of that group than a regulator with a broad mandate to regulate in the public interest.<sup>81</sup> A question that remains unresolved in Canadian jurisprudence is whether a regulator's representations may establish a duty of care to a specific group when the language of the statute is aimed broadly at the public.

*Sauer v Canada (Attorney General)*<sup>82</sup> concerns a claim for negligent regulation of the Canadian cattle industry. Following the 2003 discovery of bovine spongiform encephalopathy (BSE or "mad cow" disease) in a cow in Alberta, the plaintiff, an Ontario cattle farmer, initiated class action litigation against the federal government and a company that manufactured cattle feed alleged to be the source of the BSE contamination. In 1990, the federal government enacted a regulation under the *Feeds Act*<sup>83</sup> permitting the continuing addition of ruminant remains in cattle feed. In April 1996, the World Health Organization advocated a ban on such ruminant remains in feed.<sup>84</sup> Eighteen months later, the federal government brought into effect a feed ban under the *Health of Animals Act*.<sup>85</sup>

In *Sauer*, the plaintiff alleged the government was negligent in its 1990 and 1997 regulatory activities by permitting ruminant materials in feed and then by failing to act quickly enough to enact a feed ban. In an application to dismiss the claim, the federal government argued "there can be no relationship of sufficient proximity between commercial cattle farmers in Canada when Canada makes legislative decisions."<sup>86</sup> The plaintiff countered this argument by citing "the many public representations by Canada that it regulates the content of cattle feed to protect commercial [...] farmers,"<sup>87</sup> rather than regulating in a broad public interest. The Court refused to dismiss the claim on a preliminary basis<sup>88</sup> so it remains unclear in Canadian law when a regulator may, in effect, impose a duty of care on itself by its representations to particular groups.

79. CFIA Act, *supra* note 13 at preamble.

80. CFIA Act, *supra* note 13 at preamble.

81. Horsman and Morley, *Government Liability*, *supra* note 10 at para. 5.30.30.

82. *Sauer v Canada (Attorney General) et al.*, 2007 ONCA 454, <<http://www.ontariocourts.on.ca/decisions/2007/june/2007ONCA0454.pdf>>, 2007:225 Ontario Appeal Cases 143.

83. *Feeds Act*, *supra* note 16; *Feeds Regulations* (8 January 1990) 124:3 *Canada Gazette—Part II* 73 at ss. 5.1.6, 5.1.7.

84. *Sauer*, *supra* note 82 at para. 20.

85. *Health of Animals Act*, *supra* note 17; *Regulations Amending the Health of Animals Regulations*, (25 July 1997) 131:16 *Canada Gazette—Part II* 362 at s. 164.

86. *Sauer*, *supra* note 82 at para. 61.

87. *Sauer*, *supra* note 82 at para. 62.

88. Leave to appeal to Supreme Court of Canada dismissed, 2008 CanLII 36470 (SCC).

### 5.2. Failure to Act in Compliance with the Governing Statute

What of situations where a plaintiff alleges the regulator failed to act in compliance with its governing statute? The earlier summary of GM crop litigation in the United States and other countries illustrated a common complaint that the regulatory authority failed to follow steps required under environmental protection statutes. An analogous claim in Canada might contend that the regulator failed to follow steps as required under the *Seeds Act* in making a decision about release of a GM crop. This circumstance may give rise to judicial review on administrative law grounds (a topic outside the scope of this paper), but does a successful judicial review action expose the regulator to liability in negligence? The answer here is generally no. In the recent case of *Holland v Saskatchewan (Minister of Agriculture, Food and Rural Revitalization)*,<sup>89</sup> an elk farmer refused to participate in a government disease surveillance program and, as a consequence, the Ministry of Agriculture assigned his herd the lowest status. After successful judicial review regarding validity of the herd status certificate, the farmer sued the Minister for negligence. He argued that the Minister's act of exceeding his legal authority in issuing the herd status certificate amounted to negligence. The Minister's application to dismiss the claim was rejected at first instance but accepted on appeal. Richards JA, for the Saskatchewan Court of Appeal, articulated concerns with the farmer's claim:

The respondent's claim, if recognized in law, would put regulators and other public authorities in the position where, notwithstanding both careful efforts to determine the limits of their authority and earnest attempts to operate within those limits, they would nonetheless be exposed to private law liability if a court subsequently took a different view of the scope of their powers.<sup>90</sup>

Ultimately, the Court rejected the claim that a breach of statutory duty—that may be actionable on public law grounds—should give rise to liability in negligence.<sup>91</sup>

### 5.3. Failure to Regulate in a Particular Manner

Opponents or proponents of GM crop technology may advocate a specific regulatory regime. Some critics of the Canadian regulatory evaluation of a novel plant based on "substantial equivalence" argue that regulation should be more

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89. *Holland*, *supra* note 12.

90. *Holland*, *supra* note 12 at para. 41. See also *A.O. Farms Inc.*, *supra* note 74 at para. 8 where the Court states: "The decision to legislate and the decision how to legislate are, in my view, inseparable."

91. This principle is applicable in other jurisdictions. For example, an Australian analysis of potential regulator liability for GM crop approvals states:

A wrongful administrative decision is incapable, by itself, of supporting a claim for damages. Therefore if a person suffers damage by reason only of the Regulator issuing a licence to a person in circumstances where that person should not have been issued with a licence (for example, [...] because the Regulator uses incorrect information about the proposed GMO activity) that person cannot, without more, obtain any damages for any of the consequences of the person's wrongful decision.

See: Lee McIntosh, "Liability for Environmental Damage Caused by the Release of Genetically Modified Organisms," *For Whose Benefit?—Evaluating Genetically Modified Organisms in Western Australia from a Different Perspective*, Paper presented to the Australia Conversation Policy Conference, 10 October 2002, <[http://www.edowa.org.au/archives/5A\\_gmo\\_liability.pdf](http://www.edowa.org.au/archives/5A_gmo_liability.pdf)>, at p. 10.

explicitly precautionary and require a higher standard of safety evidence.<sup>92</sup> Can a government face negligence liability for regulating in a specific manner, for example, by establishing in law a test of substantial equivalence rather than a different standard against which to assess the novelty of a plant? Previous cases demonstrate strong judicial reluctance to accept claims of regulatory negligence based on a choice to regulate in a specific manner. This activity is generally viewed as the *sine qua non* of policy making where government is immune from private law duties.

*Attis v Canada (Minister of Health)*<sup>93</sup> concerned the safety of breast implants approved for sale in Canada and the allegation that Health Canada was negligent in its regulatory activities under the *Food and Drugs Act* and *Medical Devices Regulations*. The plaintiffs claimed that the federal government had a private law duty to enact a regulatory prohibition against breast implants manufactured by Dow Corning Inc. The Court, however, rejected the argument that a statutory regime that primarily establishes rules for device manufacturers and distributors “can be expanded by implication to include a private law duty of care owed by the government to the consumers or users of the devices.”<sup>94</sup> The Court further emphasized that “[a]n allegation that there was a ‘duty to prohibit’ is akin to an allegation that there is a duty to govern in a certain way. [...] That is a manifest policy decision and it is well-settled that, as such, it is immune from civil liability.”<sup>95</sup>

Governance choices, however, must be distinguished from the exercise of specific regulatory powers that may, in some limited cases, be actionable in negligence. In another medical devices claim against Health Canada,<sup>96</sup> an Ontario Court ruled that the defendant’s failure to enforce regulations it knew were being breached, may give rise to a private law duty of care to a specific group of plaintiffs who experienced foreseeable harm arising from the government’s conduct.

An important feature of GMO regulation is that decision-making centres on the scientific evaluation of risk of harm and discontent often stems from the view that the regulatory process does not take adequate account of potential harms. This type of claim tends to impugn the policy framework within which decisions are made and, therefore, runs afoul of the jurisprudential limit against negligence liability for policy choices. Indeed, it has been noted that “assessing [risk] acceptability is not a purely technocratic exercise but involves a political determination in that regulators must make policy choices that account for the level of risk tolerance associated with potential harm to the natural environment and human health.”<sup>97</sup> Additionally, Glenn argues that a regulatory agency’s failure to include socio-economic issues (such as market impact) or ethical considerations in the evaluation process, and issues relating to reliance on the “substantial

92. See e.g. Peter Andr e, “An Analysis of Efforts to Improve GM Food Regulation in Canada,” (2006) 33:5 *Science and Public Policy* 377. The author argues, at p. 386, that the evidence he reviews “shows that the Government of Canada is not prepared to accept the degree of precautionary scrutiny of GMOs called for by the RSC [Royal Society of Canada] Panel.”

93. *Attis v Canada (Minister of Health)* (ON Sup Ct, 2007), <<http://www.canlii.org/en/on/onsc/doc/2007/2007canlii15231/2007canlii15231.pdf>>, 46 *Carswell’s Practice Cases 6th ser.* 129, appeal dismissed 2008 ONCA 660.

94. *Attis*, *supra* note 93 at para. 17.

95. *Attis*, *supra* note 93 at para. 17.

96. *Taylor v Canada (Minister of Health)* (ON Sup Ct, 2007), <<http://www.canlii.org/en/on/onsc/doc/2007/2007canlii36645/2007canlii36645.pdf>>, 285 *Dominion Law Reports, 4th ser.* 296, leave to appeal denied, (2007) 289 *Dominion Law Reports, 4th ser.* 567.

97. Craik, Culver, and Siebrasse, “Genetically Modified Crops and Nuisance,” *supra* note 7 at p. 205.

equivalence” test, would likely be matters of “policy” for which the regulator would not be liable.<sup>98</sup>

The previous discussion indicates that a cause of action for regulatory negligence in the GM crop review process is likely quite narrow. Glenn proposes that issues pertaining to the assessment process itself, including “perceived conflict between CFIA’s regulatory and promotional roles for biotechnology, the possibility of undue industry influence and lack of transparency – might well be held to be operational and hence justiciable.”<sup>99</sup> Yet these matters would only be justiciable in a private law context where a relationship of sufficient proximity existed between the regulator and the plaintiff. Government’s legislative decisions about how to assign statutory responsibilities and reporting relationships—for example, as between the Minister of Agriculture and Agri-Food Canada and CFIA—are decisions that would be outside the scope of a negligence claim. In its assessments of GM crop applications, CFIA could likely escape negligence liability for acting outside the bounds of its statutory authority or failing to take account of environmental and health factors as prescribed in the *Seeds Regulations*, though these failures may well give rise to administrative law claims. As a final point regarding regulator liability, it is important to note that regulators must act in good faith in their policy decisions and failure to do so may expose them to liability. In the Supreme Court of Canada decision in *Brown v British Columbia*, Cory J remarked:

It will always be open to a plaintiff to attempt to establish, on a balance of probabilities, that the policy decision was not *bona fide* or was so irrational or unreasonable as to constitute an improper exercise of governmental discretion. This is not a new concept. It has long been recognized that government decisions may be attacked in those relatively rare instances where the policy decision is shown to have been made in bad faith or in circumstances where it is so patently unreasonable that it exceeds governmental discretion.<sup>100</sup>

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## 6. TRANSPARENCY IN REGULATION

IN THE CONTEXT OF GM CROP REGULATION AND LITIGATION, Canadian legal scholars have argued that “democratic legitimacy is better promoted through increased regulatory transparency than through judicial empowerment.”<sup>101</sup> Moreover, greater transparency in regulatory decisions may help avoid litigation; those who disagree with a regulatory outcome may be less litigious if the decision-making process was transparent in evaluation criteria and consistent with clearly stated processes. This final section addresses concerns about the current degree of

98. Glenn, “Genetically Modified Crops,” *supra* note 23 at p. 307.

99. Glenn, “Genetically Modified Crops,” *supra* note 23 at p. 307. For discussion of a negligence cause of action against regulators in the Australian context, see McIntosh, “Liability for Environmental Damage,” *supra* note 91 at p. 10, who concludes “it is unlikely that the Regulator would be liable at common law for any environmental damage which results from an activity which the Regulator authorised.”

100. *Brown v British Columbia* (CAN SC, 1994), <<http://scc.lexum.umontreal.ca/en/1994/1994rcs1-420/1994rcs1-420.pdf>>, 1994:1 *Supreme Court Reports* 420 at p. 435.

101. Craik, Culver, and Siebrasse, “Genetically Modified Crops and Nuisance,” *supra* note 7 at p. 204.

transparency in regulation of GM crops in Canada and briefly suggests ways in which transparency could be enhanced.

Lack of transparency has repeatedly been identified as a problem in the Canadian GM crop regulatory system. In its 2001 report, the Royal Society Panel emphasized that

the lack of transparency in the current approval process, leading as it does to an inability to evaluate the scientific rigor of the assessment process, seriously compromises the confidence that society can place in the current regulatory framework used to assess potential risks to human, animal and environmental safety posed by GMOs.<sup>102</sup>

In a 2002 report, the Canadian Biotechnology Advisory Committee identified

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 [are] made, the roles of the various regulatory bodies, and the data that are considered during the safety assessment process.<sup>103</sup>

In a 2004 report on CFIA's regulatory activities regarding plants with novel traits, the Auditor General of Canada "found that the Agency did not have complete documentary evidence and, therefore, was not transparent about how it was evaluating the long-term effects on the environment before authorizing unconfined release of plants with novel traits."<sup>104</sup> The Auditor General cautioned that its "findings provide an early warning signal that some important aspects of the Agency's processes for regulating plants with novel traits need strengthening [,particularly since] the next generation of plants with novel traits could pose new and more complex environmental risks [...]."<sup>105</sup>

While concerns have been expressed about industry influence on regulators, lack of clear assessment guidelines in the regulatory process is of considerable concern for proponents seeking GM crop approvals. A recent review of GM crop regulation in Canada observes that the

use of case-by-case assessments [by CFIA] has resulted in a situation in which there is no identifiable regulatory template for seed developers to follow. [...] This has created a scenario in which no seed developer submitting an application package for regulatory approval of a new PNT [plant with novel trait] knows what or how much scientific data are required.<sup>106</sup>

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102. Royal Society of Canada, *Elements of Precaution*, *supra* note 22 at p. 215.

103. CBAC, *Improving the Regulation*, *supra* note 25 at pp. 30–31.

104. Office of the 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* (Minister of Public Works and Government Services Canada, 2004), <<http://www.oag-bvg.gc.ca/internet/docs/20040304ce.pdf>> at para. 4.6.

105. Office of the Auditor General of Canada, *Report*, *supra* note 104 at para. 4.94.

106. Stuart Smyth and Alan McHughen, "Regulating Innovative Crop Technologies in Canada: The Case of Regulating Genetically Modified Crops," (2008) 6:3 *Plant Biotechnology Journal* 213–225, at p. 219.

These concerns indicate a need for greater transparency and clarity in the regulatory process, incorporation of a broader range of public perspectives and opinions in the policy dialogue, and an improved method of evaluating concerns and uncertainties about the potential long-term ecological and health risks associated with the use and production of GM crops. Absent major public opposition to GM crops, however, it has been suggested that “Canadian regulators [...] have had fewer incentives [...] to correct the democratic limitations of weak transparency and limited opportunities for injection of public values and concerns into plant biotechnology regulation.”<sup>107</sup>

Some other jurisdictions, such as the UK,<sup>108</sup> have established independent, expert bodies with the specific responsibility to review applications for release of GM crops and give advice to government. The Canadian Biotechnology Advisory Committee recommended that there should be “effective independence of regulatory functions for GM foods and other novel foods unencumbered by other government functions and responsibilities, including, but not limited to, policy, economic development, negotiation of international policy and trade rules, and trade promotion.”<sup>109</sup> The current regulatory system in Canada has been described as a success “as the adoption rates of GM canola, corn and soybeans has been very high, thereby providing benefits to Canadian producers with no documented damage to health or the environment.”<sup>110</sup> Yet even those who hold this view express concern that existing regulations are ill-suited to address the growing “scientific capability to detect an increasing number of potential risk factors”<sup>111</sup> of GMOs. The capacity to produce stacks of scientific data comparing GMOs to conventional counterparts is only useful if regulators have adequate frameworks for evaluating this evidence and assessing the risks and benefits of novel products. Evaluation frameworks ought to be clearly communicated to seed developers, producers and other stakeholders, with transparency around evaluation criteria, standards against which evidence is assessed and the adequacy of evidence for specific applications for GMO release.

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## 7. CONCLUSION

DESPITE ONGOING CONTROVERSY OVER GM CROP approval and commercialization in Canada, those who might wish to assert a claim of regulatory negligence against CFIA face significant legal barriers. The application of the *Anns* test limits negligence liability of government authorities to situations where a relationship of sufficient proximity exists between government and the plaintiff(s); a regulator is not liable in negligence if the nature of its relationship with the aggrieved party is too remote to give rise to a private law duty of care. Further, policy

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107. Sarah Hartley and Grace Skogstad, “Regulating Genetically Modified Crops and Foods in Canada and the United Kingdom: Democratizing Risk Regulation,” (2005) 48:3 *Canadian Public Administration* 305–327, at pp. 323–324.

108. For more information on the UK Advisory Committee on Releases to the Environment, see <<http://www.defra.gov.uk/Environment/acre/index.htm>>.

109. CBAC, *Improving Regulation*, *supra* note 25 at recommendation 1.1.

110. Smyth and McHughen, “Regulating Innovative Crop Technologies,” *supra* note 106 at p. 224.

111. Smyth and McHughen, “Regulating Innovative Crop Technologies,” *supra* note 106 at p. 224.

considerations restrict the extension of private law obligations to government actors at both stages of the *Anns* analysis. Since review of GM crop applications involves weighing complex scientific data and determining tolerable levels of risk, many aspects of Canadian GM crop regulation would likely be non-justiciable in a negligence claim.

Courts are reluctant to impose legal responsibility where accountability for regulatory and policy decisions more appropriately rests outside the judicial system. Consequently, those outside the judicial system—namely, the legislators, policy-makers and regulators that create and work within legal and policy frameworks for assessing GMOs—have responsibility for transparency and accountability. GM crop litigation in other jurisdictions demonstrates shortcomings that have occurred in regulatory processes and recourse to legal action to ensure adequate environmental and other assessments before commercialization of crops with novel traits. To date, Canadian litigation involving agricultural and health regulators has not involved disputes over GM crops and courts have not adjudicated a claim of regulatory negligence in that context. Ambiguities and shortcomings in GMO regulation have, however, been identified in other fora, such as reports by the Royal Society Expert Panel and the Auditor General of Canada. These criticisms warrant attention to maintain public, producer and industry confidence in the system, particularly as genetic modifications of greater scientific, socio-economic and ethical complexity are introduced into crop plants.