

# **Agriculture Under Threat — A Crisis Of Confidence? The Solution: Redefine Adventitious Presence Maximum Levels from Zero to Zero++**

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*The issue of Adventitious Presence (AP) of genes, those that are not “naturally” present in food and crops but rather have been placed there using recombinant deoxyribonucleic acid (DNA) technology, has become a hot issue for producers and consumers. It can also be a major problem for exporters. Part of this problem is the reality that zero presence is now impossible to guarantee in some crops and products. Pressure has arisen to establish a Low Level Presence (LLP) threshold, one that is above zero, to be determined at an international level. This would allow crops to be imported and exported without the AP genes being approved in the importing country if they are approved in another country. The reality of biotechnological innovation in crops is that it is inevitable that there will be gene “flow” between varieties. This article examines the background of AP, the current state of policy and legislation, and why this has become contentious for producers, importers and exporters. This article examines the Canadian position towards AP as an illustration of a nation that produces many agricultural products based on genetically modified crops.*

## **INTRODUCTION**

Conventional and organic agriculture is said to be struggling for survival.<sup>1</sup> Under the laws of many countries, conventional and organically grown crops are not protected from the effects that genetically modified organisms (GMOs)<sup>2</sup> may have on their marketability. Due to the lacuna in regulation, the effects and concerns caused by genetically modified crops are being addressed outside any specific

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<sup>1</sup> For a description of the situation regarding Canadian non-genetically modified farming, see Chidi Oguamanam, “Tension on the Farm Fields: The Death of Traditional Agriculture?” (2007) 27 *Bulletin of Science, Technology & Society* 260 [Oguamanam].

<sup>2</sup> Despite being mis-descriptive, “genetically modified organisms” has become the term that is generally accepted for organisms that have been created using recombinant DNA and generated by molecular cloning. Such plants transformed through this type of genetic engineering are under discussion herein.

regulatory framework.<sup>3</sup> Furthermore, the stakeholders such as biotechnology companies, conventional and organic farmers, and the public at large, are being excluded from policy making processes.<sup>4</sup> Since the Triffid flax issue, where non-approved GM in flax was exported from Canada and reached 35 countries,<sup>5</sup> the Canadian Government has lunched into action in pursuing international standards, at least for adventitious presence (AP)<sup>6</sup> that can be classified as a “Low Level Presence” (LLP).<sup>7</sup> The alteration of conventional<sup>8</sup> or organic<sup>9</sup> crops by transfer of genes from genetically modified (GM) crops through cross-pollination is now not uncommon.<sup>10</sup> Indeed, one argument being made at the international level today is that due to the wide adoption of GM crops in many exporting countries, it is becoming *impossible* to maintain a zero tolerance policy without serious trade disruption.

The CDC Triffid Flax case in Canada provides a good example of how GM can linger even after it was thought to have been removed from the ecosystem. The Triffid was developed by the Crop Development Centre of the University of Saskatchewan to give it tolerance to soil residues of the herbicides triasulfuron and metsulfuron-methyl, used to control broadleaf weeds in wheat crops, as otherwise

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<sup>3</sup> Jane Matthews Glenn, “The Coexistence of Genetically Modified and Non-genetically Modified Agriculture in Canada: A Courtroom Drama” in Luc Bodiguel & Michael Cardwell, eds, *The Regulation of Genetically Modified Organisms: Comparative Approaches* (New York: Oxford University Press, 2010) 254 at 255 [Glenn].

<sup>4</sup> *Ibid.* at 255-56.

<sup>5</sup> Mr. Alex Atamanenko during the Second Reading and Referral to Committee on 14 April 2010 of Bill C-474 “*An Act respecting the Seeds Regulations* (analysis of potential harm)” which was defeated at report stage (9 February 2011).

<sup>6</sup> Herein the term adventitious presence (AP) is used to refer to both genes that have entered conventional and organic crops, as well as mixture of GMO product with conventional/organic product, for example crop being mixed in the grain conveyor.

<sup>7</sup> Although the term is being used a lot in the current discussions on “low levels” of AP, there are arguments as to what it means.

<sup>8</sup> The issue of the makeup of conventional crops is discussed in Mark Perry, “What’s so conventional about conventional crops: non-recombinant DNA techniques for genetically modified organisms” (*Conventional*, working title, forthcoming).

<sup>9</sup> Organic production in Canada has a GM exclusion as detailed in the National Standards of Canada, “Organic Production Systems General Principles and Management Standards” CAN/CGSB-32.310-2006 as amended in June 2011 at s.1.4.1: “it is forbidden to use any of the following substances or techniques:

All materials and products produced from genetic engineering as these are not compatible with the general principles of organic production and therefore are not accepted under this standard . . .”

<sup>10</sup> Over 15 years ago, in AM Timmons, YM Charters, JW Crawford, D Burn, et al, “Risks from transgenic crops” (1996) 380 *Nature* 487, it was predicted that in a region where only 10% of the fields were sown as transgenic, genetic “contamination” would reach 0.1% at a distance of over 2km.

flax could not be typically grown on the same land for around two years.<sup>11</sup> Trials were started in 1988, and unconfined release, and its use as livestock feed, were sanctioned in May 1996.<sup>12</sup> However, the CDC Triffid was deregistered in 2001 due to indirect pressure from the European Union (which did not want to import the variety as it is a GMO) and farmers (70% of EU flax seed product imports came from Canada). At the time there were around 200,000 bushels of the seed being prepared for making commercial seed stock. This was crushed at a central location to remove the Triffid from the market. Clearly something in the removal process was at fault as in September 2009 genes from the Triffid variety were found in Germany, triggering the EU rapid response protocols. Canada responded by testing flax before export to avoid loss of crop after export. The cost over two years has been estimated at around \$29 million.<sup>13</sup>

As this shows, even very low levels<sup>14</sup> of AP can affect the price and market access for conventional and organic crops, causing economic loss to growers and dealers of such crops. AP has raised multiple issues relating to the coexistence of GM crops and other crops, liability, and some claim even the protection of health (both human and animal),<sup>15</sup> protection of the environment,<sup>16</sup> and market access.<sup>17</sup> There are some issues that are concomitant with GMO use and AP:

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- <sup>11</sup> Canadian Food Inspection Agency, “DD1998-24: Determination of the Safety of the Crop Development Centre’s ‘CDC Triffid’, a Flax (*Linum usitatissimum* L.) Variety Tolerant to Soil Residues of Triasulfuron and Metsulfuron-methyl” 1996-05.
- <sup>12</sup> *Ibid.*
- <sup>13</sup> Dr Camille Ryan, “Revisiting the Triffid Issue” presentation at Saskatoon Flax Day conference (9 January 2012).
- <sup>14</sup> With a zero tolerance policy, 0.01% is set as the threshold; this number is determined by the current testing sensitivity and reliability. This equates in a single test in corn to around one seed in 10,000, or one kernel in around 3.8kg of corn.
- <sup>15</sup> Ikechi Mgbeoji, “Adventitious Presence of Patented Genetically Modified Organisms on Private Premises: Is Intent Necessary for Actions in Infringement Against the Property Owner?” (2007) 27:4 *Bulletin of Science, Technology and Society* 314; G Lichtman, “The Economics of Innovation: Protecting Unpatentable Goods” (1997) 81 *Minnesota L Rev* 693; T Demeke, DJ Perry & WR Scowcroft, “Adventitious presence of GMOs: Scientific overview for Canadian grains” (2006) 86:1 *Canadian Journal of Plant Science* 1; M Phillipson, “Are genetically modified crops in Canada under-regulated?” (2008) 18:2 *J Envtl L & Prac* 195.
- <sup>16</sup> Martin TK Tsui & LM Chu, “Aquatic toxicity of glyphosate-based formulation: comparison between different organisms and the effects of environmental factors” (2003) 52:7 *Chemosphere* 1189; CP Rogers, “Liability for the Release of GMOs into the Environment: Exploring the Boundaries of Nuisance” (2003) 62:2 *Cambridge Law Journal* 371; J Glenn, “Genetically Modified Crops in Canada: Rights and Wrongs” (2003) 12 *J Envtl L & Prac* 281.
- <sup>17</sup> Drew L Kershen & Alan McHughen, “Adventitious Presence: Inadvertent Commingling and Coexistence among Farming Methods” (July 2005) QTA2005-1 *The Council for Agricultural Science and Technology (CAST) Commentary* [Kershen]. CG Gonzalez, “Trade liberalization, food security, and the environment: The neoliberal threat to sustainable rural development” (2004) 14:2 *Transnational Law & Contemporary Problems* 419; Richard A Repp, “Biotech Pollution: Assessing Liability for Genetically

- Should conventional or organic crops (or plants) that are found to have AP be considered to be “Plants with Novel Traits (PNTs) and regulated as such;
- Will a country allow the importation of conventional or organic products into the market with AP (non-approved) without risk assessment?
- What is the international market-access situation for agricultural products that have AP?
- Is there any mechanism that allows for coexistence of GM, conventional and organic crops, but minimizes the level of AP?
- Will there be compensation, and by whom, for farmers of conventional or organic crops who suffer loss due to AP?
- Is agricultural regulation primarily the responsibility of parliament or regional governments?
- How is AP dealt with under patent laws?<sup>18</sup>
- What is a “Low Level Presence” that can be considered insignificant?
- Is society now forced to accept GM presence?

Many of these questions remain unanswered in many nations, and have not been addressed directly by policy or regulation. This article examines the Canadian position as an illustration of a GM producing nation that is moving towards recalibrating the meaning of risk assessment, organic plants, AP in non-GM plants, and covers the issues of coexistence, liability and trade disruption.

## I. CODEX ALIMENTARIUS CONSIDERATIONS

The Codex Alimentarius Commission is a joint commission of the World Health Organisation and the Food and Agricultural Organisation, both United Nations Specialised Agencies.<sup>19</sup> It has been tasked with establishing health and safety standards and regulating international food trade, and is a powerful influence on international food regulation developments. Although the Canadian Triffid issue came as a surprise for flax exporters and the Canadian Government alike, the Sixth Session of the Codex Alimentarius Ad Hoc Intergovernmental Task Force on

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Modified Crop Production and Genetic Drift” (2000) 36:3 Idaho L Rev 585 at 593 [Repp]; Norman C Ellstrand, Honor C Prentice & James F Hancock, “Gene Flow and Introgression from Domesticated Plants into their Wild Relatives” (1999) 30 Ann Rev Ecology & Systematics 539 at 541 [Ellstrand]. See also David S Bullock, Marion Desquilbet & Elisavet Nitsi, “The Economics of Non-GMO Segregation and Identity Preservation” (2002) 27:1 Food Policy 81 at 83 [Bullock]; Katie Black & James Wishart, “Containing the GMO Genie: Cattle Trespass and the Rights and Responsibilities of Biotechnology Owners” (2008) 46 Osgoode Hall LJ 397 at paras. 10 and 11 [Black & Wishart].

<sup>18</sup> Mgbeoji, *supra* note 15.

<sup>19</sup> The Commission has a long history of over a century. It was formally established as part of the joint World Health Organisation and Food and Agricultural Organisation in 1963. See Sami Shubber, “The Codex Alimentarius Commission under International Law” (1972) 21:4 The International and Comparative Law Quarterly 631.

Foods Derived from Biotechnology set up a working group on LLP, chaired by the United States of America (USA) and co-chaired by Germany and Thailand, in 2006. The Task Force put a proposed draft forward, and had it considered at the Seventh Session at the Task Force's September 2007 meeting in Chiba, Japan.<sup>20</sup>

Although the Task Force on LLP did not address the meaning or measure of LLP, it provided an annex to the Codex Alimentarius Commissions' Plant Guidelines addressing LLP and discussed two "dietary exposure" situations. The first being from commodities, which tend to be mixed and "diluted," such as grain, beans and oils, and second from foods consumed whole, such as fruits and vegetables. The former is the more likely scenario.<sup>21</sup>

The Task Force proposal allows jurisdictions to adopt a short food safety assessment for imported product with LLP, should they wish to so do. The key advance made by the Task Force was the recommendation for there to be a database available on recombinant DNA plants that have been authorized under Codex guidelines,<sup>22</sup> to allow for the Annex to be applied. In addition to details on the authorizing country and type, the important requirement is that information on where protocols for detection can be obtained. This allows an importing country, of canola for example, to request testing data to see if imports contain recombinant DNA approved in the exporting country, or growing country.<sup>23</sup>

The Codex Alimentarius Commission accepted the Annex on LLP and it is now part of the Guideline for the conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants.<sup>24</sup> There are some limitations on the abbreviated assessment that may be adopted; for example, if a country has already rejected authorization of a recombinant-DNA instance it would not be likely that it would approve any AP, even LLP.

The key issue yet to be adopted at an international level is the meaning of LLP in terms of thresholds; that is the maximum AP that can be considered LLP, the number of tests required, and how testing is conducted. The current status of evaluation continues to lead to uncertainty for trading crops. Most countries to date have had a zero tolerance policy. In addition to Triffid and other Canadian product incidents, problems have also arisen inside the European Union. For example, in

<sup>20</sup> Codex Alimentarius CX/FBT 07/7/1, Agenda Item 1 May 2007 for the Joint FAO/WHO Food Standards Program, Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology Seventh Session Chiba, Japan, 24–28 September 2007. The United States had made a similar proposal to form an ad hoc Task Force on LLP at the Fifth Session in 2005, but it was not accepted at that time.

<sup>21</sup> Report of The Seventh Session of The Codex *Ad Hoc* Intergovernmental Task Force on Foods Derived From Biotechnology Chiba, Japan, 24–28 September 2007, ALINORM 08/31/34, Appendix IV at para. 4.

<sup>22</sup> Section 3 of the Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants — *CAC/GL 45-2003*.

<sup>23</sup> This is under *European Union Commission Regulation* No 619/2011, 24 June 2011.

<sup>24</sup> Codex Alimentarius Commission Thirty-first Session *International Conference Centre*, Geneva (Switzerland), 30 June–4 July 2008, Report al31REPe, adopting Annex on Food Safety Assessment in Situations of Low-level Presence of Recombinant-DNA Plant Material in Food (N07-2007) ALINORM 08/31/34 Appendix IV.

*Bablok*,<sup>25</sup> a German honey producer found that his honey contained MON810 Maize pollen (likely from a nearby field where the test MON810 crop had been grown). The European Court of Justice decided that as MON810 was not approved for consumption in the EU, the honey and pollen could not be sold.<sup>26</sup>

## II. PLANTS WITH NOVEL TRAITS

Canada is the fifth largest producer of GM crops in the world.<sup>27</sup> Canada's regulatory approach is to assess all plants that show "novel traits" whether these are achieved by recombinant-DNA technologies or otherwise. The most prominent of Canada's GM crops are canola, corn and soybeans which are all increasing in size of plantings. With the exception of Prince Edward Island,<sup>28</sup> which has considered banning the cultivation of GM crops, there is little market acceptance problem for GM crops in Canada. In general, the subject matter of biotechnology has been managed in Canada through regulations for Plants with Novel Traits (PNTs). There is no specific "biotechnology law" or "recombinant-DNA food regulation" in Canada. The Federal Regulatory Framework for Biotechnology (1993), which is the governmental policy addressing biotechnology, recommends using existing legislation and regulatory institutions to deal with biotechnology — the Canadian policy approach was, and still is, unique in that it examines "product" not "process."<sup>29</sup> The *Canadian Environmental Protection Act, 1999* (CEPA) requires that all products of biotechnology new to Canada be subject to an assessment of their potential "toxicity" before they can be manufactured, imported or sold in Canada. In 2004, the Standards Council of Canada adopted (as a standard) the *Standard for Voluntary Labeling and Advertising of Foods that Are and Are Not Products of Genetic Engineering*.<sup>30</sup>

<sup>25</sup> EC, *Court of Justice Decision 2011/EC Karl Heinz Bablok and Others v. Freistaat Bayern*, [2011] OJ C 442/09 [*Bablok*]. In addition to the honey, pollen and Triffid Flax cases, there have been many other occurrences of crops and foods being removed from markets due to AP.

<sup>26</sup> *Ibid.*

<sup>27</sup> Clive James, "Global Status of Commercialized Biotech/GM Crops: 2009" ISAAA Brief No 41. ISAAA: Ithaca, NY.

<sup>28</sup> Irené Novaczek & Laura Fanning, "The Economic, Social and Environmental Implications of Genetically Modified Crops (GMOs) on Islands" (2012) UPEI Institute of Island Studies, online: <[http://www.upei.ca/iis/rep\\_gmo\\_1](http://www.upei.ca/iis/rep_gmo_1)>.

<sup>29</sup> The Canadian approach is to regulate "Plants with Novel Traits," however created. This is the responsibility of the Canadian Food Inspection Agency (CFIA) under *Plant Protection Act* (SC 1990, c 22), *Seeds Act* (RSC, 1985, c. S-8) and their regulatory structure. The CFIA was established by the *Canadian Food Inspection Agency Act* (SC 1997, c. 6).

<sup>30</sup> Mark Cantley, "An Overview of Regulatory Tools and Frameworks for Modern Biotechnology: A Focus on Agro-Food" (Paper prepared for the OECD International Futures Project on "The Bioeconomy to 2030: Designing a Policy Agenda," February 2007), online: Organisation for Economic Co-operation and Development <<http://www.oecd.org/dataoecd/11/15/40926623.pdf>> at 67 [Cantley].



Canada is a signatory of the Cartagena Protocol<sup>31</sup> but has yet to ratify the Protocol. The United States Department of Agriculture has stressed the interdependence of Canada/US trade, making the point:<sup>32</sup>

Canada relies heavily on United States of America exports of major grains and oilseeds like corn and soybeans to meet the needs of its processing and livestock industries. The ratification of the Protocol by Canada could have an impact on future imports of genetically modified grains from the United States.

Canada, the USA and Mexico have been working together on the development of biotechnology regulatory policy through the North American Biotechnology Initiative for over a decade. Indeed, Canada and the USA have an unprecedented bilateral agreement on agricultural biotechnology.<sup>33</sup> They forged their agreement in 1998 with the intent to “compare and harmonize” the regulatory process and pre-market assessments of GM plants between the two countries.<sup>34</sup> In addition to harmonization of assessment, another aim is to discuss “future areas of cooperation and information exchange that will facilitate the safe incorporation of transgenic plants into agricultural production and commerce.”<sup>35</sup> Prior to this agreement, both countries were already performing case-by-case assessments of proposed GM plants before they were released.<sup>36</sup>

The Canadian regulatory approach to GM plants is unique. Unlike the use of the term “genetically modified” (GM) in the European Union and other countries, Canada prefers to use the term “genetically engineered” (GE), which is a more narrow definition.<sup>37</sup> Canada regulates plants on the basis of the traits expressed and not on the basis of the method used to introduce the traits. Plants with novel traits (PNTs) are defined as a plant containing a new trait not present in plants of the same species in Canada. Such new traits are intentionally selected, created or introduced into the population of that species using recombinant-DNA techniques, mutagenesis, cell fusion or even conventional cross breeding methods, typically to

<sup>31</sup> Cartagena Protocol on Biosafety to the Convention on Biological Diversity, 29 January 2000, UN Doc 2000 (entered into force on 11 September 2003).

<sup>32</sup> United States, United States Department of Agriculture, *USDA Foreign Agricultural Service GAIN Report CA6036: Canada, Biotechnology, Agricultural Biotechnology Report 2006* (2006) at 3 [GAIN].

<sup>33</sup> Canada and United States, *Canada and United States Bilateral on Agricultural Biotechnology*, 16 July 1998, online: United States Department of Agriculture Animal and Plant Health Inspection Service <<http://www.aphis.usda.gov/brs/canadian/usda01e.pdf>>.

<sup>34</sup> *Ibid.*

<sup>35</sup> *Ibid.*

<sup>36</sup> *Ibid.*

<sup>37</sup> In a literal sense, all living things are “genetically modified” for example creating a hybrid corn by “traditional” methods. See Mark Perry, “From Pasteur to Monsanto: Approached to Patenting Life in Canada in Ysolde Gendreau”, *An Emerging Intellectual Property Paradigm — Perspectives from Canada* (Edward Elgar 2008), online: <[http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=1291344](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1291344)>.

introduce pest or herbicide resistance, but more recently crops with “stacked” traits are being approved.<sup>38</sup>

Hence, in Canada, “Plants with Novel Traits” covers broader types of plants than the term “genetically modified plants” does in Europe or other countries:

For products like wheat and canola developed through mutagenesis, which by the definition of biotechnology in Canada fall under the PNT heading and require regulatory approval, do not require regulatory approval in the United States.<sup>39</sup>

Since PNTs have the potential to affect health (human, plant and animal) and the environment, all PNTs are subject to safety assessments before they can be produced, cultivated or commercialized.<sup>40</sup> The objective here is to protect human/animal health and the environment. Assessments include: an environmental review for field trials (confined research field trials), a second environmental review prior to commercialization (unconfined release of PNTs), a livestock feed safety review, a food safety review, and variety registration (for most field crops).<sup>41</sup>

The *Seeds Act*<sup>42</sup> and the *Seeds Regulations Part V*,<sup>43</sup> regulate confined research field trials and unconfined release of PNTs. The *Plant Protection Act*<sup>44</sup> and the *Plant Protection Regulations*<sup>45</sup> regulate the importation of PNTs. Directive 2000-07, *Directive for the Environmental Release of Plants with Novel Traits Within Confined Research Field Trials in Canada*, provides guidance for the submission of an application for the authorization of a confined research field trial. Directive 94-08, *Assessment Criteria for Determining Environmental Safety of Plants with Novel Traits*, provides guidance for the submission of an application for the authorization of an unconfined release of a PNT. Furthermore, “Scientists working with GMOs, including the development of PNTs, adhere to Canadian Institute for Health Research directives, as well as the codes of practice of their own institutional biosafety committees. These guidelines protect the health and safety of laboratory staff and ensure environmental containment.”<sup>46</sup>

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<sup>38</sup> For example SmartStax corn where eight known traits have been inserted into the plant’s genome in order to give it resistance against root and surface pests, as well as herbicide tolerance. See Mark Perry, “Genetically modified organisms: why we need a transparent system of regulation” *Lawyers Weekly* (4 September 2009) online: <<http://ssrn.com/abstract=1533657>>.

<sup>39</sup> GAIN, *supra* note 32 at 5.

<sup>40</sup> The CFIA: “A PNT is a plant that contains a trait which is both new to the Canadian environment and has the potential to affect the specific use and safety of the plant with respect to the environment and human health,” online: <<http://www.inspection.gc.ca>>.

<sup>41</sup> The CFIA provides a description of the process. Online: <<http://www.inspection.gc.ca/plants/plants-with-novel-traits/general-public/eng/1337380923340/1337384231869>> [CFIA].

<sup>42</sup> *Seeds Act*, RSC 1985, c. S-8.

<sup>43</sup> *Seeds Regulations*, CRC, c. 1400.

<sup>44</sup> *Plant Protection Act*, SC 1990, c. 22.

<sup>45</sup> *Plant Protection Regulations*, SOR/95-212.

<sup>46</sup> Cantley, *supra* note 30 at 66.



The Plant Biosafety Office (PBO) of the Canadian Food Inspection Agency (CFIA) is responsible for regulating the environmental release of PNTs. The PBO works closely with the Biotechnology Environmental Release Assessment unit (BERA), which is responsible for environmental safety assessments of PNTs. Overall, the CFIA is responsible for regulating the importation, environmental release, variety registration, and the use in livestock feeds of PNTs. This authority has been given to the CFIA by the *Plant Protection Act*,<sup>47</sup> *Plant Protection Regulations*,<sup>48</sup> *Seeds Act*<sup>49</sup> and *Seeds Regulations (Part V)*.<sup>50</sup> CFIA responsibilities include approval of unconfined release of PNTs, approval and inspection of confined research field trials of PNTs, assessment of import applications for PNTs, development of domestic regulatory policies related to the environmental release of PNTs, and development of internationally aligned regulatory policies through participation in various international forums.<sup>51</sup> If the PNT has insecticidal expression, the CFIA also works with Health Canada's Pest Management Regulatory Agency (PMRA) in the regulatory reviews. Health Canada is responsible for assessing the (human) health safety of foods, including novel foods, and approving their use in the market.<sup>52</sup> Environment Canada is responsible for administering the *New Substances Notification Regulations*<sup>53</sup> and for performing environmental risk assessments of toxic substances under the *Canadian Environmental Protection Act (CEPA)*, including organisms and micro-organisms that may have been derived through biotechnology.<sup>54</sup>

### III. FIELD TRIALS OF PNTS

In Canada, notification and authorization is needed for the commercialization of PNTs. Consequently, an environmental risk assessment is required for research using confined field trials that are evaluated by government scientists to determine that the trials will not harm the environment. Following this, a more detailed environmental assessment is required for unconfined release into the environment. If the plant or crop is to be used as livestock feed, it must be assessed for safety before it can be used for commercial production. It must also undergo a separate food safety assessment process by Health Canada in cases of human consumption. There are several purposes behind such confined research field trials:

<sup>47</sup> *Supra* note 44.

<sup>48</sup> *Supra* note 45.

<sup>49</sup> *Supra* note 42.

<sup>50</sup> *Supra* note 43.

<sup>51</sup> CFIA, *supra* note 41.

<sup>52</sup> *Food and Drugs Act* (RSC, 1985, c. F-27).

<sup>53</sup> These regulations are made under *Canadian Environmental Protection Act, 1999* (SC 1999, c 33).

<sup>54</sup> See *Canadian Environmental Protection Act, 1999* (SC 1999, c 33), *Seeds Act*, RSC 1985, c. S-8, *Seeds Regulations*, CRC, c. 1400, *Plant Protection Act*, SC 1990, c. 22, *Plant Protection Regulations*, SOR/95-212, and the flowchart "Flow Chart — Regulation of Plants with Novel Traits in Canada", online: <<http://www.inspection.gc.ca/plants/plants-with-novel-traits/general-public/eng/1337380923340/1337384231869>>.

- to give scientists opportunities to study the environmental safety of the plants;
- to give developers an opportunity to evaluate the performance of the plants in the natural environment (instead of a laboratory or greenhouse);
- to provide information that the CFIA requires to complete environmental assessments, livestock feed assessments, and food safety assessments if a developer later submits an application for unconfined release; and
- to generate data that can be used for variety registration.<sup>55</sup>

During an environmental safety assessment, the potential risks of each plant with novel traits are identified on a case-by-case basis, based on science. The process is designed to limit the impact of novel plants on the environment. The CFIA evaluators examine the plant's molecular characteristics. The evaluators determine the new or modified genes in the plant, how they are likely to behave, and if the new plants are likely to cause harm to the environment (noted below). Available peer-reviewed scientific literature and expert advice from the scientific community are also used in the assessment process. If the applicant wants to use material from the field trial in a research feeding study, the PBO of the CFIA will forward the field trial application to the Agency's livestock feed evaluators. The PBO also provides information to the Pest Management Regulatory Agency on issues involving testing novel herbicide tolerance or insect resistance. The PBO also sends non-confidential information to designated provincial governments where trials will take place. Furthermore, the CFIA sends non-confidential information on authorized field trials to the Organization of Economic Co-operation and Development Bio-Track database. After the completion of the confined research field trial, evaluators inform the applicant of their decision. A summary of the assessment is made available to the public, and the plants with novel traits, their seeds, and other plant material harvested from the confined trial will be destroyed.<sup>56</sup>

#### IV. UNCONFINED ENVIRONMENTAL RELEASE OF PNTS

A PNT cannot be authorized for unconfined release without determining its risks to health and the environment. Developers need to submit an application for the unconfined environmental release of a PNT to the PBO. An application for unconfined environmental release of a PNT must address the environmental safety requirements provided by *Directive 94-08, Assessment Criteria for Determining Environmental Safety of Plants with Novel Traits*. In this respect, *Directive 2009-09: Plants with novel traits regulated under Part V of the Seeds Regulations: Guidelines for determining when to notify the CFIA*, also provides criteria and information requirements for the environmental safety assessment of PNTs. A PNT is considered safe to be released into the environment if it does not pose potential

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<sup>55</sup> See CFIA "Confined Research Field Trials for Plants With Novel Traits (PNTs)", online: <<http://www.inspection.gc.ca/plants/plants-with-novel-traits/general-public/factsheets/field-trials/eng/1338138305622/1338138377239>>.

<sup>56</sup> *Canada, Canadian Food Inspection Agency Plant Products Directorate, Directive 94-08: Assessment Criteria for Determining Environmental Safety of Plants with Novel Traits (Ottawa: Plant Biosafety Office, 2000), and discussed by CFIA.*

safety concerns (human, animal, or environmental) *compared to traditionally developed counterparts* used in Canada.

Before these plants are released into the environment, government evaluators assess potential impacts on the environment. Environmental safety assessments of PNTs examine the following possible impacts:

- the potential of the plant to become a weed or to be invasive of natural habitats;
- the potential for gene flow to wild relatives;
- the potential for a plant to become a plant pest;
- the potential impact of a plant or its gene products on non-target species; and
- the potential impact on biodiversity.<sup>57</sup>

Of these five areas of potential impact, some may require further analysis. For example, the potential for insects to develop resistance to a pesticide as a result of releasing certain modified plants into the environment. In such a situation, the applicant may be asked by the CFIA to submit an insect resistance management plan for farmers to put in place. Also, some potential risks can be managed by imposing conditions such as limiting the geographical location for cultivation.

The above-mentioned risk assessment process has been heavily criticised:

The CFIA relies heavily on data and information provided by the biotechnology companies themselves in making its scientific assessment; this data is evaluated by CFIA scientists but not made available for peer-reviewing. The CFIA also relies on the biotechnology companies for post-release monitoring. The public is almost totally excluded from the pre- and post-release processes, and the information made available to it is sketchy.<sup>58</sup>

Variety registration is critical for a seed certification system. In Canada, only authorized PNTs are registered, and the crops that are subject to variety registration are listed under Schedule III of the *Seeds Regulation*. The CFIA Variety Registration Office (VRO) is responsible for registering varieties of PNT crops in Canada. In this area the VRO works closely with the PBO.

Canada's system of registration for newly developed crop varieties ensures that only varieties with proven benefits to producers and consumers are sold. Once approved for use in field trials, varieties are evaluated in regional field trials by whom . . . this is contradicting the above criticism. Plant varieties produced through biotechnology cannot be registered and sold in Canada until authorized for environmental, livestock feed and food safety. For products containing stacked genes, there is a notification system, which may lead to the requirement of an environmental safety assessment.<sup>59</sup>

Once environmental, feed and food safety authorizations are granted, the PNT and feed and food products derived from it can enter the marketplace, but are still subject to the same regulatory scrutiny that applies to all conventional products. Any new information arising about the safety of a PNT

<sup>57</sup> *Ibid.* at s. 6.1.

<sup>58</sup> Glenn, *supra* note 3 at 267.

<sup>59</sup> Cantley, *supra* note 30 at 67.

or its food products must be reported to government regulators who, upon further investigation, may amend or revoke authorization and/or immediately remove the product(s) from the marketplace.<sup>60</sup>

In Canada, at least to date, authorization has not been granted for commercial cultivation for Plant Molecular Farming (PMF); nor is there any commercial PMF, although there have been a number of trials.<sup>61</sup> It is expected that developers will soon seek approval for commercial production of PNTs for molecular farming. Regarding labelling and traceability, there are no specific regulatory requirements for PNTs or for novel foods in Canada. Consumer groups argue that the labelling requirement for PNTs and novel foods supports both a right to choice and a right to be informed. The Canadian government rejected a Bill requiring labelling or disclosure of genetically modified content in February 2011.<sup>62</sup> Similarly, in the United States, although the *Genetically Engineered Food Right-to-Know Act*<sup>63</sup> was tabled in Congress in 1999, it was never enacted. The FAO/WHO Codex Alimentarius Commission (Codex) has also shown interest in labelling GMO products; Codex discussions have recently come to a consensus after two decades.<sup>64</sup>

The Canadian system regulating PNTs is not without criticism, and it has been argued that the Canadian concept brings non-GMO plants within the subject matter of environmental risk assessment and varieties registration, which are not regulated in most other countries (such as European countries and the United States of America). “The concept of PNTs as developed and applied in Canada is time consuming, expensive and an innovation barrier for Canadian plant breeding. It is a threat to the constructive use of plant mutations for crop improvement . . .”<sup>65</sup> However, the regulation of only organisms that have been altered by recombinant DNA techniques seems to be a narrow approach that misses the purpose of food safety — namely to prevent harmful crops being used in agriculture.<sup>66</sup>

## V. CANADIAN LEGISLATIVE FRAMEWORK: ORGANIC PLANTS

Canadian farmers have been growing conventional and organic crops, plants and foods for a long time. While PNTs are costly and time consuming to create

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<sup>60</sup> *Ibid.*

<sup>61</sup> For example, using interleukin derived from tobacco plants to treat Crohn’s disease.

<sup>62</sup> James Bradshaw, “Ottawa rejects stronger export regulations for genetically modified crops”, *The Globe and Mail* (16 February 2011) online: The Globe and Mail <[www.theglobeandmail.com](http://www.theglobeandmail.com)>.

<sup>63</sup> United States, *Genetically Engineered Food Right-to-Know Act*, 106th Congress: 2nd Session, Section 2080 (2000).

<sup>64</sup> The Codex Alimentarius Commission, “Compilation of Codex texts relevant to labelling of food derived from modern biotechnology” (2011) CAC/GL 76-2011 online: <<http://www.codexalimentarius.org/standards/list-of-standards/en/>>.

<sup>65</sup> GG Rowland, “The Effect of Plants with *Novel Traits (PNT) Regulation* on Mutation Breeding in Canada” in QY Shu, ed, *Induced Plant Mutations in the Genomics Era* (Rome: Food and Agriculture Organization of the United Nations, 2009) 423 at 424.

<sup>66</sup> The issue of the safety of plants developed by mutagenesis is outside the scope of this article, but one that an author is considering in *Conventional*, *supra* note 8.

(and mainly it is only large companies that can afford such development), organic farming is affordable to ordinary farmers and is a source of sustainability, continuity and job creation. As in the United States of America, the European Union, Japan, and many other countries, organic crops and food are regulated in Canada. The law requires that organic producers obtain certification in order to market food as organic. Anybody who wants to claim their product as organic must comply with the Canadian laws regarding organic crops. The *Organic Products Regulations 2009*,<sup>67</sup> created under section 32 of the *Canada Agricultural Products Act*,<sup>68</sup> apply to food and feed, including agricultural crops, and also apply to the cultivation of plants.<sup>69</sup> Adherence to the Canadian Organic Standards is mandatory for such products. The Regulations introduced a uniform approach to organic product certification and labelling, and facilitate international market access. They provide specific protection to consumers against deceptive and misleading labelling practices. Section 1 of the *Organic Products Regulations* defines “organic product” as “an agricultural product that has been certified as organic in accordance with these Regulations or that has been certified as organic under section 27.”<sup>70</sup>

Under the *Organic Products Regulations*, the CFIA regulates organic agricultural products in Canada, and the CFIA is responsible for compliance, verification, and enforcement of the regulations, including label inspections in the marketplace and audits of the Conformity Verification Bodies (CVBs). The Canadian Organic Office of CFIA has also prepared an operating manual containing policies and procedures for activities applicable to the Canadian Organic Regime (COR). The Regulations set out the functions of the COR’s two oversight bodies: CVBs and Certification Bodies (CBs). In this context, the CFIA enters into agreements with Conformity Verification Bodies (CVBs). The CVBs are designated to assess, recommend for accreditation, and subsequently monitor CBs. The accredited CBs are responsible for the organic certification of agricultural products and organic product packaging and labelling certification.

The name of the certification body must be on the label. Organic products that contain at least 95 percent organic content can be labeled as “Organic” and feature the “Biologique Canada Organic” logo. This rule applies to both imported and domestic products. However, if any organic product does not meet the required qualification after the issuance of certification, such certification will be cancelled. If somebody wants to place a Canadian Organic label on crops, products or plants, the following substances or techniques, in either the production or handling stages, are forbidden by the Canadian General Standards Board:

- All materials and products produced from genetic engineering;
- Synthetic pesticides, wood preservatives or other pesticides, except as specified in CAN/CGSB-32.31;
- Fertilizer or composted plant and animal material that contains a prohibited substance;

<sup>67</sup> *Organic Products Regulations*, SOR/2009-176 [*OP Regulations*].

<sup>68</sup> *Canada Agricultural Products Act*, RSC 1985, c. 20 (4th Supp).

<sup>69</sup> *OP Regulations*, *supra* note 67 at s. 2.

<sup>70</sup> *Ibid.*

- Sewage sludge used as a soil amendment;
- Synthetic growth regulators;
- Synthetic allopathic veterinary drugs, including antibiotics and parasitocides, except as specified in this standard;
- Synthetic processing substances, aids and ingredients, and food additives and processing aids including sulphates, nitrates and nitrites, except as specified in CAN/CGSB-32.311;
- Ionizing radiation and forms of irradiation on products destined for food; and
- Equipment, packaging materials and storage containers or bins that contain a synthetic fungicide, preservative or fumigant.<sup>71</sup>

Unlike in the European Union, there is no concept of GM-free crops, seeds or products in Canadian legislation. There is a difference between the meaning of the GM-free logo and the meaning of the organic logo. In Canada, the organic logo does not mean it is purely organic or GM free. Such organic crops, plants or seeds may contain genetically modified genes. If the AP of genetically modified plants or seeds on such organic crops, plants or seeds is not more than five percent, the organic logo is allowed.<sup>72</sup> In the European Union, if there is more than 0.9 percent of the AP of genetically modified genes in a product then it is considered genetically modified and will require labelling to that effect. Furthermore, it has to be an approved GM. There is no minimum threshold point for seeds. From the European standard, many Canadian organic crops or products could potentially be considered as GMOs.<sup>73</sup>

AP can affect price and market access for conventional and organic crops. Where AP becomes part of non-GM harvests, farmers may find themselves in breach of their contractual obligations and/or without markets for their goods.<sup>74</sup> The scale of loss can be enormous. In 1999 and 2000, American farmers lost access to almost the entire US\$200 million European Union corn export market due to the contamination of food corn stocks across the United States of America by the Star-Link gene, a modification approved for feed corn only.<sup>75</sup> Also, when StarLink corn, which is also banned in Japan, was found to be mixed with non-GM corn shipments from the United States of America, the result was “trade disruption and considerable political turmoil.”<sup>76</sup> The economic harm caused by GMO contamination was not only limited to farmers who grew organic or conventional analogues

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<sup>71</sup> Canada, Canadian General Standards Board, *Organic Production Systems General Principles and Management Standards* (2006) online: Canadian General Standards Board <<http://www.tpsgc-pwgsc.gc.ca/ongc-cgsb/index-eng.html>>.

<sup>72</sup> *Organic Products Regulations*, 2009 SOR/2009-176 under the *Canada Agricultural Products Act* (RSC, 1985, c. 20 (4th Supp)).

<sup>73</sup> “Report From the Commission to the European Parliament and the Council on the application of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products” Brussels, 11.5.2012 COM(2012) 212 final.

<sup>74</sup> Black & Wishart, *supra* note 17 at para. 10.

<sup>75</sup> *Ibid.* at para. 11; see also Repp, *supra* note 17 at 593.

<sup>76</sup> *Ibid.* See also Ellstrand, *supra* note 17 at 541; Bullock, *supra* note 17 at 83.



of GM crops. In 1999, European Union authorities discovered a small percentage of transgenic pollen in Canadian honey shipments from Western Canada, much of which was produced amongst GM canola fields. The authorities responded by banning Canadian honey from the European Union, seriously damaging a ten-million dollar market.<sup>77</sup>

In response, the Government of Canada initiated negotiations of acceptance for Canadian organic products with key trading partners. It entered into an agreement for the trade of organic products with the United States of America in June 2009 and with the European Union on an organic equivalency arrangement in June 2011. However, the reality is different. Faced with the inevitable and near-permanent AP in their fields with transgenic seeds, many organic and conventional farmers have been left with no option but to sign the license agreements and sow the crops offered by the biotech corporations.<sup>78</sup>

## VI. CANADIAN LEGISLATIVE FRAMEWORK ON AP

While Canada is currently able to harness the benefits of GMOs, the issue of AP of GM genes in non-GM crops/plants has not been addressed by policy or law. AP, through pollen from GM crops for example, is unintended and unavoidable. Similarly, for some crops such as canola, it is very difficult to ensure absolute separation between GM and non-GM seeds when they share the same equipment at any stage in their processing. AP is a complex issue that has direct implications on regulations, marketing approaches, importing and exporting, and health and safety. This issue must be addressed in order to build public confidence in a science-based regulatory regime. There is neither a threshold of AP, nor even a definition, to determine when the presence in products will cause them to be considered as genetically modified crops or plants with novel traits or novel foods. At the third regular meeting of the Food Regulatory Advisory Committee of Health Canada (Consultation on Canada's Domestic Policy Review on Low-Level Presence of GMOs in Imported Crops), on October 25-26, 2011, the Canadian Government recognized that LLP has been an issue since the introduction of GMOs and is increasingly a source of trade disruption internationally. In accordance with the executive summary of the meeting, the Government is assessing three options to manage LLP in food products:

Approach 1: Apply an action level for low-level presence for products imported into Canada;

Approach 2: Apply an interim threshold for low-level presence for products where a data package has been submitted to Canadian authorities; and

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<sup>77</sup> *Ibid.*

<sup>78</sup> *Ibid.* See also Birgit Muller, "Infringing and trespassing plants: Patented seeds at dispute in Canada's courts" (2006) 48 *Focaal European Journal of Anthropology* 83 [Muller].

Approach 3: Apply appropriate case-by-case thresholds for low-level presence in products imported into Canada.<sup>79</sup>

Canada is set to unveil to the world its proposal to permit traces of unapproved genetically modified organisms in imported foods, . . . The federal government's draft plan for managing the low-level presence of GMOs in food and feed products, to be submitted to the World Trade Organization in September, will undergo more consultations in Canada.<sup>80</sup>

At last the Canadian administration is trying to address the issue, although this just covers foods being imported into Canada, although it is a part of the international WTO negotiations. However, this doesn't provide any solutions for crop producers in terms of regulation or liability for AP, nor does it meet face on the larger policy stance on the regulation of PNTs in Canada.

Measures of minimizing AP levels and issues of compensating for the loss of conventional or organic crop status due to the AP require policy direction. Currently, there are no laws or governmental policies to regulate this issue. There are also no provisions to determine compensation for any economic losses that may result from such contamination.

In Europe, when DNA of GM maize was found in honey, the European Court of Justice (ECJ) decided that honey and food supplements containing pollen derived from a GMO are considered foodstuffs produced from GMOs,<sup>81</sup> and cannot be marketed without prior authorization for the sale of the product from which the pollen came.<sup>82</sup> The ECJ set out that the Directive on genetically modified organisms (GMOs)<sup>83</sup> provides that GMOs may be released deliberately into the environment or placed on the market only when prior authorization has been given.<sup>84</sup> It stipulated the regulation on genetically modified food<sup>85</sup> provided that GMOs for food use, foodstuffs containing or consisting of GMOs, or foodstuffs produced from ingredients produced using or containing GMOs must be authorized before

<sup>79</sup> Consultation on Canada's Domestic Policy Review on Low-Level Presence of GMOs in Imported Crops, online: <<http://www.hc-sc.gc.ca/fn-an/consult/frac-ccra/meeting-reunion-2011-10-25-eng.php>>, 16 August 2012.

<sup>80</sup> Sarah Schmidt, "Canada ready to unveil plan to ease trade of genetically modified foods," *The Gazette*, 15 August 2012.

<sup>81</sup> Bablok, *supra* note 25.

<sup>82</sup> *Ibid.* at para. 109.

<sup>83</sup> EC, *Commission 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/EC*, [2001] OJ, L 106 at 1, as amended by EC, *Commission Regulation No 1829/2003 and by Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003*, [2003] OJ, L 268 at 24.

<sup>84</sup> Muller, *supra* note 78 at para. 92.

<sup>85</sup> EC, *Commission Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed*, [2003] OJ, L 268 at 1.

being placed on the market.<sup>86</sup> In Canada, neither the judicial nor legislative branches have addressed such issues. Are plants or crops or food with AP considered GMO crops or food and subject to a risk assessment procedure? There is no answer. The absence of law and policy will create confusion and lack of confidence among consumers, and will have multiple implications on Canadian agricultural products in the domestic and international markets.

In May 2004, the Saskatchewan Court of Queen's Bench, in *Hoffman v. Monsanto Canada Inc.*,<sup>87</sup> dismissed a certification application filed by a group of organic farmers to initiate a class action against Monsanto and Bayer Cropscience for revenue lost due to contamination of their organic canola crops. The plaintiffs were certified organic farmers who wanted certification to sue for financial losses suffered as a result of the introduction of Roundup Ready and Liberty Link Canola.

The dismissal of the class action suit simply means that the case cannot go forward as a class action, but organic farmers could still sue on an individual basis . . . The court's reasoning in this regard suggests that farmers who grow GM crops might find themselves as defendants in a lawsuit filed by neighbors who complain about crop contamination.<sup>88</sup>

It has been noted that in Canada a patent holder has all the benefits of ownership but none of the corresponding obligations.<sup>89</sup>

The Canadian regulatory framework takes what might be described as a hard-edged, market-driven approach to third party economic loss occasioned by GMOs. It has no specific provisions about coexistence, nor does it address the problems of economic and other fallout when cross-pollination or commingling occurs.<sup>90</sup>

Seed purity and identity are also linked to AP, and can also cause trade disruption.<sup>91</sup> As an exporter, Canada cannot ignore the influence of the demands made by its customer countries. Customers' perception of Canada's inability to limit AP may result in the loss of Canadian export markets.

<sup>86</sup> Muller, *supra* note 78 at para. 109.

<sup>87</sup> (2005), 264 Sask. R. 1 (Q.B.); affirmed 2007 SKCA 47; leave to appeal refused 2007 CarswellSask 725 (S.C.C.) [*Hoffman*].

<sup>88</sup> Jodie L Hierlmeier, "Under the microscope: litigation, law reform, and genetically modified crops" (2005) 30:2 L Now 32.

<sup>89</sup> J de Beer, "The Rights and Responsibilities of Biotech Patent Owners" (2007) 40:1 UBCL Rev 343.

<sup>90</sup> Glenn, *supra* note 3 at 256.

<sup>91</sup> As could be seen with the Triffid flax issue, *supra* note 11 et seq. The Canadian Seed Trade Association: "the international trade of seed is threatened by the lack of international standards surrounding the adventitious presence of non-approved genetic events in seed" online: <<http://cdnseed.org/archive/pdfs/press/Position%20on%20Adventitious%20Presence.pdf>>.

## VII. IS AP A PATENT ISSUE?

The Canadian *Patent Act*<sup>92</sup> defines “innovation” as “any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter.”<sup>93</sup> Since the early 1980s, the Canada Patent Office has allowed the patenting of genes. In 2002, the Supreme Court of Canada, in its decision in *Harvard College v. Canada (Commissioner of Patents)*,<sup>94</sup> ruled that genes were patentable subject matter, but higher life forms were not patentable. Canada’s approach of patenting genes is similar to the United States of America and European systems. The European Patent Convention (EPC) defines patentable subject matter as, “. . . any inventions which are susceptible of industrial application, which are new and which involve an inventive step,”<sup>95</sup> and allows gene patenting. In the United States of America, section 101 of the *Patent Act* defines patentable inventions as, “whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.” Section 101 of the *Patent Act* permits the patentability of “compositions of matter.”<sup>96</sup> The United States of America Supreme Court in *Diamond v. Chakrabarty*<sup>97</sup> held that “all compositions of two or more substances and . . . all composite articles, whether they be the results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or solids” are patentable.<sup>98</sup>

In general, a patented gene will be protected by patent law, but such protection has limitations. One of the requirements of patentability is usefulness. When GM plants or crops start to be an AP in non-GM counterparts, a different issue arises. “Concerns about adventitious presence are economic concern: market access, contract specifications, and consumer preferences. The worry is that the mere presence of the transgenic materials decreases the value of the conventional or organic crop, especially in export market.”<sup>99</sup>

In *Monsanto Canada Inc. v. Schmeiser*,<sup>100</sup> the plaintiff held a patent for a species of canola resistant to glyphosphate-based herbicides, specifically Monsanto’s Roundup Ready canola. The defendant, Schmeiser, was a canola farmer who had discovered that Roundup Ready canola had spread to his property from his neighbors. He isolated this crop by using Roundup and stored the seed. The next season he planted the Roundup Ready canola seed. Monsanto sued for patent infringement and Schmeiser alleged that: 1) the patent was not valid as it dealt with a higher life form; and 2) he was not infringing the patent as he did not use Roundup

<sup>92</sup> RSC 1985, c. P-4.

<sup>93</sup> *Ibid.* at s. 2.

<sup>94</sup> 2002 SCC 76, [2002] 4 S.C.R. 45 [*Harvard College*].

<sup>95</sup> *European Patent Convention*, 1973, c. 1 s. 52(1).

<sup>96</sup> 35 USC s. 101 (1952).

<sup>97</sup> 447 U.S. 303 (U.S. Sup. Ct., 1980).

<sup>98</sup> *Ibid.* at paras. 303 and 308.

<sup>99</sup> Kershen, *supra* note 17 at 1.

<sup>100</sup> 2004 SCC 34, [2004] 1 S.C.R. 902 [*Schmeiser*].

on the crop and thus was not making use of the patented trait. In this case in May 2004, the Supreme Court of Canada held the patent was valid because the claims pertained to the gene and cells contained within the higher life form and not the life form itself.<sup>101</sup> The majority also held that the possession of a plant composed of cells containing the patented gene constituted “use” and consequently Schmeiser had infringed the patent by growing the canola without a license from Monsanto.<sup>102</sup> In this case, the dissenting opinion focused on a narrower interpretation of the scope of the patent protection, “. . . the patent’s ‘essential elements’ restrict the scope of its protection to the gene and cell in isolation and does not extend protection over the plant and its offspring.”<sup>103</sup> The minority opinion felt that, “the plants containing the patented gene can have no stand-by value or utility as my colleagues allege. To conclude otherwise would, in effect, confer patent protection on the plant.”<sup>104</sup>

However, in *Schmeiser*, the court made it clear that they were not referring to the accidental growing of the plant by adventitious spreading, but rather the deliberate cultivation (95% of Schmeiser’s crops were Round-up Ready).<sup>105</sup> The Supreme Court noted it was up to Parliament to address the issue of treating genetically modified plants differently from other patented subject matter.<sup>106</sup> The Saskatchewan Court of Queen’s Bench, in *Hoffman*, stated:

After the decision in *Schmeiser*, the Canadian Biotechnology Advisory Committee recommended that the *Patent Act* be amended . . . to protect innocent farmers from claims of patent infringement from the accidental or spontaneous spreading (by wind or cross-pollination) of GM products. The Committee also suggested the need to address liability and damages caused by products of biotechnology, whether or not they have been patented. Canada’s regulatory system currently does not address issues of liability or damages with respect to the release of GM crops or other GM organisms into the environment.<sup>107</sup>

Although Germany gives a similar kind of patent protection to patented genes as Canada, Germany has also passed the *Genetic Engineering Act*,<sup>108</sup> which guarantees the freedom of choice between transgenic, conventional and organic crops. If GMO contamination is found on neighboring conventional or organic crops, the law requires the GM farmer compensate any loss to conventional or organic farmers. The law also requires the GM cultivator to maintain certain measures, such as isolation distance from other crops. The Supreme Court of Germany has upheld the

<sup>101</sup> *Ibid.* at paras. 17–24.

<sup>102</sup> *Ibid.* at para. 58.

<sup>103</sup> Nathan Fan, “Case Comment: Importing Cefetra’s Soy Meal Case into Canada: How Well will Patents for Genetically Modified Plant Genes and Cells Found in a Residual State Fare under Canada’s Patent Laws?” (2010) 22:3 IPJ 333 at 341.

<sup>104</sup> Kershen, *supra* note 17 at para. 160.

<sup>105</sup> Kershen, *ibid.* at para. 2.

<sup>106</sup> Kershen, *ibid.* at para. 95.

<sup>107</sup> *Hoffman*, *supra* note 87.

<sup>108</sup>  *Gentechnikgesetz*, BGB1 1990, 1 G 2121-60-1, 1080, as amended by BGB1 2010, 1 G, 1934.

constitutionality of the *Genetic Engineering Act*.<sup>109</sup> In 2005, the German Federal State of Saxony-Anhalt had brought an action against the *Genetic Engineering Act* before the Federal Constitutional Court of Germany. On 25 November 2010, the Federal Constitutional Court of Germany dismissed the action and upheld the restrictive provisions for the cultivation of GM plants and liability. This law is also known as the Coexistence Law. Sixteen European countries including France,<sup>110</sup> Belgium,<sup>111</sup> the Netherlands,<sup>112</sup> and others, have a similar “coexistence law,” guaranteeing freedom of choice and provisions of compensation to non-GM farmers in case of AP of GM crops. These types of laws provide opportunities for the coexistence between transgenic, conventional and organic farmers, and a requirement of standards for GM farmers to ensure a minimal impact of AP. These European countries have also provided patent protection to genes and remedies in case of infringement. This example clearly demonstrates that the issue raised by the AP of GMOs on conventional or organic crops is different than the issue of gene patent protection.

In Canada, 80% of the 6 million acres of canola grown are planted in GM canola. The propensity for genes to spread, in other words AP, is at the heart of the problem of coexistence between transgenic, organic and conventional crops. The Canadian courts in both *Schmeiser* and *Hoffman* did not find it necessary to address the root of the problem, but rather took a traditional perspective which can be seen as strengthening the position of biotechnology companies: they can enforce their patents but not have liability for their use.<sup>113</sup> In some sense, the horse is pretty much through the open barn door, and the concern is that if the AP issue is not addressed immediately, the organic and conventional (traditional) farming industry will simply be unable to continue.<sup>114</sup> In Canada, preliminary policy exploration of AP has underrated the seriousness of the phenomenon.<sup>115</sup> It does not recognize the

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<sup>109</sup> German Federal Constitutional Court, Press Release, 108/2010, “Leitsätze : zum Urteil des Ersten Senats vom 24. November 2010” (24 November 2010) online: Das Bundesverfassungsgericht <[http://www.bundesverfassungsgericht.de/entscheidungen/fs20101124\\_1bvf000205.html](http://www.bundesverfassungsgericht.de/entscheidungen/fs20101124_1bvf000205.html)>.

<sup>110</sup> “*Prévention des pollutions et des risques*” *Loi 2008-595 du 25 juin 2008 relative aux organismes génétiquement modifiés*, JO, 26 June 2008. See also *Code de l’Environnement* art L531-1ff.

<sup>111</sup> *Arrêté royal du 21 février 2005 réglementant la dissémination volontaire dans l’environnement ainsi que la mise sur le marché d’organismes génétiquement modifiés ou de produits en contenant*, 24 February 2005, (2005) Belgian Official Journal 7129–7165. See also Luc Lavrysen, “Belgian Report”, (Ghent: Ghent University 2006).

<sup>112</sup> *Coexistence Decree*, 2005.

<sup>113</sup> Glenn, *supra* note 3 at 254 and 257.

<sup>114</sup> M Lee & R Burrell, “Liability for the Escape of GM Seeds: Pursuing the ‘Victim’?” (2002) 65 Mod L Rev 517 at 518.

<sup>115</sup> M Fulton, H Furtan, D Gosnell, R Gray, J Hobbs, J Holzman, B Kerr, J McNaughton, J Stevens & D Stovin (eds.), “Transforming Agriculture: The Benefits and Costs of Genetically Modified Crops,” Prepared for the Canadian Biotechnology Advisory Committee, Project Steering Committee on the Regulation of Genetically Modified Foods, March 2001, 98–104.



threats posed by GMOs for traditional agriculture and conventionally-bred crops.<sup>116</sup> A loss of GM-free status caused by AP is a reality even though the demand for organic foods has been rising and organic farming is a steadily growing industry in industrialized countries.<sup>117</sup>

### VIII. CONCLUSION

AP of GM genes in non-GM crops is now a reality. In short this means that *any* foodstuff that contains product that somewhere in the world is produced through GM technologies will have AP genes in them, if not now, then in the future. The effect is that even those consumers in countries that do not allow the production of GM crops will likely end up consuming GM products; if LLP is adopted globally, they are unlikely to be aware of this new reality. One perspective of AP genes is that they not only infiltrate and commingle with conventional and organic crops, but they reduce, at least from the perspective of some of those that are growing them, the “purity” of conventional and organic crops. Consequently, conventional and organic crops face problems of market access and economic losses. Adoption of LLP will change the meaning of “GM-Free” to become shorthand for “*GM-Free (apart from some small amount that your government thinks is of such little effect that you can ignore it)*”. There may also be additional negative aspects of AP of GM genes, such as herbicide resistant weeds, which is outside the discussion here, but is one that will become more important in the next decade.<sup>118</sup> There are serious questions regarding the survival of coexistence between GM crops, conventional crops and organic crops in Canada. How can we address the problems brought by the AP of GM genes? There are neither statutes nor regulations in Canada that directly address this issue.

One approach would be to attempt to salvage some market space for non-AP in conventional and organic crops:

- The issue of coexistence between crop types should be recognized as a unique problem brought by agricultural biotechnology.
- A maximum AP level for conventional or organic crops (perhaps with regard to export markets) should be adopted;
- There should be mandatory provisions for identification of PNTs and novel foods in the Canadian market;
- Standards for “negative labeling,” for both organic plants and seeds should be broadly adopted;
- There should be evaluation of PNTs to allow for coexistence between genetically modified, conventional and organic crops, and minimize the level of AP;

<sup>116</sup> Oguamanam, *supra* note 1 at 269.

<sup>117</sup> *Ibid.* at 268.

<sup>118</sup> For example, twenty-three glycine resistant weed species have been identified to date. Online: <<http://www.weedscience.org/Summary/UspeciesMOA.asp?lstMOAID=12>>, and the ongoing survey HeapIM, “International survey of herbicide resistant weeds” Weed Science Society of America (2012). Online: <<http://www.weedscience.org/In.asp>>.

- The question of economic loss for farmers of conventional or organic crops who suffer due to AP must be addressed; and
- Jurisdictional issues between federal and provincial governments in respect of PNTs and coexistence should be settled, as well as the new roles of the PBO and CFIA.

To give effect to these recommendations, the *Plant Protection Act of 1990* and *Plant Protection Regulations*, *Seeds Act of 1985* and *Seed Regulations (Part V)*, section 32 of the *Canadian Agricultural Products Act of 1985* and *Organic Products Regulations of 2009*, Directive 2000-07, Directive 94-08 and Directive 2009-09 would need to be amended at the same time.

The truth is that as a “global society” we now have no choice but to accept AP in our food and feedstuff. In relation to some small trials, such as the Triffid flax, it may be possible to “flush the system” of undesirable genes:

It is not physically possible to eliminate GM flax from the existing breeder seed lots. Consequently, the CDC has developed and applied a protocol to reconstitute a number of flax varieties and re-release them as “Triffid-free” Breeder Seed. This new breeder seed source is one of our best opportunities to ensure the Canadian flax crop is free of Triffid seed. It is the intent of the Canadian flax industry to flush the system of existing CDC seed stocks by the fall of 2013 so that the portion of the commercial flax crop sown using the reconstituted CDC flax varieties can be planted from this new seed source as early as 2014.<sup>119</sup>

Whether this will happen remains to be seen, but even if this is a possible solution for the Triffid flax AP this is not a viable solution for other GM crops that are still in production. Technology may come to the rescue, with pollen free or male sterility being engineered with the other traits. Public acceptance of these technological solutions has not been great in the past, for example the so-called “terminator” technologies.<sup>120</sup>

International bodies are mobilising as they see this as being an issue that needs addressing soon. For example, the OECD’s Working Group on Harmonisation of Regulatory Oversight in Biotechnology is working on the issue of LLP, and “considers it a key issue in the context of environmental risk assessment.”<sup>121</sup> However, in the current situation, Canadian agricultural products carry both uncertainties and confusion in both the international and domestic markets. Internationally, there are considerable markets for conventional and organic crops/products, but the current uncertainty brings no predictability of market acceptance, and is leading to a crisis, leaving Canadian agricultural producers as the victims. AP is a relatively novel legal issue created by biotechnology that has not been addressed by traditional liability or tort provisions in Canada. Because of its unique nature, it requires separate legislation, as seen by the European precedent in the form of a Coexistence Law. It

<sup>119</sup> Helen M Booker & Eric G Lamb “Quantification of Low-level GM Seed Presence in Canadian Commercial Flax Stocks” *AgBioForum*, 15(1): 31–35. ©2012.

<sup>120</sup> See e.g. Ehsan Masood “Monsanto set to back down over ‘terminator’ gene?” *Nature* 396, 503 (10 December 1998).

<sup>121</sup> OECD “Biotechnology Update: Internal Co-ordination Group for Biotechnology newsletter No 23 (8 March 2012).

is a time to both analyze the Canadian stance on such issues, and adopt some form of a Coexistence Law to clarify the legal coexistence between transgenic, conventional and organic crops, to establish measures for minimizing adventitious presence, and to address the potential liability and damages due to the use of products based on genetically modified crops.<sup>122</sup>

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<sup>122</sup> The issue continues to be highly contentious, the latest report in the Washington Post Business 30th May 2013 “Japan suspends wheat imports from Pacific Northwest after modified wheat discovered in Oregon,” online: <[http://www.washingtonpost.com/business/usda-says-unapproved-genetically-engineered-wheat-discovered-in-oregon-field/2013/05/30/2975da22-c902-11e2-9cd9-3b9a22a4000a\\_story.html](http://www.washingtonpost.com/business/usda-says-unapproved-genetically-engineered-wheat-discovered-in-oregon-field/2013/05/30/2975da22-c902-11e2-9cd9-3b9a22a4000a_story.html)>.