FOOD FOR THOUGHT: IMPROVING THE CANADIAN GENETICALLY MODIFIED FOOD SAFETY ASSESSMENT PROCESS BY INTEGRATING THE PRECAUTIONARY PRINCIPLE AS A GUIDING FRAMEWORK

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The author assesses the ability of the precautionary principle to serve as the basis for regulatory reform in the Canadian genetically modified (GM) food safety assessment process. Given the prevalence of GM foods in the commercial market, Canada should follow the guiding framework of the precautionary principle to prevent potential harm to human health and the environment. The author examines the transparency and impartiality challenges in the Canadian GM food regulatory regime and presents the precautionary principle as a framework that Canada should follow, as required by its international commitments. The regulatory framework and governance structure for the GM food safety assessment process is analyzed to show that the Canadian regulatory regime governing genetically modified organisms hampers the effectiveness of the precautionary principle to serve as the basis for regulatory reform in the Canadian agricultural biotechnology sector, as Health Canada appears to interpret the precautionary principle to respond to the needs of the biotechnology industry. The author subsequently suggests that Canada's regulatory regime for GM foods could impact its ability to trade agricultural and agri-food products with the EU and Canada needs to further integrate the precautionary principle into its GM food regulatory framework to capitalize on the potential agricultural trade opportunities.

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Recommendations include regulatory reform in the GM food safety assessment process to improve Canada-EU agricultural trade relations, creating a distinct regulatory regime for GM foods and re-working governance structures to establish an independent regulatory body with a mandate to ensure access to information, procedural transparency, and impartiality. The author proposes public review to address consumer concerns about the potential impacts of GM foods on health and the environment. Finally, mandatory labeling of GM foods and a public list of GM foods pending approval with a public comment period to address consumer concerns should be introduced to align the Canadian GM food regulatory regime with the guiding framework of the precautionary principle.

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I. INTRODUCTION

Independent scientific studies showing accelerated aging, obesity, major organ diseases, cancerous tumors, and increased death rates on mammals fed with genetically modified organisms ("GMOs") have become the cause of increasing public speculation.[1] Some may argue that the regulatory approval by the Canadian government to authorize the introduction of 381 GMOs into the commercial market to date, including 271 genetically modified ("GM") foods or food types and 110 types of GM animal feed,[2] has been influenced by the Canadian tendency to perceive GMOs as a miracle response to global famine.[3] Since GM foods are commercialized without mandatory labeling requirements of GM food ingredients in the Canadian regulatory system, GM foods form a regular part of the daily diet for many unaware Canadians. The prolific use of GM foods in the last two decades has become the source of increasing public concern on long-term impacts on health and the environment, consumer choice,[4] as well as transparency and impartiality of the domestic regulatory regime for GMOs, particularly GM food safety assessment policies.[5]

The author assesses the ability of the precautionary principle—a policy-making framework that supports precautionary action to prevent potential harm to the environment and

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[1] Joël Spiroux de Vendômois et al., "A Comparison of the Effects of Three GM Corn Varieties on Mammalian Health," International Journal of Biological Sciences 5, no. 7 (2009): 706; Irina Ermakova, "Genetically modified soy affects posterity: Results of Russian scientists' studies," Regnum (October 12, 2005), http://publiceyeonscience.ch/resources/genetically_modified_soy_ru.pdf; Gilles-Eric Séralini et al., "Republished study: long-term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize," Environmental Sciences Europe 26, no.1 (2014): 14; Gottfried Glöckner and Gilles-Eric Séralini, "Pathology reports on the first cows fed with Bt176 maize (1997-2002)," Scholarly Journal of Agricultural Science 6, no.1 (2016): 1; L. Vecchio et al., "Ultrastructural Analysis of Testes from Mice Fed on Genetically Modified Soybean," European Journal of Histochemistry 48, no. 4 (2004): 449.

[2] Health Canada (HC), "Table of Novel Food Decisions," http://www.hc-sc.gc.ca/fn-an/gmf-agm/appro/index-eng.php; Canadian Food Inspection Agency, "Decision Documents—Determination of Environmental and Livestock Feed Safety," http://www.inspection.gc.ca/plants/plants-with-novel-traits/ approved-under-review/decision-documents/eng/1303704378026/1303704484236.

[3] Norman E. Borlaug, "Ending World Hunger. The Promise of Biotechnology and the Threat of Antiscience Zealotry," *Plant Physiology* 124, no. 2 (2000): 487.

[4] Behrokh Mohajer Maghari and Ali M. Ardekani, "Genetically Modified Foods and Social Concerns," *Avicenna Journal of Medical Biotechnology* 3, no. 3 (2011): 109.

[5] Royal Society of Canada (RSC), "Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada," 16, https://rsc-src.ca/sites/default/files/pdf/GMreportEN.pdf.

human health in the absence of "scientific certainty" of such harm for new technologies[6]—to serve as the basis for regulatory reform in the Canadian agricultural biotechnology framework. Particularly, Canadian GM food safety assessment process should follow the guiding framework of the precautionary principle to prevent potential harm to human health and the environment given the prevalence of GM foods in the Canadian commercial market.[7] The main argument is that despite judicial and legislative recognition, the Canadian regulatory framework governing the Canadian GM food safety assessment process hinders the effectiveness of the precautionary principle to serve as the guiding framework in agricultural biotechnology regulations governing GM food safety assessments.

Examining the precautionary principle and the GM food regulations is important within the current context. The recently concluded five-year negotiations of the Comprehensive Economic and Trade Agreement (CETA) between Canada and the European Union (EU) do not directly address food safety regulations, nor restrict future GMO rulemaking or decision processes in either jurisdiction.[8] However, the EU has historically opposed GM foods through trade embargoes, 'zero tolerance' policies and mandatory GM food labeling.[9] The distinct approaches of Canada and the EU toward GM foods have been marked by World Trade Organization (WTO) disputes in the agricultural sector.[10] As a result, the existing domestic regulatory regime governing GMOs could affect Canada's ability to trade agricultural and food products with the EU under the CETA, therefore examining the potential of the precautionary principle in the Canadian GM food safety assessment process may enhance Canada-EU trade. Additionally, examining the function of the precautionary principle in domestic GM food

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[6] Discussed in Section III—Precautionary Principle as a Means of Managing Technological Risk. The precautionary principle has been recognized by the Supreme Court of Canada in *114957 Canada Ltée (Spraytech, Société d'arrosage) v. Hudson (Town)*, [2001] 2 S.C.R. 241, 2001 SCC 40: "In order to achieve sustainable development, policies must be based on the precautionary principle. Environmental measures must anticipate, prevent and attack the causes of environmental degradation. Where there are threats of serious or irreversible damage, lack of full scientific certainty should not be used as a reason for postponing measures to prevent environmental degradation."

[7] Discussed in Section I.A.— Context of the Canadian GM Food Regulatory Framework.

[8] European Commission (EC), "EU-Canada Comprehensive Economic and Trade Agreement (CETA)," http://ec.europa.eu/trade/policy/in-focus/ceta.

[9] See World Trade Organization (WTO), "Dispute Settlement: Dispute DS291,"https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds291_e.htm; WTO, "Reports of the Panel: European Communities—Measures Affecting the Approval and Marketing of Biotech Products (DS291, DS292 and DS293," https://www.wto.org/english/news_e/news06_e/291r_e.htm; Sylvia P. Onusic, "The Current Status of GMO's in Europe," *Farm-To-Consumer Legal Defense Fund* (September 19, 2012), http://www.farmtoconsumer.org/news_wp/?p=1752.

[10] The beef hormone dispute was a leading agricultural dispute for the WTO, see William A. Kerr and Jill E. Hobbs, "Consumers, Cows and Carousels: Why the Dispute over Beef Hormones is Far More Important than its Commercial Value" in *The WTO and the Regulation of International Trade*, ed. Nicholas Perdikis and Robert Read (New York: Edward Elgar Publishing, 2005): 191-214.

regulations creates a template to apply the framework to future agricultural biotechnology innovations.[11] The author uses the 2001 Royal Society of Canada Report on the Safety of Food Biotechnology as the foundation to examine Canada's approach toward applying the precautionary principle to its GM food regulatory framework in light of its international commitments. A comparative perspective of the Canadian and EU implementation of precaution in their respective regulatory frameworks governing GM food safety assessment is used to support the main argument.

The author first examines the transparency and impartiality challenges in the domestic GM food regulatory regime. Subsequently, the precautionary principle is presented as a guiding framework that Canada should follow to support public safety, as required by its international commitments, including the Rio Declaration, Convention on Biological Diversity, and Convention on the Law of the Sea.[12] Finally, the author provides an analysis of the regulatory framework and governance structure for the GM food safety assessment process to show that Health Canada appears to interpret the precautionary principle to suit the needs of the biotechnology corporations, in particular by allowing industry experts to evaluate the safety of GM foods, which may lead to conflicts of interests. The author subsequently suggests that Canada's regulatory regime for GM foods could impact its ability to trade agricultural and agri-food products with the EU under the CETA and considers the EU's approach to GM food regulation, as well as examines the differences between the approaches in Canada and the EU. Specifically, the author considers the distinct perspectives of Canada and the EU on an essential factor in the GM food approval process that acutely impacts bilateral trade in the agricultural sector—'substantial equivalence' between GM and conventional foods—and concludes that the existing Canadian regulatory framework hampers the ability of the precautionary principle to improve Canada-EU agricultural trade relations. Therefore, Canada needs to further integrate the precautionary principle into its GM food regulatory framework to capitalize on potential agricultural trade opportunities with the EU. Recommendations include regulatory reform in the Canadian agricultural biotechnology sector, primarily the GM food safety assessment process, in order to improve the Canada-EU agricultural trade relations. These recommendations emphasize

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[11] HC, "Food Directorate Interim Policy on Foods from Cloned Animals," http://www.hc-sc.gc.ca/fn-an/legislation/pol/pol-cloned_animal-clones_animaux-eng.php; see also HC, "Comments on the United States Food and Drugs Administration's Center for Veterinary Medicine's 'Animal Cloning: A Draft Risk Assessment'," http://www.hc-sc.gc.ca/fn-an/gmf-agm/anim_clon_lett-eng.php.

[12] United Nations (UN), "Rio Declaration on Environment and Development," 14 June 1992, A/CONF151/26 (Vol I): 15; UN, "Convention on Biological Diversity," 5 June 1992, 1760 UNTS 79: Preamble; UN, "Convention on the Law of the Sea," 10 December 1982, 1833 UNTS 3: 194, 202.

the need to create a distinct regulatory regime for GM foods and re-work governance structures to establish an independent regulatory body with a mandate to ensure access to information, as well as procedural transparency and impartiality. The author also proposes moving away from 'substantial equivalence' to a 'comparative food safety assessment' in the GM food authorization process with normative standards based on scientific evidence, as well as public review to address consumer concerns about the potential impacts of GM foods on health and the environment. Finally, recommendations from the Royal Society Report, particularly mandatory labeling of GM foods, should be implemented to align the Canadian GM food regulatory regime with the guiding framework of the precautionary principle.

A. CONTEXT OF THE CANADIAN GM FOOD REGULATORY FRAMEWORK

Integrating the precautionary principle in the Canadian GM food regulations is especially important, as genetic engineering has become increasingly prevalent in the Canadian food market despite controversy on the potential health and environmental risks of GM foods.[13] As one of the first countries to grow GM crops on a large scale,[14] and release derivatives from main GM crops into the majority of unlabeled processed foods in its supermarkets,[15] Canada has become the third largest GMO producer in the world,[16] with over 140 agro-bio companies that produce GM crops or derived products.[17] Since embracing GM corn in 1994, Canada has commercialized 381 GMOs, including 271 GM foods or food types and 110 types of animal feed, including: fast-growing salmon, non-browning apples, delayed-ripening tomatoes, omega 3-enhanced pork, virus-resistant potatoes and papayas, juices with fish oil, eggs with lutein, and drought-tolerant corn.[18] Canadian farmers cultivate 11 million hectares of GM crops, including canola, corn, soybeans and sugar beets, and Canada ranks fifth in the world in terms of hectares

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[13] Jeffrey M. Smith, *Genetic Roulette: The Documented Health Risks of Genetically Engineered Foods* (Fairfield: Yes! Books, 2007): 257-260.

[14] Clive James, "Brief 46–Global Status of Commercialized Biotech/GM Crops: 2013," *International Service for the Acquisition of Agri-Biotech Applications*, 89-90, http://www.isaaa.org/resources/publications/briefs/46/download/isaaa-brief-46-2013.pdf.

[15] Derivatives from main GM crops are found in over 70% of foods in the supermarket, principally processed foods in the form of protein or traces, Smith, S*eeds of Deception: Exposing Industry and Government Lies about the Safety of the Genetically Engineered Foods You're Eating* (Fairfield: Yes! Books, 2003): 38, 236-242, 267-268; Smith, *Genetic Roulette: The Documented Health Risks of Genetically Engineered Foods*, 257-260; Non-GMO Project, "What is GMO," http://www.nongmoproject.org/learn-more/what-is-gmo.

[16] Environment Canada, "Genetically Modified Organisms," http://www.ec.gc.ca/inre-nwri/default.asp?lang=En&n=E8A9C49D-1.

[17] BIOTECanada, Member Listing, 2016, http://www.biotech.ca/about/member-listings.

[18] See HC, "Table of Novel Food Decisions," note 2.

planted with biotech crops.[19] GM crops and the use of biotechnology in agriculture account for almost $2.2 million of the Canadian economy and agricultural biotechnology represents almost 25% of total national revenue in the biotech sector.[20] Furthermore, the Canadian government is more proactive than most in increasing the prominence of GM foods by approving "stacked traits": up to three GM traits in one crop,[21] though GM foods with up to eight GM traits have been conditionally approved for release into the Canadian market.[22] The 2015 *Global Commercialization of Biotech Crops and Biotech Crop* report developed by the International Service for the Acquisition of Agri-biotech Applications, an industry trade group, indicates that Canada is among 28 countries that grow GM crops on a record high 444 million acres of land worldwide.[23] The Global Area of Biotech Crops Chart shows that worldwide GMO farming has generally been on an upward trend since the introduction of GM foods in 1996:[24]

[19]Clive James, "Brief 51: 20th Anniversary (1996 to 2015) of the Global Commercialization of Biotech Crops and Biotech Crop Highlights in 2015," *International Service for the Acquisition of Agri-Biotech Applications*, Executive Summary, http://www.isaaa.org/resources/publications/briefs/51/executivesummary/default.asp.

[20] Centre for the Study of Living Standards, *Measuring the Contribution of the Biotechnology Industry to the Canadian Economy* (Ottawa: CSLL, 2011): 10, 36 respectively, http://www.csls.ca/reports/csls2011-18.pdf; see also William Pellerin and D. Wayne Taylor, "Measuring the biobased economy: A Canadian perspective," *Industrial Biotechnology* 4, no. 4 (2008): 363.

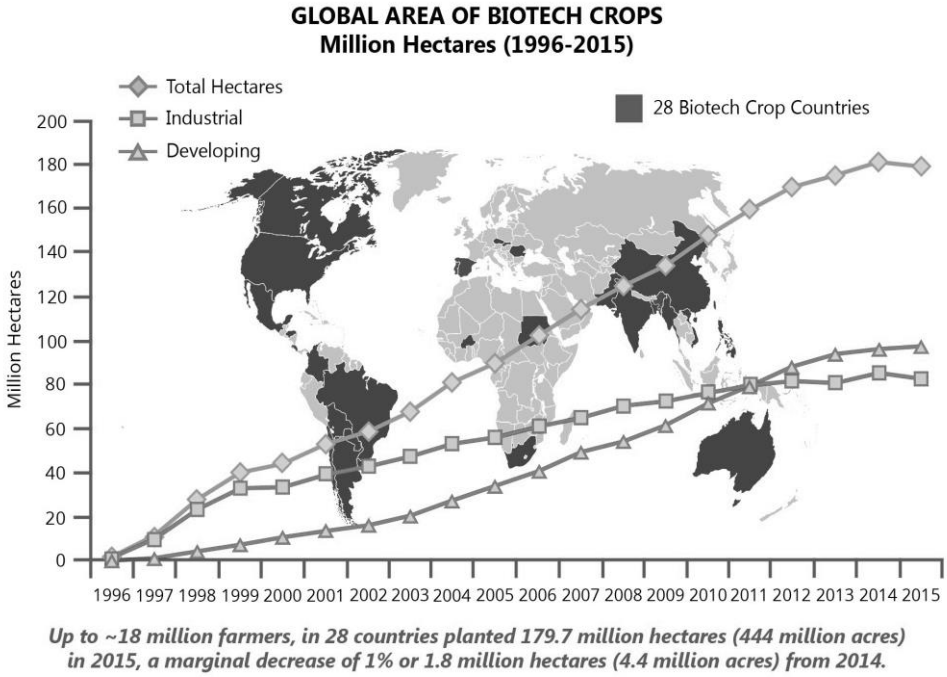
[21] USDA Foreign Agricultural Service, "Canada Agricultural Biotechnology Annual–2015," (2015): 1, http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Agricultural%20Biotechnology%20Annual_Ottawa_Canada_7-13-2015.pdf. The Canadian Food Safety Inspection Agency lists 29 stacked GM corn varieties that may be on the commercial market, Canadian Food Inspection Agency, "Regulating the Environmental Release of Stacked Plant Products in Canada," http://www.inspection.gc.ca/plants/plants-with-novel-traits/approved-under-review/stacked-traits/eng/1337653008661/1337653513037?.

[22] Canadian Food Safety Agency has conditionally approved 'SmartStax' GM corn, which produced six different insecticidal toxins and is tolerant to two herbicides, Canadian Food Inspection Agency, "Archived–CFIA authorization of SmartStax™ Corn," http://news.gc.ca/web/article-en.do?m=%2Findex&nid=469209.

[23] James, "Brief 51–20th Anniversary (1996 to 2015) of the Global Commercialization of Biotech Crops and Biotech Crop Highlights in 2015," note 19.

[24] Ibid., PPT Slides and Tables, 6, http://www.isaaa.org/resources/publications/briefs/51/pptslides/default.asp.

FIGURE 1 – GLOBAL AREA OF BIOTECH CROPS (1996-2015)



Source: International Service for the Acquisition of Agri-Biotech Applications, *Brief 51–20th Anniversary (1996 to 2015) of the Global Commercialization of Biotech Crops and Biotech Crop Highlights in 2015*

Additionally, Canada remains among the majority of countries worldwide that have relatively permissive GM food regulations and trade agreements in comparison with the EU,[25] which has integrated the most precautionary approach in GM food regulations.

II. CHALLENGES IN THE CANADIAN GM FOOD REGULATORY REGIME

[25] Worldwide regulatory frameworks on the cultivation and sale of GMOs and GM foods vary between the supportive GMO regulatory system in Canada and the United States and the restrictive GMO legal regime in the EU. The regulatory frameworks in Argentina, Brazil, Egypt and China support GMO development in contrast to the GMO regulatory frameworks in England and Wales, France, Germany, New Zealand, Netherlands, Norway, Sweden, Italy, South Korea and South Africa. Belgium, Japan, Mexico, Russian Federation seem to have intermediate level of GMO regulatory restrictions, while Israel and Lebanon continue to develop a regulatory framework, see The Law Library of Congress, Global Research Center, "Restrictions on Genetically Modified Organisms," https://www.loc.gov/law/help/restrictions-on-gmos/restrictions-on-gmos.pdf. The transboundary actions of GMOs have been addressed by two international Protocols: UN, "Cartagena Protocol on the Prevention of Biotechnological Risks," 29 January 2000; UN, Doc.: UNEP/CBD/BS/COP-MOP/5/17 and UN, "Nagoya - Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety," 15 October 2010, under the "Convention on Biological Diversity," note 12.

Despite the current proliferation of GM foods in the Canadian biotechnology sector, the federal government was originally reluctant to embrace agricultural biotechnology in the mid-1990s. In response to a request by Health Canada, Environment Canada, and the Canadian Food Inspection Agency (CFIA), the Royal Society of Canada published the 2001 report entitled *Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada* ("Royal Society Report").[26] The conclusion of this investigation report authored by a panel of Canadian expert academics, researchers, and practitioners was a "broad agreement" to embrace the precautionary principle in GM food regulations.[27] Specifically, the expert panel stated that "because the [precautionary] principle has become deeply embedded in the many international agreements and protocols to which the Canadian government is a party..., it is appropriate that Canadian biotechnology regulatory policy reflect the basic sentiments and spirit of the principle."[28] Although the Royal Society Report recommended implementing a precautionary approach in the regulation of agricultural biotechnology regulations, most recommendations in the Royal Society Report relating to the precautionary principle remain unimplemented.

In 2007, the Polaris Institute—a nonprofit organization that aims to challenge the influence of corporations on public policy[29]—assessed government progress on implementing the recommendations from the Royal Society Report to determine that only one out of 58 objectives had been fully achieved: concurrent approval of both GM food and animal feed crops to prevent contamination of the human food supply.[30] The follow-up report ("Polaris Report") concluded that "it is time for the Government to finally legislate mandatory labeling for all GM foods," since "important holes still exist in the regulation of GMOs and [since] there has been no public debate, consumers must be given the opportunity to avoid the consumption of GM foods."[31] Despite the release of the Polaris Report, the Canadian government has not followed the guiding framework of the precautionary principle in the GM food safety assessment process. The challenges in the domestic regulatory regime for GM foods remain as follows:[32]

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[26] RSC, "Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada," 6, note 5.
[27] Ibid., 4.
[28] Ibid., 225.
[29] The Polaris Institute, "Polaris Institute," http://www.polarisinstitute.org/about_polaris_institute.
[30] Peter Andrée and Lucy Sharratt, "Genetically Modified Organisms and Precaution: Is the Canadian Government Implementing the Royal Society of Canada's Recommendations?" (Ottawa: The Polaris Institute, 2007): ii.
[31] Ibid.
[32] Ibid., iii-vii.

- No independent, arms-length, peer reviews of regulatory decisions to permit unconfined release.
- No public availability of nutritional data for GM food decisions and experimental data for GM crop regulatory decisions.
- No government acknowledgement of the inherent biases in a regulatory approach based on the concept of "substantial equivalence."
- No institutionalized precautionary approach to food safety and environmental protection in GMO regulatory decisions.
- No assessment process for GM animals, resulting in inadvertent release of GM animals into the food chain following experiments and accidents.
- No comprehensive environmental assessments.
- No clear policy to restrict GM fish from land-based facilities.
- No mandatory alternatives to antibiotic-resistance marker genes.
- No comprehensive, national research program on the long-term effects of GMOs in food and the environment.
- No action to examine the ongoing domination of the public research agenda by commercial interests.
- No whole food testing as part of the safety evaluation of GM foods.
- No action to address potential GM plant/microbe/animal interactions, though these interactions could result in higher levels of toxins in animal feed.
- No action to systematically monitor insect resistance to GM plants that are toxic to insect pests, nor action to ensure compliance with existing insect resistance monitoring schemes.
- No government action to support agricultural genetic diversity.
- No conservation despite significant civil society input.
- No new support for research of agro-ecosystems and adjacent bio-systems.
- No tests to detect the allergic potential of GM proteins not previously identified as allergens and no long-term surveillance test.
- Impossibility to implement surveillance strategies as researchers cannot distinguish between GM and non-GM food consumers, due to the lack of GMO labeling.

Both the Royal Society Report and the Polaris Report emphasize the continuing deficiencies in the Canadian regulatory regime governing GM foods, as well as the need to

embrace the precautionary principle as a guiding framework in GM food regulations to support public safety.

Another challenge in the domestic regulatory regime for GMOs is the public controversy on the potential risks of producing and consuming GM foods.[33] The impact of GM foods on human health, biodiversity and ecosystems elicits public reservations due to their irreversible release into the environment by the patent holders. Public concerns include increased health risks of cancer, diabetes, Alzheimer's disease, reproductive damage, chronic illnesses or epidemics,[34] as well as environmental concerns with modification of toxicity, accumulated herbicide or pesticide tolerance, as well as GMO infiltration to the water courses.[35] It is also interesting to note that public opinion polls indicate that many Canadians are concerned about GMOs. For instance, a 2012 poll reveals that "76 per cent of respondents said the federal government has not provided them enough information to make an informed decision on GM foods. Another nine per cent said they'd never even heard of GM foods."[36] This lack of public awareness of GM foods is demonstrated by a recent report, which concludes that "[c]ompared to 29 OECD countries, Canadians see the least amount of media reporting on GMOs."[37]

Public concerns relating to the production and consumption of GM foods may partly stem from science-based uncertainty. The biotechnology industry routinely conducts 90-day

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[33] Smith, *Genetic Roulette: The Documented Health Risks of Genetically Engineered Foods,* 257-260.

[34] Ibid.,1-11.

[35] A. A. Snow et al., "Genetically engineered organisms and the environment: current status and recommendations," Ecological Applications 15, no. 2 (2005): 377; R. Tirado and P. Johnston, "Food security: GM crops threaten biodiversity," Science 328, no. 5975(2010): 170; E. J. Rosi-Marshall et al., "Toxins in transgenic crop byproducts may affect headwater stream ecosystems," Proceedings of the National Academy of Sciences of the United States of America 104, no. 41 (2007): 16204; T. Bøhn et al., "Compositional differences in soybeans on the market: Glyphosate accumulates in Roundup Ready GM soybeans," Food Chemistry 153 (2014): 207; Dhan Prakash et al., "Risks and Precautions of Genetically Modified Organisms," ISRN Ecology 2011 (2011): 1; G.L. Lövei and S. Arpaia, "The impact of transgenic plants on natural enemies: a critical review of laboratory studies," Entomologia Experimentalis et Applicata 114, no. 1 (2005): 1; Thomas Bøhn and Marek Cuhra, "How "Extreme Levels" of Roundup in Food Became the Industry Norm," Independent Science News, March 24, 2014, https://www.independentsciencenews.org/news/how-extreme-levels-of-roundup-in-food-became-the-industry-norm/.; A. J. Conner, Jan-Peter Nap et al., "The Release of Genetically Modified Crops into the Environment–Part II. Overview of Ecological Risk Assessment," *Plant Journal* 31 (2003): 19.

[36] Joe Fries, "Poll Indicates Lack of Information on Genetically Modified Food," *Penticton Western News* (July 5, 2012): 4.

[37] Lorraine Chan, "GMOs Next Global Lightning Rod Issue," *UBC Reports* 53 (2007): 7.

scientific studies, typically on rats, before GM foods are approved for consumption in Canada.[38] Despite findings of no adverse health effects or effects of "no biological significance,"[39] these 90-day feeding experiments are equivalent to seven to nine human years,[40] and do not account for longer periods of GM food consumption, nor the cumulative effects of many distinct GM products interacting with each other and the potential of GM food diets to interact with pre-existing health conditions. In essence, the main concern is the absence of evidence of risk or harm, as well as inconsistent information regarding the effects of GM foods on human health given that 90-day tests may not detect organ damage and cancer that take time to develop. Furthermore, the European Network of Scientists for Social and Environmental Responsibility released an international statement with over 310 signatories, including Canadian scientists, professors, and doctors who "strongly reject claims by GM seed developers and some scientists, commentators, and journalists that there is a 'scientific consensus' on GMO safety and that the debate on this topic is 'over.'"[41] Therefore, following the guiding framework of the precautionary principle in the Canadian GM food assessment process would support increased public access to information, enhance consumer choice, as well as strengthen the transparency and impartiality of the GM food safety assessment policies.

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[38] See e.g. Bruce G. Hammond et al., "Results of a 90-day safety assurance study with rats fed grain from corn rootworm-protected corn," *Food and Chemical Toxicology* 44 (2006) 147; Maoxue Tang, "A 90-day safety study of genetically modified rice expressing rhIGF-1 protein in C57BL/6J rats," *Transgenic Research* 21, no. 3 (2012): 499; C. Zhou, "A 90-day safety study in Sprague-Dawley rats fed milk powder containing recombinant human lactoferrin (rhLF) derived from transgenic cloned cattle," *Drug and Chemical Toxicology* 34, no. 4 (2011): 359; M.D. Dryzga, "Evaluation of the safety and nutritional equivalence of a genetically modified cottonseed meal in a 90-day dietary toxicity study in rats," *Food and Chemical Toxicology* 45, no. 10 (2007): 1994; Ib Knudsen and Morten Poulsen, "Comparative safety testing of genetically modified foods in a 90-day rat feeding study design allowing the distinction between primary and secondary effects of the new genetic event," *Regulatory Toxicology and Pharmacology* 49, no. 1 (2007): 53; Marlene Schroder et al., "A 90-day safety study of genetically modified rice expressing Cry1Ab protein (Bacillus thuringiensis toxin) in Wistar rats," *Food and Chemical Toxicology* 45 (2007): 339; Monsanto, "Animal Performance Assessments," http://www.monsanto.com/products/pages/animal-safety-assessment.aspx; Shiying Zou et al., "A 90-day subchronic study of rats fed lean pork from genetically modified pigs with muscle-specific expression of recombinant follistatin," *Regulatory Toxicology and Pharmacology* 73, no. 2 (2015)" 620; Hai Bai et al., "A 90-day toxicology study of meat from genetically modified sheep overexpressing TLR4 in Sprague-Dawley rats," *PLoS One* 10, no. 4 (2015).

[39] European Food Safety Authority, "Opinion of the Scientific Panel on Genetically Modified Organisms on a request from the Commission related to the safety of foods and food ingredients derived from herbicide-tolerant genetically modified maize NK603, for which a request for placing on the market was submitted under Article 4 of the Novel Food Regulation (EC) No 258/97 by Monsanto," *EFSA Journal* 9 (2003): 9.

[40] Morando Soffritti, Fiorella Belpoggi and Davide Degli Esposti, "Cancer prevention: The lesson from the lab," in *Cancer Medicine at the Dawn of the 21st Century: The view from Bologna*, ed. G. Biasco and S. Tanneberger (Bologna: Bononia University Press, 2006): 49.

[41] European Network of Scientists for Social and Environmental Responsibility, "Statement: No scientific consensus on GMO safety," http://www.ensser.org/increasing-public-information/no-scientific-consensus-on-gmo-safety/.

III. PRECAUTIONARY PRINCIPLE AS A MEANS OF MANAGING TECHNOLOGICAL RISK

In the context of GM food regulations, the spirit of precaution embodies proactive decision-making to assess and manage risks, as opposed to a remedial approach of damage control. In the absence of facts, appropriate risk evaluation science, or complete scientific information about cause and effect, the precautionary principle supports the implementation of temporary regulations until there is sufficient information on the safety of the new technologies to proceed with confidence. The fundamental assumption of the precautionary principle is that science is unable to predict all outcomes of the proposed technologies and, in turn, society is unable to wait for full evidence of their potential for harm.

The precautionary principle is rooted in the German legislative *Vorsorgeprinzip* (foresight principle), which was developed in the 1970s to prevent air pollution from damaging forests.[42] The principle was first articulated in international law at the 1982 World Charter for Nature and has since then been integrated in over 100 international treaties,[43] often serving as a guiding principle in national environmental and public health policies. The most widely recognized definition of the precautionary principle is Principle 15 in the Rio Declaration on Environment and Development ("Rio Declaration"):

> In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.[44]

This interpretation of the principle states that if the possible technological impact on the environment includes serious or irreversible damage, and scientific evidence is incomplete as far as the probability of such damage, then cost-effective measures are justified to prevent this harm. The principle seems to discourage inaction, as well as addresses resource management and

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[42] Sonja Boehmer-Christiansen, "The Precautionary Principle in Germany-Enabling Government," in *Interpreting the Precautionary Principle*, ed. Tim O'Riordan and James Cameron (London: Cameron May, 1994): 31, 36; see Anne Ingeborg Myhr, "Chapter 29: The precautionary principle in GMO Regulations," in *Biosafety First* , ed. T. Traavik and L. C. Lim (Trondheim: Tapir Academic Publishers, 2007): 2.

[43] UN, General Assembly, *World Charter for Nature*, A/RES/37/7 (28 October 1982); Chris Tollefson and Jamie Thornback, "Litigating the Precautionary principle in Domestic Courts," *Journal of Environmental Law and Practice* 19 (2007): 36.

[44] UN, "Rio Declaration on Environment and Development," note 12.

proportionality by suggesting that measures should be implemented according to the respective financial capability of member states.

The definition of the precautionary principle from the Rio Declaration has been adopted in the Canadian legislative and judicial context in the realm of environmental law,[45] which suggests that Canada understands the precautionary principle, but appears not to implement it in the GMO regulatory regime. The Royal Society Report uses a relatively stronger (i.e. less permissive) interpretation of the precautionary principle,[46] however the 'spirit' of the principle remains the same in both the Report and the Rio Declaration.[47] It is important to note that "no definition [of the precautionary principle] is universally accepted" and the "pervasive" nature of the concept supports a consistent implementation of the spirit of precaution,[48] as applicable to each situation. In this way, most recommendations in the Royal Society Report support integrating the 'spirit' of precaution into the food biotechnology regulations.

IV. CANADA'S INTERNATIONAL COMMITMENTS AND THE PRECAUTIONARY PRINCIPLE

It is important to note that several international agreements, in particular the Rio Declaration, Convention on Biological Diversity, Convention on the Law of the Sea, as well as Agreement on the Conservation and Management of Straddling Fish Stocks and Highly Migratory Fish Stocks commit Canada to apply the precautionary principle, however without explicit consequences for non-implementation.[49] With respect to the potential impacts of GM foods and crops on human health and the environment, the Rio Declaration explicitly embraces the precautionary principle as a guiding principle to protect against threats of serious or irreversible damage predominantly to the environment and human health[50] and the Convention on Biological Diversity makes reference to the precautionary principle as a guiding principle to

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[45] Canada, "Canadian Environmental Protection Act," S.C. 1999, c. 33: 2(1)(a); Canada, "Oceans Act," S.C. 1996, c. 31: preamble paragraph 6; Canada, "Species at Risk Act," S.C. 2002, c. 29; Canada, "Endangered Species Act," S.O. 2007, c. 6: 2(1)(h), 11(1); *114957 Canada Ltée (Spraytech, Société d'arrosage) v. Hudson (Town)*, note 6; *Castonguay Blasting Ltd. v. Ontario (Environment)*, 2013 SCC 52: 20.

[46] K. J. Barrett, "Canadian Agricultural Biotechnology: Risk Assessment and the Precautionary Principle," (PhD diss., University of British Columbia, 1999): 214.

[47] The Wingspread Statement on the Precautionary Principle does not include an economic limitation: "When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically." Wingspread Conference on the Precautionary Principle, "The Wingspread Statement on the Precautionary Principle," January 26, 1998, http://www.sehn.org/wing.html.

[48] HC, "Decision-Making Framework for Identifying, Assessing, and Managing Health Risks," http://www.hc-sc.gc.ca/ahc-asc/pubs/hpfb-dgpsa/risk-risques_tc-tm-eng.php.

[49] An in-depth analysis of the Canadian legal approach toward the precautionary principle as a guiding framework in light of its international obligations is outside the scope of this article.

[50] UN, "Rio Declaration on Environment and Development," 14-15, note 12.

protect against the loss or reduction of biodiversity.[51] It is also important to note that the World Health Organization (WHO) Regional Office in Europe has extended the precautionary principle to health.[52] The Convention on the Law of the Sea requires member states to prevent marine pollution, as well as protect and preserve fragile ecosystems and the habitat of marine life.[53] With respect to the potential impact of GM salmon on human health and the environment in instances of their escapes to local water systems, the Agreement on the Conservation and Management of Straddling Fish Stocks and Highly Migratory Fish Stocks requires state members to follow the precautionary principle in conserving, managing, and exploiting fish stocks to protect marine resources through data collection, research programs, and action plans, particularly when scientific information is uncertain or inadequate.[54] As a result, a strong argument can be made that Canada's international commitments require it to follow the precautionary principle as applicable to GM foods.

A. INTERPRETING THE PRECAUTIONARY PRINCIPLE AS A RESULT OF INTERNATIONAL COMMITMENTS

The recent statement of the Canadian government on the application of precaution to GM foods in relation to Canada's international commitments helps assess the role of the precautionary principle in improving agricultural biotechnology regulations.[55] In 2013, the Global Compliance Research Project "allege[d] that Canada has failed to apply the precautionary principle related to a number of its international environmental commitments."[56] The petitioner questioned the Auditor General of Canada as to why GMOs have not been prohibited in light of Canada's international commitments due to sufficient scientific evidence of their potential harm to human health and asked Health Canada to "outline how international environmental

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[51] UN, "Convention on Biological Diversity," 1, note 12.
[52] Marco Martuzzi and Joel A. Tickner, eds., *The Precautionary Principle: Protecting Public Health, the Environment and the Future of our Children* (Copenhagen: WHO Regional Office in Europe Publications, 2004): 2.
[53] UN, "Convention on the Law of the Sea," 194(4)-(5), note 12.
[54] UN, "Agreement on the Conservation and Management of Straddling Fish Stocks and Highly Migratory Fish Stocks," 4 December 1995, 2167 UNTS 3: 6, 66(1)-(2).
[55] "Environmental Petition No. 349–Non-compliance with International Obligations and Commitments: The Precautionary Principle," was submitted to the Auditor General of Canada by the Global Compliance Research Project under Canada, "Auditor General Act," R.S.C. 1985, c. A-17, s. 22, Office of the Auditor General of Canada, "Applying the precautionary principle in relation to a number of Canada's international environmental commitments," April 8, 2013, http://www.oag-bvg.gc.ca/internet/English/pet_349_e_38460.html.
[56] Ibid.

commitments are being met."[57] The Auditor General of Canada subsequently passed the petition to Health Canada.

In response, Health Canada does not address its binding international commitments that endorse the precautionary principle. Rather, the government references the Framework for the Application of Precaution in Science-Based Decision Making about Risk ("Framework on Precaution") and notes it does not create legal obligations.[58] With respect to the alleged risks from consuming GM food, Health Canada states that "[b]y imposing a pre-market safety assessment, as opposed to the post-market compliance and enforcement approach taken for the majority of foods, Health Canada has demonstrated its commitment to the precautionary principle," as well as public health and the safety of the food supply. This approach is flawed as discussed in the following section.

Health Canada further states that the "full safety assessment of GM foods involves a rigorous scientific evaluation by Departmental scientific evaluators" who supplement the information provided by the company with the relevant published data. However, Health Canada acknowledges that, in reference to biotechnology corporations, "many of the studies published in scientific journals are the result of company testing."[59] Health Canada concludes that despite scientific studies that "seek to demonstrate a health risk associated with GM foods, Health Canada has yet to find a study that caused Departmental scientists to change their conclusions regarding any GM food product that has been assessed and authorised" for sale by Health Canada and the CFIA.[60] Health Canada does not address whether agricultural biotechnology regulations, and specifically the GM food safety assessment process, respects Canada's international obligations, though some may argue that the GM food approval process honors the Agreement on the Application of Sanitary and Phytosanitary Measures ("SPS Agreement") in the WTO regime.[61] Health Canada also does not mention access to information issues or note that 'scientific evaluators' are employed by the biotechnology industry, as opposed to impartial experts from public service, regulatory bodies, academia, or nonprofit sectors. The statement of Health Canada on the application of the precautionary principle indicates the pre-market safety assessment is an insufficient application of the precautionary principle in consideration of the suspected long-term effects of GM foods.

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[57] Ibid.; Organic Consumers Association, **"**Leading Geneticist Exposes Hazards of Gene-Altered Foods & Crops," http://www.organicconsumers.org/ge/hazards111504.cfm.

[58] Government of Canada, "Framework for the Application of Precaution in Science-Based Decision Making about Risk," (Ottawa: Privy Council Office, 2003): 6.

[59] Office of the Auditor General of Canada, "Applying the precautionary principle in relation to a number of Canada's international environmental commitments," note 55.

[60] Ibid.

[61] WTO, "Agreement on the Application of Sanitary and Phytosanitary Measures," 15 April 1994, 1867 UNTS 493.

V. REGULATION OF AGRICULTURAL BIOTECHNOLOGY IN CANADA

A. GM FOOD SAFETY ASSESSMENT PROCESS

The effectiveness of the precautionary principle to serve as the guiding principle in the GM food safety assessment process is limited by the impartiality and transparency challenges in the Canadian GM food safety assessment process. Under the existing regulatory regime governing GMOs, Health Canada permits biotechnology corporations to assess the safety of GM foods, which may lead to conflicts of interest.

Canada's agricultural biotechnology regulations govern all novel foods, including GM foods and foods containing GM ingredients. The safety assessment of a novel food is triggered by the uniqueness of the food product, irrespective of its production process.[62] There is no distinct regulatory regime for GM foods and the current system does not seem to require a separate regulatory framework for foods from future agricultural inventions.

Health Canada is responsible for assessing the safety of novel foods for human consumption, as well as authorizing their commercial release pursuant to the *Food and Drugs Act* (1985) and the ensuing Food and Drug Regulations (2006).[63] These Food and Drug Regulations, including Division 28: Novel Foods ("Novel Food Regulations"), came into force after the release of the Royal Society Report and after legislative and judicial recognition of the precautionary principle in Canadian environmental law.

The Novel Food Regulations establish the safety assessment criteria and process for novel foods, including their scope and the response timeframe from Health Canada to approve applications for market access. Novel food includes "food that is derived from a plant, animal or microorganism that has been genetically modified," which means "chang[ing] the heritable traits of a plant, animal or microorganism by means of intentional manipulation"[64] without accounting for the process or extent of genetic modification. As a result, the GM plant, animal, or microorganism: (a) exhibits characteristics that were not previously observed; (b) no longer exhibits characteristics that were previously; or (c) has one or more characteristics that no longer falls within the anticipated natural range for that plant, animal or microorganism. Some would argue that the definition of GM foods acknowledges the possibility of "nutritional scarcity" of GM foods on account of novel genes whose introduction eliminates the beneficial characteristics

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[62] Tariq Ahmad, "Restrictions on Genetically Modified Organisms: Canada," *Library of Congress* (March 2014), http://www.loc.gov/law/help/restrictions-on-gmos/canada.php.

[63] Canada, "Food and Drugs Act," R.S.C., 1985, c. F-27; Canada, "Food and Drug Regulations," C.R.C., 2006, c. 870: B.28.001.

[64] Ibid. Modification outside accepted limits of natural variations includes composition, structure, physiological effect, nutritional quality, manner of metabolism, microbiological/chemical safety or safe use.

of the conventional food.[65] The definition of GM foods in Canada is relatively more extensive than the definition of GM foods recognized by the WHO, which includes foods whose DNA "has been modified in a way that does not occur naturally by reproduction or fertilization."[66] Although the meaning is similar, the scope of GM foods in Canada accounts for the possibility of approving future agricultural inventions under the existing safety assessment process. This emphasizes the need to incorporate the precautionary principle as a duty in the Canadian regulatory framework governing GM foods.

The safety assessment process for "manufacturers and importers who wish to sell or advertise a GM food in Canada" is established by Health Canada procedures.[67] These procedures state that the safety assessment "provides assurance that the food is safe when prepared or consumed according to its intended use."[68] The authorization process to release GM foods into the environment encompasses a 'pre-submission consultation' between Health Canada and the manufacturer or the importer, followed by a 'pre-market notification' where the proponents submit an application to "notif[y] the Director in writing of their intention to sell or advertise for sale the novel food."[69] Health Canada then 'coordinates' a 'scientific assessment' of a GM food with a 'scientific evaluator' from the biotechnology industry. The 'scientific evaluator' conducts the 'scientific assessment' pursuant to the Guidelines for the Safety Assessment of Novel Foods ("Safety Assessment Guidelines").[70] Once the 'scientific evaluators' complete their assessments, they "summarize their findings and recommendations in a report."[71] If the 'scientific evaluator' finds that the information provided by the proponent is 'insufficient,' then 'further documentation is requested.' The Safety Assessment Guidelines do not specify whether 'further information' is requested by Health Canada, nor clarify the threshold of 'insufficient' information. There are also no publically available statistics on the number of applications where the information submitted by the proponent is deemed 'insufficient.' The safety assessment reports available to the public provide a summary of conclusions on the relative safety of GM foods, in comparison to their conventional counterparts, without a sound scientific basis.[72]

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[65] *The GMO Trilogy: Unnatural Selection*, directed by Bertram Verhaag and Gabriele Kröber (Munich: DENKmal-Films & Haifisch Films, 2004), DVD.

[66] World Health Organization (WHO), "20 Questions on GM Foods," http://www.who.int/foodsafety/publications/biotech/en/20questions_en.pdf.

[67] HC, "The Regulation of Genetically Modified Food," http://www.hc-sc.gc.ca/sr-sr/pubs/biotech/reg_gen_mod-eng.php.

[68] Ibid.

[69] Canada, "Food and Drug Regulations," B.28.002(1)(a), note 63.

[70] HC, "Guidelines for the Safety Assessment of Novel Foods," http://www.hc-sc.gc.ca/fn-an/legislation/guide-ld/nf-an/guidelines-lignesdirectrices-eng.php; HC, "The Regulation of Genetically Modified Food," note 67; HC, "Regulation of Novel Foods," http://www.hc-sc.gc.ca/fn-an/gmf-agm/fs-if/faq_1-eng.php.

[71] Health Canada, "The Regulation of Genetically Modified Food," note 67.

[72] See e.g. HC, "Genetically Modified (GM) Foods & Other Novel Foods–Approved Products: Arctic Apple Events GD743 and GS784," http://www.hc-sc.gc.ca/fn-an/gmf-agm/appro/arcapp-arcpom-eng.php.

Following the assessment report conducted by a 'scientific evaluator,' a "Health Canada Food Rulings Proposal is prepared."[73] This Food Rulings Proposal "is reviewed by senior staff (Directors and Director General) in the Food Directorate" and "a decision is made whether or not to approve the product."[74] Following a successful assessment, a "'Letter of No Objection' is sent to the product proponent."[75] Pursuant to the Novel Food Regulations, the Health Canada Directorate has the following role:[76]

> B.28.003 (1) Within 45 days after receiving a notification referred to in paragraph B.28.002(1)(a) [pre-market notification], the Director shall review the information included in the notification and
>
> > (a) if the information establishes that the novel food is safe for consumption, notify the manufacturer or importer in writing that the information is sufficient; or
> >
> > (b) if additional information of a scientific nature is necessary in order to assess the safety of the novel food, request in writing that the manufacturer or importer submit that information.
>
> (2) Within 90 days after receiving the additional information requested under paragraph (1)(b) the Director shall assess it and, if it establishes that the novel food is safe for consumption, notify the manufacturer or importer in writing that the information is sufficient.

It is crucial to note that the existing GM food safety assessments under the Novel Food Regulations and Health Canada procedures undermine the impartiality of the GM food safety approval process. As noted, Health Canada Directorate reviews the pre-market GM food notification file and makes a decision whether or not to approve GM foods by sending a 'letter of no objection' to the proponent within 45 to 90 days based on the health and safety testing by 'scientific evaluators' from the biotechnology industry. In essence, Health Canada "does… not do its own testing of GM foods," as biotechnology corporations spend millions of dollars to hire industry experts in order to test their products.[77] The industry experts—who presumably sign confidentiality agreements—are remunerated by the biotechnological corporations whose

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[73] HC, "The Regulation of Genetically Modified Food," note 67.
[74] Ibid.
[75] Ibid.
[76] Canada, "Food and Drug Regulations," B.28.003(1), note 63.
[77] HC, "Frequently Asked Questions—Biotechnology and Genetically Modified Foods: Part 2: Safety Assessment of Genetically Modified Foods," http://www.hc-sc.gc.ca/fn-an/gmf-agm/fs-if/faq_1-eng.php#p2; see generally HC, "The Regulation of Genetically Modified Food," note 67.

products they are responsible for approving. This paradoxical situation raises the argument of whether the GM food safety assessment and approval process is impartial or whether the biotechnological industry is paying to have new inventions approved under the pretext of cost recovery. In fact, some are concerned that unlabeled GM foods are approved for human consumption based on company-produced science, as scientific data remains undisclosed to the public without peer-review by independent scientists.[78] It is also important to note that the GM food approval process does not include monitoring strategies of any health impacts.

Accordingly, the challenges in the current process include conflicts of interests for the 'scientific evaluators' and a void in governance. This is supported by the fact that "no applications [from proponents] have been turned down" by the Canadian government with respect to the release of GM foods into the environment,[79] only withdrawn by the manufacturer or importer. Some are also concerned that the Novel Food Regulations and Safety Assessment Guidelines do not regulate the time frame of the GM food safety assessments. The issue is whether the typical 90-day safety assessments conducted by 'scientific evaluators,' and their subsequent approval by the Health Directorate within 90 days without requiring long-term GM food safety studies, are sufficient enough to investigate biological processes in the human body.

The importance of procedural transparency has been recognized in Canadian public policy. The Framework on Precaution emphasizes "a high degree of transparency"[80] and the Decision-Making Framework for Identifying, Assessing, and Managing Health Risk ("Framework on Health Risks") provides the following guidelines for transparency in science-based decision-making:

> Clearly document all activities, considerations, assumptions, uncertainties, and decisions, to ensure that all aspects of the risk management decision-making process are clear and easily understandable. Bearing in mind any requirement for confidentiality, make this information accessible to interested and affected parties. Individuals who review the documentation should be able to understand how and why things were done, what decision-making processes were used, and who is accountable and responsible for various activities and decisions.[81]

In addition to implementing a transparent process, the Framework on Health Risks recommends clearly defining the relationship of the government with participating parties, including "identifying who is responsible for undertaking comprehensive risk assessments" given the

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[78] Canadian Biotechnology Action Network, "Frequently Asked Questions: Are GM Foods Safe to Eat," http://www.cban.ca/FAQs/Are-GM-Foods-Safe-to-Eat.

[79] HC, "Frequently Asked Questions—Biotechnology and Genetically Modified Foods: Part 2: Safety Assessment of Genetically Modified Foods," note 77.

[80] Canada, "Framework for the Application of Precaution in Science-Based Decision Making about Risk," 9, note 58.

[81] HC, "Decision-Making Framework for Identifying, Assessing, and Managing Health Risks," 10, note 48.

shared responsibility with citizens, communities, and industry.[82] The Framework on Health Risks differentiates between the role of scientists who assess potential risks based on scientific evidence and provide risk management options, as well as policy makers who use results of the risk assessments to make risk management decisions. The current GM food safety assessment process confirms that the precautionary guidelines in the Framework on Health Risks and the Framework on Precaution have not been implemented. Engaging independent scientists to conduct or review GM food safety assessments, similarly to the EU regulatory system,[83] may build trust in the Canadian GM food safety assessment process among the public to help strengthen Canada's domestic regulatory regime for GM foods.

B. GOVERNANCE STRUCTURE IN THE NOVEL FOOD SECTOR

The potential of the precautionary principle to improve the domestic GM Food Safety Assessment Process is undercut by existing and cumbersome public governance structures in Canada due to shared and overlapping functions in GM food safety assessment, an ambiguous legal framework, and the absence of coherent public policies. There is no clear leader of GM food governance and regulation in the realm of public administration, since GM food regulation and governance is shared among several federal agencies: Health Canada (GM food, safety assessments), Environment Canada (fish products of biotechnology), and the CFIA (GM crops and seeds, fertilizer supplements, animal feed and environmental assessments).[84] It is important to note that no agency has been mandated to take the lead on food labeling,[85] which remains voluntary,[86] and may create a disorientation of responsibilities and challenges to moving in the same direction.

The absence of a regulatory leader in GM food labeling also hinders public awareness and access to information, which is further constrained by a lack of public list of GM foods

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[82] Ibid.

[83] European Food Safety Authority (EFSA), "Genetically Modified Organisms," www.efsa.europa.eu/en/topics/topic/gmo.

[84] Canadian Food Inspection Agency (CFIA), "Regulating Agricultural Biotechnology in Canada: An Overview," http://www.inspection.gc.ca/plants/plants-with-novel-traits/general-public/overview/eng/1338187581090/1338188593891; HC, "Health Canada Decision-Making Framework for Identifying, Assessing, and Managing Health Risks," http://www.hc-sc.gc.ca/fn-an/legislation/guide-ld/nf-an/guidelines-lignesdirectrices-eng.php.

[85] CFIA, "Regulating Agricultural Biotechnology in Canada: An Overview," note 84.

[86] Public Works and Government Services Canada, "Voluntary Labelling and Advertising of Foods that are and are not Products of Genetic Engineering," http://www.tpsgc-pwgsc.gc.ca/ongc-cgsb/programme-program/normes-standards/internet/032-0315/index-eng.html.

pending approval and non-disclosure exemptions for commercially sensitive information in the federal *Access to Information Act* (1985).[87] The Supreme Court of Canada clarified the scope of protected information under the Act, including trade secrets, information that may prejudice the competitive position of the proponent, as well as confidential financial, commercial, or scientific information.[88] The Court also confirmed that the government must notify the proponent of the disclosure, unless there is no reason to believe that the information would be exempted under the Act. In this way, the government is legally justified from publically withholding the details of GM food safety assessments and proponent applications. While the public sector attempts to balance commercial interests, health protection and institutional transparency, the current regulatory framework seems to favor the protection of commercial interests for biotechnology corporations, as opposed to the public right to be informed and choose non-GM foods.

In summary, coherent public policies are necessary to ensure specific accountability in a governance structure with shared responsibilities. The Framework on Precaution promotes "clear accountability" among all parties in the applicable decision-making process, and the Framework on Health Risks advocates "clearly defin[ing] roles, responsibilities and accountabilities," explicitly identifying "conflicting regulations and overlapping jurisdictions of governments" to eliminate gaps.[89] The current governance and legal structures in the novel food sector have prevented the guidelines in the Framework on Health Risks and the Framework on Precaution from being implemented. Integrating the precautionary principle into novel food governance would require reforming the governance structures to establish an independent regulatory body with a mandate to ensure access to information, as well as procedural and scientific integrity.

C. GUIDELINES FOR THE SAFETY ASSESSMENT OF NOVEL FOODS

The effectiveness of the precautionary principle to improve the domestic GM food safety assessment process is limited by a lack of transparent scientific standards and normative standards based on scientific evidence in the Canadian regulatory framework governing GM foods. According to the Safety Assessment Guidelines, the safety assessment for GM foods derived from plants encompasses a review of their history, dietary exposure, as well as nutritional, toxicology, allergenic, and chemical considerations. The safety assessment for GM foods derived from micro-organisms includes a characterization of the derived GM strain with unique antibiotic resistance or gene transfers, as well as the history and dietary exposure of the organism, nutritional, toxicology, allergenic, and chemical considerations. The Safety

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[87] Canada, "Access to Information Act," R.S.C., 1985, c. A-1: 20(1).

[88] *Merck Frosst Canada Ltd v. Canada (Health)*, 2012 SCC 3: 20(1), 107, 129, 142, 147-149, 188. See the legal protection for trade secrets: Canadian Intellectual Property Office, "Protect your innovation," http://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr03586.html#secret.

[89] Canada, "Framework for the Application of Precaution in Science-Based Decision Making about Risk," 9, note 58; HC, "Decision-Making Framework for Identifying, Assessing, and Managing Health Risks," 9, note 48.

Assessment Guidelines provide the following norms with respect to the safety assessments of GM foods:[90]

- Safety assessment: characterization of the novel food for comparison with its conventional counterpart;
- General information: proposed use and description of the GM food, including information on DNA modifications, such as pesticide resistance or cold environment tolerance;
- Dietary exposure: GMO level in the food and anticipated consumption rates;
- Nutrient data: dietary details and nutrient composition of the GM food, any nutritional effects of large intake amounts;
- Potential allergenic testing: known food allergens in the host and donor organisms; and
- Toxicity: examined only in light of relevant concerns after assessments in the previous sections.

These normative standards indicate that the safety assessment of novel foods in Canada is based on the characteristics of a novel food or crop (product-based approach), as opposed to the safety assessment of a novel technology or a novel application of an existing technology used to manufacture a novel food (process-based approach), which is used in the EU.[91] This reiterates the point that future agri-food innovations in Canada may not require distinct safety assessment processes under the existing regulatory framework.

The Safety Assessment Guidelines do not provide scientific standards to evaluate these norms. In addition to concerns with respect to scientific evidence, there may be disagreement on the interpretation of the safety assessment terms. In this way, integrating an obligation to apply the precautionary principle into the GM food regulatory framework supports the development of scientific standards, and normative standards based on scientific evidence, in the GM food safety assessment process.

D. PUBLIC POLICY PRINCIPLES IN THE APPLICATION OF THE PRECAUTIONARY PRINCIPLE

[90] HC, "Guidelines for the Safety Assessment of Novel Foods," note 70.

[91] Biotechnology and Biological Sciences Research Council, "New Techniques for Genetic Crop Improvement," (Position Statement, September 2014), http://www.bbsrc.ac.uk/web/FILES/Policies/genetic-crop-improvement-position-statement.pdf.

The ability of the precautionary principle to improve the domestic GM food safety assessment process is limited by an inconsistency among government policies in applying the precautionary principle. Specifically, in the context of agricultural biotechnology regulations, the Government of Canada Framework on Precaution provides a unique application of the precautionary principle in comparison with the 2013-2018 Agriculture and Agri-Food Canada ("AAFC") policy Growing Forward 2, as a follow-up to the 2008-2013 policy Growing Forward.

While public policies on precaution in the context of agricultural biotechnology regulations are not legally binding, the Framework on Precaution provides guiding principles on implementing protective measures in situations characterized by a potential risk of harm and lack of full scientific knowledge and evidence, including "meaningful public involvement" and the need to guide science-based decision making by society's chosen level of protection against risk "established in advance through domestic policy instruments such as legislation and international agreements."[92] The Framework on Precaution specifically states that implementing the SPS Agreement requires "scientific monitoring and follow-up" and the "basis for decision making should be drawn from a variety of scientific sources and experts from many disciplines," as well as recommends "independent advisory processes that include widely recognized and credible individuals."[93] In the context of agricultural biotechnology regulations, the Framework on Precaution supports the establishment of an independent regulatory body with a mandate to promote transparent and accountable safety assessments that address public concerns.

The guiding principles on implementing precaution in the Framework on Precaution emphasize that any adopted measures be reconsidered in light of society's chosen level of protection against risk, scientific, and technological evolution, as well as proportionality of the potential severity of risks. The Framework on Precaution also notes that "Canada's application of precaution is flexible" based on the circumstances and the scientific information base, as knowledge evolves, however the Framework recommends that precaution be implemented "for the protection of health and safety and the environment and the conservation of natural resources,"[94] supporting the core values of health and environmental safety emphasized in the Royal Society Report.

These guiding principles address the most common criticisms of the precautionary principle discussed in the Royal Society Report: trade protectionism and over-regulation leading to a loss of potential benefits.[95] The Framework on Precaution also recommends precautionary

[92] Canada, "Framework for the Application of Precaution in Science-Based Decision Making about Risk," 9, 7, note 58.
[93] Ibid., 4, 5, 5.
[94] Ibid., 3, 2.
[95] RSC, "Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada," 196, note 5.

measures that are cost effective, least trade restrictive, and consistent with measures taken in similar circumstances.

It is worth noting that the EU has adopted analogous principles for precautionary measures in science-based decision making with the exception of choosing the least trade-restrictive options. The paradox that Canada has embraced imported GM foods, while the EU has adopted trade restrictions and GMO bans may be explained by cultural and ethnic factors, including a cultural identity built on national food traditions, skepticism due to historical food controversies, as well as varying degrees of faith in science in relation to food, and trust in public and private actors.[96]

Conversely, AAFC has endorsed the national policy Growing Forward 2 in order to generate innovation, competitiveness, and market-based economic growth in the agricultural and agri-food sectors. Growing Forward 2 is a $3 billion public investment and the foundation for public agricultural programs and services pursuant to the Food and Drug Regulations. Under Growing Forward 2, the AAFC partners with industry stakeholders to bring new technologies into the market through free workshops, education, and funding for producers and processors to grow profits, innovate, expand markets, and manage risks,[97] as well as provide licensing opportunities, template license agreements for new technologies, and protect the intellectual property of the AAFC.[98] The general lack of consistency among the Canadian government institutions in applying the precautionary principle in GM food regulations is demonstrated by the priorities of Growing Forward 2, established in collaboration with the biotech industry: commercialize and adopt agricultural innovations, facilitate market development and access, advance regulatory modernization and harmonization to increase competitiveness, encourage industry responsibility for business risks, and support new model development.[99] Given that the policy subsidizes agricultural innovation and technological progress, it is unclear how Growing Forward 2 will address the precautionary principle or support the public health and food safety policies. Accordingly, the function of the precautionary principle in improving the domestic GM food safety assessment process by applying recognized guiding principles is limited by policy

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[96] Hannes R. Stephan, *Cultural Politics and the Transatlantic Divide over GMOs* (London: Palgrave Macmillan, 2014).

[97] Agriculture and Agri-Food Canada, "Growing Forward 2," http://www.agr.gc.ca/eng/about-us/key-departmental-initiatives/growing-forward-2/?id=1294780620963.

[98] Agriculture and Agri-Food Canada, "Technology Transfer and Licensing," http://www.agr.gc.ca/eng/science-and-innovation/technology-transfer-and-licensing/?id=1196968351190.

[99]Agriculture and Agri-Food Canada, "The Next Agricultural Policy Framework: Update on Growing Forward 2" (Presentation to the Grain Industry Symposium, Ottawa, ON, Canada, November 23, 2011), http://www.canadagrainscouncil.ca/uploads/Greg_Meredith_GIS_2011.pdf.

variations between balancing the implementation of precaution and industry collaboration to generate new technologies.

The potential risk-benefit assessment between improving the GMO regulatory regime by integrating the precautionary principle into the GM food safety assessment process and the economic growth in agriculture is also an important consideration. Adding more regulations and processes in line with the precautionary principle, although beneficial, could stifle one of Canada's strongest economic sectors. The strong lobbying power of agricultural and agri-food producers could also make change difficult.[100] As a result, reform in the GM food regulatory framework may have to be phased in. This may mitigate the other risks and, at minimum, it would protect public health.

VI. TRADE IN THE AGRICULTURAL SECTOR WITH THE EU UNDER THE CETA

Canada's economy is largely dependent on international trade and its integration within regional trading networks is a means to sustain the incomes and living standards of Canadians. Canada's imports and exports of goods and services amount to about $1.1 trillion with international trade accounting for almost 65% of the Canadian economy, as measured by the GDP.[101] The country exports half of its food production and is the fifth largest world exporter of agriculture and agri-food products with almost 580,000 employees in this sector, which accounts for almost 3% of the GDP.[102] With respect to the EU, Canada's annual exports of $2.5 billion in agriculture and food products to the 28 member states, including almost $915 million in processed food and beverages, face an average of 13.9% in agricultural tariffs and significant non-tariff restrictions.[103] The CETA eliminates almost 94% of EU agricultural tariffs averaging

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[100] Thomas Moran, Nola M. Ries and David Castle, "A Cause of Action for Regulatory Negligence? The Regulatory Framework for Genetically Modified Crops in Canada and the Potential for Regulator Liability," *University of Ottawa Law & Technology Journal* 6, nos. 1 & 2 (2009): 3-4, 10-11, http://www.uoltj.ca/articles/vol6.1-2/2009.6.1-2.uoltj.Moran%20.1-23.pdf; Aaron Freeman, "Canadian Consumers Concerned About Biotechnology and GMO Food," *Watershed Sentinel*, April/May 2002, http://www.watershedsentinel.ca/content/canadian-consumers-concerned-about-biotechnology-and-gmo-food; National Farmers Union, "Farmers, the Food Chain and Agriculture Policies in Canada in Relation to the Right to Food" (Submission of the National Farmers Union of Canada to the Special Rapporteur On The Right To Food, Ottawa, ON, Canada, May 2012): 3, 9, http://www.nfu.ca/sites/www.nfu.ca/files/NFU%20Final%20Report%20to%20Special%20Rapporteur%20on%20the%20Right%20to%20Food,%20May%202012_1.pdf.

[101] Foreign Affairs, Trade and Development Canada, "Canada's State of Trade: Trade and Investment Update 2012,", April 30, 2013, http://www.international.gc.ca/economist-economiste/performance/state-point/state_2012_point/2012.

[102] Foreign Affairs, Trade and Development Canada, "Canada-European Union: Comprehensive Economic and Trade Agreement (CETA)," September 26, 2014, http://www.international.gc.ca/trade-agreements-accords-commerciaux/agr-acc/ceta-aecg/benefits-avantages/agriculture-agricoles.aspx?lang=eng.

[103] Office of the Prime Minister, "Canada-European Union Trade Agreement Summary of Benefits," September 26, 2014, http://pm.gc.ca/eng/news/2014/09/26/canada-european-union-trade-agreement-summary-benefits. In 2013,

about 13.9%,[104] providing preferential access to the EU market and a competitive advantage over producers from countries with no free trade agreements. The CETA could generate $1 billion in new agri-food exports to the EU—the world's largest importer of agriculture and food commodities[105]—including raw ingredients, processed foods, nutritional supplements and beverages. However, the CETA does not impact GM food trade regulations, nor restrict future rulemaking or decision-making processes. Under the CETA, both Canada and the EU maintain their respective jurisdictions in regulating GM food safety assessments, and Canadian agri-food products must be imported into the EU under the EU protocol and import requirements, which could impact Canada's ability to take advantage of the CETA given the distinct regulatory frameworks on GM foods.

The Canada-EU agricultural trade relationship has historically been marked by disagreements due to the EU's cautious approach to importing GMOs. The disputes climaxed in 2003, when Canada, the United States, and Argentina challenged the alleged EU barriers to GM food trade as illegal under the SPS Agreement.[106] The WTO dismissed many allegations, though found the unofficial 1998-2004 EU moratorium, delays in approving GMOs, and existing GMO safety measures inconsistent with its international obligations.[107] In particular, the safety measures were not based on risk assessments within the scope of the SPS Agreement and could be upheld without sufficient scientific evidence. Following the ruling, Canada and the EU settled the dispute with a mutually agreed solution,[108] including bilateral dialogue on market access. Since the WTO dispute, the EU has perhaps maintained the most reserved approach to GM foods among all jurisdictions,[109] and as noted by the Canadian Agri-Food Trade Alliance (CAFTA),

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the value of bilateral trade in goods between EU and Canada was an estimated $88 billion: see European Commission, "Canada," April 28, 2016, http://ec.europa.eu/trade/policy/countries-and-regions/countries/canada.

[104] Ibid.

[105] In 2013, the EU imported more than $138 billion of agriculture and agri-food products, see Foreign Affairs, Trade and Development Canada, "Canada-European Union: Comprehensive Economic and Trade Agreement (CETA)," note 102.

[106] Kerr and Hobbs, "Consumers, Cows and Carousels: Why the Dispute over Beef Hormones is Far More Important than its Commercial Value," 191, note 10.

[107] WTO, "Dispute Settlement: Dispute DS291," note 9; Farm-To-Consumer Legal Defense Fund, "The Current Status of GMO's in Europe," note 9.

[108] WTO, "Dispute Settlement: Dispute DS291," note 9; WTO, "Dispute Settlement: Dispute DS292," February 24, 2010, https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds292_e.htm; WTO, "Dispute Settlement: Dispute DS293," April 6, 2010, https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds293_e.htm.

[109] John Davison, "GM plants: Science, politics, and EC regulations," *Plant Science* 178, no. 2 (2010): 94.

"EU consumers just seem to be uninterested in consuming products that are derived from biotech products."[110]

A particular challenge in implementing the CETA is Canada's planned export of $100 million in GM grains, oilseeds, and sugar.[111] Though the CETA notes the "importance of... cooperating on low-level presence" and "commitment to ensuring the efficient processing of canola applications and the expeditious movement of these proposals through the EU approval process," as well as establishes a committee on biotechnology market access,[112] the divergent Canada-EU perspectives may impede dialogue on the GM food approval process, canola oil exports for biofuels, and low-level GM presence in non-GM food products.[113] Unless certified organic or non-GMO, Canadian grain and oilseed growers who wish to export to the EU will find it challenging to prove their products have not been contaminated with GMO particles mixed in with bulk shipments, wandering genes, or GM pollen blown with the wind.[114] Conversely, broad penetration of GMOs into the respective food chains of the largest agriculture and agri-food producing nations may make the EU trade barrier temporary rather than sustainable. As a result, Canada's regulatory regime governing GM foods may impact the country's ability to trade agricultural and agri-food products with the EU under the CETA, at least until the spread of GMOs makes the EU trade barrier impossible to implement.

In 2015, the European Parliament cemented its commitment to consumer protection with a new directive that allows member states to restrict or ban GMO cultivation within their territory,[115] despite approval at the EU level, and the EU Agriculture Commissioner confirmed that mandatory labeling of GM foods will continue.[116] The CAFTA acknowledges that the "value of the deal [CETA] starts to evaporate," should GM food issues remain unresolved. At the very least, Canada should consider the economic value of GMOs to the Canadian economy versus the costs of implementing labeling measures and segregating GM and non-GM foods to improve Canada-EU agricultural trade relations. The overview of the trade sector provides background

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[110] Canada, Parliament, House of Commons, Standing Committee on Agriculture and Agri-Food, 2nd Sess., 41st Parl., Meeting No. 003 (November 5, 2013): 1615 (Ms. Kathleen Sullivan, Canadian Agri-Food Trade Alliance).
[111] Ibid. (Mr. Alex Atamanenko, NDP).
[112] Foreign Affairs, Trade and Development Canada, "Canada-European Union: Comprehensive Economic and Trade Agreement (CETA)—Technical Summary of the Final Negotiated Outcome," November 10, 2014, http://international.gc.ca/trade-agreements-accords-commerciaux/agr-acc/ceta-aecg/understanding-comprendre/technical-technique.aspx?lang=eng.
[113] Canada, Parliament, House of Commons, Standing Committee on Agriculture and Agri-Food, note 110.
[114] Ibid., see also *Monsanto Canada Inc. v. Schmeiser*, [2004] 1 S.C.R. 902, 2004 SCC 34.
[115] Laeticia Markakis, "New law gives EU member states right to authorize or ban GMO," *Euranet Plus News Agency*, January 14, 2015, http://euranetplus-inside.eu/new-law-gives-eu-member-states-right-to-authorize-or-ban-gmo/.
[116] Nicole Sagener, "Agriculture Commissioner promises GMO labelling, despite TTIP," trans. Erika Koerner, *EurActiv*, January 16, 2015, http://www.euractiv.com/sections/agriculture-food/agriculture-commissioner-promises-gmo-labelling-despite-ttip-311324.

information for a brief comparative analysis with EU regulations to illustrate how similar challenges for public policymakers are managed in a way that reflects the precautionary principle.

A. THE EU APPROACH TO REGULATING GM FOODS

The EU embraces a relatively more rigorous GM food safety assessment process than its Canadian counterpart. The regulatory framework governing GM foods is based on the precautionary principle, which has been integrated into the Treaty on the Functioning of the European Union as a constitutional principle guiding EU public policy.[117] The EU agricultural biotechnology regulations generally require scientific evidence of the presence (not the absence) of the potential risks of GM foods: GM foods must not endanger, mislead, or nutritionally disadvantage consumers.[118]

The EU approval procedure for GM foods distinguishes between safety assessments that are conducted by the European Food Safety Authority (EFSA) in its role as an independent scientific advisor on the potential health and environmental risks of GM foods, as well as the risk management processes and GM food approvals that are the responsibility of the European Commission ("Commission") and representatives from member states in their role as risk managers.[119] The GM food safety assessments are conducted on a case-by-case basis with an emphasis on regulatory action before there is evidence of possible health and environmental harm.[120] The commercial release of GM foods into the agricultural markets of EU member states

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[117] European Union (EU), "Consolidated version of the Treaty on the Functioning of the European Union," 13 December 2007, 2008/C 115/01; European Parliament and Council of the European Union, "Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC–Commission Declaration," 12 March 2001, OJ L 106, 17.4.2001; European Parliament and Council of the European Union, "Directive 2008/27/EC of the European Parliament and of the Council of 11 March 2008 amending Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms, as regards the implementing powers conferred on the Commission," 11 March 2008, OJ L 81, 20.3.2008.

[118] European Parliament and Council of the European Union, "Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients," 27 January 1997, OJ L 43, 14.2.1997.

[119] EFSA, "Genetically Modified Organisms," note 83.

[120] European Commission "Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms," 14 January 2004, OJ L 10, 16.1.2004.

depends on multiple and independent levels of authority. Before entering the EU market, GMOs for food, animal feed, cultivation, or release must pass the following approval process:[121]

> (a) Proponent sends the application, scientific studies, opinion of substantial equivalence from a food assessment body,[122] proposed product labeling and monitoring, GM detection methods and material for an initial safety assessment by the national scientific body that, in consultation with the Commission and the remaining states, forwards the application to the EFSA, notifies member states and makes the application summary publically available, should an additional assessment be deemed necessary;[123]
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> (b) Within six months, the EFSA provides an opinion based on a scientific evaluation from the GMO expert panel: independent scientists from member states who determine if GM products are within the range of its natural counterparts. The EFSA opinion includes proposed product labeling, monitoring, and evaluation of GM detection methods from the EU reference laboratory. The EFSA opinion, panel proceedings and safety assessment are made public. Release requires an environmental impact assessment, consultation with state agencies and evidence the applicant took all measures to prevent negative health and environmental effects;
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> (c) Within three months, the Commission and state representatives assess the EFSA report and may consider ethical, societal and environmental factors, as well as public expectations in their decision.[124] The Standing Committee on the Food

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[121] European Parliament and Council of the European Union, "Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC - Commission Declaration," note 117; European Parliament and Council of the European Union, "Directive 2008/27/EC of the European Parliament and of the Council of 11 March 2008 amending Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms, as regards the implementing powers conferred on the Commission, note 117;" European Parliament and Council of the European Union, "Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed," 22 September 2003, OJ L 268, 18.10.2003; European Parliament and Council of the European Union, "Regulation (EC) No. 298/2008 of the European Parliament and of the Council of 11 March 2008 amending Regulation (EC) No. 1829/2003 on genetically modified food and feed, as regards the implementing powers conferred on the Commission," 11 March 2008, OJ L 97, 9.4.2008.

[122] Directorate General for Health and Consumers, "Novel Foods and Novel Food Ingredients," http://ec.europa.eu/food/food/biotechnology/novelfood/index_en.htm; European Parliament, "Regulation concerning novel foods and novel food ingredients," note 118.

[123] European Parliament and Council of the European Union, "Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients," note 118.

[124] WHO and Food and Agriculture Organization of the United Nations (FAO), "Statements of principle concerning the role of science in the codex decision-making process and the extent to which other factors are taken into account," 21st Sess., Codex Alimentarius Commission, General Decision, (July 8, 1995): Appendix.

> Chain and Animal Health, which includes representatives from all states, evaluates the Commission's decision through a majority vote and may engage the European Council of Ministers.

All authorizations are limited to renewable periods of ten years.[125] Release into the environment requires additional mandatory public consultations, monitoring, consultations with scientific and ethical committees composed of EU member state representatives, annual reports on ethical issues, as well as follow-up reports on implementation and socio-economic issues, including farmer and consumer interests.[126]

The following requirements restrict the circulation of GM foods in EU territory: (a) compulsory GMO labeling, including a unique nine-character code for each product to permit traceability,[127] which enables member states to implement measures for monitoring, inspection

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[125] European Parliament and Council of the European Union, "Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC–Commission Declaration," note 117; European Parliament and Council of the European Union, "Directive 2008/27/EC of the European Parliament and of the Council of 11 March 2008 amending Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms, as regards the implementing powers conferred on the Commission, note 117; European Parliament and Council of the European Union, "Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, note 121; European Parliament and Council of the European Union, "Regulation (EC) No. 298/2008 of the European Parliament and of the Council of 11 March 2008 amending Regulation (EC) No. 1829/2003 on genetically modified food and feed, as regards the implementing powers conferred on the Commission," note 121.

[126] European Parliament and Council of the European Union, "Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC–Commission Declaration," note 117; European Parliament and Council of the European Union, "Directive 2008/27/EC of the European Parliament and of the Council of 11 March 2008 amending Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms, as regards the implementing powers conferred on the Commission, note 117.

[127] European Parliament and Council of the European Union, "Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC," 22 September 2003, OJ L 268, 18.10.2003; European Parliament and Council of the European Union, "Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, note 121; European Parliament and Council of the European Union, "Regulation (EC) No. 298/2008 of the European Parliament and of the Council of 11 March 2008 amending Regulation (EC) No. 1829/2003 on genetically modified food and feed, as regards the implementing powers conferred on the Commission," note 121.

including sampling, label verification, as well as withdrawal from the market;[128] (b) regulations and standards for GM crops (as opposed to the EU not having its own framework);[129] (c) 'zero tolerance rule' permitting only authorized GM foods to enter the EU with the burden on the proponent to prove safety of any new foods before introduction into the market;[130] as well as (d) national laws restricting or prohibiting the cultivation of GM crops and GMO-free regions.[131] Uncontrolled release of GM micro-organisms is prevented through safety standards and hierarchical risk assessments, public information, and protective measures.[132] The EU legislation also provides for public access to information held by public authorities and public participation in decision-making on GM foods.[133]

In essence, the EU regulatory framework authorizes GM foods as long as each raw material, food ingredient, or additive produced from GMOs contains the label 'This product contains genetically modified organisms' or 'Product produced from GM (name of organism)'. GM food and feed products containing less than 0.9% of GMOs are not subject to mandatory labeling on the condition that the proponent demonstrates to the authorities that the presence of the GMO is adventitious and technically unavoidable.[134]

The precautionary approach to GM food safety assessments and the transboundary movement of GM foods within the EU reflects the principles in the Cartagena Protocol on the

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[128] European Commission "Commission Regulation (EC) No 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for genetically modified organisms," note 120; European Parliament and Council of the European Union, *"*Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC."

[129] European Commission, "GMO Legislation," http://ec.europa.eu/food/plant/gmo/legislation/.

[130] European Commission, Joint Research Centre "GMOs," https://ec.europa.eu/jrc/en/research-topic/gmos.

[131] European Commission, "GMO authorisations for cultivation," http://ec.europa.eu/food/plant/gmo/authorisation/cultivation/index_en.htm; GMO-Free Europe, "GMO-Free Regions by Country," http://www.gmo-free-regions.org/.

[132] European Parliament and Council of the European Union, "Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms on the contained use of genetically modified micro-organisms," 6 May 2009, OJ L 125, 21.5.2009.

[133] European Council, "Council Decision 2005/370/EC of 17 February 2005 on the conclusion, on behalf of the European Community, of the Convention on access to information, public participation in decision-making and access to justice in environmental matters," 17 February 2005, OJ L 124, 17.5.2005. The EU regulatory framework does not prevent public access to information held by public authorities given the current absence of harmonized EU legislation to protect disclosure of trade secrets: European Commission, "Trade Secrets," http://ec.europa.eu/growth/industry/intellectual-property/trade-secrets/index_en.htm.

[134] European Parliament and Council of the European Union, *"*Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC," note 127.

Prevention of Biotechnological Risks ("Cartagena Protocol"),[135] which Canada has not ratified. The Cartagena Protocol authorizes governments to implement precautionary measures in the presence of scientific uncertainty in order to protect biodiversity from GM crops containing bio-pesticides, as well as establishes a pre-trade information exchange procedure and an Information Exchange Centre for member states to share scientific knowledge on GM foods and manage biotechnological risks.[136]

VII. DIFFERENCES BETWEEN THE APPROACHES TO GM FOOD REGULATION IN CANADA AND THE EU

The distinct approaches of Canada and the EU to GM food regulations are rooted in their diverse approaches to adopting the guiding framework of the precautionary principle. Some may argue that the EU seems rigid in its GMO regulatory regime,[137] though others may contend that the EU seems to interpret the precautionary principle as a duty to prevent harm through an extremely careful risk assessment.[138] On the other hand, Canada appears to interpret the precautionary principle to suit the needs of the biotechnology corporations. The EU governance structure of GM food assessments is characterized by multiple independent instances, while the Canadian governance structure is characterized by a public approval process dependent on the evaluation of biotechnology experts. Particularly, the differences between the Canadian and the EU approaches to GM food regulation concern the role of precaution in the norm of 'substantial equivalence' between GM and conventional foods: the quintessential threshold for approving GM food safety.

A. 'SUBSTANTIAL EQUIVALENCE' AS A CATALYST FOR APPROVING GM FOODS

In 1993, the Organization for Economic Cooperation and Development introduced 'substantial equivalence' as a comparative risk assessment measure based on the idea that "existing organisms used as food, or as a source of food, can be used as the basis for comparison when assessing the safety of human consumption of a food or a food component that has been

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[135] UN, "Cartagena Protocol on the Prevention of Biotechnological Risks," note 25; European Parliament and Council of the European Union, "Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movement of genetically modified organisms," 15 July 2003, OJ L 287, 5.11.2003.

[136] UN, "Cartagena Protocol on the Prevention of Biotechnological Risks," 20, note 25.

[137] See e.g. Robert Wager and Alan McHughen, "Zero sense in European approach to GM," *EMBO Reports* (2010): 258-259.

[138] See e.g. Dhan Prakash et al., "Risks and Precautions of Genetically Modified Organisms," *ISRN Ecology* 2011 (2011): 8.

modified."[139] The WHO subsequently approved the notion of 'substantial equivalence' as the normative standard in the GM food safety assessment processes using the following interpretation: "if a new food or food component is found to be substantially equivalent to an existing food or food component, it can be treated in the same manner with respect to safety."[140] The threshold for 'substantial equivalence' in GM food safety assessments sparks debates due to its imprecise and discretionary nature with respect to GM food testing requirements. Some also perceive this standard as a "conceptual tool," as opposed to a scientific formulation,[141] supporting the argument that 'substantial equivalence' concerns normative standards, as opposed to scientific evidence.

The safety assessment process conducted by 'scientific evaluators' focuses on the equivalence between modified and conventional foods on the basis of documented risks. 'Substantial equivalence' between GM and conventional foods is the key to success in releasing the GM foods into the market: once the 'scientific evaluator' establishes 'substantial equivalence' between a modified and an existing food, no additional safety testing or evaluations are necessary. Health Canada reviews the 'Food Rulings Proposal' and approves the commercialization of the GM food in the national market.

The GM food safety assessment process assumes that because of an established history of safe consumption for a conventional food, a conclusion of 'substantial equivalence' between the GM and the conventional food means the GM food will also be safe. This presumption is comparable to the reasoning in approving crop varieties in conventional plant breeding where the interactions of any novel traits generally have no negative impacts: if a product variety is *prima facie* substantially equivalent to the original product, a complete risk assessment is unnecessary.[142]

A key point in the GM food approval process is that the Health Directorate seems to apply 'substantial equivalence' as a decision threshold, as opposed to a safety standard,[143] where a safety standard considers the estimated amount of risk, strength of evidence and public

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[139] Organization for Economic Cooperation and Development, *Safety Evaluation of Foods Derived by Modern Biotechnology: Concepts and Principles*, (Paris: OECD Publications, 1993): 13-15.

[140] WHO, "Application of the Principles of Substantial Equivalence to the Safety Evaluation of Food or Food Components from Plants Derived by Modern Biotechnology: Report of a WHO Workshop" (Geneva: World Health Organization, 1995): 7, embraced at the WHO and FAO, "Joint FAO/WHO Expert Consultation on Biotechnology and Food Safety," (Rome: Food and Agriculture Organization of the United Nations, 1996): 4.

[141] See e.g. Henry Miller, "Substantial Equivalence: Its Uses and Abuses," *Nature Biotechnology* 17, no. 11 (1999): 1043; Les Levidow, Joseph Murphy and Susan Carr, "Recasting 'Substantial Equivalence': Transatlantic Governance of GM Food," *Science, Technology and Human Values* 32, no. 1 (2007): 37.

[142] RSC, "Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada," 178, note 5. In conventional plant breeding, novel traits like seed colors, herbicide tolerance or disease resistance are monitored in the field.

[143] Ibid., 182.

concerns, and a decision threshold is a 'line in the sand' where the weight and amount of the evidence from the decision-maker's perspective is strong enough to take action.[144] If the assessment is above the decision threshold, action is taken. In the context of GM foods, the safety assessment is based on the strength of the scientific evidence, though it is unclear to what extent the typical 90-day feeding experiments consider the potential impacts on public health and the environment, cumulative effects, as well as public concerns with the lack of conclusive long-term safety testing. The decision threshold following the safety assessment is 'substantial equivalence,' however the specifics of this threshold are ambiguous.

Interpreting 'substantial equivalence' as a decision threshold leads to a paradox referred to by the Royal Society Report as a "logical impasse."[145] In linking the concept of a novel trait with the threshold of substantial equivalence, if conventional and novel food with a GM trait—predicted to have no additional safety impacts—are evaluated to be 'substantially equivalent', then would the novel food without the GM trait no longer be 'substantially equivalent' to the conventional food?[146] Based on the reasoning from the Royal Society Report, would there be a GM trait present in the new food product?

The Royal Society Report proposes a "rigorous scientific analysis"[147] that interprets 'substantial equivalence' as a safety standard by establishing that novel food products present no additional risks to health and the environment in comparison to conventional foods, as a result of the GM traits. It is what the Royal Society Report calls, a "careful assessment of safety impacts"[148] that would support the integration of the precautionary principle into the GM food safety assessment process. The food safety testing would consequentially be based on a process-based approach of assessing novel technologies, as opposed to a product-based approach focused on assessing product characteristics on a case-by-case basis. This policy change would provide the procedural framework to evaluate the alternatives and inherent risks in complex agricultural inventions, as well as monitor the release of GM foods to gather conclusive data on their consumptive and ecological impacts.

It is worth noting that EU regulatory standards and policies on GM food safety assessments are also based on 'substantial equivalence': the proponent must provide scientific

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[144] American Humane Association, "The Decision-Making Ecology," http://www.americanhumane.org/assets/pdfs/children/cprc-dme-monograph.pdf.
[145] RSC, "Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada," 183, note 5.
[146] Ibid. 181.
[147] Ibid. 183.
[148] Ibid.

studies to prove 'equivalence' between the GM and the conventional food.[149] However, the rigorous EU legislative framework, which governs the GM food approval and safety testing process, suggests the EU interprets 'substantial equivalence' as a safety standard, as opposed to a decision threshold.

The nuances and relativism in interpreting 'substantial equivalence' as a decision threshold or a safety standard in the GM food safety assessment process suggest it may also be worthwhile to consider other options to integrate the precautionary principle into the GM food regulations as a means of improving the GM food safety assessment process.

VIII. RECOMMENDATIONS

The Canadian GM food safety assessment process should be based on the precautionary principle pursuant to the outstanding recommendations from the Royal Society Report to prevent potential harm to human health and the environment given the prevalence of GM foods in Canada. These recommendations may be adapted by the executive branch to reflect the interpretation of the precautionary principle from the Rio Declaration, which has been recognized by both the judicial and legislative branches. In light of the regulatory framework, the institutional and regulatory progress in adopting precaution for health and environmental protection in GM food regulatory decisions should encompass:[150]

- Mandatory GM food labeling and surveillance strategies;
- Public research program for long-term safety testing of GM foods, including whole foods, on health and the environment, including allergic reactions and increased exposure to toxins from GM proteins;
- Independent peer-reviews of regulatory decisions to approve GM foods;
- Public review of the concept of 'substantial equivalence' to eliminate any preconceived notions; and
- Conservation program for agricultural diversity and agro-ecosystems.

The most important recommendation remains mandatory labeling of GM foods.

It would be important to integrate the precautionary paradigm into the GM food safety assessment process by creating a distinct regulatory regime for GM foods and re-working public governance structures. Canada would improve the GM food safety assessment process by creating an external review committee composed of independent experts to oversee GM food approvals by the Health Directorate and industry experts. Given the shared and overlapping functions by government agencies under the governance structures in the novel food sector, limited access to quality non-GM food due to voluntary labeling, as well as access to information

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[149] Stephan, *Cultural Politics and the Transatlantic Divide over GMOs*, note 96.

[150] Andrée and Sharratt, "Genetically Modified Organisms and Precaution: Is the Canadian Government Implementing the Royal Society of Canada's Recommendations?" iii-vii, note 30.

constraints, it would be crucial to establish an independent regulatory body with a mandate of promoting procedural accountability and transparency, public access to information through mandatory GMO labeling, and a public list of GM foods pending approval with a public comment period to address consumer concerns, as well as impartiality of scientific experts in conducting GM food safety assessments.

Perhaps the best option for Canada is regulatory reform by moving away from 'substantial equivalence' to a peer-reviewed 'comparative food safety assessment' with transparent scientific standards and normative standards based on rigorous scientific evidence. As recommended in the Royal Society Report, such a 'comparative safety assessment' would require the "presence of [a] novel trait... [to] be rigorously demonstrated to be harmless (or the harm [would] not surpass a certain agreed-upon threshold) in the tested genetic/environmental context."[151] A 'comparative food safety assessment' with a scientific basis for GM food safety approvals would support a scientifically sound conclusion that GM foods are as safe as the original foods with respect to long-term human health and environmental impacts. It would be important to engage public review in developing the regulatory framework and safety assessment process in order to respect the democratic right of consumer choice. This regulatory and governance reform would improve not only the Canadian approval process of GM foods, but may also help Canada's ability to trade agricultural and agri-food products with the EU under the CETA.

IX. CONCLUSION

The ability of the precautionary principle to serve as the basis for reforming the Canadian agricultural biotechnology regulations, in particular the GM food safety assessment process, is limited by the existing regulatory framework. Improving the Canadian GM food safety assessment process by integrating the precautionary principle as a guiding framework may be possible with public support and legal recognition of the principle in the context of public health. At present, the precautionary principle remains an underused trade development strategy in the Canadian agricultural biotechnology sector, potentially resulting in missed opportunities to make the most of the CETA. The precautionary principle remains difficult to implement in the Canadian GM food regulations on account of the transparency and impartiality concerns with the GM food safety assessment process and access to information challenges, however the pervasiveness of GM foods, lack of informed consumer choice, as well as unknown health and

[151] RSC, "Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada," 183, note 5.

environmental risks justify the need to integrate precaution into the GM food safety assessment process. Implementing the precautionary principle as an enforceable duty is fundamental to improving the Canadian regulatory regime governing GM foods and capitalizing on the economic benefits of agricultural and agri-food trade with the EU market under the CETA.