Labeling of Genetically Modified Organisms: Law, Science, Policy and Practice

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Abstract

The labeling of genetically modified organisms (GMOs) has been the subject of a global debate for decades. This dissertation, by conducting comprehensive and inter-disciplinary research – from legal, scientific, political and practical perspectives, aims to provide an in-depth analysis of fundamental factors that have contributed to the formation of different labeling regimes, and to justify claims of significant concerns that an optimal labeling regime should be based on and protect. It finds that not only rationales for a mandatory GMO labeling system cannot be justified but also the implementation of mandatory labeling measures may trigger a number of pragmatic problems. It is worth noting that mandatory GMO labeling measures, which lead to conflicts in global agricultural trade, might well violate WTO trade law obligations that are binding on Canada, China, the EU and the US etc. Based on these findings, this study supports voluntary labeling requirements and stands in sharp contrast to the mandatory labeling regimes implemented by the EU and other jurisdictions. It argues that three conditions should be considered to establish an optimal GMO domestic labeling regime. They are: (1) the regime must be based on scientific evidence; (2) it must employ scientific risk assessment and management as the basis for labeling requirements; and (3) the labeling should be accurate and the mission of GMO labeling should be primarily to protect the health of consumers. It thereby suggests that the mandatory labeling requirement should be abandoned in all jurisdictions, and replaced with a voluntary labeling regime and a globally harmonized system of GMO approval procedures and

detection methods. The dissertation ends with some lessons drawn from the current GMO labeling controversies to ensure better management of future GMO labeling conflicts and regulation of new agricultural biotechnology. It offers suggestions for perfecting the current Canadian GMO labeling regime.

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ACRONYMS

AB – Appellate Body

Bt – Bacillus thuringiensis

CBD – Convention on Biological Diversity

CCFL – Codex Committee on Food Labeling

CFIA – Canadian Food Inspection Agency

DSB – Dispute Settlement Body (WTO)

EU – European Union

FAO – Food and Agricultural Organization

GATT – General Agreement on Tariffs and Trade

GE – Genetic engineering

GM – Genetically modified or genetical modification

GMO – Genetically modified organism

ICJ – International Court of Justice

LMO – Living Modified Organism

rDNA – Recombinant Deoxyribonucleic Acid

SPS – WTO Agreement on the Application of Sanitary and Phytosanitary Measures

TBT – WTO Agreement on Technical Barriers to Trade

US/USA – United States of America

WTO – World Trade Organization

Chapter 1 Introduction

A. Background

A genetically modified organism (GMO) can be generally understood as an organism whose genetic material has been altered by genetic engineering techniques.[1] The terminology "genetic engineering" (GE) is commonly used to describe the application of recombinant deoxyribonucleic acid (rDNA) technology to the genetic alteration of microorganisms, plants and animals.[2] This advanced molecular technology, developed in 1973, allows for effective and efficient transfer of genetic material from one organism to another.[3] Since 1994 when the first genetically modified (GM) crop (the FlavrSavr tomato) was authorized for marketing in the United States (US),[4] GM crops have been widely cultivated in some parts of the world in less than a decade. According to the International Service for the Acquisition of Agri-biotech Applications (ISAAA), an industry body, the global total of cultivated areas using GM crops was over 175 million hectares in twenty-seven countries in 2013, of which 18 were developing countries and 19 were industrialized countries.[5] GM technology has been vigorously embraced in the Americas, e.g., the US, Canada, Brazil and Argentina, and in many Asian countries such as India and China.[6] In contrast, the cultivation of GM crops is considerably smaller in many

[1] See *infra* Section E.
[2] See The Institute of Technologists, *Genetically Modified Organisms*, online: Quackwatch <http://www.quackwatch.org/03HealthPromotion/ gmo.html>.
[3] *Ibid.*
[4] Arne Holst-Jensen, "Testing for Genetically Modified Organisms (GMOs): Past, Present and Future Perspectives" (2008) 27:6 Biotechnology Advances 1071.
[5] ISAAA, *ISAAA Brief 46-2013: Top Ten Facts*, online: *International Service for the Acquisition of Agri-biotech Application (ISAAA)* <http://www.isaaa.org/resources/publications/briefs/46/topfacts/default.asp>.
[6] ISAAA, *Brief 46-2013: Executive Summary Global Status of Commercialized Biotech/GM Crops: 2013*, online: ISAAA <http://www.isaaa.org/resources/publications/briefs/46/executivesummary/default.asp>.

European Union (EU) countries (mainly GM-maize grown in Spain) due to their severe restrictions on growing GM crops.[7] It is worth noting that since 2010 the growth of planting GM crops in developing countries has been faster than that in wealthier nations and the adoption of GM crops is estimated to continue to expand.[8]

By virtue of GE techniques, GMOs are created to resist certain diseases and reduce the need for pesticides, thereby with the goal, among others, of offering higher yielding and safer environmental strategies for pest and disease control.[9] The PG Economics study published in 2008 indicated that, as a result of cultivation of GM insect-resistant cotton, there had been a 22.9 percent reduction in the volume of insecticide application since 1996.[10] The GE techniques can also increase the qualities of food production[11] and desired characteristics, such as a better texture, higher nutritional value or faster growth, and can be chosen to produce what some in the media have called a kind of "super food".[12] An example is "golden rice", which contains high levels of

[7] *Ibid*. The European Union can be traced to the creation of a European Economic Community (EEC) by the Treaty of Rome in 1957. The European Union was established when the Maastricht Treaty on European Union took effect in November 1993. In December 2007, the Treaty of Lisbon was concluded. It entered into force on December 1, 2009. The treaty abolished the three-pillar structure introduced by the Maastricht Treaty. It recognized the political, economic and social rights enumerated in the "Charter of Fundamental Rights. John McCormick, *Understanding the European Union A Concise Introduction*, 5th ed (UK: Palgrave Macmillan, 2011) at 75; see also *Treaty of Lisbon amending the Treaty on European Union and the Treaty establishing the European Community, signed at Lisbon,* 13 December 2007, [2007] O.J.C 306/01, online: Europa <http://eur-lex.europa.eu/JOHtml.do?uri=OJ:C:2007:306:SOM:EN:HTML>. The Treaty of Lisbon amends the EU's two core treaties: the Treaty on European Union and the Treaty on the Functioning of the European Union. *Consolidated versions of the Treaty on European Union and the Treaty on the Functioning of the European Union*, 30 March 2010, [2010] O.J.C 2010/C83/01. To date, the EU has 28 member states: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, and United Kingdom. See Countries, online: Europa. eu <http://europa.eu/about-eu/countries/index_en.htm>.

[8] ISAAA, *supra* note 6.

[9] See the Institute of Technologists, *supra* note 2.

[10] Graham Brookes, *Peter Barfoot, GM Crops: Global Socio- economic and Environmental Impacts 1996-2006*, online: PG Economics Ltd, UK <http://www.pgeconomics.co.uk/pdf/2009globalimpactstudy.pdf> at 12-13.

[11] Guillaume P. Gruere, *A Review of International Labeling Policies of Genetically Modified Food to Evaluate India's Proposed Rule* (2007), online: AgBioForum <http://agbioforum.org/v10n1/v10n1a06-gruere.htm>.

[12] *In-depth: Genetic Modification Genetically Modified Food: A Primer*, online: CBC News Online <http://www.cbc.ca/news/background/genetics_ modification/>.

beta-carotene, a precursor of Vitamin A, for treating Vitamin A deficiency.[13] Currently, the GM soybean is the most popular GM crop in the world, and the most common GM trait so far is tolerance to herbicides.[14]

B. GMO Labeling regimes

This emerging agricultural biotechnology has also been associated with a range of risks and social controversy. Since scientists have not fully explored the long-term environmental and health risks, some scientists and civil society organizations are worried that GMOs may create potential health and environmental harms, such as food allergies, genetic erosion (i.e., the extinction of populations and the significant change of genetic structure of populations), and increased vulnerability of crop plants to pests and diseases.[15] As a result of these concerns, particularly those associated with human health and consumers' informed choices, the public has expressed a desire for more information about GMOs.[16]

[13] J. Chow, Y. E. Klein & R. Laxminarayan, "Cost-effectiveness of 'Golden Mustard' for Treating Vitamin A Deficiency in India" (2010) 5: 8 PLoS One 1.

[14] See Tanya Kerssen, *The Science of Wishful Thinking: ISAAA's Report on GM Crops*, online: Food First <http://www.foodfirst.org/en/ node/2879>.

[15] See *Genetically Engineered Soybeans May Cause Allergies July 08, 2010*, online: Mercola <http://Art. s.mercola.com/sites/Art.s/archive/2010/07/08/genetically-engineered-soybeans-may-cause-allergies.aspx>; GMO Allergy Concerns, online: Livestrong <http://www.livestrong.com/Art./230667-gmo-allergy-concerns/>; also see Edith Brown Weiss, John Howard Jackson & Nathalie Bernasconi-Osterwalder, *Reconciling Environment and Trade* (Netherlands: Leiden, Martinus Nijhoff Publishers/Koninklijke Brill 2008) at 587; also see Alan McHughen & Robert Wager, "Popular Misconceptions: Agricultural Biotechnology" (2010) 27:6 New Biotechnology 724; K. Hammer & Y. Teklu, "Plant Genetic Resources: Selected Issues from Genetic Erosion to Genetic Engineering" (2008) 109:1 Journal of Agriculture and Rural Development in the Tropics and Subtropics 15.

[16] According to research released by the Institute of Grocery Distribution (IGD) on 8 Oct, 2008, consumers want more information on genetically modified foods. See Consumer Attitudes to GM Foods, online: IGD <http://www.igd.com/index.asp? id=1&fid=1&sid=8&tid=30&cid=1487>; also see FDA Hearing Focuses on the Labeling of Genetically Engineered Salmon, September 21, 2010, online: the New York Times <http://www.nytimes.com/2010/09/22/business/22salmon.html>.

In response to public pressure, governments throughout the world have developed a variety of regulatory frameworks. A traceability and labeling system for GMOs is one such regime. GMO labeling is information found on the label of prepackaged food or the written document for non-prepackaged food stating either the product contains or consists of GMOs or is GMO-free.[17] The European Community (now EU) first proposed traceability and labeling system for GMOs, and the system has been considered important in EU countries as a way to ensure food quality and preserve freedom of choice for consumers.[18] Today, more than forty countries have promulgated GMO labeling laws, and they vary significantly. In general, GMO labeling schemes can be classified into two categories: mandatory and voluntary labeling regimes. Moreover, based on conditions that will trigger a labeling requirement, GMO labeling regimes can be divided into two modes: process-oriented (or process-based) and product-oriented (or product-based) labeling systems.[19] The current EU GMO labeling regulations are the process-based type. They mandate that all food products that have used GM techniques during their production be subjected to labeling requirements, even when the physical properties of the end products are not changed. Under the product-based labeling system, however, food products must be labeled only when the physical and chemical composition of the resulting products has changed, which may result in allergens or toxins. For example, Japan uses a product-based mandatory labeling system, thereby not requiring the labeling of food products such as soy sauce or soybean oil because no GMO

[17] See *General Standard for the Labeling of Prepackaged Foods*, Codex STAN 1-1985.
[18] Yves Bertheau & John Davison, Soybean In the European Union, Status and Perspective, online: <http://cdn.intechopen.com/pdfs/22595/InTech-Soybean_in_the_european_union_status_and_perspective.pdf>.
[19] Peter W.B. Phillips & Grant Isaac, "GMO Labeling: Threat or Opportunity?" (1998) 1:1 AgBioForum 25.

content can be detected in these end products, even though the processing of the products involves GM soybeans.[20]

In addition, the labeling of GMOs can take the form of either positive labeling or negative labeling. Positive labeling involves statements such as "This product contains GMOs", or "This product has been genetically modified." Negative labeling examples would read: "This product contains no GM ingredients," or "This seed has not been genetically modified."[21]

C. Problem statement

Based on the sovereignty, each country can independently decide which GMO labeling system to use within its jurisdiction. However, when GMO products join the international food trade, conflicts of different labeling requirements occur, and debates concerning GMO labeling regimes become an internationally controversial legal issue. Such debates, combined with controversies over the application of GM technology to agriculture has attracted significant interest from legal scholars, who have explored and discussed regulatory systems for GMOs. Some of them have provided considerably comprehensive analyses of how GMOs should be regulated, how such legislation has been formed, and what form regulatory legislation should take.[22] The

[20] Michael Howlett & David Laycock ed, *Regulating Next Generation Agri-Food Biotechnologies Lessons from European, North American, and Asian Experiences*, (Oxon: Routledge 2012) at 117.

[21] C. Ford Runge, Gian-Luca Bagnara & Lee Ann Jackson, Differing U.S. and European Perspectives on GMOs: Political, Economic and Cultural Issues, online: <http://dspace.cigilibrary.org/jspui/bitstream/123456789/7961/1/Differing%20US%20and%20European%20Perspectives%20on%20GMOs.pdf?1>.

[22] For example, Iain E. P. Taylor ed., Genetically *Engineered Crops Interim Policies, Uncertain Legislation* (US: New York, Haworh Food & Agricultural Products Press, 2007); Les Levidow & Susan Carr, *GM Food on Trial Testing European Democracy* (US: New York, Routledge, 2010); Michael Baram & Mathilde Bourrier, *Governing Risk in GM Agriculture* (US: New York, Cambridge University Press 2011).

controversies of GMO labeling have been touched on in these studies but they are small-scale explorations.[23] Specialized discussions on GMO labeling can be found in many scholarly papers, while books that examine GMO labeling regimes are far less common. In 2010, Marchant, Cardineau and Redick published a monograph entitled *Thwarting Consumer Choice the Case against Mandatory Labeling for Genetically Modified Foods* that focused on discussing which GMO labeling regimes should be used.[24] In this book, the authors launched strong arguments against the mandatory labeling of GM foods, claiming that rationales in favor of a GMO mandatory labeling regime are convincing at first glance but they cannot stand scrutiny in any in-depth analysis. They built their arguments on the ground of extensive research from legal, ethical and scientific perspectives. That being said, most of their discussion was in the context of the US and the EU. The legislation of other major players in the GMO industry, such as Canada and China, were not discussed in their study. More importantly, international laws, including international food and environmental laws and international trade law, which have significant influence on domestic legislation on GMO labeling were not addressed.

A main topic of the existing literature is whether the labeling of GMOs should be mandatory. Rationales proclaimed by the proponents of a mandatory labeling regime include *inter alia*: the given level of uncertain risks presented by GMOs and the subsequent adoption of the

[23] For example, one subsection in Chapter 4 of the book: *EU Regulation of GMOs* used 7 pages for discussing the EU labeling issues. See Maria Lee, *EU Regulation of GMOs* (UK: Edward Elgar Publishing Limited, 2008). Similar examples can also be found in Colin A. Carter, GianCarlo Moschini & Ian Sheldon, *Genetically modified Food and Global Welfare* (UK: Emerald Group Publishing Limited, 2011) Ch. 11; Edith Brown Weiss, John H. Jackson & Nathalie Bernasconi-Osterwalder, *Reconciling Environment and Trade*, 2d ed (Leiden: Martinus Nijhoff Publishers/Koninklijke Brill 2008) Ch. 13.

[24] See Gary E. Marchant, Guy A. Cardineau, & Thomas P. Redick, *Thwarting Consumer Choice: The Case Against mandatory Labeling for Genetically Modified Foods* (Washington. D.C.: The AEI Press, 2010).

precautionary principle; providing consumers with information related to contents of foods so that they can make informed choices; and the consumer's right to have information on GMOs in the food for sale.[25] The opponents of a mandatory regime, however, argue that there are no fundamental differences between GMOs and non-GM foods and so far there is no well-established scientific evidence showing that GM crops are more risky than traditional crops to human and animal health.[26] They also argue that the consumer's right to know and consumers' demand for information alone cannot justify mandatory labeling of GMOs, and that the labeling of GMOs is often misleading which will not lead to a meaningful choice.[27]

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[25] Michael A. Whittaker, "Reevaluating the Food and Drug Administration's Stand on Labeling Genetically Engineered Foods" (1998) 35 San Diego L Rev 1215; Lara B. Winn, "Special Labeling Requirements for Genetically Engineered Food: How Sound Are the Analytical Frameworks Used by FDA and Food Producers?" (1999) 54 Food & Drug LJ 667; Diane T. Vasquez, "Genetic Engineering and Food Labeling: A Continuing Controversy" (2000) 10 San Joaquin Agric L Rev 77; J. Teel "Regulating Genetically Modified Products and Processes: An Overview of Approaches" (2000) 8 NYU Envtl LJ 649; F. X. Perrez "Taking Consumers Seriously: the Swiss Regulatory Approach to Genetically Modified Food" (2000) 8 NYU Envtl LJ 585; Alicia T. Simpson, "Buying and Eating in the Dark: Can the Food and Drug Administration Require Mandatory Labeling of Genetically Engineered Foods? Alliance for Bio-Integrity v. Shalala, Et Al., 116 F. Supp.2d 166 (2000)" (2001) 19 Temp Envtl L & Tech J 225; S. L. Kirby, "Genetically Modified Food: More Reasons to Label Than Not" (2001) 6 Drake J Agric L 35; H. N. Ellison, "Genetically Modified Organisms: Does the Current Regulatory System Compromise Consumer Health?" (2002) 10 Penn St Envtl L Rev 345; Taiwo A. Oriola, "Consumer Dilemmas: The Right to Know, Safety, Ethics and Policy of Genetically Modified Food" (2002) 2002 Sing J Legal Stud 514; Andrew J. Nicholas, "As the Organic Food Industry Gets Its House in Order, the Time Has Come for National Standards for Genetically Modified Foods" (2003) 15 Loy Consumer L Rev 277; E. Robertson, "Finding A Compromise in the Debate over Genetically Modified Food: An Introduction to A Model State Consumer Right-To-Know Act" (2003) 9 BU J Sci & Tech L 156; Graham M. Wilson, "A Day on the Fish Farm: FDA and the Regulation of Aquaculture" (2004) 23 Va Envtl LJ 351; M. Gihooley, "Reexamining the Labeling for Biotechnology in Foods: The Species Connection" (2004) 82 Neb L Rev 1088; Jamie E. Jorg Spence, "Right to Know: A Diet of the Future Presently Upon US" (2005) 39 Val U L Rev 1009; Comment, "A Tale of Two Systems: A Comparison Between US and EU Labeling Policies of Genetically Modified Foods" (2006) 15 San Joaquin Agric L Rev 193; David A. Nauheim, "Food Labeling and the Consumer's Right to Know: Give the People What They Want" (2009) 4 Liberty U. L. Rev. 97; Valery. Federici, "Genetically Modified Food and Informed Consumer Choice: Comparing U.S. and E.U. Labeling Laws" (2010) 35 Brook. J. Int'l L. 515.

[26] US FDA, *Foods Derived from Genetically Engineered Plants*, online: US FDA <http://www.fda.gov/Food/FoodScienceResearch/Biotechnology/ucm346858.htm>.

[27] Frederick. H. Degnan, "The Food Label and the Right-to-know" (1997) 52 Food & Drug LJ 49; J. E. Beach, "No 'Killer Tomatoes': Easing Federal Regulation of Genetically Engineered Plants" (1998) 53 Food & Drug LJ 181; Kristen S. Beaudoin, "On Tonight' Menu: Toasted Cornbread with Firefly Genes? Adapting Food Labeling Law to Consumer Protection Needs in the Biotech Century" (1999) 83 Marq L Rev 237; Frederick H. Degnan, "Biotechnology and the Food Label: A Legal Perspective" (2000) 55 Food & Drug LJ 301; J. Howard Beales, "Modification and Consumer Information: Modern Biotechnology and the Regulation of Information" (2000) 55 Food & Drug LJ 105; Karen A. Goldman, "Labeling of Genetically Modified Foods: Legal and Scientific Issues" (2000) 12 Geo Int'l Envtl L Rev 717; P. Reimer & B. Schwartz, "Trade and Genetically Modified Foods Biotechnology: A Canadian Perspective" (2001) 1 Asper Rev Int'l Bus & Trade L 91; Kelly. A. Leggio, "Limitations on the Consumer's Right to Know: Settling the Debate over Labeling of Genetically Modified Foods in the United States" (2001) 38 San Diego L Rev 893; J. Halloran, "Regulating Genetically Modified Foods: Is Mandatory Labeling the Right Answer?" (2003) 10 Rich JL & Tech 12; Stan Benda, "It's all about Elmer Gantry ... There is no Frankenstein!!! — Part II" (2003) 16 IPJ 393; P. Burchett, "A Castle in the Sky: the Illusory Promise of Labeling Genetically Modified Food in Europe" (2004) 23 Penn St Int'l L Rev 173; Carl R. Galant, "Labeling Limbo: Why Genetically Modified Foods Continue to Duck Mandatory Disclosure" (2005) 42 Hous L Rev 125; Matthew R. Kain, "Throw Another

The other topic of the existing literature is the relationship between domestic or regional labeling laws and relevant international laws. As mentioned above, the debate on this topic results from the international trade disputes concerning GM products.[28] The arguments have been focused on the roles of different international laws in dealing with different GMO labeling regimes. Some scholars argue that the labeling conflicts can be solved under the World Trade Organization (WTO) system.[29] By taking advantage of the WTO dispute settlement mechanism, they argue that the WTO can handle the challenge of conflicts between different GMO labeling regimes and protect consumers. Others challenge the WTO system, arguing that it alone cannot address the food safety problem properly and sufficiently, and that international food and environmental laws are more suitable for regulating the globalization of the GM food industry.[30]

Regrettably, these legal studies have not formed a consensus on the labeling regime for GMOs, neither on the international nor the domestic levels. The conflict between mandatory and voluntary labeling regimes remains unsettled. So far, both the EU and the US are sticking to their

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Cloned Steak on the Barbie: Examining the FDA's Lack of Authority to Impose Mandatory Labeling Requirements for Cloned Beef" (2007) 8 NC J L & Tech 303.

[28] See WTO disputes discussed in more detail, *infra* Chapter Three.

[29] Victoria H. Zerjav, "United States/European Union Trade Relations: the Need for a Solution to the Bovine Trade Disputes" (2000) 78 Wash U LQ 645; Arthur. E. Appleton, "The Labeling of GMO Products Pursuant to International Trade Rules" (2000) 8 NYU Envtl LJ 566; John S. Fredland, "Unlabel Their Frankenstein Foods!: Evaluating A US Challenge to the European Commission's Labeling Requirement for Food Products Containing Genetically Modified Organisms" (2000) 33 Vand J Transnat'l L 183; Heather B. Freeman, "Trade Epidemic: the Impact of the Mad Cow Crisis on EU-US Relations" (2002) 25 BC Int'l & Comp L Rev 343; Paulette L. Stenzel, "Why and How the World Trade Organization Must Promote Environmental Protection" (2002) 13 Duke Envtl L & Pol'y F 1; Michele M. Compton, "Applying World Trade Organization Rules to the Labeling of Genetically Modified Foods" (2003) 15 Pace Int'l L Rev 359; D. Schramm, "The Race to Geneva: Resisting the Gravitational Pull of the WTO in the GMO Labeling Controversy" (2008) 9 Vt J Envtl L 93.

[30] Bruce A. Silverglade, "The WTO Agreement on Sanitary and Phytosanitary Measures: Weakening Food Safety Regulations to Facilitate Trade?" (2000) 55 Food & Drug LJ 517; Marguerite A. Hutchinson, "Moving Beyond the WTO: A Proposal to Adjudicate GMO Disputes in An International Environmental Court" (2008) 10 San Diego Int'l LJ 229.

adopted approach.[31] On the international law level, in 2011 the Codex Alimentarius and Codex Committee on Food Labeling, an international organization specializing in food labeling, abandoned its decades-old effort to establish an internationally uniform standard for GMO labeling.[32] Instead it adopted a guideline that regulated the labeling of GM food and GM food ingredients under the existing Codex texts.[33] As a result, conflicts over GMOs in world trade will remain because of different labeling requirements. The deadlock seems likely to be sustained.

My dissertation is built on the existing research by exploring the question of which labeling regime can and should be used by states. In this dissertation I focus on the scientific analysis of GMOs and GM techniques, the examination of relevant social considerations, the applicable international laws and domestic GMO labeling legislation, and the interaction between the international, EU and domestic legal systems. The combination of these three perspectives has not been comprehensively addressed by the existing legal research and is of significant value to understanding the development of GMO labeling legislation and to suggesting possible solutions for conflicts of labeling policy.

[31] "In 2009, France, as a member state of the EU, was reported that it would join the trend to introduce a new labeling regime, which was even more stringent than the current EU labeling laws." See H. Holder, *EU GMO-labeling Laws Judged Insufficient*, online: Friends of the Earth Europe <http://www.foeeurope.org/press/2009/Nov03_EU_GMO_LABELLING_LAWS_JUDGED_ INSUFFICIENT.html>. "In 2010, this year the US Food and Drug Agency (hereinafter "FDA") claimed that the genetically modified salmon would not be required to be labeled." See L. Layton, *FDA Rules Won't Require Labeling of Genetically Modified Salmon*, online: The Washington Post <http://www.washingtonpost.com/wp-dyn/content/Art. /2010/09/18/AR201009 1803520.html>.

[32] The 2011 Draft, *The Proposed Draft Compilation of Codex Texts Relevant to the Labeling of Foods Derived from Modern Biotechnology*, REP 11/FL, Quebec, 2011, Appendix III.

[33] *Ibid*.

To make sense of the many issues concerning GMO safety and possible risk, a modest scientific knowledge of what constitutes a GMO and how genetic engineering works is essentially helpful. For example, it is important to understand (1) the types of GM techniques and how they realize a high-quality breeding in a more accurate and efficient way than conventional breeding and (2) the mechanisms of horizontal gene transfer and its possibility of occurrence in the context of GM crops as well as the associated risks from such transfer. Moreover, a moderate level of knowledge of molecular biotechnology is necessary to understand and evaluate the scientific evidence behind different GMO labeling laws and policies, and to discover the fundamental reasons that have caused confusion in the implementation of GMO labeling laws. With regard to relevant international laws and national GMO labeling regimes, my dissertation has paid more attention to social factors that have contributed to the current different labeling requirements in different international law regimes. Meanwhile, the exploration of the interaction between international laws and national authorities further reveals the political factors behind different national GMO labeling regimes.

The research questions that drive my dissertation are: (1) in the context of international GMO product trade, how has the labeling of GMOs been regulated under international law?; (2) how do relevant EU law and selected domestic laws regulate GMO labeling and what social factors impact the existing GMO legislation?; (3) can a mandatory labeling regime can be justified by scientific evidence, the precautionary principle, or the consumers' right to know?; (4) what are the practical problems involved in the implementation of mandatory labeling laws and what

causes enforcement difficulties?; (5) what objectives should an optimal labeling regime achieve?; and (6) should and, if so, how can the Canadian GMO labeling regime be improved?

D. Central Thesis

Based on a comparative analysis of the applicable international instruments and the selected domestic and EU labeling regimes, my research finds that rationales for different labeling requirements vary, but they have some concerns in common. For example, rationales for a mandatory labeling regime usually contain arguments that (1) GM foods are not natural and hence are not safe for consumption; (2) the precautionary principle should be applied to facilitate tracing back the source of certain GM varieties; and (3) consumers have a right to know whether their foods are genetically modified or contain GM ingredients. On the basis of a comprehensive inter-disciplinary research, this study argues that rationales for a mandatory labeling regime cannot stand up to critical scrutiny. The presumption about GMO safety is not supported by solid scientific evidence, and the use of the precautionary principle and the argument of the consumer's right to know cannot provide sufficient justification for mandatory GMO labeling.

I further argue that not only the rationales for a mandatory GMO labeling cannot be justified but also the implementation of a mandatory labeling measure might trigger a number of pragmatic problems. For instance, the labeling would increase GM and non-GM food prices; due to inaccurate statements of the labeling and limitations of testing methods for GM content, the labeling measure might not provide consumers with accurate and sufficient information for

making a meaningful informed choice. Moreover, based on the examination of three international law areas, I argue that mandatory GMO labeling measures, which caused conflicts in global agricultural trade, might well violate the WTO trade law that are binding on Canada, China, the EU, the US and many other states.

My final arguments, therefore, is in line with the Canadian voluntary labeling requirements and stand in sharp contrast to the mandatory labeling regimes implemented by the EU and other jurisdictions. I argue that three conditions should be considered to establish an optimal GMO domestic labeling regime. They are: (1) the regime must be based on scientific evidence; (2) it must employ scientific risk assessment and management as the basis for labeling requirements; and (3) the labeling should be accurate and the mission of GMO labeling should be primarily to protect the health of consumers. I suggest that the mandatory labeling requirement should be abandoned in all jurisdictions, and replaced with a voluntary labeling regime and a globally harmonized GMO approval procedure and detection method.

Finally, based on the entire research, I draw some lessons from the current GMO labeling controversies for a better management of future GMO labeling conflicts and regulation of new agricultural biotechnology. I argue that it is important to (1) secure a balanced discussion for any emerging agricultural biotechnology; (2) provide consumers with accurate information by using simple language that can be understood by the public; and (3) promote global transparency for

the GM information that would facilitate the establishment of globally harmonized GMO risk assessment procedures and testing methods.

I have chosen Canada as an example of a domestic law system to explain how improvements should be made based on the three conditions provided earlier to achieve an optimal GMO labeling regime. I suggest that Canada should keep its current GMO labeling regime and seek negotiations with the EU on the potential labeling conflicts under a Comprehensive Economic and Trade Agreement (CETA), the agreement in principle that was reached in October 2013.[34] Moreover, the Canadian GMO labeling system should improve allergenicity assessment for GM foods, provide more information to educate the public about the knowledge of GM techniques and GMOs, and endeavor to promote the establishment of an international harmonized GMO approval procedure and GMO detection standards.

E. Definitions and scope

There has been debate concerning the definition of GMOs. The main difficulty in defining a GMO lies in diverse understandings of genetic modification. For example, according to Health Canada's understanding, a GMO is considered as a class of "novel food".[35] It is defined as an organism whose genetic material not only has been altered by genetic engineering techniques, but also by artificial mutagenesis, which involves treating cells of an organism with external agents

[34] European Commission, Trade Policy Countries and Regions: Canada, online: europa <http://ec.europa.eu/trade/policy/countries-and-regions/countries/canada/>.

[35] Health Canada, *Genetically Modified (GM) Foods and Other Novel Foods*, online: Health Canada <http://www.hc-sc.gc.ca/fn-an/gmf-agm/index-eng.php>.

(e.g. UV light, certain chemicals) in order to produce changes in its genetic material. The EU's definition of a GMO,[36] however, does not include the organism in which the genetic material has been *naturally* altered by techniques other than recombinant nucleic acid molecules, for example, "cell fusion of plant cell which can exchange genetic material through traditional breeding methods."[37]

In this dissertation, GMO refers strictly to an organism whose genes have been altered by a genetic engineering technique that aims to produce desirable traits, e.g., growth rate, food conversion efficiency and resistance to disease.[38] Moreover, since the term GMO covers a wide range of life forms, i.e., plants and animals, this dissertation only addresses the labeling of genetically modified crops, which are the most commercially significant applications of biotechnology to food. So far, GM animals are not commercially available for human

[36] The 2001/18EC defines the term GMO as "an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination." The genetic modification includes, according to 2001/18/EC: "(1) recombinant nucleic acid techniques involving the formation of new combinations of genetic material by the insertion of nucleic acid molecules produced by whatever means outside an organism, into virus, bacterial plasmid or other vector system and their incorporation onto a host organisms in which they do not naturally occur but in which they are capable of continued propagation; (2) techniques involving the direct introduction onto an organism of heritable material prepared outside the organism including micro-injection, macro-injection and micro-encapsulation; (3) cell fusion (including protoplast fusion) or hybridization techniques where live cells with new combinations f heritable genetic material are formed through the fusion of two or more cells by means of methods that do not occur naturally." "Techniques referred to in Art. 2(2)(b) which are not considered to result in genetic modification, on condition that they do not involve the use of recombinant nucleic acid molecules or genetically modified organisms made by techniques/methods other than those excluded by Annex I B: (1) in vitro fertilization, (2) natural processes such as: conjugation, transduction, transformation, (3) polyploidy induction." EC, *Directive 2001/18 of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC*, [2001] O.J. L106/1.

[37] Annex I B of Directive 2001/18/EC the EU adopted a legislative framework on the deliberate release of GMOs into the environment and the placing of GMOs on the market in accordance with the precautionary principle. This principle has been continually adopted in Regulations (EC) No 1829/2003 and 1830/2003. See *Deliberate release of GMOs*, online: Europa <http://europa.eu/legislation_summaries/agriculture/food/l28130_en.htm>.

[38] See *Biotechnology and Genetically Modified Foods*, online: Health Canada <http://www.hc-sc.gc.ca/ fn-an/gmf-agm/fs-if/faq_4-eng.php>.

consumption,[39] but GM corn, canola and soybeans have been widely used in food. The definition of terms used in this dissertation include:

"Food and food ingredients obtained through certain techniques of genetic modification/genetic engineering" means food and food ingredients composed of or containing genetically modified/engineered organisms obtained through modern biotechnology, or food and food ingredients produced from, but not containing genetically modified/engineered organisms obtained through genetic engineering biotechnology.

"**Organism**" means any biological entity capable of replication, reproduction or of transferring genetic material.

"**Genetically modified/engineered organism**" means an organism in which the genetic material has been changed through genetic engineering biotechnology in a way that does not occur by conventional breeding.

[39] See L. Gray, *Giant Salmon Will Be First GM Animal Available for Eating*, online: The Telegraph <http://www.telegraph.co.uk/foodanddrink/7857310/Giant-salmon-will-be-first-GM-animal-available-for-eating.html>, See also Valery Federici, "Genetically Modified Food and Informed Consumer Choice: Comparing U.S. and E.U. Labeling Laws" (2010) 35 Brook J Int'l L 515. In December 2013 European Commission announced two proposals that aimed to ban animal cloning for food purposes and the marketing of food products from cloned animals in the EU. These two proposals are: (1) *Proposal for a Directive of the European Parliament and of the Council on the cloning of animals of the bovine, porcine, ovine, caprine and equine species kept and reproduced for farming purposes*; (2) *Proposal for a Council Directive on the placing on the market of food from animal clones*. See EC, *Proposal for a Directive of the European Parliament and of the Council on the cloning of animals of the bovine, porcine, ovine, caprine and equine species kept and reproduced for farming purposes*, December 18, 2013, 2013/0433(COD); EC, *Proposal for a Council Directive on the placing on the market of food from animal clones*, December 18, 2013, 2013/0434 (APP). See also USDA, *Animal Cloning*, online: USDA <http://www.usda-eu.org/topics/animal-cloning/>.

"**Genetic engineering biotechnology**" means the application of:

a. In vitro nucleic acid techniques,[40] including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or

b. Fusion of cells beyond the taxonomic family, that overcome natural physiological, reproductive or recombination barriers and that are not techniques used in traditional breeding and selection[41]

that overcome natural physiological, reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.[42]

F. Methodology

Three methodological approaches had been followed in completion of the thesis.

1. Library-based research

This thesis primarily was completed based on library research. Using both primary and secondary legal resources, I explore the rationales for and against GMO labeling regimes, review different GMO labeling regulatory systems in selected international and domestic laws and examine the justifications for these systems.

[40] These include but are not limited to: recombinant DNA techniques that use vector systems and techniques involving the direct introduction into the organism of hereditary materials prepared outside the organism such as microinjection, acro-injection, chemoporation, electroporation, micro-encapsulation and liposome fusion.

[41] Fusion of cells (including protoplast fusion) or hybridization techniques that overcome natural physiological, reproductive, or recombination barriers, where the donor cells/protoplasts do not fall within the same taxonomic family.

[42] This definition is taken from the Cartagena Biosafety Protocol under the Convention on Biosafety Diversity.

For primary legal resources, the international law instruments legal relating to the GMO labeling are the WTO Agreement on Sanitary and Phytosanitary Measures (SPS Agreement), WTO Agreement on Technical Barriers to Trade (TBT Agreement),[43] the 1992 Convention on Biological Diversity,[44] the 2000 Cartagena Protocol on Biosafety[45] and the Codex Committee on Food Labeling (CCFL)[46] which can be found at their official websites.[47] For EU laws, the EU treaties, regulations, directives, decisions, and recommendations concerning the labeling of GMOs are available on the EU website.[48] Also, websites such as the GMO Compass and Europa have provided comprehensive collections of the information about the EU GMO labeling issues, which include news and current affairs, GMO database and regulations etc. On the domestic legal level, the relevant laws of the Canadian and the Chinese GMO labeling systems can be consulted at the related authorities' websites[49] or professional legal databases, such as Westlaw and Lexis.

For secondary legal resources, books and articles in English regarding GMO labeling are available at the J. A. Weir Law Library, the University of Alberta library system, websites of

[43] *Agreement on the Application of Sanitary and Phytosanitary Measures* (*SPS Agreement*), 14 April 1994, 33 ILM 1125, online: <www.wto.org/ english/docs_e/legal_e/legal_e.htm>; *Agreement on Technical Barriers to Trade* (*TBT Agreement*), 15 April 1994, 33 ILM 1125, online: <http://www.wto.org/english/tratop_e/tbt_e/tbtagr.htm>.

[44] *Convention on Biological Diversity*, 5 June 1992, 1760 UNTS 79, 31 ILM 818, online: <http://www.cbd.int/>.

[45] *The Cartagena Protocol on Biosafety*, 29 January 2000, 2226 UNTS 208, 39 ILM 1027, online: <http:// bch.cbd.int/protocol/>.

[46] See Codex Committee on Food Labeling under Codex Alimentarius International Food Standards, online: <http://www.codexalimentarius.org/committees-and-task-forces/en/?provide=committeeDetail&idList=7>.

[47] The full documents of the WTO Agreement on Sanitary and Phytosanitary Measures and *Agreement* on Technical Barriers to Trade are available at WTO website: <http://www.wto.org/>; The complete content of the Cartagena Protocol on Biosafety can be acquired at <http://bch.cbd.int/protocol/>. Also, through the Codex website: <http://www. codexalimentarius.net/web/index_en.jsp>, the latest progress of the Codex Committee on Food Labeling can be tracked.

[48] *Access to European Union Law*, Online: EUR-Lex <http://eur-lex.europa.eu/en/>.

[49] For example, the US regime: the U.S. Food and Drug Administration (hereinafter the "FDA") statement on GMO labeling: 1992 Statement of Policy in the Federal Register for Foods derived from New Plant Varieties can be acquired at: <http://www.fda.gov/>; for Canadian GMO labeling regime, National Standard of Canada CAN/CGSB-32.315-2004: Voluntary Labeling and Advertising of Foods That Are and Are Not Products of Genetic Engineering, can be checked at <http://www.tpsgc-pwgsc.gc.ca/cgsb/on_the_net/032_0315/standard-e.html>; for Chinese regulations on GMO labeling, Regulations on Identification Tags of Agricultural Genetically Modified Organisms Labeling 2007 and the Food Hygiene Law of the People's Republic of China 2009, can be checked through the Chinese legal databases: Faobao and Fayi.

non-government organizations (NGOs), Westlaw and Lexis. The relevant Chinese literature has been acquired at the Wuhan University Law School Library, the Wuhan University library system, the Chinese Journal Database[50] and the Chinese legal research databases, i.e. Beida Fabao and Beida Fayi.[51]

2. Comparative approach

The thesis also employs a comparative approach. By identifying similarities and differences among international and national solutions for GMO labeling, this comparative research identifies whether there are any mandatory obligations of states pursuant to their treaty obligations, whether states have gone beyond what they were required to do under international law, and whether they are violating any international law obligations. This approach has also given insights to understanding the relevant social factors that might contribute to differences in GMO legislation on the international, EU and national levels, and provides evidence to support my arguments against the mandatory labeling system.

For the international law models, I compare the WTO SPS Agreement and TBT Agreement,[52] the Convention on Biological Diversity and its Cartagena Protocol on Biosafety,[53] and the FAO CCFL.[54] The reason for choosing these regimes is that they are the representative international

[50] The Chinese Journal Data Base, CNKI for short, is the biggest journal database in China. It can be available at <www.cnki.net>.
[51] These two databases are the most comprehensive professional legal databases in China. They are developed by Beijing University Law School and contain both primary and secondary legal sources in China. They can be reached at <http://vip.chinalawinfo.com/> and <http://www. lawyee.net>.
[52] *The SPS Agreement and TBT Agreement*, *supra* note 43.
[53] *Convention on Biological Diversity*, *supra* note 44; *The Cartagena Protocol on Biosafety*, *supra* note 45.
[54] See Codex Committee on Food Labeling under Codex Alimentarius International Food Standards, *supra* note 46.

instruments for international trade law, international environmental law and international food and agricultural law, and they address the regulation of GMO labeling. By identifying the differences and similarities between these international laws, this study reveals the ambitions of different national authorities in different international fora and to the extent to which they require, or they fail to require, mandatory labeling. I discuss why no harmonized/unified standards for GMO labeling exists in the international system.

On the domestic law level, the regimes of Canada and China are compared. These countries have different legal systems – common law and civil law, different stages of economic development, different population sizes and hold different positions on GMO labeling requirements. Canada possesses advanced agricultural biotechnology and represents a large proportion of global GM canola production.[55] The Canadian government's assessment of existing GM products concludes that they are not materially different as compared to conventional food products, and they have adopted a voluntary labeling system for GMOs.[56] China, as a developing country, has been increasingly emphasizing the development and cultivation of GM crops, and uses a mandatory labeling system.[57] Facing an already huge and growing population, China has to improve yield with the help of agricultural biotechnology when arable land growth is stagnant.[58] Therefore, it is a representative and significant example of a developing country GM regulatory system.

[55] See John Davison, "GM Plants: Science, Politics and EC Regulations" (2010) 178(2) Plant Science 94 at 94.
[56] See *Labeling of Genetically Engineered Foods in Canada*, online: Canadian Food Inspection Agency <http://www.inspection.gc.ca/english/fssa/labeti/novnou/novnoue.shtml>.
[57] "China will accelerate development of its own genetically modified (GMO) crops, seeking to secure food security and international competitiveness", see Chris Buckley and Niu Shuping, *China Says Has not Allowed Imported GMO Grain Seeds in for Planting*, online: Reuters <http://www.reuters.com/Art. /idUSTOE62109P20100303>.
[58] *Ibid*.

3. Comprehensive literature review

The thesis is written mainly based on a comprehensive literature review. The interdisciplinary research is based on collections through literature reviews, surveys, and internet searches. I focus on three perspectives. The first perspective is consumer reactions to GMO labels.[59] The research materials cover the following questions: do consumers want GM products to be labeled? What factors contribute to their desires to label GM products? What kind of labeling system do they prefer: voluntary or mandatory? How do consumers respond in the marketplace to information about how a product and/or its ingredients were produced? Will consumers pay a premium for the labeling information? The second perspective is producers' and retailers' attitudes to GMO labeling. For instance, how do producers perceive the mandatory labeling of GM products? What factors influence producers' perceptions and opinions regarding mandatory labeling of GM products? etc.[60] The third perspective addresses the cost of implementation of mandatory labeling

[59] Researchers at Colorado State University's Department of Agricultural and Resource Economics have undertaken a series of surveys and analyses to understand Colorado consumers' attitudes toward GE food, especially potatoes. They found that "78 percent supported mandatory labeling of GE foods. However, the respondents were not willing to pay a premium for such labeling. Women appeared to favor mandatory labeling more than men, younger consumers were less likely to support mandatory labeling, and those who considered themselves better informed about biotechnology were less concerned that GE foods be labeled.", see M. L. Loureiro & S. Hine, "Preferences and Willingness to Pay for GM Labeling Policies" (2004) 29 Food Pol'y. 467; also researchers at Department of Agricultural, Environmental and Development Economics, Ohio State University, and Department of Resource Economics and Policy, University of Maine designed a survey to find elicit consumer reaction to various approaches to labeling genetically modified (GM) foods. Based on the survey result, they discuss several practical policy implications, including how different label messages may impact consumer reactions in markets involving GM products, see Brain Roe and Mario F. Teisl, "Genetically Modified Food Labeling: The Impacts of Message and Messenger on Consumer Perceptions of Labeling and Products" (2007) 32 Food Pol'y 49**;** see also Maurizio Canavari & Rodolfo M. Nayga, "On Consumers' Willingness to Purchase Nutritionally Enhanced Genetically Modified Food" (2009) 41 Applied Economics 125; also see Wuyang HU, W. L. Adamowicz and M. M. Veeman, "Consumers' Preferences for GM Food and Voluntary Information Access: A Simultaneous Choice Analysis" (2009) 57 Canadian Journal of Agricultural Economics 241.

[60] Researchers from Alabama A & M University and Tuskegee University conducted a survey on producers' opinions on mandatory labeling of GM products. The population for this survey was farmers in the states of Alabama, Louisiana, Texas, Oklahoma, Florida, Mississippi, Tennessee, South Carolina, Arkansas and Georgia, see E'licia L. Chaverest, *et al*, *An analysis of producers' opinions on mandatory labeling of GM products*, online: selected paper prepared for presentation at the Southern Agricultural Economics Association Annual Tulsa, Oklahoma, February 18, 2004 <http://ageconsearch.umn.edu/bitstream/34624/1/sp04ch06.pdf>.

of GMOs. For example, what will the cost be as a result of segregating products that are GMOs or contain GM ingredients and traditional products throughout the food supply chain, namely "from farm to fork"? The review and analyses of the literature collected are used as evidence to support my arguments against the adoption of mandatory labeling requirements.

G. Structure of this dissertation

In Chapter Two, I examine the treatment of labeling regimes in international agricultural and food law, and international environmental law. Since there are a number of important WTO cases on GMO labeling, a discussion of GMO labeling controversies in the context of international trade law is developed separately in Chapter Three. My exploration of international law shows the continuing efforts that the international fora has devoted to this field and the review further provides legal and political explanations of why the realms of these international models work separately. I argue that, although the WTO system may not substantially solve the conflicts between different approaches to GMOs labeling, it indeed does provide a mechanism that can subject the conflict to a legal settlement process, monitor compliance and clarify members' legal obligations. However, the discussion of GMO labeling under the WTO rules in Chapter Three finds that without a further scientific and economic exploration of GMO labeling, a conclusion that the mandatory labeling is inconsistent with the WTO rules cannot be reached.

In Chapter Four, I examine the labeling regime in EU law and in the domestic laws of Canada and China to find out the domestic sources of international conflicts of GMO labeling

requirements. As previously indicated, the EU imposes severe restrictions and regulatory oversight on the cultivation and marketing of biotech foods. Its mandatory system for GMO labeling requires that "if a food contains or consists of genetically modified organisms, or contains ingredients produced from GMOs, this must be indicated on the label."[61] My exploration of EU law has not only addressed the current regime but also explores the development of EU labeling laws. Moreover, from social, political and commercial perspectives, and based on the literature review, I analyze relevant considerations that result in the strong anti-GM products attitudes of EU nationals and the current stringent EU GMO labeling system. Similar to the examinations of EU labeling laws, I explore the current laws in Canada and China as well as the development of each country's GMO labeling regimes. When addressing the Canadian GMO labeling regime, I concentrate on the discussions concerning why Canadian consumers are less troubled by GMOs compared to consumers in the EU, and what factors lead to the Canadian laws regarding GMOs being less stringent. The research on the Chinese GMO labeling regime demonstrates a developing country's attitude to GM products and GMO labeling requirements when it is faced with a huge population and limited arable land.

After the comprehensive exploration of GMO labeling laws on both international and domestic levels, I summarize rationales in favor of mandatory labeling regimes at the beginning of Chapter Five. In the following sections, I explore conflicting claims, positions and arguments, and the

[61] Regulation (EC) 1830/2003. EC, *Regulation No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labeling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (Regulation (EC) No 1830/2003)*, [2003] O.J. L268/24.

scientific evidence to support my understanding of an optimal labeling model. Since most of my evidence-based arguments are against the mandatory labeling regime, it is not surprising to find that my conclusions support a voluntary labeling regime. I argue that agriculture should shift towards use of more GM crops since no established evidence exists indicating that GM crops are unsafe for human and animal consumption and that conventional agriculture is not as sustainable as biotechnological agriculture. In regard to the argument that GM crops might have long-term potential risks for human health and environment, I contend that the precautionary principle, which is proclaimed to be one of the methods for the risk management of GM crops as well as one of the rationales supporting a mandatory labeling regime, is not a scientific approach in risk assessment and management. I also argue that the precautionary principle has not developed into a binding principle of customary international law and there is no treaty obligation on states to implement it in the agricultural foodstuffs area, hence it is not a legally binding international obligation. Furthermore, the purported consumers' right to know is also examined in this chapter. This superficially compelling argument had been widely used in numerous campaigns for GMO mandatory labeling, but commentators have challenged it from both academic and legal practice perspectives. I argue that the consumers' right to know alone cannot justify the implementation of a mandatory labeling regime.

In Chapter Six, I continue my arguments against mandatory labeling regimes from the perspectives of regulation enforcement. They include the: (1) labeling costs, (2) labeling statement, (3) labeling threshold for GM content, and (4) consistency with obligations under the

WTO Agreements. I rely on numerous economic studies to argue that the mandatory labeling requirement will increase the cost of both GM and non-GM foods, which will negatively influence the interests of stakeholders other than consumers, and as a result might cause unfair competition in both GM seeds supplier markets and the GM end product marketplace. Moreover, the label content statement regulated in most current GMO labeling legislation is not able to realize a meaningful informed choice. According to food labeling laws in nearly every jurisdiction, food labeling must not be done in a manner that "is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety."[62] However, consumer survey studies demonstrate that the statements used by many current labels are vague and inaccurate, and many of them are usually misleading and have been taken as a warning sign by consumers.[63] Thus, the statements on labels need improvement to make them more accurate and informative.[64] The next concern is the GM content threshold. This issue refers not only to the cost of the labeling regime but also to the technical problems of GMO detection. I discuss the fundamental reasons that cause confusion in the implementation of the threshold regulations. On the basis of all the evidence gained above, I conclude the WTO analysis at the end of this Chapter, arguing that mandatory GMO labeling may well violate WTO trade laws.

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[62] Section 5 of *Food and Drug Act*, online: *Canada Food and Drug Act (R.S., 1985, c. F-27)*, online: Department of Justice <http://laws.justice.gc.ca/eng/ F-27/page-2.html#anchorbo-ga:l_I-gb:s_3>.

[63] According to Donna Byrne's research, less knowledgeable consumers are more likely to regard GMO labeling as a warning with implications about the quality or safety of the product. See Donna M, Byrne, "Cloned Meat, Voluntary Food Labeling, and Organic Oreos" (2009) 8 Pierce L Rev 31.

[64] Both Canadian and EU laws have provisions that the food labeling rules will protect consumers from misrepresentation and fraud with respect to food labeling, packaging and advertising, and for prescribing basic food labeling and advertising requirements. *Food and Drug Act*, *supra* note 67; and *Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the Approximation of the Laws of the Member States Relating to the Labeling, Presentation and Advertising of Foodstuffs*, [2000] O.J. L109/29. online: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2000L0013:20070112:EN:PDF>.

Finally, in Chapter Seven, I make some concluding marks, draw lessons from the policy decisions on GMO labeling regimes, and provide suggestions for current Canadian GMO labeling laws. I conclude that regulators and policy makers should abandon the use of mandatory GMO labeling regimes, and place much more weight on promoting globally harmonized approval procedures for GMOs and unified detection standards for GM materials. It is hoped that, through these methods, a more effective management of GMO risk and better protection of human and animal health and the environment could be realized. Based on my concluding remarks, I provide some suggestions for the improvement of the current Canadian GMO labeling system.

Chapter 2 The Labeling of GMOs, International Food, Agricultural, and International Environmental Law

On the international law level, a collection of several different and overlapping multilateral regimes, such as the Food and Agriculture Organization (FAO), Codex Alimentarius Commission (Codex), the Convention on Biological Diversity (CBD) framework, and the World Trade Organization (WTO), addresses issues related to the labeling of GMOs. They have different area focuses and provide a patchwork of persuasive perspectives for regulation of GMO labeling. In this chapter, I will explore how international food and agricultural law (i.e., FAO and Codex) and international environmental law (i.e., the CBD framework) responded to and shaped the regulation of GMO labeling. I will address WTO discussions in the next chapter.

The FAO deals with food safety and foodborne disease concerns.[1] It contributes to a comprehensive evaluation of GMOs that engages with issues of food security, and social and ethical discussions, and provides member states with GMO-related technical assistance and socio-economic and environmental analyses.[2] The Codex Alimentarius Commission, created by the FAO and World Health Organization (WHO), develops international food standards and guidelines, and promotes coordination of international food standards work.[3] In particular, the Codex Committee on Food Labeling (CCFL), which is subordinate to the Codex Alimentarius Commission, is responsible for developing international standards for food labeling. So far, the

[1] Meredith T. Mariani, *The Intersection of International Law, Agricultural Biotechnology, and Infectious Disease*, (Leiden: Martinus Nijhoff Pulishers, 2007) at 52; see also, FAO, *Who We Are*, online: FAO <http://www.fao.org/about/who-we-are/en/>.

[2] *Ibid.*

[3] Codex, *About Codex, online*: Codex Alimentarius International Food Standards <http://www.codexalimentarius.org/about-codex/en/>; see also Meredith T. Mariani, *ibid* at 63.

CCFL works on promoting unified standards for the labeling of GMOs, and, to date, is the only international body that has launched discussions directly on issues concerning GMO labeling.

A. International food and agricultural law

1. UN Food and Agriculture Organization (FAO)

The FAO is an international organization that is a UN specialized agency.[4] Its main goal is to achieve food security; to this end, it implements programs that raise food nutrition levels, improve agricultural productivity, better the lives of rural populations, and contribute to the growth of the world economy.[5] The FAO also works to provide food security and safety through the Codex Alimentarius Commission, which establishes (but does not enforce) international standards for food safety and the promotion of international food trade.[6]

The FAO has not worked on a specific instrument related to the labeling of GMOs, but has published some documents discussing food safety, risk assessment, and social and ethical concerns regarding GMO foods. For example, in September 2001, the FAO published *Genetically Modified Organisms in Food and Agriculture: Where are we? Where are we going?*, which provided the public with information on GM technology and GMO foods.[7] In its later report, *Genetically Modified Organisms, Consumers, Food Safety and the Environment* (*GMO Ethics Series 2*), the FAO emphasized issues related to GMO safety concerns, their impacts on the environment, and the role of ethics in food and agriculture policy-making processes.[8] The

[4] FAO, *FAO and the UN*, online: <http://www.fao.org/partnerships/partner-un/en/>. See also Mariani, *supra* note 1 at 52.
[5] FAO, *About FAO, FAO's Mandate*, online: FAO <http://www.fao.org/about/en/>.
[6] See *Codex Committee on Food Labeling under Codex Alimentarius International Food Standards*, online: <http://www.codexalimentarius.org/committees-and-task-forces/en/?provide=committeeDetail&idList=7>.
[7] Louise O. Fresco, *Genetically Modified Organisms in Food and Agriculture: Where are we? Where are we going?*, online: < http://www.fao.org/ag/magazine/GMOs.pdf>.
[8] FAO, *Ethics Series 2: Genetically Modified Organisms, Consumers, Food Safety and the Environment 2001*, online: <http://www.fao.org/DOCREP/003/X9602E/x9602e08.htm#P0_0>.

FAO report suggested that decision-making processes concerning GMOs should involve all stakeholders and should be based on a science-based evaluation system that secures an "accurate and objective assessment of the benefits and risks associated with the use of genetic technologies".[9] It also argued that governments and scientists should inform the public about GMOs, and that experts had an ethical obligation to communicate with laypersons in understandable terms.[10]

It is worth noting that the FAO argued, in the *GMO Ethics Series 2*, that consumers have the right to an informed choice.[11] This right, according to the FAO, is derived from the ethical concept of the autonomy of individuals.[12] As I will discuss in Chapter Four, such consumers' rights claims have been cited by the EU and EU member states to support more stringent requirement for labeling of GMOs and GM ingredients as well as the implementation of stricter legislation when it comes to approving of importation of GM foods and feeds.[13]

However, while the FAO *GMO Ethics Series 2* document highlighted the importance of consumers having access to information and resources (through which informed decisions about GMOs can be made), it did not advocate directly that a mandatory labeling measure should be applied to GMO foods by member states, nor did it set up legal obligations for member states to

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[9] *Ibid.*
[10] *Ibid.*
[11] In the GMOs and human rights section, the FAO states that: "The existence of GMOs raises the issue of the right to informed choice, which derives from the ethical concept of autonomy of individuals. This principle can be applied, for example, in the debate on labelling food derived from GMOs to ensure that consumers know what they are consuming and are able to make informed decisions. Informed choice and resulting actions require access to information and resources. Consumers do not all have the same access to information and resources to make informed decisions about GMOs. Particularly in developing countries, the very poor (both women and men) may lack the most basic information to make decisions that may affect their health and capacity to sustain themselves. Appropriate methods to reach the least educated, the poorest and the most disadvantaged groups should form part of any strategy to inform the public so that individuals are able to choose according to their needs." FAO, *GMOs and Human Rights* of *Ethics Series 2: Genetically Modified Organisms, Consumers, Food Safety and the Environment 2001*, online: <http://www.fao.org/docrep/003/X9602E/x9602e03.htm#TopOfPage>.
[12] *Ibid.*
[13] Debra M. Strauss, "Defying Nature: the Ethical Implications of Genetically Modified Plants" (2007) 3:1 J Food L & Pol'y 1.

implement mandatory GMO labeling regimes.[14] Moreover, the FAO's rationales for the argument of the right to informed choice in GMO foods indicates that relevant considerations are largely based on the concerns of developing countries. These concerns emerge from general worries about the lack of allergency labeling or basic component-labeling regimes affecting the health of populations in very poor countries.[15] Thus, it can be argued that the very fundamental reason for requiring informed choice in relation to GMO foods still stems from human health and food safety concerns.

2. The Codex Alimentarius Commission

The Codex Alimentarius Commission was created in 1961 in the eleventh session of the Conference of the FAO, and formally approved by the Sixteenth World Health Assembly as the principal organ of the Joint FAO/WHO Food Standard Programme in May 1963.[16] It is an international food standards-setting body, and the first session of the Commission was held in the same year in Rome. Around 120 participants from 30 countries and 16 international organizations attended the session.[17] The US, EU and Canada were among the first members of the Codex Alimentarius Commission, and China became a member in 1984. In the past decades, an increasing number of countries, especially developing countries, have joined the Codex Alimentarius Commission and played an active part in its process. Today, the Codex Alimentarius Commission has 186 members (185 countries and the EU), and 220 observers (50

[14] *Ibid.*
[15] FAO, *supra* note 11.
[16] The World Health Organization (WHO), as the UN specialized authority for directing and coordinating health, was formally established in 1948, and the World Health Assembly is the decision-making body of the WHO. See Kelley Lee, *The World Health Organization* (Abingdon: Routledge, 2009) at 1-2; See also WHO, *World Health Assembly*, online: <http://www.who.int/mediacentre/events/governance/wha/en/>; Codex, *supra* note 3; see also Mariani, *supra* note 1 at 62.
[17] Jack A. BOBO, "Two Decades of GE Food Labeling Debate Draw to An End – Will Anybody Notice" (2012) 48 Idaho L Rev 251; Codex, *Codex Members and Observers*, online: Codes International Food Standards <http://www.codexalimentarius.org/members-observers/en/>.

intergovernmental organizations, 154 nongovernmental organizations and 16 UN agencies).[18] Its members cover 99 percent of the world's population.[19]

By developing Codex food standards, guidelines and related texts, the Codex Alimentarius Commission aims to protect the health of consumers and ensure fair food trade.[20] Another important purpose of the Codex Alimentarius Commission is to promote the coordination of all food standards work undertaken by international governmental and non-governmental organizations.[21] It works as an international commission, and provides an important platform for countries to work together to develop international food standards that represent each member country's own national interests.[22] The Codex Commission's work can be classified into three categories: (1) defining a specific commodity (e.g., Standard for Preserved Tomatoes,[23] Standard for Honey[24]); (2) setting acceptable levels of food additives, veterinary drugs, and pesticide residue (e.g., Maximum Residue Limits for Pesticides,[25] Maximum Residue Limits for Veterinary Drugs in Food[26]); and (3) developing all codes of conduct, principles, and guidelines related to food, such as the Code of Hygienic Practice for Dried Fruits,[27] Principles for Traceability/Product Tracing as a Tool Within a Food Inspection and Certification System,[28] and Guideline for the Conduct of Food Safety Assessment of Food Derived from Recombinant-DNA

[18] Codex, *ibid.*
[19] Codex, *supra* note 3; see also Ching-Fu Lin, "Scientification of Politics or Politicization of Science: Reassessing the Limits of International Food Safety Lawmaking" (2013) 15 CLMSTLR 1.
[20] *Ibid*.
[21] *Ibid*; also see Fresco, *supra* note 7.
[22] Codex, *Understanding the CODEX ALIMENTARIUS*, online: <ftp://ftp.fao.org/codex/Publications/understanding/Understanding_EN.pdf> at 3.
[23] *Codex Standard for Preserved Tomatoes*, Codex STAN 13-1981.
[24] *Codex Standard for Honey*, Codex STAN 12-1981.
[25] *Maximum Residue Limits (MRLs) for Pesticides*, CAC/MRL 1.
[26] *Maximum Residue Limits for Veterinary Drugs in Food*, CAC/MRL 2.
[27] *Code of Hygienic Practice for Dried Fruits*, CAC/RCP 3-1969.
[28] *Principles for Traceability/Product Tracing as a Tool Within a Food Inspection and Certification System,* CAC/GL 60-2006.

Animals.[29] To date, the Codex Alimentarius Commission has been evaluated as "a very effective mechanism for obtaining consensus among Codex member countries on a wide range of food standards."[30] An assessment report from the Codex Alimentarius highlighted that "Codex standards were considered a vital component in promoting food control systems designed to protect consumer health."[31]

Once a new Codex standard is adopted, all the member countries are encouraged to incorporate it into their domestic or regional laws. As a form of "soft law", the Codex standards are not legally binding on members. Member countries can apply a higher level of protection than a Codex standard in order to better protect human and animal health, or safety and environment, in their own jurisdictions. However, the Codex standards have been "hardened" in the context of the WTO "hard law" dispute settlement system ever since the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) formally recognized the Codex Alimentarius', "reference points for facilitating international trade and resolving trade disputes in international law."[32] WTO members who wish to apply stricter food safety measures than levels set by the Codex will be required to justify their measures based on scientific evidence or other considerations. I will explore relevant issues in detail in Chapter Three.

3. The Codex Committee on Food Labeling

[29] *Guideline for the Conduct of Food Safety Assessment of Food Derived from Recombinant-DNA Animals*, CAC/GL 68-2008.
[30] Stan Benda, "It's All about Elmer Gantry ... There Is No Frankenstein!!! -- Part II" (2003) 16 IPJ 393. However, no mechanism is deemed to be perfect. Critics argue that the Codex Alimentarius is so strictly science-based that leaves socio-economic concerns in the background. See Kristian Høyer Toft, "GMOs and Global Justice: Applying Global Justice Theory to the Case of Genetically Modified Crops and Food" (2012) 25 J Agric Environ Ethics 223.
[31] Codex, *Understanding the CODEX ALIMENTARIUS*, online: <ftp://ftp.fao.org/codex/Publications/understanding/Understanding_EN.pdf> at 4.
[32] *Agreement on the Application of Sanitary and Phytosanitary Measures*, 14 April 1994, 33 ILM 1125, online: <www.wto.org/english/docs_e/legal_e/legal_e.htm>; Codex, *ibid* at 2.

The Codex Alimentarius and its Commission works through two types of subsidiary bodies: Codex Committees and Coordinating Committees.[33] A Codex Committee is usually hosted by a member country whose main responsibility is to draft standards for submissions to the Commission. Among these committees, the Codex Committee on Food Labeling (CCFL) is the body that drafts provisions for food labeling requirements.[34] The main tasks of the CCFL are:

> (a) to draft provisions on labelling applicable to all foods; (b) to consider, amend if necessary, and endorse draft specific provisions on labelling prepared by the Codex Committees drafting standards, codes of practice and guidelines; (c) to study specific labelling problems assigned to it by the Commission; and, (d) to study problems associated with the advertisement of food with particular reference to claims and misleading descriptions.[35]

Since 1993, the CCFL has initiated efforts on conducting risk assessment for foods derived from biotechnology, and on drafting guidelines for the labeling of GM foods.[36] This being said, consensus had been difficult to achieve over the decades in which the CCFL has been developing standards. Several countries strongly opposed mandatory labeling for GM food, e.g. the US and Canada, while countries such as India and the EU were very supportive of labeling all biotechnology-derived foods.

Prior to 2011, the CCFL attempted to draft four instruments on GMO labeling but none of them were adopted given the lack of consensus. The first three drafts, i.e., the 1997 *Proposed Draft Recommendations for the Labeling of Food Obtained through Biotechnology*[37] (the 1997 *Draft*); the 2001 *Proposed Draft Recommendations for the Labeling of Foods Obtained through Certain*

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[33] Codex, *supra* note 31 at 16.
[34] Codex, List of Active Codex Committees, online: Codex Alimentarius International Food Standards <http://www.codexalimentarius.org/committees-task-forces/en/?provide=committeeDetail&idList=7>.
[35] *Ibid.*
[36] Codex Alimentarius for Consumers, online: <http://www.consumersinternational.org/media/302887/codex%20alimentarius-%20a%20set%20of%20three%20resource%20manuals.pdf> at11.
[37] Codex Alimentrius Commission, *Recommendations for the Labeling of Foods obtained through Biotechnology*, Codex, ALINORM 97/22A, Geneva, 1997, Appendix VI.

Techniques of Genetic Modification/Genetic Engineering[38] (the 2001 *Draft*); and the 2004 *Proposed Draft Guidelines for the Labeling of Food and Food Ingredients Obtained through Certain Techniques of Genetic Modification/Genetic Engineering*[39] (the 2004 *Draft*), had gradually formed comprehensive provisions related to mandatory food labeling and ingredients obtained through biotechnology. These drafts had defined the scope of application, set up labeling provisions, exemptions and threshold levels etc. However, the 2008 *Proposed Draft Recommendations for the Labeling of Food and Food Ingredients Obtained through Certain Techniques of Genetic Modification/Genetic Engineering*[40] (the 2008 *Draft*) abandoned attempts to agree on comprehensive provisions, and terminated drafting labeling guidelines targeted at GM foods and ingredients. Rather than facilitate consensus on comprehensive conditions, the 2008 *Draft* regulated the labeling of GMOs under the existing Codex texts. This method was followed by the 2011 *Proposed Draft Compilation of Codex Texts Relevant to the Labeling of Foods Derived from Modern Biotechnology*[41] (the 2011 *Draft*), which was finally accepted by the Codex Commission.

3.1 The 2008 Draft Provisions

3.1.1 Providing consumer essential information

Under the 2008 *Draft*, the term "labeling" denoted "[a]ny written, printed or graphic matter that is present on the label, accompanies the food, or is displayed near the food, including that for the

[38] Codex Alimentrius Commission, *Proposed Draft Recommendations for the Labeling of Foods Obtained through certain Techniques of Genetic Modification/Genetic Engineering (Proposed Draft Amendment to the General Standard for the Labeling of Prepackaged Foods)*, ALINORM 01/22A, Geneva, 2001, Appendix V.

[39] Codex Alimentrius Commission, *Proposed Draft Guidelines for the Labeling of Foods Obtained through certain Techniques of Genetic Modification/Genetic Engineering: Labeling Provisions*, ALINORM 04/27/22, Rome, 2004, Appendix VI.

[40] Codex Alimentrius Commission, *Draft Recommendations for the Labeling of Foods Obtained Through Certain Techniques of Genetic Modification/Genetic Engineering Definitions*, ALINORM 08/31/22, Geneva, 2008, Appendix VI.

[41] Codex Alimentarius Commission, *The Proposed Draft Compilation of Codex Texts Relevant to the Labeling of Foods Derived from Modern Biotechnology*, REP 11/FL, Quebec, 2011, Appendix III.

purpose of promoting its sale or disposal."[42] However, only essential information had to be placed on the label.[43] The 2008 *Draft* emphasized that the purpose of GMO labeling is not to provide any information as to whether or not GM foods and food ingredients are safe. Rather, labeling should merely provide an additional assurance on *safe* and *appropriate use* of food. The reason behind such a definition of labeling is that "labeling of a food is considered only after the food has undergone appropriate safety assessments to deem it safe for human consumption."[44] According to the 2008 Draft, "essential information" references any significant alteration to physical, chemical, or functional characteristics of a food due to production or processing.[45] Hence, GMO labeling is required only when those essential changes have occurred due to GM techniques used in production or processing. For example, any ingredients that are known to cause hypersensitivity must be labeled.[46]

3.1.2 Truthful and non-misleading labeling

The 2008 *Draft* also underlined the importance of truthful and non-misleading labeling. It required that, when the labeling of a product was necessary, the description and presentation on the labeling should be in a manner that was "truthful and not misleading and likely to create an erroneous impression regarding its character in any respect."[47] In cases where a traditional name of a GM food needs to be changed or qualified with additional words or phrases, the label should describe "the true nature of the food and to avoid misleading or confusing the consumer."[48]

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[42] Art. 2 of the *2008 Draft*, *supra* note 40.
[43] Chapeau 1 of the *2008 Draft*, *ibid.*
[44] Art. 3 of the *2008 Draft*, *ibid.*
[45] Art. 6 of the *2008 Draft*, *ibid.*
[46] Art. 4.2.1.4 of *General Standard for the Labeling of Prepackaged Foods*, CODEX STAN 1-1985.
[47] Art. 6 of the *2008 Draft*, *supra* note 40.
[48] *Ibid.*

3.2 *The Compilations of Codex Text Relevant to Labeling of Foods Derived from Modern Biotechnology*

After almost 20 years of debate, in May 2011, with the US compromise that ended their opposition to the adoption of a Codex guideline on the voluntary labeling of GMOs, the 39th Session of the CCFL reached a consensus on labeling standards for GMO foods that was developed as the 2011 *Draft*. This proposed draft was subsequently adopted by the Codex Commission during the 34th Session of the Codex Alimentarius in July 2011.

3.2.1 No special labeling requirements for GM foods

The 2011 *Compilations of Codex Text Relevant to Labeling of Foods Derived from Modern Biotechnology* (*Compilation*) adopts the method used by the 2008 *Draft*; namely, it does not specifically endorse the labeling of GM food products. It is worth noting that the *Compilation* does not even separate the mandatory and voluntary labeling requirements as the 2008 draft did. It just "[r]ecalls and assembles in a single document some important elements of guidance from Codex texts, which are relevant to the labeling of foods derived from modern biotechnology."[49] These relevant Codex texts include *General Standard for the Labeling of Prepackaged Foods and General Guidelines on Claims*, and another eight Codex texts that address: nutrition and health claims; production, processing, labeling and marketing of organically produced foods; risk analysis of foods derived from modern biotechnology; and the conduct of food safety assessments of foods derived from r-DNA plants, microorganisms and animals.[50] In light of these

[49] Section 1 of the *2011 Compilation*, *Compilation of Codex Texts Relevant to the Labeling of Foods Derived from Modern Biotechnology*, CAC/GL 76-2011.

[50] These relevant Codex texts includes: "1) Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997); Introduction and particularly, Sections 1.1,1.2,1.3,1.4 and 1.5; 2) Guidelines for the Production, Processing, Labeling and Marketing of Organically Produced Foods (CAC/GL 32-1999); and particularly Section 1.5; 3) General Guidelines for Use of the Term "Halal" (CAC/GL 24-1997); 4) Working Principles for Risk Analysis for Food Safety for Application by Governments (CAC/GL 62-2007); 5) Principles for the Risk Analysis of Foods Derived from Modern Biotechnology(CAC/GL 44-2003); and particularly, Paragraph 19.; 6) Guidelines for the Conduct of Food Safety Assessments of Foods Derived from

compilatory guidelines and principles, Codex members are allowed to use different approaches when labeling foods derived from modern biotechnology as long as they follow the condition of being consistent with already adopted Codex texts.

3.2.2 The *Compilation* and the WTO

One caveat against allowing member countries to apply different approaches to the labeling of GM foods is that such a practice will lead to a significant impact on the international GM food trade. As previously mentioned, the WTO, which is the multilateral organization for international trade, refers explicitly to the Codex as the international standard-setter. It encourages members to incorporate the Codex international standard into their relevant domestic rules and legislation.[51] Consequently, any domestic GM food labeling requirements that are consistent with already adopted Codex texts are thereby protected by the newly introduced guidelines from accusations of arbitrarily setting barriers against free trade under the WTO Agreements. In other words, the WTO member states can adopt different label regimes for GM foods as they wish, and they cannot be challenged under the WTO dispute resolution system as long as they are consistent with the existing Codex texts.

3.3 Indications from the Codex CCFL

The continuing efforts that the Codex has devoted to providing guidance on the labeling of GMOs for almost 20 years reflects the controversial and complicated aspects of labeling issues. Some consumer and environment groups have celebrated the approval of the *Compilation*, taking

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Recombinant-DNA plants (CAC/GL 45-2003); 7) Guidelines for the Conduct of Food Safety Assessments of Foods Derived from Recombinant-DNA microorganisms (CAC/GL 46-2003); 8) Guideline for the Conduct of Food Safety Assessment of Foods derived from Recombinant-DNA Animals(CAC/GL 68-2008)." *Ibid.*

[51] Art. 3.1 of the *SPS Agreement*, *Agreement on the Application of Sanitary and Phytosanitary Measures*, 14 April 1994, 33 ILM 1125, online: <www.wto.org/ english/docs_e/legal_e/legal_e.htm >.

it as a win against the US because of that country's strong and persistent position against the mandatory labeling of GM foods and food ingredients.[52] However, since the *Compilation* has not formed a unified GMO labeling regime, conflicts in the international trade of GM food will not be resolved due fundamentally to the member countries' individualized approaches to GMO labeling. As a newly adopted instrument, it is still not clear to what extent the *Compilation* can be used to settle such disputes. Nevertheless, one important message has been delivered by the *Compilation*: that the Codex *does not* consider GM foods and non-GM foods as two different categories. The *Compilation* emphasizes that the labeling does not need to "suggest or indicate that foods derived from modern biotechnology are necessarily different from other foods simply due to their method of production."[53] This statement is of a very strong persuasive value for determining whether GM and non-GM foods are "like" products in the context of the WTO TBT Agreement. I will provide an analysis of this issue in Chapter Three.

On the other hand, the entire process of establishing the 2011 Codex *Compilation* has indicated that the Codex does indeed provide an effective communication forum and evidence-based decision-making mechanism. In the Codex forum, negotiators from different countries and organizations can bargain extensively and intensively on issues concerning new regulatory principles and standards. It is also noteworthy that, although the Codex guidance for the labeling of GM foods is a non-binding international instrument (soft law), the Codex standards have undergone a process of hardening by the WTO system.[54] The reference to the Codex standard

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[52] *Consumer Right Victory as US Ends Opposition to GM Labeling Guidelines, online: The Global Voice for Consumers* <http://www.consumersinternational.org/news-and-media/news/2011/07/gm-labelling-victory-as-us-ends-opposition#.UZxZbCvF3zk>; See also, *Codex Alimentarius Adopts Labeling of Genetically Modified Foods*, online: Food Freedom <http://foodfreedom.wordpress.com/2011/07/05/codex-alimentarius-adopts-labeling-of-genetically-modified-foods/>.

[53] Section 2 of the *2011 Compilation*, *Compilation of Codex Texts Relevant to the Labeling of Foods Derived from Modern Biotechnology*, CAC/GL 76-2011.

[54] For example, Art. 12 of the *SPS Agreement* requires that the Committee on Sanitary and Phytosanitary Measures shall

under the WTO Agreements, along with the frequent citation of the Codex standard in WTO dispute settlement proceedings (see Chapter Three, part B "Applying the WTO agreements to GMO labeling"), has increased the legal significance of the Codex standard.[55] It has even led to the argument that Article 2(4) of the TBT Agreement and Article 3(1) of the SPS Agreement have regarded the Codex guidance, at least literally, as an obligation within the WTO system that WTO member states *shall* comply with the "hardening" Codex standards.[56] This reference from the WTO may also explain the increasing numbers of Codex members and the increasing incentive of Codex members – including the US, Canada and the EU – to participate in the negotiation of establishing Codex standards regarding the labeling of GMOs.

B. International Environmental Law

International environmental law obligations on living GMOs are primarily addressed under the Convention on Biological Diversity (CBD) framework.[57] The CBD and its two supplementary agreements – the Cartagena Protocol on Biosafety and the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety[58]– have formed the basis of the international environmental management of living GMOs. Several principles and

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encourage all member states to use international standards, guidelines or recommendations, and that the Committee shall work with the relevant international organizations such as the Codex Alimentarius Commission to secure the best available scientific and technical advice for the administration of the SPS Agreement. See Art. 3.1, 3.3 and Art. 12.1, 12.3 of the SPS Agreement, *supra* note 51.

[55] Lars Bracht Andersen, "Transboundary Trade in Genetically Modified Foods" (2013) 2:6 American International Journal of Social Science 12.

[56] Filippo Fontanelli, "ISO and Codex Standards and International Trade Law: What Gets Said Is Not What's Heard" (2011) 60 ICLQ 895.

[57] See Edward Christie, *Finding Solutions for Environmental Conflicts Power and Negotiation* (Cheltenham: Edward Elgar Publishing Limited, 2008) at 177.

[58] *Convention on Biological Diversity (CBD)*, 5 June 1992, 1760 UNTS 79, 31 ILM 818, online: <http://www.cbd.int/>; *The Cartagena Protocol on Biosafety*, 29 January 2000, 2226 UNTS 208, 39 ILM 1027, online: <http:// bch.cbd.int/protocol/>; *Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety (the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress)*, online: the CBD <http://bch.cbd.int/protocol/NKL_text.shtml>.

provisions of the CBD framework are relevant to GMO labeling, and have influenced the domestic legislation on GMOs.

1. The Convention on Biological Diversity

1.1 Background

The CBD was adopted and opened for signature during the 1992 UN Conference on Environment and Development held in Rio de Janeiro.[59] It entered into force on December 29, 1993, and has 193 parties, with Canada, China and the EU included as contracting parties.[60] The US signed the CBD, but has not ratified, hence legal obligations contained in the CBD have no application to the US.[61]

1.1.1 Conservation and sustainable use of biodiversity

As an environmental treaty, the CBD recognizes the inherent value of biodiversity and the conservation of biodiversity as a "common concern of humankind."[62] It provides a legal framework for the sustainable human use and benefit of the utilization of genetic resources."[63] The CBD was not particularly designed for managing GMOs, but, rather, LMOs, which it defines as: "any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology."[64] That being said, some provisions of the CBD are relevant to managing the use of biotechnology. For example, the in-situ[65]conservation requirement regulated

[59] *History of Convention on Biological Diversity*, online: the CBD <http://www.cbd.int/history/>.
[60] *CBD*, *List of Parties*, online: CBD <http://www.cbd.int/convention/parties/list/>.
[61] *CBD*, *Treaty state description*, online: CBD <http://www.cbd.int/world/ratification.shtml>.
[62] Francesco Francioni & Tullio Scovazzi, *Biotechnology and International Law* (USA, Portland: Hart Publishing, 2006) at 66.
[63] Art. 1 of the *CBD*, "Biological diversity" means "the variability among living organisms from all sources including, inter alia, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems." Art. 2 of the *CBD*, *supra* note 58.
[64] *Ibid*, Art. 3(g) of the *CBD*.
[65] "In-situ" means "the conservation of ecosystems and natural habitats and the maintenance and recovery of viable populations of species in their natural surroundings and, in the case of domesticated or cultivated species, in the surroundings where they

under Article 8(g) of the CBD, which mandates parties to "[e]stablish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health."[66] Moreover, the CBD also recommends that parties should set out appropriate procedures, e.g., an *advance informed agreement*, in the area of safe transfer, handling, and use of any living modified organism engendered from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity.[67] These suggested procedures were accepted and developed as established mechanisms in the Cartagena Protocol.

1.1.2 The CBD and the management of GMOs

Although the CBD does not directly address issues concerning GM foods, it indeed has provided a significant legal basis for regulating GMOs.[68] For example, four sections under Article 19 ("Handing of Biotechnology and Distribution of its Benefits of the Convention") focus on the safe transfer, handling and use of any LMOs, and deal with distributing "benefits arising from biotechnologies based upon genetic resources provided by those Contracting Parties."[69]

Moreover, the CBD also set up solutions for the settlement of a biodiversity dispute. According to Article 27, when a dispute arises because of the disagreement between contracting parties in the interpretation or application of the Convention, the parties shall seek the solution through negotiation, arbitration, or mediation by a third party, or shall submit the dispute to the

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have developed their distinctive properties." *Ibid*, Art. 2 of the *CBD.*

[66] *Ibid*, Art. 8(g) of the *CBD.*

[67] *Ibid*, Art. 19(3) of the *CBD.*

[68] Mariani, *supra* note 1 at18.

[69] LMOs (living modified organisms) Arts. 19.2 and 19.3 of the *CBD*, *supra* note 58.

International Court of Justice.[70] Although the dispute settlement mechanism under the CBD has not been used to date, it creates an applicable dispute resolution system for GMOs and is separate from the WTO dispute settlement body. Such independence can assure that the settlement of disputes will be divorced and insulated from legal obligations under the WTO multilateral trade system, and, accordingly, that the aims of the CBD can be secured.

1.2 Limitations

In practice, the application of the CBD to GM foods is limited. One contributing factor to this limitation is that GM foods have only been grown commercially since 1996, whilst the CBD was formulated in the early 1990s. The Convention is aimed at the sustainable use of the biologically diverse resources and the prevention of any possible hazards to environmental biodiversity that could be caused by LMOs. This being said, most GM foods are no longer living, especially GM products that have been thoroughly processed, and which cannot thereby pose threats to the conservation and sustainable use of biological diversity.

Another factor that limits practical application of the CBD is its condition of only being binding on contracting parties, which, as a result, means that the treaty cannot impose any obligations on non-parties. As explored above, the US, which is the main developer, producer, importer and exporter of GMOs,[71] is not a CBD contracting party. Consequently, when trade conflicts over GMOs happen, the US will seek dispute resolution outside the CBD framework, filing complains under the WTO dispute settlement system. Furthermore, the CBD is not a prohibitionist charter.

[70] *Ibid*, Art. 27 of the *CBD*.
[71] Canada signed the *CBD* but has not ratified the treaty, online: <http://www.cbd.int/>.

Rather it is an instrument in favor of promoting environmental sustainability.[72] As a result, its obligations are weak and/or in soft terms. Vague expressions such as "as far as possible and as appropriate" makes it difficult to evaluate both the extent of the obligation and how well or to what extent the contracting parties have implemented their obligations. As a legal framework for protecting biological diversity, the CBD has a limited application to GMO-labeling issues. This being said, the CBD does allow for the development of protocols to deal more explicitly with potential environmental and health problems associated with GMOs.[73] Accordingly, pursuant to Paragraph 3 of Article 19 of the CBD, the parties agreed to develop the Cartagena Protocol on Biosafety.[74]

2. The Cartagena Protocol on Biosafety and the Nagoya-Kuala Lumpur Supplementary Protocol

2.1 The Cartagena Protocol on Biosafety

2.1.1 Background

The Cartagena Protocol on Biosafety (Cartagena Protocol) is the first multilateral treaty that settles any procedures related to the safe handling, transport, and use of LMOs that may have adverse effects on biological diversity and negative impacts on human health.[75] The Cartagena Protocol was adopted on January 29, 2000, and entered into force on September 11, 2003.[76] As of December 30, 2013, the Cartagena Protocol has 166 contracting parties, including the EU and

[72] Francioni & Scovazzi , *supra* note 62 at 67.

[73] Art. 28 of the *CBD*, "1) The Contracting Parties shall cooperate in the formulation and adoption of protocols to this Convention; 2) Protocols shall be adopted at a meeting of the Conference of the Parties; 3) The text of any proposed protocol shall be communicated to the Contracting Parties by the Secretariat at least six months before such a meeting." *Convention on Biological Diversity*, *supra* note 58.

[74] Art.19, Paragraph 3 of the *CBD*: "The Parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity.", *ibid.*

[75] *The Cartagena Protocol on Biosafety*, *supra* note 58; See also Pablo A. Pellegrini, "What Risks and fro Whom? Argentina's Regulatory Policies and Global Commercial Interests in GMOs" (2013) 35:2 Technology in Society 129.

[76] *Ibid.*

China.[77] The US has not signed or ratified the Cartagena Protocol. As a contracting party to the CBD, the Canadian government has shown a very supportive attitude to the objective of the Protocol, holding that the Protocol is "[a] major step forward towards strengthening Canada's regulatory framework internationally."[78] Canada signed the Protocol on April 19, 2001, but has not ratified it.[79]

The Cartagena Protocol applies to the trade and transfer of LMOs across borders. Subordinate to the CBD framework, the Cartagena Protocol primarily addresses issues concerning the conservation and sustainable use of biological diversity. Its major focus is on the potential adverse effect that LMOs may have on biological diversity, while also taking into account risks to human health as a secondary consideration.[80] With regard to the operating mechanism of the Cartagena Protocol, the Protocol's governing *body is* the Conference of the Parties to the Convention on Biological Diversity serving as the Meeting of the Parties to the Protocol (COP-MOP).*[81]* Its main role is to review the implementation of the Protocol periodically (i.e., every two years in conjunction with the meetings of COP to the CBD)[82] and make resolutions to facilitate the Protocol's enforcement.[83] As of 2012, the COP-MOP had held six meetings.[84]

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[77] Secretariat of the Convention on Biological Diversity, *Cartagena Protocol on Biosafety Ratification List*, online: <http://www.cbd.int/doc/lists/cpb-ratifications.pdf>; see also Mariani, *supra* note 1 at 19.

[78] *Canada Signs the Cartagena Protocol to the United Nations Convention on Biological Diversity*, online: Environment Canada, <http://www.ec.gc.ca/media_archive/press/2001/010419_n_e.htm>.

[79] *Ibid.*

[80] Art. 1 of the Cartagena Protocol on Biosafety, "The In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements." *The Cartagena Protocol on Biosafety*, *supra* note 58; also see Marie-Clarire Cordonier Segger, Frederic Perron-Welch & Christine Frison ed, *Legal Aspects of Implementing the Cartagena Protocol on Biosafety* (New York: Cambridge University Press, 2013) at 19.

[81] *Convention on Biological Diversity*, online: ICGEB <http://www.icgeb.org/~bsafesrv/library/intlorg/cbd.html>; also see Meetings of the COP-MOP, The Cartagena Protocol on Biosafety, online: Convention on Biological Diversity, <http://bch.cbd.int/protocol/>.

[82] Meetings of the COP-MOP, *ibid.*

[83] *Ibid.*

[84] *Ibid*; see also Sixth Meeting of the Parties, online: Cartagena Protocol on Biosafety <http://bch.cbd.int/mop6/>.

2.1.2 Features of the Cartagena Protocol

i) Precautionary Approach

Following the CBD approach, the Cartagena Protocol adopts the precautionary approach in keeping with the language of Article 15 of the Rio Declaration on Environment and Development (Rio Declaration).[85] Also, Article 1 of the Protocol acknowledges the requirement of the precautionary approach as the legal basis of the Protocol's objective.[86] Moreover, the precautionary approach has been incorporated in different provisions of the Protocol. For example, Articles 10 and 11, which lay out the terms for making decisions on imports clearly invoke the main elements of the precautionary principle. Articles 10(6) and 11(8) state that a:

> [l]ack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of that living modified organism intended for direct use as food or feed, or for processing, in order to avoid or minimize such potential adverse effects.[87]

The adoption of the precautionary notion, however, does not mean that the Cartagena Protocol allows the states parties to use the precautionary approach arbitrarily. Scientific risk assessment and management are given a significant role in the decision-making for the import of LMOs and setting standards for contained use within domestic jurisdictions.[88]

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[85] Art. 1 and Preamble of the *Cartagena Protocol on Biosafety*, *The Cartagena Protocol on Biosafety*, *supra* note 58; *United Nations Conference on Environment and Development (UNCED), Rio de Janeiro*, 3-14 June 1992, 31 ILM 874 (1992).
[86] Art. 1 of the *Cartagena Protocol on Biosafety*, *ibid.*
[87] Arts. 10 and 11 of the *Cartagena Protocol on Biosafety*, *ibid.*
[88] Art. 6 (2) of the *Cartagena Protocol on Biosafety*, *ibid.*

ii) Labeling

The Cartagena Protocol established a Biosafety Clearing-House to "[f]acilitate the exchange of scientific, technical, environmental, and legal information on, and experience with, living modified organisms."[89] It also initiated two kinds of information exchange mechanisms. The first one is the communication of information, which works mainly through an Advance Informed Agreement (AIA)[90]; the second is the disclosure of information, which is primarily based on the labeling regime.[91]

The labeling requirement is a key component of the information exchange mechanisms under the Cartagena Protocol, and is a significant method for assisting states parties to implement the Protocol as well. Ever since it was first agreed to in 2000, the requirements for labeling LMOs intended for direct use as food or feed, or for processing (LMO-FFPs), have undergone several changes.[92] The original provision, i.e., paragraph 2(a) of Article 18, requires that each party shall clearly identify LMOs by using "may contain" labeling and ensuring they are intended for direct use as food or feed, or for processing, but not for intentional introduction into the environment.[93] Furthermore, according to paragraph 2 (a) of Article 18, a decision on the detailed requirements for this labeling purpose, including specification of their identity and any unique identification

[89] Art. 20 of the *Cartagena Protocol on Biosafety*, *ibid.*

[90] Under the AIA, an exporter is required to provide a notification to potential participatory countries of the information specified in Annex I before the LMOs, which are intentionally introduced into the environment, can be exported. When LMOs are intended for direct use as food or feed, or for processing, a Party that makes a finial decision regarding their domestic use, including placing them on the market, shall inform the Parties through the biosafety Clearing-House within fifteen days of making that decision. "With two hundred and seventy days of the date of receipt of notification", a Party may take a decision on the import of living modified organisms intended for direct use as food or feed, or for processing, under its domestic regulatory framework that is consistent with the objective of this Protocol. Arts. 7 and 11.1 of the *Cartagena Protocol on Biosafety*, *ibid.*

[91] Art. 7 of the *Cartagena Protocol on Biosafety*, *ibid.*

[92] This issue has been discussed from the first of the Conference of the Parties serving as the meeting of the Parties to the Protocol (the COP-MOP) to the fifth conference, but consensus has not fully reached. See online: <http://bch.cbd.int/protocol/>.

[93] Art. 18.2 of the *Cartagena Protocol on Biosafety*, *supra* note 58.

should be worked out by the COP-MOP no later than two years after the date of the Protocol's entry into force.[94]

In March 2006, the COP-MOP 3 finally came to a consensus on labeling requirements.[95] Paragraph 4 of MOP 3 Decision BS-III/10 required that "[d]ocumentation accompanying living modified organisms intended for direct use as food or feed, or for processing, in commercial production and authorized in accordance with domestic regulatory frameworks,"[96] should be in compliance with the requirements of importing countries, and should clearly state:

> "(a) In cases where the identity of the living modified organisms is known through means such as identity preservation systems, that *the shipment contains living modified organisms* that are intended for direct use as food or feed, or for processing; (b) In cases where the identity of the living modified organisms is not known through means such as identity preservation systems, that *the shipment may contain one or more living modified organisms* that are intended for direct use as food or feed, or for processing; (c) That the living modified organisms are not intended for intentional introduction into the environment; (d) The common, scientific and, where available, commercial names of the living modified organisms; (e) The transformation event code of the living modified organisms or, where available, as a key to accessing information in the Biosafety Clearing-House, its unique identifier code; (f) The Internet address of the Biosafety Clearing-House for further information."[97]

Paragraph 7 of the MOP 3 Decision BS-III/10 decided:

> …to review and assess, at its fifth meeting, experience gained with the implementation of paragraph 4 above, with a view to considering a decision, at its sixth meeting, to ensure that documentation accompanying living modified organisms intended for direct use as food or feed, or for processing covered by paragraph 4 clearly states that the shipment contains living modified organisms that are intended for direct use as food or feed, or for processing, and includes the detailed information in items (c) to (f) of that paragraph.[98]

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[94] *Ibid.*
[95] *COP-MOP 3 Press Coverage*, online: COP8 MOP3 <https://www.cbd.int/meetings/cop8mop3/mop-03-press-coverage.shtml>.
[96] *Handling, Transport, Packaging and Identification of Living Modified Organism: Paragraph 4 of Art. 18, MOP 3 Decision BS-III/10*, online: <https://www.cbd.int/decision/mop/?id=11066>.
[97] *Ibid.*
[98] *Ibid.*

However, the COP-MOP 5 did not form any final decision on the labeling of LMOs-FFPs. Rather, due to the limited amount of experience gained with the years in the implementation of paragraph 4 of Decision BS-III/10, the COP decided to postpone the decision taking until the COP-MOP 7 meeting to be held in October 2014.[99]

2.1.3 Limitations

The Cartagena Protocol is the first international environmental regulation for bioengineered foods. It has provided the comprehensive regulation applicable to LMOs regarding their safe development, handling, transport, use, transfer and release etc. As well, the Cartagena Protocol has established several management mechanisms, such as the Green Biosafety Clearing-House, the Advanced Informed Agreement procedures, and labeling requirements. However, the Protocol does not address standards or principles of food safety, and its application to the labeling of GMOs is limited.[100]

i) "LMOs"

Following the CBD, the Cartagena Protocol exclusively uses the term "living modified organism."[101] In the light of the concept of LMOs, defined in article 3(g) of the Protocol,[102] only living GMOs that are intended for direct use as food or feed, or for processing, and that are capable of transferring or replicating genetic material, fall within the scope of the Protocol's

[99] *Handling, Transport, Packaging and Identification of Living Modified Organism: Paragraph 2 (a) of Art. 18, MOP 5 Decision BS-V/8*, online: < http://www.cbd.int/decision/mop/default.shtml?id=12321>; see also Segger, Perron-Welch & Frison ed, *supra* note 80 at 33.

[100] *Fact Sheet: Cartagena Protocol on Biosafety*, online: United States Department of Agriculture Foreign Agricultural Service <http://www.fas.usda.gov/info/factsheets/biosafety.asp>.

[101] According to the Cartagena Protocol, a live modified organism is defined as any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology, *The Cartagena Protocol on Biosafety*, *supra* note 58.

[102] "… any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology." Art. 3 (g) of the *Cartagena Protocol on Biosafety*, *ibid.*

application. The limitation of the term "living modified organisms" has excluded a large part of GMO foods from the Protocol's coverage, since a majority of GM foods and food ingredients including GMOs are no longer living organisms, e.g., milled maize or other processed food products.[103] Beside the exclusion of non-living organisms, GM foods can fall within the scope of the Cartagena Protocol only if they contain LMOs that are capable of transferring or replicating genetic material.[104]

ii) Legal status

The legal status of the Cartagena Protocol as a treaty requires that all contracting parties must abide by the provisions and pursue the purpose of the Protocol. Non-parties, on the other hand, are not subject to the Protocol obligations. To mitigate any potential conflicts between parties and non-parties over different applicable laws, and to ensure the achievement of the Protocol's purpose, Article 24 of the Protocol specifically addresses situations where non-parties are involved in trans-boundary movements of LMOs. It requires that:

> (1) Transboundary movements of living modified organisms between Parties and non-Parties shall be consistent with the objective of this Protocol. The Parties may enter into bilateral, regional and multilateral agreements and arrangements with non-Parties regarding such transboundary movements; (2) The Parties shall encourage non-Parties to adhere to this Protocol and to contribute appropriate information to the Biosafety Clearing-House on living modified organisms released in, or moved into or out of, areas within their national jurisdictions.[105]

According to Article 24, although the Protocol cannot create legal obligations for the non-parties, it encourages parties to behave in accordance with the objectives of the Protocol when non-

[103] Francioni & Scovazzi ed, *supra* note 62 at 197; *Fact Sheet: Cartagena Protocol on Biosafety*, online: United States Department of Agriculture Foreign Agricultural Service <http://www.fas.usda.gov/info/factsheets/biosafety.asp>.
[104] Arts. 3 and 4 of the *Cartagena Protocol on Biosafety*, *The Cartagena Protocol on Biosafety*, *supra* note 58; also see *20 Questions on Genetically Modified Foods*, online: WHO <http://www.who.int/foodsafety/publications/biotech/20questions/en/>.
[105] Art. 24 of the *Cartagena Protocol on Biosafety*, *ibid.*

parties are involved. Consequently, in situations where activities are between parties and non-parties, the parties are required to ensure that activities are undertaken in a manner that prevents or reduces risks to biological diversity, also taking into account risks to human health. Non-parties are not required to carry out the Protocol's detailed provisions, such as the AIA procedures; but the Protocol parties have the obligation to establish and maintain appropriate domestic mechanisms, measures and strategies to regulate, manage, and control risks associated with the use, handling and trans-boundary movement of LMOs.[106]

However, since there is no legal basis for asking a non-party to abide by the Cartagena Protocol, a non-party does not have legal obligations to behave in accordance with requirements under the Cartagena Protocol, particularly where both parties are bound by other treaties, such as the WTO Agreement.[107] Moreover, given that the "precautionary approach" is proclaimed as one of the objectives of the Cartagena Protocol while both the US and Canada are strongly against the adoption of the precautionary principle for the management of GMOs, as non-parties, the US and Canada are not bound by Article 24 of the Protocol, which requests use of the precautionary approach.

Besides the definition of LMOs, the stated objectives of the Cartagena Protocol also influence its effect on the management of GM foods. The primary focus of the Protocol is on protecting biodiversity, leaving the considerations of human health in second place. Nevertheless, human

[106] Ruth Mackenzie *et al*, *An Explanatory Guide to the Cartagena Protocol on Biosafety*, online: International Union for Conservation of Nature <http://data.iucn.org/dbtw-wpd/html/EPLP046-explanatory_guide/Art. 24.html>.

[107] Art. 34 of the *Vienna Convention on the Law of Treaties* speculates that generally a treaty shall not create any obligations or rights for a third State without its consent, *Vienna Convention on the Law of Treaties*, 27 January 1980, 1155 UNTS 331, 8 ILM 679, online: United Nations Treaty Collection <http://treaties.un.org/pages/ViewDetailsIII.aspx?&src=TREATY&mtdsg_no=XXIII~1&chapter=23&Temp=mtdsg3&lang=en>; Also see John M. Marshall, "Commentary: The Cartagena Protocol in the Context of Recent Releases of Transgentic and Wolbachia-infected Mosquitoes" (2011) 19:3 AsPac J Mo Biol Biotechnol 93.

health concerns are the most significant issues vis-à-vis food safety management and consumer interest protection. Moreover, as the core innovation of the Cartagena Protocol, AIA procedures apply only to LMOs for international introduction into the *environment* of the importing party. This limitation means that the majority of international trade in LMOs falls outside the scope of the AIA procedure. In addition, as previously explored, the final decision on LMO-FFP labeling requirements remains undetermined by the latest COP-MOP 6. This lengthy negotiation again indicates how complicated are the issues surrounding LMO labeling, and how difficult it can be to reach agreement among parties. As a result of all these limitations explored above, the Cartagena Protocol alone cannot sufficiently resolve trade conflicts over GMO products due to different GMO labeling regimes.[108]

2.2 The Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress

In pursuit of the mandate under Article 27 of the Cartagena Protocol,[109] the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress (N-KL Supplementary Protocol) was adopted in the fifth meeting of COP-MOP.[110] It was opened for signature on March 7, 2011 and will enter into force when ratified by 40 parties.[111] Until March 6, 2012, the date that the Supplementary Protocol closed for signature, it had received 51 signatories.[112] The EU signed on

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[108] Debra M. Strauss, "The International Regulation of Genetically Modified Organisms: Importing Caution in the U.S. Food Supply" (2006) 61 Food Drug L.J. 167.

[109] Art. 27 of *the Cartagena Protocol on Biosafety*, "The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, adopt a process with respect to the appropriate elaboration of international rules and procedures in the field of liability and redress for damage resulting from transboundary movements of living modified organisms, analyzing and taking due account of the ongoing processes in international law on these matters, and shall endeavor to complete this process within four years." *The Cartagena Protocol on Biosafety*, *supra* note 58.

[110] COP-MOP Decision BS-V/11 "International rules and procedures in the field of liability and redress for damage resulting from transboundary movements of living modified organisms"

[111] *Ibid.*

[112] *Notification Closing Date for Signature of the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety (Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress)*, online: the CBD <http://www.cbd.int/doc/notifications/2012/ntf-2012-007-nkl-en.pdf>; See also *Press Release The Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress Receives 51 Signatories*, online: <http://www.cbd.int/doc/press/2012/pr-2012-03-08-nklr-en.pdf>. Countries can still accede to the Protocol after March 6, 2012.

May 11, 2011 and ratified it on March 21, 2013.[113] China has not yet signed. Canada and the US have not/cannot sign the Protocol. As of December 30, 2013, twenty Cartagena Protocol parties have ratified or acceded to the Supplementary Protocol.[114]

The N-KL Supplementary Protocol applies to "[d]amage resulting from transboundary movements of living modified organisms."[115] It allows parties to "[u]se criteria set out in their domestic law to address damage that occurs within the limits of their national jurisdiction."[116] Following the Cartagena Protocol, the N-KL Supplementary Protocol empowers the party to apply its domestic laws to implement the Supplementary Protocol when damage is caused by the transboundary movements of LMOs from non-parties.[117] According to Article 12 of the Supplementary Protocol, such domestic law can be: (1) the party's existing domestic law applicable for general rules and procedures on civil liability; (2) a newly developed civil liability law specifically for that the damage; or (3) both the existing domestic civil liability law and newly developed special law.[118]

Since the N-KL Supplementary Protocol has not yet entered into force, it is unclear whether the parties will use the stringent domestic liability rules and procedures to prevent the transboundary

[113] *Parties to the Protocol and Signature and Ratification of the Supplementary Protocol*, online: CBD <http://bch.cbd.int/protocol/parties/#tab=1>.

[114] The twenty parties include: Albania, Bulgaria, Burkina Faso, Cambodia, Czech Republic, the European Union, Germany, Guinea-Bissau, Hungary, Ireland, Latvia, Lithuania, Luxembourg, Mexico, Mongolia, Norway, Romania, Spain, Sweden and the Syrian Arab Republic. See The Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress Reaches the Halfway Mark to Entry into Force with Ratification by Hungary, online: CBD <http://www.cbd.int/doc/press/2013/pr-2013-12-17-bs-en.pdf>.

[115] Art. 3 of the *Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress,* online: the CBD <http://www.cbd.int/doc/notifications/2012/ntf-2012-007-nkl-en.pdf>.

[116] Art. 3(6) of the *Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress*, *ibid.*

[117] Art. 3(7) of the *Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress*, *ibid.*

[118] Art. 12 of the *Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress*, *ibid.*

trade of LMOs with non-parties. It is also unclear how the WTO dispute settlement regime will deal with the relationship between the N-KL Supplementary Protocol and the WTO rules.

Conclusion

The FAO, Codex and the CBD frameworks provide advisory perspectives for the development of domestic, regional, and international law for GMO labeling. The FAO does not establish any law for GMO labeling, but does indeed provide valuable understandings of the management of GMOs. For example, the FAO promotes a scientific evidence-based system to assess GMO risks and benefits on a case-by-case basis. It also argues that the access to GM information is very important for consumers because they have the right to informed choice. However, the FAO does not formulate any instruments to mandate GMO labeling requirements to GMO foods within member states.

With regard to the Codex and its Commission, it has endeavored to act as an effective negotiation forum for the representatives from member states to bargain and set up international standards, principles or guidelines for labeling GMOs. The successful adoption of the *2011 Compilation*, the guidance for GMO labeling, has shown that the Codex mechanism, which provides a relatively nonpolitical international forum for negotiation and communication, is beneficial for resolving disputes concerning mandatory and voluntary GMO labeling regimes, particularly where the conflicts involve complex social, economic, and ethical contributing factors. It is argued that a major incentive for members to actively participate in this voluntary body is the reference by the WTO system, in which Codex guidance has been recognized as an international standard.

Given that the *2011 Compilation* is newly introduced, it is hard to determine, at this current stage, to what extent it will influence member states' domestic legislation on the labeling of GMOs. As well, it is difficult to estimate how this new instrument will impact the settlement of future international disputes over the labeling of GMOs. However, it is worth noting that the *Compilation* has provided the international community with an important understanding on notions of GM and non-GM foods. It proclaims that GM and non-GM foods should not be deemed different due simply to their production methods. In other words, the Codex does not consider the method of production to change the nature of the food.[119] Based on existing Codex texts, the Codex recognizes health-related concerns to be the only legitimate reasons for implementing mandatory labeling requirements. While the provision of consumer information in the context of Codex standards is regarded as one of the rationales for GMO labeling, it alone cannot justify a mandatory labeling rule.

In the international environmental law sector, the CBD framework (including the CBD, Cartagena Protocol and the N-KL Supplementary Protocol) places much more attention on the potential adverse effects or harm associated with LMOs on biosafety, as well as the conservation and sustainable use of biological diversity. It promotes the implementation of precautionary approach-based traceability and labeling requirements, and allows parties to make decisions themselves and base them on the precautionary notion when it comes to LMO importation.[120] However, in terms of GMO labeling, the use of the CBD framework will encounter limited applicability. This is partly due to its objective and scope of application. First, it is applicable to GMOs only when they are, or contain, LMOs that are intended for direct use as foods or feeds, or

[119] Bobo, *supra* note 17.
[120] See Daniel Wuger & Thomas Cottier, *Genetic Engineering and the World Trade System* (UK: Cambridge University Press, 2008) at197. See also Francioni & Scovazzi, *supra* note 62 at 245.

for processing, and are capable of transferring or replicating genetic material. Hence, most GMO foods do not fall into the CBD framework scope. Second, the CBD framework is aimed at the conservation and sustainable use of biological diversity values. As an environmental framework, it takes the matter of human health as a secondary consideration for the management of LMOs, and does not address food safety issues. However, issues regarding GMO labeling are mainly related to human health and safety concerns. Therefore, the CBD framework cannot effectively resolve conflicts over the labeling regimes.

More importantly, as the major global GMO developers, producers, importers and exporters, both the US and Canada are not parties to the Cartagena Protocol or the N-KL Supplementary Protocol. The EU, China, and Canada are contracting parties to the CBD, but the CBD is not a prohibitionist instrument and its obligations are weak or framed in soft terms. The non-Protocol parties, i.e., the US and Canada, consider GMO traceability and labeling requirements required in the Cartagena Protocol to be trade barriers. Thus, when trade conflicts due to GMO labeling happen, the US and Canada will seek dispute resolution in the WTO system instead of the Cartagena Protocol and N-KL Supplementary Protocol regime. Nevertheless, the EU and China, the CBD framework parties, insist on the use of the precautionary approach recognized in the CDB framework, and require that the precautionary approach should be adopted to interpret WTO rules in the settlement of GMO-related disputes. Hence, conflicts between the CDB framework and the WTO system are unavoidable. In the next chapter, I will explore these conflicts and examine how the labeling of GMOs has been regulated under the WTO system.

Chapter 3 GMOs Labeling and the WTO Agreements

In Chapter Two, I have examined international food, agricultural, and environmental law related to the labeling of GMOs. In this Chapter, I will continue to explore GMO labeling legislation in the context of international law, and specifically will focus on international trade law. Since different domestic labeling regimes will impact, directly or indirectly, on free trade of foods, collisions over GM foods in the international agricultural products trade are inevitable. In this Chapter, I will concentrate on the WTO system, exploring how the labeling of GMOs is addressed under the WTO rules and on whether a mandatory labeling GMO regime is in accordance with the WTO agreements.

To date, no complaint about the labeling of GMO foods has been brought before the WTO dispute settlement mechanism and there is no WTO agreement that specifically regulates GMO labeling. However, provisions in some WTO agreements, such as the General Agreement on Tariffs and Trade 1994 (GATT 1994), the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and Agreement on Technical Barriers to Trade (TBT Agreement), do have particular relevance to the issue of labeling GM products.[1] Moreover, several recent WTO cases also provide the views of the WTO Panels and Appellate Body on the application of WTO rules to the labeling of foods and provide persuasive guidance for the settlement of potential disputes over different GMO labeling requirements. Thus, in order to have a clear understanding and evaluation of the relevant WTO rules, a probe of applicable WTO agreements and an in-depth analysis of outcomes of relevant WTO cases are necessary. To begin

[1] *GATT 1994*, First January 1995, 1867 UNTS 187; 33 ILM 1153 (1994), online: <http://www.wto.org/english/docs_e/legal_e/06-gatt.pdf>; *Agreement on the Application of Sanitary and Phytosanitary Measures* (*SPS Agreement*), 14 April 1994, 33 ILM 1125, online: <www.wto.org/english/docs_e/legal_e/legal_e.htm>; *Agreement on Technical Barriers to Trade* (*TBT Agreement*), 15 April 1994, 33 ILM 1125, online: <http:// www.wto.org/english/tratop_e/tbt_e/tbtagr.htm>.

with, I will first briefly explore the background of the WTO, introduce the structure of the WTO Agreement and its dispute settlement system, and then discuss whether a mandatory GMO labeling measure is allowed under the applicable WTO rules.

A. WTO Background

As the largest global international organization that deals with the rules of trade between member states, the WTO has played a key role in promoting free trade and settlement of inter-state trade disputes.[2] As of February 5, 2014, it had 159 member states, and active global trade players such as Canada, the EU, the US and China are all WTO members.[3] In general, the WTO system governs four areas, i.e., trade in goods, trade in services, trade-related intellectual property matters and dispute settlement, and all the effort made by the WTO is to "[e]nsure the trade flows as smoothly, predictably and freely as possible."[4] With regard to international trade in goods, although the prominent goal of the WTO is to reduce barriers to trade, it pursues other values as well. For example, the GATT 1994 sets out core and general obligations of member states for international trade in goods; the SPS Agreement specifically addresses issues of human, animal or plant life or health in the context of international trade in goods; and the TBT Agreement covers the regulations that lay down technical product and process requirements that lie outside the SPS Agreement's scope, mainly "technical regulations" and "standards".[5]

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[2] *WTO*, Online: WTO <http://www.wto.org/english/thewto_e/whatis_e/whatis_e.htm>; see also Simon Lester, Bryan Mercurio & Arwel Davies, *World Trade Law Text, Materials and Commentary* (UK, Oxford: Hart Publishing Ltd., 2012) at 3.

[3] WTO, *Understanding the WTO: the Organization*, online: WTO <http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm>.

[4] WTO, *The WTO in Brief*, online: WTO <http://www.wto.org/english/thewto_e/whatis_e/inbrief_e/inbr03_e.htm>; see also WTO, *Understanding the WTO: Who We Are?*, online: the WTO <http://www.wto.org/english/thewto_e/whatis_e/who_we_are_e.htm>.

[5] Mark A. Pollack, *When Cooperation Fails the International Law and Politics of Genetically Modified Foods* (New York: Oxford University Press, 2009) at146. In practice, determining which agreement i.e., the SPS or TBT Agreements applies to a special measure complained about by the WTO members is not an easy task. The decision-making becomes increasing difficult where the measures in question embrace multiple motives, such as ethical concerns, promoting consumer's informed choice, environment protection and health concerns.

Compared with the FAO and the CBD framework, which I explored in the last Chapter, an important feature of the WTO is its binding dispute settlement mechanism, without which the rules-based system would be less effective.[6] It is governed by the Understanding on Rules and Procedures Governing the Settlement of Disputes (Dispute Settlement Understanding or DSU) rules and administered by the Dispute Settlement Body (DSB).[7] The DSU provides many rules to increase the efficiency of dispute settlement.[8] For example, the DSU mandates strict deadlines on various stages in the consultation, the composition of a Panel, and the dispute settlement process. Different Panels are established for every dispute under the DSU, and if a complaining party does not agree with the Panel report it can appeal on matters of law to the Appellate Body (AB).[9] Moreover, decisions of the Panel and AB are automatically adopted by the DSB unless there is a consensus not to adopt i.e., "negative consensus".[10] In terms of the DSB, it alone can decide on the composition of Panels and acceptance or rejection of Panel findings or the AB reports.[11] The DSB also has the power to authorize sanctions when a member state does not comply with a ruling.[12]

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[6] *Understanding the WTO: Setting Disputes*, online: WTO <http://www.wto.org/english/thewto_e/whatis_e/tif_e/disp1_e.htm>.

[7] *Understanding on Rules and Procedures Governing the Settlement of Dispute*, 15 April 1994, 1869 UNTS 401; 33 ILM 1226(1994), online: <http://www.wto.org/english/docs_e/legal_e/28-dsu.pdf >. Michael J. Trebilcock, *Understanding Trade Law* (UK: Edward Elgar Publishing Limited 2011) at 28.

[8] Trebilcock, *ibid* at 29.

[9] The Appellate Body (AB) is a standing body with seven experts appointed for four-year terms. See Giorgio Sacerdoti, Alam Yanovich & Jan Bohanes ed, *The WTO at Ten The Contribution of the Dispute Settlement System* (UK, Cambridge: Cambridge University Press, 2006) at 216.

[10] Before the adoption of DSU, the positive consensus rule allows the member states to exercise veto rights to resist formal dispute settlement. The DSU replaces the positive consensus rule with a negative consensus rule. As a result, "panel and Appellate Body decisions are deemed to be adopted by the General Council of the WTO in the absence of a consensus favoring rejection, which would entail the prevailing party acquiescing in the rejection of a decision in its favor." Trebilcock, *supra* note 7 at 26.

[11] The AB need not delve into the substance of the appeal. The panel report and AB report only become binding when the DSB has adopted it. See Andrew D Mitchell, *Challenges and Prospects for the WTO* (UK. London: Cameron May Ltd, 2006) at 213; see also The WTO Secretariat, *A Handbook on the WTO Dispute Settlement System* (UK, Cambridge: Cambridge University Press, 2004) at 61.

[12] *Understanding the WTO: Settling Disputes*, *supra* note 6.

B. Applicable rules for GMO labeling under the WTO system

Since different GMO labeling measures affect the free trade of GMO products, the applicable WTO rules are those agreements relevant for trade in goods. They include the GATT 1994, SPS Agreement and TBT Agreement.

1. The GATT 1994 and its Article XX General Exception

1.1 Overview

The GATT 1994 is designed to reduce government tariffs and non-tariff barriers to trade by implementing legal principles of non-discrimination between goods and member states. A trade restrictive measure affecting GM products trade may violate GATT 1994 rules. For example, if a member state treats like products from other WTO member states on a discriminatory basis, the measure may violate the obligation of "most-favored-nation treatment" (MFN treatment) in Article I of GATT 1994.[13] A government measure may violate the national treatment obligation in Article III of GATT 1994 if it discriminates between domestic and imported like products.[14] Also an import ban or restriction imposed at the point and time of importation might violate the prohibition of quantitative restrictions in Article XI:1 of GATT 1994.[15] As a result, WTO member states must not use their domestic law, such as food labeling law to discriminate against foreign products in favor of like domestic products, discriminate between like products in various

[13] Christophe Bonneuil, "How Does the World Trade Organization Know? The Mobilization and Staging of Scientific Expertise in the GMO Trade Dispute" (2012) 42:1 Social Studies of Science 75; See also Art. I of *GATT 1994*, "With respect to customs duties and charges of any kind imposed on or in connection with importation or exportation or imposed on the international transfer of payments for imports or exports, and with respect to the method of levying such duties and charges, and with respect to all rules and formalities in connection with importation and exportation, and with respect to all matters referred to in paragraphs 2 and 4 of Art. III,* any advantage, favour, privilege or immunity granted by any contracting party to any product originating in or destined for any other country shall be accorded immediately and unconditionally to the like product originating in or destined for the territories of all other contracting parties." *GATT 1994*, *supra* note 1.

[14] Art. III (4) of the *GATT 1994*, "The products of the territory of any contracting party imported into the territory of any other contracting party shall be accorded treatment no less favorable than that accorded to like products of national origin in respect of all laws, regulations and requirements affecting their internal sale, offering for sale, purchase, transportation, distribution or use. The provisions of this paragraph shall not prevent the application of differential internal transportation charges which are based exclusively on the economic operation of the means of transport and not on the nationality of the product." *ibid.*

[15] Art. XI of the *GATT 1994*, *ibid*.

WTO member states, or impose import bans or restrictions without justification provided for in other GATT or WTO agreement provisions.

Although the GATT 1994 does not focus on public health and protection of the environment, an exception from the obligations in the GATT 1994 is available for member states under Article XX if they can justify their restrictive measures on imported products in certain defined circumstances. According to specific exceptions listed in the sub-paragraphs of Article XX,[16] a demand for mandatory labeling of imported GMO foods can fall within exceptions: "(b) necessary to protect human, animal or plant life or health," and/or "(g) relating to the conservation of exhaustible natural resources if such measures are made effective in conjunction with restrictions on domestic production or consumption."[17] In both cases, the mandatory labeling measure must still satisfy the terms of the Article XX chapeau, i.e., the measure must not be applied in a manner that constitutes "arbitrary" discrimination, "unjustifiable" discrimination, or a "disguised restriction on international trade".[18]

1.2 Applicable limitations

[16] These exceptions cover measures that are: "(a) necessary to protect public morals; (b) necessary to protect human, animal or plant life or health; (c) relating to the importations or exportations of gold or silver; (d) necessary to secure compliance with laws or regulations which are not inconsistent with the provisions of this Agreement, including those relating to customs enforcement, the enforcement of monopolies operated under paragraph 4 of Art. II and Art. XVII, the protection of patents, trade marks and copyrights, and the prevention of deceptive practices; (e) relating to the products of prison labour; (f) imposed for the protection of national treasures of artistic, historic or archaeological value; (g) relating to the conservation of exhaustible natural resources if such measures are made effective in conjunction with restrictions on domestic production or consumption; (h) undertaken in pursuance of obligations under any intergovernmental commodity agreement which conforms to criteria...; (i) involving restrictions on exports of domestic materials necessary to ensure essential quantities of such materials to a domestic processing industry during periods...; (j) essential to the acquisition or distribution of products in general or local short supply..." These listed exceptional measures are limited by the chapeau to Art. XX, which states that the justification of these exceptions is: "subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade..." Art. XX of *GATT 1994*, *ibid*; also see Riidiger Wolfrum, Peter-Tobias Stoll & Anja Seibert-Fohr, *WTO – Technical Barriers and SPS Measures* (The Netherlands, Leiden: Martinus Nijhff Publishers, 2007) at 64.

[17] *GATT 1994* Art. XX (b) and (g), *ibid*; see also Marie Kreipe, *Genetically Modified Food Trade Regulation in view of Environmental Policy Objectives* (Hamburg, Diplomic Veriag, 2010) at 10.

[18] Lester, Mercurio & Davies, *supra* note 2 at 401- 402.

As a fundamental agreement of the WTO system, the GATT 1994 is based on general principles for liberalizing trade in goods. These principles must be applied to all areas of international trade in goods and should be enforced by all members. GATT 1994 has shown considerations other than promotion of free trade, i.e., exceptions under Article XX, but much of the language of Article XX is broad and vague.[19] Thus, in situations where trade measures are based on objectives of protecting human and animal health, or conserving exhaustible natural resources, the application of Article XX will be heavily dependent on interpretation from the Panel and AB. To meet the increasing concerns of human and animal health, and protection of the environment, two new legally binding agreements applicable to trade in goods – the SPS Agreement and TBT Agreement –were annexed to the WTO Agreement.[20]

2. The SPS Agreement

Based on Article XX (b) of the GATT 1994, the SPS Agreement was formed to provide a clearer and more applicable regulation for instructing WTO members to introduce sanitary and phytosanitary measures (the SPS measures). According to Annex A of the SPS Agreement, the SPS measures apply to protect against "risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms", "additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs", "diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests" and to prevent or limit other damage in the member state from the entry, establishment or spread of pests.[21] The SPS measures include "[a]ll relevant laws, decrees, regulations, requirements and

[19] *Ibid* at 415.
[20] *Ibid*; see also Merlinda D. Ingco & John D. Nash, *Agriculture and the WTO Creating A Trading System for Development* (US, Washington, DC: the World Bank and Oxford University Press) at 216. In event of conflict between GATT 1994 and an Annex 1A listed agreement, the latter prevails.
[21] Annex A of the *SPS Agreement*, Art. 1(1) and (2) states that "[t] his Agreement applies to all sanitary and phytosanitary

procedures including, inter alia, end product criteria; processes and production methods; testing, inspection, certification and approval procedures…and packaging and *labeling requirements* directly related to food safety."[22] Specifically, the SPS Agreement acknowledges that WTO members have the right to erect barriers to trade based on affirmative scientific evidence of danger to the protection of human, animal or plant safety, life or health.[23]

2.1 On a basis of scientific evidence and risk assessment

As mentioned above, one prominent feature of the SPS Agreement is that it relies heavily on scientific evidence to distinguish legitimate safety measures from disguised protectionism.[24] Article 2.2 and 2.3 require that:

> "…Members countries shall ensure that any SPS measure is applied only to the extent necessary to protect human, animal or plant life or health*, is based on scientific principles and is not maintained without sufficient scientific evidence*…Members shall ensure that their SPS measures do not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail, including between their own territory and that of other Members. SPS measures shall not be applied in a manner which would constitute a disguised restriction on international trade."[25]

Article 5 of the SPS Agreement specifies the relationship between assessment of risk and determination of the appropriate level of SPS protection. It requires that members shall ensure their SPS measures are based on assessments of "risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international

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measures which may, directly or indirectly, affect international trade. Such measures shall be developed and applied in accordance with the provisions of this Agreement," and that "[f]or the purpose of this Agreement, the definitions provided in Annex A shall apply." *Agreement on the Application of Sanitary and Phytosanitary Measures*, *supra* note 1.

[22] Annex A 1(d) of the *SPS Agreement*, *ibid* (emphasis added).

[23] Saul Halfon, "Confronting the WTO: Intervention Strategies in GMO Adjudication" (2010) 35:3 Science Technology Human Values 307; Art. 2(1) of the *SPS Agreement*, *ibid.*

[24] Steve Keane, "Can A Consumer's Right to Know Survive the WTO?: The Case of Food Labeling" 2007, 16:29 Transnat'l L & Contemp Probs 291.

[25] Arts. 2.2, 2.3 of the *SPS Agreement*, *supra* note 1 (emphasis added).

organizations."[26] According to Article 5.2 of the SPS Agreement, when assessing risks, the following factors shall be taken into account: 1) available scientific evidence; 2) relevant process and production methods; 3) relevant inspection, sampling and testing methods; 4) prevalence of specific diseases or pests; 5) existence of pest – or disease – free areas; 6) relevant ecological and environmental conditions; and 7) quarantine or other treatment.[27]

Since the labeling of food can be considered a SPS measure under the SPS Agreement, the application of such measures to GMO goods by a member has to meet these requirements under the SPS Agreement. The member state has to prove that a mandatory labeling of GMOs requirement is carried out based on scientific evidence or risk assessment and it is applied in a manner that does not constitute a disguised restriction on international trade.

2.2 International harmonized standards

Under the SPS Agreement, harmonized SPS measures are advised to be formed on the basis of international standards, guidelines and recommendations developed by relevant international organizations, such as the Codex Alimentarius Commission.[28] The SPS Agreement recognizes the Codex Commission as credible international authority on food related issues.[29] In Chapter Two, I explored the 2011 *Codex Compilation* that is expected to be followed by every WTO member on the basis of Article 3.1 of the SPS Agreement. Nevertheless, the WTO members can still use more stringent measures than the Codex standards in cases where member states hold that the Codex guidance is not sufficient to protect the public health and safety in their states. The

[26] Art. 5.1 of the *SPS Agreement*, *ibid.*
[27] Art. 5.2 of the *SPS Agreement*, *ibid.*
[28] Art. 3.1 of the *SPS Agreement*, *ibid.*
[29] Peter J. Aggett et al., "Nutrition Issues in Codex: Health Claims, Nutrition Reference Values and WTO Agreements: A Conference Report" (2012) 51 Eur J Nutr S1.

SPS Agreement permits the member states to unilaterally impose more stringent measures deemed necessary to protect domestic human, animal, or plant life or health, but these measures must be justified by sufficient scientific evidence.[30] If relevant scientific evidence is insufficient, the member states can provisionally adopt a SPS measure, i.e., a law that prohibits imports of certain items or requires mandatory labeling of products (e.g., labeling of GM foods or foods containing GM ingredients).[31] The condition for retaining these temporary SPS measures is that they have to be supported by the additional information necessary for a more objective assessment of risk within a reasonable period of time.[32]

2.3 Relationship between the GATT 1994 and the SPS Agreement

As both Article XX(b) of GATT 1994 and the SPS Agreement address issues concerning protection of human, animal or plant life or health, we need to determine which agreements should be examined first in a particular dispute. In *European Communities – Measures Concerning Meat and Meat products (Hormones)* (*EC – Hormones*),[33] the US and EU had different views on the relationship between the GATT 1994 and SPS Agreement, namely, which agreement should apply first. The EU argued that only when a violation of a GATT provision(s) was established could the SPS Agreement be applied.[34] The US, by contrast, argued that the SPS Agreement should be addressed first since it was the *lex specialis* for a review of sanitary

[30] Arts 2.2 and 3.3 of the *SPS Agreement*, *supra* note 1.
[31] Art. 5.7 of the *SPS Agreement*, *ibid.*
[32] *Ibid.*
[33] Report of the Appellate Body, *European Communities – EC Measures Concerning Meat and Meat Products (Hormones)* (1998) WT/DS26/AB/R, WT/DS48/AB/R; see also Wolfrum, Stoll & Seibert-Fohr, *supra* note 16 at 58-62.
[34] "The EC makes a distinction between the "substantive" and "procedural" provisions of the SPS Agreement. According to the European Communities, the substantive provisions only interpret Art. XX(b) of GATT, without adding any new obligations, while the procedural provisions contain requirements additional to GATT. Therefore, the European Communities concludes, the "substantive" provisions of the SPS Agreement can only be addressed if recourse is made to GATT Art. XX(b), i.e., if, and only if, a violation of another provision of GATT is first established. The additional "procedural" provisions, on the other hand, can be examined directly and independently of a prior GATT violation." See *ibid*, Report of the Appellate Body, paragraph 8.33.

measures.[35]

The Panel held that, based on the *Vienna Convention on the Law of Treaties* (*Vienna Convention*),[36] a treaty should be interpreted "in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose."[37] According to Article 1.1 of the SPS Agreement, two conditions have to be met to apply the SPS Agreement: (1) the measure in the case is a sanitary and phytosanitary measure; and (2) the measure in dispute may, directly or indirectly, affect international trade.[38] Except for these two conditions, there are no additional requirements. The Panel noted that:

> the general approach adopted in Article XX(b) of GATT is fundamentally different from the approach adopted in the SPS Agreement. Article XX(b), which is not limited to sanitary or phytosanitary measures, provides for a general exception which can be invoked to justify any violation of another GATT provision. The SPS Agreement, on the other hand, provides for specific obligations to be met in order for a Member to enact or maintain specific types of measures, namely sanitary and phytosanitary measures.[39]

The Panel further analyzed that:

> If we were to examine GATT first, we would in any event need to revert to the SPS Agreement: if a violation of GATT were found, we would need to consider whether Article XX(b) could be invoked and would then necessarily need to examine the SPS Agreement; if, on the other hand, no GATT violation were found, we would still need to examine the consistency of the measure with the SPS Agreement since nowhere is consistency with GATT presumed to be consistency with the SPS Agreement.[40]

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[35] *Ibid.*

[36] *Vienna Convention on the Law of Treaties*, *Vienna Convention on the Law of Treaties*, 23 May 1969, 8 ILM 679 (1969). Online: <http://untreaty.un.org/ilc/texts/instruments/english/conventions/1_1_1969.pdf>.

[37] *Ibid*, Art. 31 of the *Vienna Convention*.

[38] Art. 1.1 of the *SPS Agreement*, "This Agreement applies to all sanitary and phytosanitary measures which may, directly or indirectly, affect international trade. Such measures shall be developed and applied in accordance with the provisions of this Agreement", *Agreement on the Application of Sanitary and Phytosanitary Measures*, 14 April 1994, 33 ILM 1125, online: <www.wto.org/ english/docs_e/legal_e/legal_e.htm>.

[39] Report of the Panel, *European Communities – EC Measures Concerning Meat and Meat Products (Hormones)* (1998) WT/DS26/AB/R, WT/DS48/AB/R, paragraph 8.39.

[40] *Ibid*, paragraph 8.42.

Thus, on a basis of most efficient manner, the Panel decided to examine the claims raised under the SPS Agreement first.[41]

3. TBT Agreement

3.1 Technical regulations, standards and procedures

The TBT Agreement applies to domestic health and environmental technical regulations and standards not covered by the SPS Agreement.[42] According to Annex 1 of the TBT Agreement:

> a. "technical regulation" is a "[d]ocument which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is *mandatory*. It may also include or deal exclusively with terminology, symbols, packaging, marking or *labeling requirements* as they apply to a product, process or production method."[43]
>
> b. "standard" is defined as a "[d]ocument approved by a recognized body that provides, for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, with which compliance is *not mandatory*. It may also include or deal exclusively with terminology, symbols, packing, marking or labeling requirements as they apply to a product, marking or labeling requirements as they apply to product, process or production method."[44]

In addition, to determine whether relevant requirements in technical regulations or standards are fulfilled, the TBT Agreement establishes "conformity assessment procedures," which include: *inter alia*, "procedures for sampling, testing and inspection; evaluation, verification and assurance of conformity; registration, accreditation and approval as well as their combination."[45] In the context of the labeling of GMOs, labeling requirements applied to a GM-based product can

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[41] *Ibid.*

[42] Art. 1.5 of the *TBT Agreement* states that "the provisions of this Agreement do not apply to SPS measures as defined in Annex A of the Agreement on the Application of SPS Measures." *Agreement on Technical Barriers to Trade*, *supra* note 1; also see Epps & Trebilcock ed, *Research Handbook on the WTO and Technical Barriers to Trade* (UK, Cheltenham: Edward Elgar Publishing Ltd., 2013) at 26.

[43] The *TBT Agreement*, Annex 1.1, *ibid*, (emphasis added).

[44] The *TBT Agreement*, Annex 1.2, *ibid* (emphasis added).

[45] *Explanatory note for "conformity assessment procedures" in Annex I of the TBT Agreement*, online: WTO <http://www.wto.org/english/res_e/booksp_e/analytic_index_e/tbt_02_e.htm#ann_1>.

be considered as either a technical regulation (i.e., if it is a mandatory labeling regime) or a standard (i.e., if it is a voluntary labeling regime). I will explore this issue in further depth in the following section.

3.2 Non-discrimination for trade in goods

The TBT Agreement requires that technical regulations adopted by members shall not be applied in a manner that would constitute a means of arbitrary or unjustifiable discrimination or a disguised restriction on international trade. According to Article 2.1 of the TBT Agreement, "[m]embers shall ensure that in respect of technical regulations, products imported from the territory of any Member shall be accorded treatment no less favourable than that accorded to like products of national origin and to like products originating in any other country."[46] It is recognized that Article 2.1 is a combination of national treatment and MFN treatment obligations.[47] In *United States – Measures Affecting the Production and Sale of Clove Cigarettes* (*US – Clove Cigarettes*), the WTO AB held that the TBT Agreement was linked to GATT 1994, which aimed to achieve a balance between national treatment and other obligations and the general exceptions provision of Article XX.[48] However, Article 2.1 of the TBT Agreement applies only in respect of technical regulations, while GATT 1994 Article III:4 covers "laws, regulations and requirements affecting the international sale, purchase, transportation, distribution or use of products."[49]

3.3 Relationship between trade-restrictiveness and fulfillment of a legitimate objective

[46] Art. 2.1 of the *TBT Agreement*, *Agreement on Technical Barriers to Trade*, 15 April 1994, 33 ILM 1125, online: <http://www.wto.org/english/tratop_e/tbt_e/tbtagr.htm>; see also Epps & Trebilcock ed, *supra* note 42 at 54.
[47] Report of the Appellate Body, *United States – Measures Affecting the Production and Sale of Clove Cigarettes* (*US – Clove Cigarettes*) (2012) WT/DS406/AB/R, paragraph 87.
[48] *Ibid*, paragraphs 88-89, 109.
[49] Art. III: 4 of the *GATT 1994*, *GATT 1994*, *supra* note 1.

The TBT Agreement allows member states to use technical regulations to fulfill a legitimate objective. Article 2.2 of the TBT Agreement provides some examples of legitimate objectives, which include, *inter alia*: "national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the environment." However, Article 2.2 also requires that such technical regulations shall not be "prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. For this purpose, technical regulations shall not be more trade-restrictive than necessary to fulfill a legitimate objective, taking account of the risks non-fulfillment would create."[50] Hence, the term "unnecessary obstacles" in Article 2.2 implies that some trade-restrictiveness is allowed under the TBT Agreement provided that it does not exceed what is necessary to achieve the degree of contribution that a technical regulation makes to legitimate objectives.[51]

3.4 Differences between the SPS and TBT Agreements

The TBT Agreement aims to ensure that WTO member states do not use technical regulations and standards (including packaging, marking and labeling requirements, and procedures for assessment of conformity with technical regulations and standards) to create unnecessary obstacles to international trade (e.g., Article 2.2 of the TBT Agreement). The TBT Agreement also aims at "[r]educing the extent to which technical regulations and standards operate as barriers to market access, primarily by encouraging governments to harmonize national laws by reference to international standards."[52] Different from the SPS Agreement, the "international standards", however, are not defined in the TBT Agreement and there is no list of international standard-setting bodies whose standards are recognized in the text of the Agreement. Article 2.4

[50] Art. 2.2 of the *TBT Agreement*, *supra* note 1.
[51] Report of the Appellate Body, *United States – Measures Concerning the Importation, Marketing and Sale of Tuna Products (Mexico)* (2012) WT/DS381/AB/R, paragraph 319.
[52] Trebilcock, *supra* note 7 at 154-155.

of the TBT Agreement just require members to use or partly use "the *relevant* international standards" as a basis for their technical regulations when these regulations are required and "relevant international standards exist or their completion is imminent"[53]

Also, unlike the SPS Agreement, the TBT Agreement contains a stringent prohibition on discrimination. As we have seen, the TBT Agreement contains national and MFN treatment obligations, asserting that, in respect of technical regulations, members shall accord imported product treatment "not less favorable than that accorded to like products of national origin and to like products originating in any other country" (i.e., Article 2.1 of the TBT Agreement).[54] In contrast, the SPS Agreement acknowledges that discrimination may occur between like products, prohibiting only measures that arbitrarily or unjustifiably discriminate between members where identical or similar conditions prevail.[55]

C. Applying the WTO agreements to GMO labeling

In this section, I will examine how the relevant WTO agreements address the differences between member states regarding labeling requirements. To date, no GMO labeling disputes have been heard by the WTO dispute resolution mechanism. However, several other important WTO cases may provide valuable insights into how WTO tribunals balance the evolving relationship between the objective of trade liberalization and member states' right to regulate, and may indicate possible outcomes of potential future GMO labeling disputes.[56] These cases include *inter alia*: *European Communities – Measures Affecting Asbestos and Asbestos Containing Products* (2000)

[53] Art. 2.4 of the *TBT Agreement*, *supra* note 1; also see Epps & Trebilcock ed, *supra* note 42 at 59 (emphasis added).
[54] Art. 2.1 of the *TBT Agreement*, *ibid.*
[55] Arts. 2.3 and 5.5 of the *SPS Agreement*, *supra* note 1; also see Trebilcock, *supra* note 7 at 154-155.
[56] The Preamble of the *TBT Agreement*, *supra* note 1.

(*EC-Asbestos*);[57] *United States – Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna Products*, (*US – Tuna II*);[58] *Brazil – Measures Affecting Imports of Retreaded Tyres* (*Brazil – Retreaded Tyres*);[59] *EC – Biotech*;[60] *US – Clove Cigarettes*;[61] and the *United States – COOL* cases.[62] Thus, the following examination will be primarily based on the analysis of these cases.

1. Applying Article XX of the GATT 1994

As explored above, Article XX (b) and (g) of the GATT 1994 provide policy exceptions that can be used to justify a mandatory labeling measure when it violates obligations under the GATT. In *Brazil –Retreaded Tyres* (2007), the AB noted that examination of a measure under Article XX is two-tiered: a panel must first examine whether a measure falls under one of the exceptions under Article XX, and secondly, a panel must examine whether the measure in question satisfies the requirements of the chapeau of Article XX.[63] Accordingly, if a member attempts to use Article XX (b) or (g) to defend its mandatory labeling measures, both elements of the two-tiered test must be met. I will first examine the application of the two sub-paragraphs of Article XX and then the chapeau.

1.1 Article XX(b): Human, animal or plant life or health

[57] Report of the Panel, *European Communities – Measures Affecting Asbestos and Asbestos Containing Products* (*EC – Asbestos*) (2000) WT/DS135/R; Report of the Appellate Body, *EC – Asbestos* (2000) WT/DS135/AB/R.
[58] Report of the Appellate Body, *supra* note 51.
[59] Report of the Appellate Body, *Brazil – Measures Affecting Imports of Retreaded Tyres* (*Brazil – Tyres*) (2007) WT/DS332/AB/R.
[60] Report of the Panel, *European Communities – Measures Affecting the Approval and Marketing of Biotech Products* (*EC – Biotech*) (2006), WT/DS291/R, WT/DS292/R, WT/DS293/R.
[61] Report of the Appellate Body, *US – Clove Cigarettes*, *supra* note 47.
[62] Report of the Panel, *United Sates – Certain Country of Origin Labelling (COOL) Requirements* (*US – COOL*), (2011) WT/DS384/R, WT/DS386/R; Report of the Appellate Body, *US – COOL* (2012) WT/DS384/AB/R, WT/DS386/AB/R.
[63] Report of the Appellate Body, *Brazil –Tyres*, *supra* note 59, paragraph 139.

If a member country uses Article XX(b) to defend its adoption of a mandatory labeling requirement for GMO foods that are consumed by humans and animals, it is necessary to determine first whether the mandatory measure is based on the consideration of protecting human and animal health or plant life. If it does fall within the scope of the provision, we next need to analyze whether the measure is "necessary" to implement the objectives. With regard to the first issue, the AB in *EC – Asbestos* recognized that the WTO members had the right to use a more stringent health protection measure that they considered appropriate in a given situation based on scientific evidence.[64] Accordingly, the determination of whether a mandatory labeling measure falls within the scope of "human, animal or plant life or health" must be made on the basis of scientific evidence or risk assessment that can demonstrate GM foods cause known health risks to humans and animals.

On the necessity issue, the WTO Panel and AB have provided interpretations in several relevant cases. In *Thailand – Restrictions on Importation of and Internal Taxes on Cigarette* (1990)[65], the Panel ruled that "[a]n import ban would only be 'necessary' for public health reasons, within the meaning of Article XX(b) of the GATT 1994, if alternative non-trade restricting measures were not available to achieve the public health objectives in question."[66] In *Korea – Measures Affecting Imports of Fresh, Chilled and Frozen Beef* (2000),[67] the AB addressed the issue of "necessary" under Article XX(d). It took the position that the "necessary" referred to a range of degrees of necessity: "at one end of this continuum lies 'necessary' understood as

[64] Report of the Appellate Body, *EC – Asbestos*, *supra* note 57, paragraph 167.
[65] In this case, the U.S. challenged a ban on imports of cigarettes in Thailand as a violation of Art. XI of the *GATT*. Thailand defended the ban under Art. XX (b) as necessary for the protection of public health. The Thai government claimed that American imports were more likely to induce women and young persons to take up smoking, because of sophisticated advertising directed at these groups. See *Thailand – Restrictions on Importation of and Internal Taxes on Cigarettes* (1990) FS10/R – 37S/200 paragraph, 21.
[66] *Ibid*, paragraph 75.
[67] Report of the Appellate Body, *Korea – Measures Affecting Imports of Fresh, Chilled and Frozen Beef* (2000) WT/DS161/AB/R.

'indispensable'; at the other end, was 'necessary' taken to mean as 'making a contribution to.'"[68] The AB also observed that "the [m]ore vital or important the common interests or values pursued, the easier it would be to accept as 'necessary' measures designed to achieve ends."[69]

These observations were referred to in *EC-Asbestos*.[70] In this case, France used a ban – Decree No. 96-1133 that prohibited all forms of amphibole asbestos, and severely restricted the use of chrysotile asbestos – to cease the spread of asbestos-related health risks.[71] Canada argued that the Panel erred in applying the "necessity" test under Article XX(b) of the GATT 1994. It proclaimed four arguments to support this assertion and provided "controlled use of asbestos" as an alternative measure that would achieve the same objective but was less trade restrictive than a total ban.[72] However, the AB rejected all of them, noting that the protection of human and animal health by eliminating a known harm or life-threatening risk is a value that is "vital or important", and agreed with the Panel that there were no alternative measures available since the effectiveness of controlled use of asbestos had not been demonstrated.[73] The AB upheld the French Decree as "necessary" within the meaning of Article XX (b) to protect human life or health.[74] Therefore, based on the AB's argument, if a member intends to use Article XX(b) to justify its adoption of a mandatory labeling requirement, it has to provide evidence to testify that consumption of GM products will trigger a known harm or life-threatening risk to human, animal

[68] *Ibid*, paragraph 161.
[69] *Ibid*, paragraph 162.
[70] Report of the Appellate Body, *EC –Asbestos*, *supra* note 57.
[71] Decree No. 96-1133 entered into force on 1 January 1997, see Report of the Panel, *EC –Asbestos Containing Products*, *ibid*, paragraph 2.3.
[72] Canada argues that "(1) the Panel erred in finding, on the basis of the scientific evidence before it, that chrysotile-cement products pose a risk to human health; (2) the Panel had an obligation to "quantify" itself the risk associated with chrysotile-cement products and that it could not simply "rely" on the "hypotheses" of the French authorities; (3) the Panel erred by postulating that the level of protection of health inherent in the Decree is a halt to the spread of asbestos-related health risks. According to Canada, this "premise is false because it does not take into account the risk associated with the use of substitute products without a framework for controlled use"; and (4) the Panel erred in finding that "controlled use" is not a reasonably available alternative to the Decree.", Report of the Appellate Body, *EC –Asbestos*, *ibid*, paragraph 165.
[73] Report of the Appellate Body, *EC –Asbestos*, *ibid*, paragraph 174.
[74] *Ibid*, paragraph 192.

or plant life or health. The more vital this known harm or life-threatening risk is, the bigger the chances that the mandatory labeling measure will be accepted as a 'necessary' measure under the GATT 1994.

1.2 Article XX(g): Conservation of exhaustible natural resources

In a case where a member state uses Article XX(g) to justify its mandatory labeling requirement for GM products, two issues need to be determined. The first one is whether the local biodiversity can be considered to be "exhaustible natural resources". In *United States – Import Prohibition of Certain Shrimp and Shrimp Products* (*US – Shrimp*) (1998), the AB observed that the term "exhaustible natural resources", which was crafted more than fifty years ago, should be broadly interpreted "in the light of contemporary concerns of the community of nations about the protection and conservation of the environment."[75] In *US – Gasoline* and *US – Shrimp*, Panels and the AB have considered that clean air and sea turtles are exhaustible natural resources.[76] Therefore, if GM products might threaten local biodiversity through gene flow, which is alleged by proponents of a mandatory labeling regime, the local biodiversity can be regarded as "exhaustible natural resources".

Another issue that needs to be decided is whether the mandatory labeling measure is "related to" the conservation of exhaustible natural resources. In *US – Gasoline*, the AB held that "relating to" should be determined based on whether the measure was primarily aimed at the conservation of natural resources under Article XX(g), and that there should be a *substantial* relationship between

[75] Report of the Appellate Body, *United States – Import Prohibition of Certain Shrimp and Shrimp Products* (*US – Shrimp*) (1998) WT/DS58/AB/R, paragraph 192.
[76] *Ibid*, paragraph 129; also see Report of the Panel, *United States – Standards for Reformulated and Conventional Gasoline* (*US – Gasoline*) (1996) WT/DS2/R, paragraphs 6.36-6.37.

the measure and the environmental purpose at issue.[77] However, as we have seen in Chapter Two, the labeling of authorized GM foods, different from the management of GMO release into the environment, is not directly related to conservation of local biodiversity because most GM foods are no longer living.[78] Subsequently, the labeling information does not have a substantial relationship with the objective of protecting biodiversity. On this basis, I would argue that a mandatory labeling requirement for GMO foods should not be considered to be a measure "relating to" the conservation of an exhaustible resource within the meaning of Article XX(g) of the GATT 1994.

1.3 GATT 1994 Article XX Chapeau

Since a mandatory labeling measure may fall within Article XX(b), as a measure that is necessary to protect human, animal or plant life or health, I will examine whether the measure meets the terms of the chapeau of Article XX. In *US – Gasoline*, the AB made a finding that, to examine a violation of "arbitrary or unjustifiable discrimination", or "disguised restriction", the chapeau requires the existence of discriminatory intent, and the "resulting discrimination must have been foreseen and was not merely inadvertent or unavoidable."[79] Hence, to decide whether a mandatory GMO labeling measure is in violation of the chapeau, we have to decide if the member state has a discriminatory intent when adopting the labeling measure. If the member has such intent, the mandatory labeling measure cannot be justified under Article XX even it meets the condition of protecting human, animal or plant life or health (Article XX(b)).

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[77] *Ibid*, paragraph 19.

[78] There are research papers indicating that the release of GMOs to the environment may cause harm for the local biodiversity through gene flow etc. However, based on materials collected, so far there is no commentary that supports that the mandatory labeling of GMO foods can contribute to the protection of local biodiversity. See Debra M. Strauss, "Food Security and Safety" in Karinne Ludlow, Stuart J. Smyth & José Falck-Zepeda ed, *Socio-Economic Considerations in Biotechnology Regulation* (New York: Springer, 2014) at110; Alan Miller, "Debate of Genetically Modified Organisms Used in Food" (2011) 8 US-China Review 137.

[79] Report of the Appellate Body, *US –Gasoline*, *supra* note 76 at 28.

Therefore, mandatory labeling of GMOs could be recognized as "necessary" to protect human, animal or plant life or health, where: 1) there is scientific evidence or risk assessment to show GM products are harmful for human and animal health and life; 2) this harm or risk is life-threatening; 3) no alternative non-trade restricting measures are available to achieve the same objectives of protecting human and animal health; and 4) the adoption of a mandatory labeling requirement does not constitute arbitrary or unjustifiable discrimination, or a disguised restriction in international GM food trade. When these conditions are satisfied, mandatory labeling can be characterized as an exception under Article XX, and hence will not be challenged for being inconsistent with other requirements of the GATT 1994. However, my analyses later in this Chapter and in Chapters Five and Six will reveal that it is difficult to satisfy all of the above four criteria so it is unlikely that mandatory labeling of GMO food or crops will be permitted under the GATT 1994.

2. Applying the SPS Agreement

If a WTO member state argues that a mandatory GMO labeling requirement is based on food safety concerns, i.e., potential toxin or allergicity, the SPS Agreement will be applied and the member state has to prove that its mandatory labeling measure is in accordance with the SPS Agreement.

2.1 Applying Codex standards

As noted above, the SPS Agreement has referenced the Codex guidance, the international standards for the labeling of GMOs. However, the 2011 *Codex Compilation* on labeling of foods derived from modern biotechnology is not an endorsed guidance that specifies which labeling

regime should apply, e.g., mandatory or voluntary labeling. It is actually a recognition that different approaches concerning GMOs labeling may exist if they are consistent with already adopted Codex texts.[80] As a result, the *Codex Compilation* does not provide any determinative standard to a WTO Panel/the AB for deciding which GMO labeling regime is consistent or inconsistent with the WTO rules. Without a determinative international standard for the labeling of GMOs, the settlement of conflicts over labeling regimes will have to rely on other relevant provisions of the SPS Agreement.

2.2 An autonomous right to use higher-level protection measures

A first question is whether a higher level of protection, i.e., use of a mandatory labeling measure, is an exception to general international standards or an autonomous right of a member under the SPS Agreement. In the *EC-Hormones case*, this issue was understood remarkably differently between the Panel and the AB. The Panel interpreted Article 3.3 of the SPS Agreement as an exception to Article 3.1 and 3.2 assimilated together, shaping into them a "general rule – exception" relationship, i.e., Article 3.1 (the general obligation) and Article 3.3 (an exception).[81] Based on this interpretation, the Panel held that the EC measures for the five hormones at issue (i.e., oestradiol-17β, testosterone, progesterone, zeranol and trenbolone), which were not based on existing international standards, were not necessarily inconsistent with the requirements of the SPS Agreement, but that the EU bore the burden of proof to justify its measures.[82]

[80] Jack A. Bobo, "Two Decades of GE Food Labeling Debate Draw to An End – Will Anybody Notice" (2012) 48 Idaho L Rev 251.
[81] See Report of the Panel, *European Communities – EC Measures Concerning Meat and Meat Products (Hormones)* (*EC – Hormones*) (1998) WT/DS26/R/USA; Report of the Appellate Body, *EC – Hormones* (1998) WT/DS26/AB/R, WT/DS48/AB/R.
[82] *Ibid.*

However, the AB disagreed with the Panel's findings, insisting that Article 3.1, 3.2 and 3.3 addressed separate situations and were not in a relationship of "general rule – exception".[83] According to the AB, Article 3.1 of the SPS Agreement encourages member states to adopt an international standard, while Article 3.3 allows a member state to establish a higher level of protection provided that the member complies with certain requirements in promulgating SPS measures to achieve that level. The AB emphasized that setting up a higher level of sanitary protection under Article 3.3 of the SPS Agreement is an autonomous right for a member rather than an "exception" from a "general obligation" under Article 3.1.[84] Based on this interpretation, the AB reversed the Panel's conclusion, stating that when a member's measure is not based on an international standard in accordance with Article 3.1, the burden is on that member, who has to provide scientific evidence or risk assessment that can justify its Article 3.3 higher-level measure.[85]

Accordingly, in the context of the labeling of GMOs, under Article 3 of the SPS Agreement, a member has a right to adopt a mandatory labeling regime if it holds that other labeling systems, i.e., voluntary labeling, could not result in the same level of protection of human and animal health or life. However, it has to prove that the mandatory requirement is based on scientific evidence or risk assessment.

2.3 Risk assessment

Article 5.1 of the SPS Agreement addresses the issue of risk assessment. It reads: "[M]embers shall ensure that their sanitary or phytosanitary measures are based on an assessment, as

[83] *Ibid*, paragraph 35.
[84] See Report of the Appellate Body, *ibid*, paragraph 36.
[85] *Ibid*, paragraph 36.

appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations."[86] A first controversial question is whether Article 5.1 is a procedural requirement for risk assessment. In *EC-Hormones*, the Panel stated that Article 5.1 implied a "procedural requirement" for the risk assessment, namely "the [M]ember imposing a sanitary measure needs to submit evidence that at least it actually took into account a risk assessment when it enacted or maintained its sanitary measure in order for that measure to be considered as based on a risk assessment."[87] However, the AB clarified that Article 5.1 does not insist that a member that has adopted a sanitary measure should have carried out its own risk assessment; it only requires that the SPS measures be "[b]ased on an assessment, as appropriate for the circumstances ..."[88] Therefore, a SPS measure, i.e., a mandatory labeling requirement, can find its objective justification based on a risk assessment conducted by the member state itself, another member, or an international organization.[89]

However, in the context of agricultural biotechnology, it is difficult for the Panel to a make a decision for the evaluation of scientific risk assessment on biotech-based products. In *EC – Hormones* and *EC – Biotech*, the Panels did not adopt results of risk assessment provided by both parties, and they even avoided directly answering whether or not biotech-based products were safe for consumption on grounds of scientific evidence. The Panels just based their decisions on the procedural grounds under Article 5.7 of the SPS Agreement ruling that the EC should not insist on a ban, which prohibited importation of biotech-based products, as it could not provide

[86] Art. 5.1 of the *SPS Agreement*, *supra* note 1.
[87] See Report of the Appellate Body, *EC – Hormones*, *supra* note 81, paragraph 37.
[88] *Ibid*, paragraph 73.
[89] *Ibid*, paragraph 74.

any established scientific evidence within a reasonable period to prove that the foods at issue were more harmful for human consumption.[90]

The discussion above indicates that the SPS Agreement has given scientific evidence and risk assessment very important roles in determining whether a higher-level measure is in accordance with the SPS Agreement. Consequently, to decide whether the mandatory labeling of GMOs is consistent with the SPS Agreement, a scientific review of GMOs and GM technology is crucial at this point, and the examination of risk analysis is demanded when the risk associated with the GMOs is uncertain. In cases where further scientific evidence or information cannot be provided within a reasonable period of time, pursuant to its WTO SPS Agreement obligation the member shall not retain the measure.

3. Applying the TBT Agreement

If the adoption of a mandatory labeling requirement is not based on food safety concerns but on providing consumers with information that helps them to make informed choices, the TBT Agreement may apply. Under the TBT Agreement, when a member state uses a technical regulation or standard, such as labeling, it does not need to supply scientific evidence to justify the measure, but it has to prove the measure does not create unnecessary obstacles to international trade.[91] With regard to a mandatory labeling requirement, determining whether the measure has contributed an unnecessary barrier to international GM food trade, three controversial issues are in need of an in-depth analysis: (1) whether a mandatory labeling measure can be considered a technical regulation; (2) whether GM products and non-GM

[90] Nathalie Bernasconi-Osterwalder & Maria Julia Oliva, *EC – Biotech: Overview and Analysis of the Panel's Interim Report*, online: <CIEL: http://www.ciel.org/Publications/EC_Biotech_Mar06.pdf >.
[91] Preamble of the *TBT Agreement*, *supra* note 1.

counterparts are "like" products; and (3) whether the mandatory labeling measure constitutes a less favorable treatment on importing producer/its product, that is whether the stringent mandatory labeling measure is more trade-restrictive than necessary to fulfill a legitimate objective with the option of voluntary labeling.

3.1 Does the mandatory labeling requirement constitute a "technical regulation" within the meaning of TBT Annex 1?

When determining whether a measure in dispute is a "technical regulation" under the TBT Agreement, the AB established a three-part test in *EC – Asbestos*. For a measure to constitute a technical regulation: (a) the measure applies to an identifiable product or group of products; (b) it lays down one or more characteristics of the product; and (c) compliance with the product characteristics is mandatory.[92] The three elements were derived from the wording of the definition in Annex 1.1, and this test was then followed in *European Communities – Trade Description of Sardines* (*EC – Sardines*) and *US – Tuna II*.[93] Accordingly, I will analyze whether a mandatory labeling measure constitutes a technical regulation on the basis of the three-element test.

3.1.1 Does the measure apply to an identifiable product or group of products?

As discussed in Chapter four, most GMO labeling regimes apply specifically to a "GMO" or products "produced from GMOs", and almost all GMO labeling laws provide definitions of "genetically engineered organism" or "GMO".[94] For example, Article 2(2) of *Directive*

[92] Report of the Appellate Body, *EC – Asbestos*, *supra* note 57, paragraphs 67-70.
[93] The Report of the Appellate Body, European Communities – Trade Description of Sardines (*EC – Sardines*) (2002) WT/DS231/AB/R; The Report of the Appellate Body, *US – Tuna II*, *supra* note 51.
[94] Art. 3 (1) (2) of *Regulation 1830/2003EC*, EC, *Regulation No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labeling of genetically modified organisms and the traceability of food*

2001/18/EC defines a GMO as "an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination."[95] In addition, some GMO labeling legislation has established a notification procedure, which has considered the GM varieties as a special category.[96] Therefore, GM products constitute an "identifiable" product or group of products.

3.1.2 Do mandatory labeling measures lay down one or more characteristics of the product?

With regard to the characteristic of the products, the AB in *EC – Asbestos* ruled that "product characteristics" should include, "not only features and qualities intrinsic to the product itself, but also related 'characteristics', such as the means of identification, the presentation and the appearance of a product."[97] The AB also found that, based on the wording of Annex 1.1 of the TBT Agreement, the labeling was a product characteristic.[98] In the case of GMO labeling, as I will explore in Chapter Four, many labeling laws have set out the labeling threshold, which specifies a certain level of GM content beyond which GM products have to be labeled. Accordingly, the genetical modification has been considered as a characteristic of GM products in many mandatory labeling regimes, and hence a GMO labeling requirement indeed addresses a product characteristic that satisfies the second elements of the "technical regulation" test under Annex 1.1 to the TBT Agreement.

3.1.3 Is a mandatory labeling measure "mandatory"?

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and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (Regulation (EC) No 1830/2003), [2003] O.J. L268/24.

[95] EC, *Directive 2001/18 of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC*, [2001] O.J. L106/1.

[96] Art. 13 of *Directive 2001/18EC*, *ibid*.

[97] Report of the Appellate Body, *EC – Asbestos*, *supra* note 57, paragraph 67.

[98] *Ibid*, paragraph 67.

The last test is whether a mandatory labeling measure is "mandatory" within the meaning of Annex 1.1. The AB observed in *EC – Asbestos* that "a 'technical regulation' must, in other words, regulate the 'characteristics' of products in a binding or compulsory fashion,"[99] and that "enforceability through sanctions indicates mandatory compliance."[100] In *EC – Trademarks and Geographical Indications (Australia)*, the Panel noted the use of the word "shall" was indicative of mandatory compliance.[101] As we will see in Chapter Four, most mandatory labeling regimes have used "shall" laying down the requirement of GMO labeling. For example, Article 4(6) of *Regulation 1830/2003 EC* specifies that pre-packaged products consisting of or containing GMOs "shall" be labeled as "this products contains genetically modified organisms" or "this product contains genetically modified [name of organism(s)],"[102] and that for non-pre-packaged products offered to the final consumer the words 'this product contains genetically modified organisms' or 'this product contains genetically modified [name of organism(s)]' 'shall' appear on, or in connection with, the display of the product."[103] Moreover, *Regulation 1830/2003 EC* also contains a penalty provision。 Article 11 of the Regulation requires that "[m]ember states shall lay down the rules on penalties applicable to infringements of this regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive."[104] Accordingly, the compliance regulated by mandatory GMO labeling requirements meets the third element of the legal test under Annex 1.1 to the TBT Agreement.

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[99] *Ibid*, paragraph 68.
[100] *Ibid*, paragraph 72.
[101] Report of the Panel, *EC – Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs* (2005) WT/DS290/R, paragraph 7.453.
[102] Art. 4(6)(a) of *Regulation 1830/2003EC*, *supra* note 94.
[103] Art. 4(6)(b) of *Regulation 1830/2003EC*, *ibid*.
[104] Art. 11 of *Regulation 1830/2003EC*, *ibid.*

In light of the above, a mandatory labeling regime meets the three elements of the legal test under Annex 1.1 of the TBT Agreement, and thus constitutes a technical regulation within the meaning of TBT Annex 1.

3.2. Are the GM and non-GM products "like" products?

The second issue, which is also the most controversial and complex due to scientific uncertainty, is whether GM products and their counterparts are "like" products. Under the TBT Agreement, there has been little jurisprudence concerning the determination of what constitutes "like products." In *EC – Asbestos*, the AB investigated the "likeness" issue and confirmed four criteria to evaluate "likeness" in the context of Article III:4 of the GATT 1994. These criteria include: "(a) the products' properties, nature and quality; (b) the products' end-uses in a given market; (c) consumer tastes and habits in respect of the products; and (d) the tariff classification of the products."[105] The AB also confirmed that these criteria should be applied on a case-by-case basis. In the US-COOL case, Canada, based on these four criteria, argued that Canadian cattle and hogs were like products in relation to US cattle and hogs:

> "(i) cattle and hogs imported from Canada are physically indistinguishable from US-origin cattle and hogs, they belong to the same breeds and are raised in the same way; (ii) both Canadian and US cattle and hogs share the same end use of producing beef and pork; (iii) the consumers of cattle and hogs in the United States, i.e. feeding operations and slaughterhouses, view Canadian and US cattle and hogs as interchangeable and base their purchasing decisions on price, quality and availability; and (iv) under the harmonized system of tariff classification, both Canadian and US cattle are classified under subheading 0102.90. Canadian hogs are also classified under the same subheading as US hogs (0103.91 for live swine weighing less than 50kg and 0103.92 for live swine weighing more than 50kg)."[106]

[105] See Report of the Appellate Body, *Japan – Alcoholic Beverages II*, (1996) WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R, pp. 20-21; also see Report of the Appellate Body, *EC – Asbestos*, *supra* note 57, paragraph 101.
[106] Report of the Panel, *US - COOL*, *supra* note 62, paragraph 7.249.

The US did not contest the Canadian government's arguments for the likeness. It just simply denied the products' likeness by arguing that the origin of cattle and hogs was different.[107] According to the US statements, the primary purpose and reason of the COOL measure was to address and indicate a product's origin. The US explained that under the COOL measure, the origin of muscle cuts was distinguished according to the country in which the birth, raising and slaughtering of the animal from which meat was derived took place.[108] The US argued that it was because of this difference that a label of origin was required.

The Panel did not agree with the US argument on "likeness" of the products at issue. It held that the US was not able to provide counterarguments to the Canadian contention, and that a difference between two countries' cattle and hogs could not be established based only on their different origins. The Panel concluded that the Canadian and US cattle were like products and Canadian and US hogs were also like products.[109]

However, determining whether GMOs and conventional crops are "like products" is not easy. The evaluation process will be affected by multiple factors, such as scientific assessment, political factors and other social-economic contributors. This complexity was present in the *EC-Biotech* case, where the Panel showed a very cautious attitude toward different arguments held by two parties about "likeness" regarding GM products and their conventional counterparts.

In 2003, the US, Canada and Argentina initiated a formal legal action under the WTO dispute settlement process, claiming that the moratorium applied by the EC since October 1998 on the

[107] *Ibid*, paragraph 7.251.
[108] *Ibid*, paragraph 7.251.
[109] *Ibid*, paragraph 7.256.

approval of biotech products had restricted imports of agricultural and food products from the US, Canada and Argentina, and that several EC (now EU) member states had prevented the use of GM crops even though they had been approved through EC procedures.[110] With regard to the "likeness" issue, the US and Canada held a similar point of view. Canada argued that the GM products at issue were "like" their domestically-grown non-biotech counterparts:

> "1) A comparison of the s*pecific products* with domestically-grown non-biotech canola/oilseed rape reveals that *their physical differences are minor, and occur only at the genetic level*…there is no reason to consider that product to be different from its non-biotech counterpart in terms of the products' properties, nature and quality, particularly where physical differences between the biotech product and its non-biotech counterpart can be perceived only at the molecular level.
>
> 2) The s*pecific products* and their domestic non-biotech counterparts are intended to be used interchangeably as food, feed and industrial processing materials, as the case may be.
>
> 3) …No reliable evidence exists regarding the consumer tastes and preferences for the s*pecific products* as compared to their domestically-grown non-biotech counterparts. *In these circumstances, consumer tastes and preferences cannot be considered a reliable indicator of "likeness" given the amount of conflicting information publicly available.*
>
> 4) Lastly, no differentiation is made in respect of the tariff classifications between biotech products and their non-biotech, conventionally bred, counterparts.[111]

In response, the EC claimed that the biotech products in question were not "like products" to their non-biotech counterparts.[112] China, as one of the third parties, also held the same opinion, arguing that:

> 1) …when the panel considers the physical and natural similarity of biotech products and non-biotech products, the anti-natural character of

[110] Although there are differences in the way in which each party made its complaint, the Panel was established to deal with all three cases together. Other Members joined as third parties, namely, Australia, New Zealand and Norway. See Report of the Appellate Body, *EC—Hormones*, *supra* note 80, paragraphs 7, 92.
[111] Report of the Panel, *EC – Biotech*, *supra* note 60, paragraph 4.225 (emphasis added).
[112] *Ibid*, paragraph 4.622.

> biotech products must be given more weight in evaluation. "Genetically Modified Organism (GMO)" is defined as an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.
>
> 2) …There are some unique characters for biotech products intertwined with its end-use, such as insect-resistance, pesticide-tolerance…this panel shall give more weight on the unique character of biotech products.
>
> 3) ...the consumers' tastes and preferences in Europe, which are unfavourable towards biotech products, shall be taken into consideration by this panel to conclude biotech products are not like products of non-biotech products.
>
> 4) …because commercial applications of biotechnology came into being in 1990s, it is understandable that there is no distinction under tariff classification between biotech products and non-biotech products...[113]

In its final report, the Panel did not provide an opinion on whether or not the agricultural biotech products in question were "like" products in comparison to their conventional counterparts.[114] The Panel's decision was mainly based on procedural grounds, not the substantive justifications, leaving the "likeness" question unresolved.[115] In my opinion, however, compared with China's arguments, Canada's argument is more convincing. First of all, when applying the "properties, nature and quality" criteria, China emphasized that GMOs were not produced by natural breeding, and hence were different from conventional crops. Nevertheless, "natural" is a confusing word. For example, what is the concept of "natural" in the context of the agricultural breeding process? Since the vast majority of the traditional plant-breeding techniques have already used artificial selection of genetic traits, it is scientifically inaccurate to distinguish biotech products from conventional counterparts only based on the "natural" process.[116] Therefore, a scientific

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[113] *Ibid*, paragraph 5.36-5.39

[114] Pollack, *supra* note 5 at187.

[115] Lars Bracht Andersen, "Transboundary Trade in Genetically Modified Foods" (2013) 2:6 American International Journal of Social Science 12.

[116] See Alison Shaw, "'It Just Goes Against the Grain.' Public Understanding of Genetically Modified (GM) Food in the UK" (2002) 11:3 Public Understanding of Science 273; Henrik Mielby, Peter Sandøe & Jesper Lassen, "The Role of Scientific Knowledge in Shaping Public Attitudes to GM Technologies" (2013) 22:2 Public Understanding of Science 155; Nicole Kronberger, Wolfgang Wagner & Motohiko Nagata, "How Natural Is 'More Natural'? The Role of Method, Type of Transfer,

exploration of GM techniques and GMOs is needed to give a clear and scientific profile of GMOs, and to clarify some misguided understanding about differences between GM and non-GM products.

Secondly, traits such as "insect-resistance and pesticide-tolerance" do not fundamentally change the end-use of the biotech products. Rather, they are improvements for the crops, which can be also achieved by traditional plant breeding techniques. Thus, these preferable traits cannot be used as evidence to support the argument that GM products are not like products in relation to their conventional counterparts because of the changed end-use. Lastly, with regard to consumer preference, although there has been data indicating that some European consumers do not like GM foods, there are also several surveys showing that a large group of European consumers do not care whether foods have been genetically modified or not.[117] As Canada proclaimed in its submission, there is no *reliable* evidence regarding consumer preferences for GM products as compared to their conventional counterparts. Consequently, consumer tastes and preferences should not have too much weight in the decision whether GMOs are like products vis-à-vis their conventional counterparts.

Without a comprehensive scientific analysis of GM techniques and a review of consumers' attitude towards GM products, it is difficult to determine whether GM products are "like products" vis-à-vis non-GM foods in the sense of Article 2.1 of the TBT Agreement. At this point, I will not explore the issues in further detail since I will discuss scientific evidence and consumer studies of GMOs in Chapter Five. However, what I want to reiterate here is the statement noted

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and Familiarity for Public Perceptions of Cisgenic and Transgenic Modification" (2014 36:1 Science Communication 106.

[117] See a review of consumer studies on GM products in more detail, *infra* Chapter Five.

in the Codex *Compilation*, which reads: "[t]his document is not intended to suggest or imply that foods derived from modern biotechnology are necessarily different from other foods simply due to their method of production."[118] This statement at least indicates that the Codex does not consider different production methods as a determinative factor for considering whether GM and non-GM foods are "like" products.

3.3. Does a mandatory labeling measure result in less favorable treatment of the imported product compared to the like domestic product?

The next question is whether a mandatory labeling requirement results in less favorable treatment of the imported product compared to the like domestic product within the meaning of Article 2.1 of the TBT Agreement. In *US-COOL*, the Panel reviewed the costs of compliance with the COOL measure to figure out if the costs of the COOL measure were higher for the imported livestock than for domestic livestock. It found that, although the COOL measure did not explicitly require the segregation of domestic and imported livestock, it called for an unbroken chain of reliable information on country of origin which practically requested the segregation of meat and livestock according to origin as defined by the COOL measure.[119] Accordingly, it is not hard to imagine that if the labeling of all GMOs is required, the entire food system, from farm to fork, would have to be separated into two subsystems.

In *US – COOL*, by exploring segregation costs under different business scenarios,[120] the Panel found that business scenarios involving imported livestock, including exclusively and partially

[118] Considerations of Compilation Document, Compilation Document, CAC/GL 76-2011, online: <http://www.codexalimentarius.net/download/standards/11769/cxg_076e.pdf>.
[119] Report of the Panel, *US - COOL*, *supra* note 62, paragraph 7.336.
[120] In terms of whether the livestock being processed has domestic or imported origin, there are five possible business scenarios

imported livestock, were overall more costly than those involving the exclusively domestic livestock due to the COOL measures.[121] As a result, the requirement of labeling country of origin created an incentive for participants to process domestic rather than imported livestock because, under the COOL measure, processing meat from exclusively domestic livestock was less costly than other business scenarios.[122] On the basis of economic studies submitted by Canada, the Panel examined whether costs for the COOL measure were significant as Canada proclaimed or were small as the US contested. Based on two economic studies on the segregation cost of the COOL measure -- one prepared by Informa Economics in June 2000 and the other conducted by Professor Sumner's economic simulation model published in June 2010 [123] -- the Panel acknowledged that the COOL measure had led to a significant and negative impact on the imported livestock due to the increased cost.[124]

The AB upheld the Panel's findings that the COOL measure had created an incentive for the US processors to use exclusively domestic livestock and a disincentive to use like livestock imported from Canada.[125] The AB noted that "[w]hile a measure may not legally require certain treatment of imports, it may nevertheless create incentives for market participants to behave in certain ways, and thereby have the 'practical effect'". [126] According to the AB, the recordkeeping and verification requirements under the COOL measure had imposed a burdensome duty and cost on upstream producers and processors of livestock but, on the other hand, only a considerably small

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under the COOL measure: (a) processing domestic and imported livestock and meat irrespective of origin and solely according to price and quality; (b) processing meat from exclusively domestic livestock; (c) processing meat from exclusively imported livestock; (d) processing exclusively domestic and exclusively imported livestock at different times; or (e) processing both domestic and imported meat by commingling the two on the same production day. *Ibid*, paragraph7.333.

[121] *Ibid*, paragraph7.402.
[122] *Ibid*, paragraphs7.403-7.404.
[123] *Ibid*, paragraph7.488.
[124] *Ibid*, paragraph7.548.
[125] *Ibid*, paragraph 496.
[126] *Ibid*, paragraph 288.

part of meat sold in the US market was imported from other countries.[127] As a result, the least expensive way of complying with the COOL measure was to avoid segregation by relying exclusively on US livestock.[128] The AB concluded, "if a specific technical regulation adopted by a Member gives rise to adverse effects in the market, which disparately impact imported products, such effects will be attributable to the technical regulation for purposes of examining less favourable treatment under Article 2.1."[129] Moreover, the AB also found that "the labels prescribed by the COOL measure reflect origin information in significantly less detail than the information regarding the countries in which the livestock were born, raised, and slaughtered, which upstream producers and processors are required to be able to identify in their records and transmit to their customers."[130] Consequently, while upstream producers and processors of livestock had incurred high costs in meeting the recordkeeping and verification requirements, only a small amount of information had been accurately disclosed to consumers in an understandable manner.[131] Hence, the AB held that the US COOL measures constituted less favorable treatment of Canadian livestock.

Therefore, in the context of GMOs, to decide whether a mandatory labeling measure is consistent with Article 2.1of the TBT Agreement, a discussion of how mandatory labeling measures would influence the cost of GMO foods and the use of GMOs is needed. To answer this question, I will conduct an investigation of the economic impact of GMO labeling in Chapter Six. If the result of my research indicates that the mandatory labeling of GMOs will increase the costs of GMO food

[127] *Ibid*, paragraph 346.
[128] *Ibid*, paragraph 346.
[129] *Ibid*, paragraph 289.
[130] *Ibid*, paragraph 346.
[131] *Ibid*, paragraph 347.

and it in turn has a detrimental impact on the use of GMOs, then the mandatory labeling of GMOs may not comply with the requirements under Article 2.1 of the TBT Agreement.

3.4. Is a mandatory labeling requirement creating unnecessary obstacles to international trade?

Another controversial and significant issue is whether a mandatory labeling requirement is more trade-restrictive than necessary, i.e., more restrictive than voluntary labeling, to fulfill a legitimate objective. Article 2.2 of the TBT Agreement mandates that:

> "Members shall ensure that technical regulations are not prepared, adopted or applied with a view to or with the effect of creating unnecessary obstacles to international trade. For this purpose, technical regulations *shall not be more trade-restrictive than necessary* to fulfill a legitimate objective, taking account of the risks non-fulfillment would create. Such legitimate objectives are, *inter alia*: national security requirements; the prevention of deceptive practices; *protection of human health or safety, animal or plant life or health, or the environment.* In assessing such risks, relevant elements of consideration are, *inter alia:* available scientific and technical information, related processing technology or intended end-uses of products."[132]

To analyze this necessity issue, we can follow the three-step examination used by the Panel and the AB in the *US – COOL*. The first step is to determine whether the objective pursued by the member country was legitimate.

3.4.1 Is providing consumer information legitimate?

In *US – COOL*, the US claimed that the COOL measure was established to provide consumers information on origin.[133] Canada held a position that providing consumers with information could be "legitimate when the objective is sufficiently specific, such as to allow consumers to make

[132] Art. 2.2 of the *TBT Agreement*, *supra* note 1 (emphasis added).
[133] Report of the Panel, *US - COOL*, *supra* note 62, paragraph 6.110.

decisions and choices based on food safety or environmental protection consideration."[134] However, the US, according to Canada's observation, had not "[e]xplained why the information provided by the COOL measure was important for consumers to have or why consumers need that information"[135] All it found was that the US consumers wanted information on origin due to their desire to purchase food produced in their own country, and this cannot form the basis of a legitimate objective within the meaning of Article 2.2 of the TBT Agreement.[136]

When analyzing the "legitimacy" of the measure's objective, the AB in *US - COOL* noted that the determination of the legitimacy should be based on an independent and objective assessment by considering its "design, architecture, structure, legislative history, and evidence relating to its operation."[137] The AB also recognized that Article 2.2 of the TBT Agreement had listed specific examples of "legitimate objectives", i.e., 1) national security requirements; 2) the prevention of deceptive practices; and 3) protection of human health or safety, animal or plant life or health, or the environment.[138] Thus, if the objective of the measure is among those examples enumerated in Article 2.2 then the objective is legitimate.[139] The AB agreed with the Panel's finding that the objective of the COOL measure was to provide consumers with information as to origin. Although this objective was not among the list in Article 2.2, the AB observed that the COOL measure was related to the objective of prevention of deceptive practices specified in both Article 2.2 and 1994 GATT Article XX(d).[140] It is worth noting that the AB emphasized two points regarding the objective of the COOL measure: (1) both Article XX(d) and Article IX of the

[134] *Ibid*, paragraph 7.623.
[135] *Ibid*.
[136] *Ibid*, paragraph 7.624.
[137] Report of the Appellate Body, *ibid*, paragraph 395.
[138] *Ibid*, paragraph 370.
[139] *Ibid*, paragraphs 370-372.
[140] Art. XX(d) of the *GATT 1994*, *GATT 1994*, *supra* note1.

GATT 1994 "recognize the right of WTO Members to require that imported products carry a mark of origin";[141] and (2) "providing accurate and reliable information may protect consumers from being misled or misinformed."[142]Accordingly, the AB held that the objective of the COOL measure was legitimate within the meaning of Article 2.2 of the TBT Agreement.

In the context of GMO labelling, as we will see in Chapters Five and Six, providing consumers with information on whether foods are genetically modified or containing GM ingredients is one of the rationales that has been frequently argued as the objective of mandatory labelling of GMOs. However, whether providing consumers with GMO information can be regarded as a legitimate objective under Article 2.2 is not certain. To date no analyses from the WTO Panels and AB have addressed this issue, and no provisions of WTO agreements recognize that member states have a right to require import products to carry GMO information marks. Following the AB's reasoning in the *US – COOL* case, if the provision of information can fall within the scope of legitimate objective (prevention of deceptive practices) under Article 2.2, the subsequent question is whether providing consumers with information on a specific type of issues, i.e., as to whether foods are GMO or containing GM ingredients can also be linked to the objective of prevention of deceptive practices?[143] To verify this linkage, a member state has to prove that GM and non-GM are different products, and that deceptive purchases will occur because of the confusion due to the absence of labeling. Accordingly, the member state will have to justify that the uses of GM techniques have impacted on the quality or property of the end products, which have distinguished GM products from non-GM counterparts. If the member state's mandatory GMO labeling measures are base on the process and production methods rather than different properties

[141] Report of the Appellate Body, *US – COOL*, *supra* note 62, paragraph 445.
[142] *Ibid*, paragraph 451.
[143] *Ibid*, paragraph 444.

of end-products, according to the Panels and AB opinions in the *US – Shrimp*,[144] the member state has to justify its labeling measure under Article XX (b) of the GATT 1994 (protect human, animal or plant life or health), because non-health-related or non-environmental protection-related process-based measures are unlikely to be justified under the GATT 1994 and the TBT Agreement.[145]

Based on an assumption that provision of GMO information is a legitimate objective, i.e., preventing deceptive practice, the next sections will analyze whether a mandatory labeling regime is more trade-restrictive than necessary (i.e., compared to a voluntary labeling system) to fulfill the legitimate objective of prevention of deceptive practices.

3.4.2 Is the mandatory GMO labeling measure more trade-restrictive than necessary to fulfill a legitimate objective?

Regarding the assessment of whether a technical regulation is "more trade-restrictive than necessary to fulfill a legitimate objective" within the meaning of Article 2.2 of the TBT Agreement, the AB explained in the US – Tuna II (Mexico) that the following factors needed to be considered at the same time: "(i) the degree of contribution made by the measure to the legitimate objective at issue; (ii) the trade-restrictiveness of the measure; and (iii) the nature of the risks at issue and the gravity of consequences that would arise from non-fulfillment of the objective(s) pursued by the Member through the measure."[146]

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[144] Report of the Appellate Body, *United States – Import Prohibition of Certain Shrimp and Shrimp Products* (*US – Shrimp*) (1998) WT/DS58/AB/R.
[145] Keane, *supra* note 24; Grant E. Isaac & William A. Kerr, "Genetically Modified Organisms and Trade Rules: Identifying Important Challenges for the WTO" (2003) 26:1 The World Economy 29.
[146] Report of the Appellate Body, *US – COOL*, *supra* note 62, paragraph 322.

i) Does a mandatory GMO labeling measure fulfills a legitimate objective?

In *US – COOL*, the Panel held that a measure could be deemed consistent with Article 2.2 of the TBT Agreement only if a certain level of fulfillment of legitimate objective had occurred.[147] Nevertheless, the AB did not agree with the Panel's reasoning. It highlighted that "the assessment should focus on ascertaining the degree of contribution achieved by the measure, rather than on answering the questions of whether the measure fulfills the objective completely or satisfies some minimum level of fulfillment of that objective."[148] Subsequently, the AB noted that, although the country of origin label types B and C were confusing because of multiple country names listed on these labels, according to the Panel's analysis, the COOL measure indeed had contributed, at least to some degree, to the objective of providing consumers with information as to the country of origin of meat products.[149] Based on this understanding of "fulfill", the AB reversed the Panel's conclusion, holding that the COOL measure did fulfill the legitimate objective in the meaning of Article 2.2 of the TBT Agreement.[150]

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[147] Report of the Panel, *Ibid*, paragraph 7.719.

[148] To evaluate the fulfillment of the objective pursued by the COOL measures, the Panel was in the position that the evaluation should depend on to what extend the labels could convey clear and accurate information on origin. The Panel reviewed the specific labeling scheme under the COOL measure, particularly the content and categorization of different categories of labels, to examine whether clear and accurate country of origin information of meat products was conveyed to consumers under the COOL measure. The Panel found that commingling can take place in multiple stages of the meat production process (e.g. processors and packers), including at the retail level. The commingling, according to the Panel's observation, would further diffuse the content and impact of origin labels as defined by the measure. For example "[i]f a retailer were to decide to commingle meat products that had already been commingled during the production process, the resulting labels affixed to these products would be even less accurate in terms of the origin of such products as defined by the United States." The Panel held that:

> "labelling under the COOL measure provided information on meat with regard to the possible, but not necessarily actual, or for that matter accurate, origin as defined by the measure… it falls short of providing consumers with information on the country of origin of meat products in an accurate and clear manner…considered in light of the origin definition as determined by the United States for meat products, the description of origin for Label B and Label C is confusing in terms of the meaning of multiple country names listed in these labels."

The Panel concluded that the COOL measure did not fulfill the identified objective within the meaning of Art. 2.2 because it failed to convey meaningful origin information to consumers, hence the US acted inconsistently with Art. 2.2 of the TBT Agreement. Report of the Appellate Body, *ibid*, paragraph 468.

[149] *Ibid*, paragraph 468.

[150] *Ibid*.

According to the AB's "degree of contribution" rationale in the COOL case, to verify that a mandatory GMO labeling measure has fulfilled the objective of providing consumers with information, a member state has to provide evidence that the mandatory labeling has achieved a certain degree of contribution to the objective. If the labeling statements are proved to be inaccurate and misleading and the current testing method limits the accuracy of GMO labeling, the mandatory labeling measure cannot be regarded as fulfilling the objective under Article 2.2.

ii) Are mandatory GMO labeling measures trade-restrictive?

In the *US – Tuna II (Mexico)* and *US – COOL* cases, the AB interpreted the trade-restrictive measures as measures that have "a limiting effect on trade."[151] The AB held that the determination of "trade-restrictive" did not require any demonstration of actual trade effects.[152] Given this broad scope of the term "trade-restrictive", the Panel in the *US – COOL* case concluded that the COOL measures, which imposed higher segregating costs on imported livestock, had a considerable degree of trade-restrictiveness that affected the competitive conditions of imported livestock.[153] Following this reasoning, it is reasonable to believe that a mandatory GMO labeling regime will be deemed to be a trade-restrictive measure under Article 2.2 of the TBT Agreement, since it does have a limiting effect on trade by prohibiting unlabeled GM food products from accessing the domestic market and by increasing GMO food costs that affects the competitive conditions of labeled GMO foods.

iii) Will any risks create because of the non-fulfillment of the objective pursued through the mandatory GMO labeling measures?

[151] Report of the Appellate Body, *US – Tuna II*, *supra* note 51, paragraph 319; Report of the Appellate Body, *US – COOL*, *supra* note 62, paragraph 375.
[152] Report of the Appellate, *US – COOL*, *ibid*, paragraph 477.
[153] *Ibid.*

The AB in the *US – Tuna II (Mexico)* emphasized that "[i]n most cases, a comparison of the challenged measure and possible alternative measures should be undertaken" to "access the nature of the risks at issue as well as the gravity of the consequences that would arise from non-fulfillment of the objective pursued by the Member through the measure."[154] In *US – COOL*, Canada and Mexico proposed four alternative methods, which were purported to be less trade restrictive while achieving an equal, or higher, level of fulfillment of the objective (providing consumers with information on the country of origin).[155] One of the suggested methods was use of a voluntary country of origin labeling requirement. However, the AB held that, due to inadequate factual findings by the Panel and the insufficient uncontested data, it could not evaluate "(i) whether these alternative measures are less trade restrictive than the COOL measure; (ii) whether they would make an equivalent contribution to the relevant objective, taking account of the risks non-fulfillment would create; and (iii) whether they are reasonably available to the United States;" hence it was not able to reach a conclusion on whether the COOL measure was more trade restrictive than necessary to fulfill its legitimate objective.[156]

Although the AB did not make a final decision on the necessity issue in *US - COOL*, its reasoning has provided persuasive guidance on how to determine whether a mandatory GMO labeling measure, compared to a voluntary labeling requirement, is more trade-restrictive than necessary to fulfill a legitimate objective. That is, we have to explore solid data or evidence to indicate how a voluntary labeling requirement would operate in the market in terms of trade-restrictiveness. At the same time, we have to examine to what extent the voluntary labeling

[154] Report of the Appellate Body, *US – Tuna II*, *supra* note 51, paragraph 322.
[155] These four alternative measures include: "(i) a voluntary country of origin labeling requirement; (ii) a mandatory country of origin labeling requirement based on the criterion of substantial transformation; (iii) a voluntary country of origin labeling regime combined with a mandatory country of origin labeling requirement based on substantial transformation; and (iv) a trace-back regime." See Report of the Appellate, *US – COOL*, *supra* note 62, paragraph 480.
[156] Report of the Appellate, *ibid*, paragraph 491.

requirement can contribute to the objective of providing consumers with information on whether or not products have been genetically modified, or how much a contribution would compare to the degree of contribution made by the mandatory labeling measure itself.

Conclusion

With regard to the management of GMO labeling, Chapters Two and Three have revealed that the realms of different international agreements actually operate separately. The labeling of GMOs is creating controversy in terms of world trade, but currently there is no an overarching inter-governmental organization that can effectively address all of the trade, environmental and food safety issues under one umbrella. Compared with the FAO/Codex regime and the environmental/CBD framework, the WTO possesses a detailed rule/obligation system, a fairly strong and legalistic dispute resolution body and procedure, and an effective mechanism that can review members' trade policies regularly. Given all these features and the reality of fragmentation of international law regimes, the WTO system is a more attractive regime for those states that want to contest mandatory labeling because of the economic liberalism philosophy of the WTO. Amongst the existing multilateral regimes, the WTO is a more feasible legal framework for the settlement of disputes concerning GMO labeling compared to other multilateral regimes, such as the FAO and the CBD framework.

Within the WTO system, as discussed in this Chapter, there are no agreements that explicitly regulate the labeling of GMOs, but provisions of the GATT 1994, the SPS Agreement and the TBT Agreement are applicable to trade disputes over GMO products due to different GMO labeling regimes. At the same time, analyses in this Chapter also indicate that, no matter which

WTO agreement applies, a determination of whether a mandatory GMO labeling measure is a violation of WTO rules needs further exploration on a number of issues.

When discussing GATT 1994, we find that Article XX(b) of the GATT can be used to justify a member's mandatory labeling requirement if the adoption of the measure is based on the protection of human and animal health and life. However, in order to meet the requirements under Article XX(b), the member has to prove that: 1) there exists solid scientific evidence that shows GM products are more harmful than conventional crops to human and animal health and life, 2) the related harm is severe and life-threatening; 3) there are no alternative non-trade restricting measures available for achieving the same objectives of protecting human and animal health, and 4) the measure does not constitute arbitrary or unjustifiable discrimination, or a disguised restriction in international GM food trade. All these four criteria must be satisfied at the same time, otherwise the mandatory labeling measure cannot be upheld/permitted under the GATT 1994.

Different from general principles in the GATT, the SPS Agreement specifically addresses issues associated with human, animal and plant life or health in the context of international trade in goods. In cases where a member state argues that the reason for labeling is based on food safety concerns, the SPS Agreement will govern the dispute and the member state has to justify that its requirements of GMO mandatory labeling are consistent with the obligations under the SPS Agreement. Accordingly, the member state must prove that the SPS measures in dispute, i.e., mandatory GMO labeling requirements, are based on scientific evidence and risk assessment. Even if relevant scientific evidence is not sufficient, it has to review its measure from time to time, and has to seek additional information necessary for a more objective assessment of risk

within a reasonable period of time. As a result, under the SPS Agreement, the member state may not insist on a long-term control over GM food or food containing GM ingredients (e.g., requesting imported GMOs mandatorily be labeled) if there is no established scientific evidence within a reasonable period to prove that GM foods are harmful for human consumption. Thus, without sufficient scientific evidence, it is unlikely that mandatory labeling can be upheld under the SPS Agreement.

In the case that a member state's argument for the adoption of a mandatory labeling requirement is based on reasons other than food safety concerns, i.e., providing consumers with information that helps them to make informed choices, the TBT Agreement may apply. Unlike strict evidence-based requirements under the SPS Agreement, the provisions in the TBT Agreement are more flexible, and the scientific evidence is probably not determinative when applying the TBT Agreement provisions. As previously discussed, if a member country intends to justify its mandatory GMO labeling requirement based on the rationale of providing consumers with information, the member has to provide evidence to justify its labeling measure under Articles 2.1 and 2.2 of the TBT Agreement. To be in accordance with Article 2.1, the member state has to approve that 1) GM products in question are not "like products" compared to their conventional counterparts, and 2) the mandatory labeling measure does not result in less favorable treatment of the imported product compared to the like domestic product. With regard to verifying its mandatory labeling measures are not creating unnecessary obstacles to international trade, i.e., to be consistent with the obligations under Article 2.2, the member state has to demonstrate with evidence that 1) providing consumers with information as to whether foods have been genetically modified is a legitimate objective within the meaning of Article 2.2; 2) the measure has fulfilled the objective of the measure; and 3) the measure is not trade-restrictive; and 4) there are no

alternative non-trade restricting measures that can achieve the same objectives (i.e., providing consumers with information) and is not more trade-restrictive than necessary to fulfill a legitimate objective.

To prove all these conditions is not an easy job. As explored above, determinations of some conditions are even controversial within the WTO Panels, e.g., whether GM and non-GM counterparts are like products. Base on the analyses of this Chapter, at the current stage, I can only conclude that mandatory GMO labeling measures are trade-restrictive under Article 2.2 of the TBT Agreement. Other conditions, however, cannot be determined without further investigation. Subsequently, to examine whether a mandatory labeling measure for GM products is in accordance with the WTO rules, I will conduct: 1) a comprehensive scientific analysis of GM techniques and GMOs, aiming to discuss whether GM and non-GM products are "like products", 2) a review of consumer attitudes to GM products, which attempts to figure out whether consumers are interested in knowing about GMO information and are willing to pay a premium due to mandatory labeling requirements, 3) an exploration of whether the increased cost of GM foods will in turn have a detrimental impact on the use of GMOs, and 4) a discussion on whether the less-trade-restrictive voluntary labeling regime can reach a similar degree of contribution made by mandatory labeling measures to the objective of providing consumers with information. Before I explore these important questions, I will first cast some light on EU law and selected domestic law on the labeling of GMOs in the next Chapter. A comparative study of laws at the domestic and EU levels will provide a more comprehensive understanding of factors that have caused the strong and diverse attitudes toward GMOs and GMO labeling requirements in different legal systems.

Chapter 4 Different Labeling Regimes: European Union, Canada and China

Chapters Two and Three have provided a landscape showing how issues regarding GMO labeling have been handled on the international level. This chapter will comprehensively examine the labeling of GMOs at the level of regional and domestic law, exploring sources of transnational conflicts over GMO labeling regimes. I have selected three different labeling regimes – EU, Canada and China – to make a comparative analysis. The EU imposes the most severe restrictions and regulatory oversight on the approval and marketing of biotech foods, and these restrictions must be implemented by the EU's 28 member states,[1] while Canada leans more heavily on scientific based regulation, adopting a voluntary labeling regime. China, as a developing country, has to balance security of food supply and food safety, along with the needs of a huge population and limited arable land. The combination of all these considerations influences the national regulation of GMOs and requirements for GM food labeling. Currently, China is using a mandatory labeling system for GM products.

This Chapter begins by exploring the labeling laws of these three different jurisdictions. It proceeds to analyze the rationales for each labeling regime and evaluates their implementation in practice. It then summarizes similarities and differences between these three GMO labeling systems and, finally, explores the explanations offered for the difference in the EU, Canadian and Chinese regulatory frameworks.

A. EU

[1] As of July 1, 2013, the EU has 28 member states: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, German, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Span, Sweden, and United Kingdom. See Countries, online: Europa. eu <http://europa.eu/about-eu/countries/index_en.htm>.

Before exploring the EU's regulatory framework on GMOs and the labeling of GMOs, the structure of EU law has to be made clear at the beginning. EU law has three sources: primary sources, secondary sources, and supplementary sources.[2] Primary sources are mainly the founding EU treaties that form the foundation of the EU legal order: the Treaty on European Union (TEU) and the Treaty on the Functioning of the European Union (TFEU).[3] These treaties function as a "constitution" of the EU that "[s]et out the distribution of competences between the Union and the member states and establishes the powers of the European institutions."[4] With regard to secondary sources, they are unilateral acts and agreements.[5] Unilateral acts include legislative acts that are binding laws adopted by the EU and non-legislative acts that are nonbinding instruments but may result in policy change, such as Recommendations and Opinions.[6] With respect to the legislative acts, there are three forms of secondary legislation derived from the EU treaties:

> (1) Regulation: are the most powerful and most direct form of EU law, and most like conventional acts of a national legislature. They are directly applicable in that they do not need to be turned into national law, they are binding in their entirety, and they take immediate effect on a specified date…; (2) Directives are binding in terms of goals, but it is left up to the member states to decide what action they need to take to achieve those goals… Directives usually include a date by which national action must be taken, and member states must tell the Commission what they are doing; (3) Decisions: are also binding, but are usually fairly specific in their intent, and aimed at one or more member states, at institutions, or even at individuals. Some are aimed at making changes in the powers of EU institutions, some are directed towards internal administrative matters, and others are issued when the Commission has to adjudicate disputes between member states or corporations.[7]

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[2] Europa, Sources of European Union Law, online: Europa Summaries of EU Legislation <http://europa.eu/legislation_summaries/institutional_affairs/decisionmaking_process/l14534_en.htm>.

[3] *Treaty on European Union (Consolidated version 2012)*, 26 October 2012, [2012] O.J. C 326, online: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2012:326:0047:0200:EN:PDF>; *Treaty on the Functioning of the European Union (Consolidated version 2012)*, 26 October 2012, [2012] O.J. C 326, online: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2012:326:0047:0200:EN:PDF>.

[4] Europa, Sources of European Union Law, online: Europa Summaries of EU Legislation <http://europa.eu/legislation_summaries/institutional_affairs/decisionmaking_process/l14534_en.htm>.

[5] *Ibid.*

[6] Tomasz Kramer, *Primary and Secondary Sources of EU Law Practical Analysis of EU Legal Instruments*, online: <http://www.abgs.gov.tr/files/EKYB/egitim_materyalleri/primary_and_secondary_sources_of_eu_law.pdf>.

[7] John McCormick, *Understanding the European Union A Concise Introduction*, 5th ed (UK: Palgrave Macmillan, 2011) at 85.

Agreements are international agreements signed by the EU, agreements between member states, and inter-institutional agreements.[8] Supplementary sources are the case law of the Court of Justice and international law and general principles of law.[9]

According to the International Service for the Acquisition of Agri-biotech Application (ISAAA),[10] in 2012, the EU planted 129,071 hectares of Bt Maize. Compared with 2011, it has increased 13%, but it is still far below the US record: 69.5 million hectares of biotech crops in 2012.[11] Spain is currently the largest user of Bt maize in Europe (116.307 hectares in 2012), and accounts for 90% of such farming on the continent in terms of hectares planted.[12] However, the overall amount of bioengineered seeds used in European farming remains tiny compared with cultivation of conventional crops.[13]

The EU and EU members are not alone in the world in requiring GMO labeling: more than thirty countries also have some form of labeling laws e.g., Australia, New Zealand, Japan, South Korea and Indonesia all have requirements that GM content making up more than a certain amount of the total weight of a product must be labeled.[14] However, the principles and requirements of the

[8] Europa, *supra* note 4.
[9] *Ibid*.
[10] The International Service for the Acquisition of Agri-biotech Application (ISAAA) is a non-profit, industry and government funded international organization. It aims to promote the use and sharing of agricultural biotechnology. It produces annual report on the use and benefits of biotech crops. See ISAAA in Brief, online: International Service for the Acquisition of Agri-biotech Application <http://www.isaaa.org/>.
[11] *Top Ten Facts about Biotech / GM Crops in 2012 A New Overview of Biotech Crops in 2012*, online: ISAAA <http://www.isaaa.org/resources/publications/briefs/44/toptenfacts/default.asp>; also see *Global Status of Commercialized Biotech / GM Crops: 2012*, online: ISAAA <http://www.isaaa.org/resources/publications/briefs/44/executivesummary/default.asp>.
[12] *Top Ten Facts about Biotech / GM Crops in 2012 A New Overview of Biotech Crops in 2012*, *ibid*.
[13] James Kanter, *A New Push to Win EU Acceptance for Biotech*, online: The New York Times <http://www.nytimes.com/2009/02/16/business/worldbusiness/16iht-biotecha.4.20227796.html?pagewanted=all>.
[14] The number of courtiers that have used mandatory GMO labeling regimes is based on a 2013 report of the Center for Food Safety. See Anton E. Wohlers, "Labeling of Genetically Modified Food Closer to Reality in the United States" (2013 32:1 Politics and the Life Sciences 73; *Genetically Modified Food Labeling*, online: GM. Org <http://www.gm.org/gm-

EU's current labeling laws render them the strongest in the world. Since 1997, the EU has implemented gradually more stringent legislation on the labeling of GMOs. A brief exploration of these laws will provide a clear route that helps to understand the complexity and scope of the EU's current labeling legislation.

1. Regime Review

Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients (Regulation (EC) No 258/97) was the first instrument to address regulatory issues regarding novel food and food ingredients,[15] and it formed the basis for mandatory labeling requirements for GM foods.[16] In virtue of this Regulation, an additional specific labeling requirement shall apply to foodstuffs to "inform the final consumer of the presence of an organism genetically modified by techniques of genetic modification."[17] It is worth noting that Regulation (EC) No 258/97 used the product-based labeling method, namely "genetically modified foods required labeling only if GM content could be detected in the final product."[18]

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foods/genetically-modified-food-labeling/>.

[15] The following food and food ingredients can be recognized as novel food and food ingredients: "(c) foods and food ingredients with a new or intentionally modified primary molecular structure; (d) foods and food ingredients consisting of or isolated from microorganisms, fungi or algae; (e) foods and food ingredients consisting of or isolated from plants and food ingredients isolated from animals, except for foods and food ingredients obtained by traditional propagating or breeding practices and having a history of safe food use; (f) foods and food ingredients to which has been applied a production process not currently used, where that process gives rise to significant changes in the composition or structure of the foods or food ingredients which affect their nutritional value, metabolism or level of undesirable substances." Regulation of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredient (Regulation (EC) 258/97), EC, *Regulation of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredient*, [1997] O.J. L43.

[16] Art. 8 of *Regulation (EC) 258/97*, "additional specific labeling requirements shall apply to foodstuffs in order to ensure that the final consumer is informed of 1) any characteristic or food property, such as composition, nutritional value or effects, and intended use of the food, which render a novel food or food ingredients no longer equivalent to an existing food or food ingredients; 2) the presence in the novel food or food ingredient of material which is not present in an existing equivalent foodstuff and which may have implications for the health of certain sections of the population; 3) the presence in the novel food or food ingredient of material which is not present in an existing equivalent foodstuff and which gives rise to ethical concerns; 4) the presence of an organism genetically modified by techniques of genetic modification, the non-exhaustive list of which is laid down in Annex I A, Part 1 of Directive 90/220/EEC." *Ibid*.

[17] Art. 8.1 (d) of *Regulation (EC) 258/97*, *ibid*.

[18] GMO Compass, *GMO Labeling: Guidelines New Labeling Laws: What Has Changed?*, online: GMO Compass

Over the period 1996-1998, the EU approved around 14 GMOs for commercial release.[19] Since 1998, there has been a *de facto* moratorium on the processing and approval of new GM varieties for commercial release and human consumption. The moratorium was officially notified by five EU member states -- Denmark, Greece, France, Italy and Luxembourg -- in June 1999. They informed the European Commission that they would "take steps to have any new authorizations for growing and placing on the market suspended" until legislation for the labeling and traceability of GMOs and GMO-derived products was introduced.[20]

In 2001, Directive 2001/18 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 (Directive 2001/18/EC), was adopted by co-decision between the Council and the European Parliament.[21] Article 21 of the Directive provided that labeling for GMOs "as or in products" is mandatory at all stages of the placing on the market,[22] and that when adventitious or technically unavoidable traces of authorized GMOs cannot be excluded a minimum threshold should be established below which GMO products should not have to be

<http://www.gmo-compass.org/eng/regulation/labelling/93.new_labelling_laws_gm_products_eu.html>.

[19] *The EU Moratorium – More Than A Trade barrier*, Online: <http://www.sustainabilitynz.org/docs/EU%20Moratorium%20on%20GMOs.pdf>.

[20] Mark A. Pollack & Gregory C. Shaffer, *When Cooperation Fails the International Law and Politics of Genetically Modified Foods* (New York: Oxford University Press, 2009) at 58.

[21] Co-decision procedure: Decision European Parliament given on 14 February 2001 and Decision Council given on 15 February 2001. See Legislative History, online: EUR-Lex <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32001L0018:EN:NOT>.

[22] According to Art. 2(4) of Directive 2001/18 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 (Directive 2001/18/EC), "'placing on the market' means making available to third parties, whether in return for payment or free of charge". But the following operations were defined as non-placing on the market. They include: "making available genetically modified microorganisms for activities regulated under Council Directive 90/219/EEC of 23 April 1990 on the contained use of genetically modified microorganisms (1) including cultural collections, making available GMOs other than microorganisms refereed to in the first indent, to be used exclusively for activities where appropriate stringent containment measures are used to limit their contact with and to provide a high level of safety for the general population and the environment, the measures should be based on the same principles of containments as laid down in Directive 90/219/EEC, making available GMOs to be used exclusively for deliberate releases complying with the requirements laid down in part B of this Directive." EC, *Directive 2001/18 of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC*, [2001] O.J. L106/1.

labeled.[23] However, the adoption of Directive 2001/18 did not satisfy a core number of member states, such as Austria, Denmark, France, Greece, and Italy.[24] They continually insisted on the *de facto* moratorium on GMOs and persisted in emphasizing the need to impose national safeguard bans, thereby appealing for a more stringent and transparent regulatory framework for the approval of GMOs and on traceability and labeling of GM products.[25]

To break the deadlock on approvals and secure the removal of existing national bans, the Commission kept working on revisions of the legislative framework for the marketing of GMOs. Two resulting regulations, namely Regulation 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (Regulation (EC) No 1829/2003) and Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labeling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (Regulation (EC) No 1830/2003)[26] were adopted in September 2001 and went into effect in April 2004.[27] These two new regulations are stricter than the previous legislation with a broader scope of application and a more stringent threshold for GMO contents.

[23] Art. 21 of *Directive 2001/18/EC*, *ibid*.
[24] Pollack & Shaffer, *supra* note 20 at 239-240.
[25] Debra Holland & Helen Pope, *EU Food Law and Policy* (The Netherlands, The Hague: Kluwer Law International 2004) at 110.
[26] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed (Regulation 1829/2003/EC), EC, *Regulation 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, O. J. Legislation (2003) No L268*/1, [2003] O.J. L268/1. EC, *Regulation No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labeling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (Regulation (EC) No 1830/2003)*, [2003] O.J. L268/24.
[27] Preamble (2) of *Regulation 1829/2003/EC*, *ibid*.

Regulation (EC) No 1829/2003 covers comprehensive aspects of the marketing of GM foods and feeds. It focuses on establishing "harmonized procedures for risk assessment and authorization that are efficient, time-limited and transparent, and criteria for evaluation of the potential risks arising from GM foods and feeds."[28] With regard to the labeling of GMOs, the Regulation uses a process-based system and lays down specific labeling requirements. Under this Regulation, GM foods and feeds which are delivered as such to the final consumer or mass caterers (restaurants, hospitals, canteens etc.) must be labeled, regardless of whether DNA or proteins derived from genetic modification are contained in the final product.[29] With regard to Regulation (EC) No1830/2003, its main goal is to create a more centralized and harmonized EU framework for the traceability and labeling of GMOs.[30] Since Directive 2001/18/EC mandates member states shall take steps to ensure the traceability and labeling of authorized GMOs at all stages of their placing in the market, conflicts of laws between member states might arise due to different national laws.[31] Such conflicts would consequently contribute to an ineffective functioning of the internal marketing of GMOs. Therefore, Directive 2001/18/EC was amended accordingly. Under the new regulation, the Commission is required to establish a harmonized system of unique identifiers for each GMO in order "to trace GMOs and products produced from GMOs at all stages of their placing on the market through the production and distribution chain."[32]

2 Summary of labeling requirements

2.1 Categories of food/feed that must be labeled

[28] Preamble (30) of *Regulation No 1829/2003/EC*, *ibid.*
[29] *GMOs in A Nutshell*, online: Europa <http://ec.europa.eu/food/food/biotechnology/qanda/e4_en.htm#e>.
[30] Preamble (2) of *Regulation 1830/2003/EC*, *supra* note 26.
[31] *Ibid.*
[32] Preamble (1) of *Regulation 1830/2003/EC*, *ibid.*

Before Regulation (EC) No1829/2003, labeling requirements for GMOs only applied to two categories of GM foods and feeds: (1) food or feed which is a GMO (e.g., GM tomatoes, GM potatoes) and (2) food or feed containing GMOs (e.g., GM sweet corn in tins).[33] Regulation (EC) No1829/2003 extends the labeling requirement to food and feed produced from or containing ingredients produced from GMOs (i.e. oil from GM soy beans, corn-flakes from GM corn, oil from GM canola, and bread with GM soy protein etc.).[34] Regulation (EC) N 50/2000 of 10 January 2000 on the labeling of foodstuffs and food ingredients containing additives and flavourings that have been genetically modified or have been produced from genetically modified organisms (Regulation (EC) No 50/2000) provides provisions on labeling requirements for GM additives and flavourings intended to be used in foodstuffs.[35] According to this Regulation, the labeling requirement for GM additives and flavourings is in accordance with "the same principles as those laid down for the labeling of ingredients that are, contain, or are produced from GMOs."[36] Thus, a specified label must be added if the additive and flavouring used are, or contain, or have been produced from GMOs.

2.2 Categories of food/feed that need not be labeled

Under Regulation (EC) 1829/2003 and Regulation 1830/2003, the mandatory labeling requirement is applied to almost all GM foodstuffs. However, there are two important

[33] Preamble (16) of *Regulation (EC) No 1829/2003/EC*, *supra* note 26.
[34] Art. 4 of *Regulation No 1829/2003/EC*, *ibid*.
[35] Regulation (EC) No 258/97, in contrast, only applied to novel food and food ingredients. Additives and flavorings intended to be used in foodstuffs are not covered by it, and they are also excluded from the scope of Council Regulation (EC) No 1139/98 of 26 May 1998 concerning the compulsory indication of the labeling of certain foodstuffs produced from genetically modified organisms of particulars other than those provided for in Directive 79/112/EEC (Regulation (EC) 1139/98). The resulting legislation Regulation (EC) N 50/2000 of 10 January 2000 on the labeling of foodstuffs and food ingredients containing additives and flavorings that have been genetically modified or have been produced from genetically modified organisms (Regulation (EC) No 50/2000) was adopted to deal with the labeling issue of GM additives and flavorings. See Regulation 50/2000/EC, EC, *Regulation N 50/2000 of 10 January 2000 on the labeling of foodstuffs and food ingredients containing additives and flavorings that have been genetically modified or have been produced from genetically modified organisms (Regulation (EC) No 50/2000)*, [2000] O.J. L6/15.
[36] Preamble (8) of *Regulation (EC) No 50/2000/EC*, *ibid*.

exemptions: (1) food and feed produced with (the aid of) a GMO; and (2) "foods containing material which contains, consists of or is produced from GMOs in a proportion no higher than 0.9 percent of the food ingredients considered individually or food consisting of a single ingredient, provided that this presence is adventitious or technically unavoidable."[37]These exceptions also apply to GM additives or flavourings that are produced with GMOs.[38]

Food and feed produced 'with' the aid of GMOs need not be labeled.[39] The reasoning for this exception is that "processing aids that are only used during the food or feed production process are not covered by the definition of food or feed."[40] Consequently, food or feed produced with the help of processing aids that are genetically modified should not be covered by the Regulation.[41] That is, "products obtained from animals fed with genetically modified feed or treated with genetically modified medicinal products (e.g. meat, milk and eggs) will not be subject to the labeling requirements."[42]

2.3 Threshold of GMO content

Directive 2001/18 suggested the establishment of a minimum threshold level of GMO content.[43] Regulation (EC) 1829/2003 sets up three distinct thresholds: (1) food or feed products, where adventitious or technically unavoidable traces of authorized GMOs cannot be excluded, need not be labeled if they "consist of or are produced from GMOs in a proportion no higher than 0.9 percent of the food ingredients considered individually or food consisting of a single

[37] Art. 12 of *Regulation (EC) No 1829/2003*, *supra* note 26.
[38] Preamble (14) of *Regulation N50/2000/EC*, *supra* note 35.
[39] Preamble (16) of *Regulation 1829/2003/EC*, *supra* note 26.
[40] *Ibid.*
[41] *Ibid.*
[42] *Ibid.*
[43] Art. 21 of *Directive 2001/18/EC*, *supra* note 22.

ingredient"[44]; (2) food or feed material that contains, consists of or is produced from not yet unauthorized GMOs in a proportion no higher than 0.5 percent shall not be labeled, provided that it has a favorable assessment from an EU scientific committee and the presence of the GM material is adventitious or technically unavoidable;[45] and (3) from April 2007, namely three years after the application of Regulation (EC) 1829/2003, such unauthorized GM material cannot be present at any level in food or feed products unless new regulations are enacted, i.e., "zero tolerance".[46]

2.4 Labeling formats

Directive 2001/18/EC initially established an example of the labeling format for GMOs. Under Directive 2001/18, "This product contains genetically modified organisms"[47] had to be displayed "on a label or in an accompanying document, on the presence of GMOs"[48] to provide consumers with clear information.[49] Regulation (EC) 1829/2003 provides further details on the exact form, location, and content of the label. It requests that:

> (1) For packaged foodstuffs with a list of ingredients, the words 'genetically modified' or 'produced from genetically modified (name of the ingredient)' shall appear in the list of ingredients (these texts may also appear in a footnote to the list of ingredients); (2) for packaged foodstuffs without a list of ingredients, the texts 'genetically modified' or 'produced from genetically modified (name of organism)' shall appear clearly on the labeling; (3) for unpackaged foodstuffs, or "pre-packaged food in small containers of which the largest surface has an area of less than 10 c m^2, the texts must be permanently and visibly displayed either on the food display

[44] Art. 12 of *Regulation 1829/2003/EC*, *supra* note 26.
[45] Art. 47 of *Regulation 1829/2003/EC*, *ibid*.
[46] *Ibid*.
[47] Art. 26 (1) of the *Directive 2001/18/EC*, "The GMOs to be made available for operations referred to under Art. 2(4), second subparagraph, shall be subject to adequate labeling requirements in accordance with the relevant sections of Annex IV in order to provide for clear information, on a label or in an accompanying document, on the presence of GMOs. To that effect the words 'This product contains genetically modified organisms' shall appear either on a label or in an accompanying document." *Directive 2001/18/EC*, *supra* note 22.
[48] *Ibid*.
[49] *Ibid.*

> or immediately next to it, or on the packaging material, in a font sufficiently large for it to be easily identified and read."[50]

In addition to the words, i.e., 'genetically modified' or 'produced from genetically modified (name of the ingredient)', information about characteristics or properties that make a food different from its conventional counterpart or may create ethical or religious concerns must also be displayed on the label. These characteristics or properties relate to: (1) composition; (2) nutritional value or nutritional effects; (3) intended use of the food; and (4) implications for the health of certain sections of the population.[51]

With regard to GM additives or flavourings, the words 'genetically modified' should appear in the list of ingredients immediately after the indication of the additive or flavouring, or in a prominently displayed footnote to the list of ingredients, linked to the additive or the flavouring concerned by an asterisk (*).[52] For specified foodstuffs for which there is no list of ingredients, this wording shall appear clearly on the product's label.[53]

3. Rationales for the labeling requirements

Rationales claimed in support of the EU's mandatory labeling requirements for GMOs, as found in policy documents and the relevant academic literature, can be summarized as follows: (1) promoting the consumer's informed choice for food; (2) protecting human health and environment; and (3) the precautionary principle.

3.1. Protecting the consumer's right to know

[50] Art. 13 of *Regulation 1829/2003/EC*, *supra* note 26.
[51] Preamble (22) of *Regulation 1829/2003/EC*, *ibid*.
[52] Art. 4 (2) of *Regulation No 50/2000/EC*, *supra* note 35.
[53] *Ibid.*

The EU legislation for the labeling of GMOs has consistently emphasized the protection of the consumer's right to know. The EU considers that mandatory labeling is an important tool for protecting consumers' interests. It claims that, by providing consumer information for the food they consume, consumers are given the ability to know exactly what they are buying. The label allows consumers who are sensitive about GMOs to make informed buying decisions and educated decisions.[54] Although the consumer's right to know appears to be an important consideration in EU GMO labeling legislation, it is difficult to find GM products in the EU market, which means that consumers in the EU are not likely to have real choices.[55]

3.2 Protecting human health and environment

Regulation 1830/2003 calls for measures to secure the traceability and labeling of approved GMOs at all stages of their placing in the EU's food market. The EU regulators have considered labeling of GMOs as an effective method of both tracing GMOs' potential effects on the environment, and facilitating the withdrawal of GMO products where their unforeseen adverse effects on human health and environment, including ecosystems, are established.[56] Advocates of mandatory labeling believe that such a labeling regime would enable monitoring and detection of any long-term health risks associated with GMOs.[57] Once a GM product is proven harmful, the arguments goes, the labels would help to both identify individuals who have consumed that product and recall the remaining products on the market.

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[54] Jonathan Benson, *EU Commission Tries to Destroy Zero Tolerance Policy for GMO Food Contamination*, online: Nature News <http://www.naturalnews.com/031224_GMOs_contamination.html#ixzz1nYxVdZbx>.

[55] Annie H. Liu, My Bui & Market Leach, "Considering Technological Impact When Selecting Food Suppliers: Comparing Retailers' Buying Behavior in the United States and Europe" (2013) 20:2 Journal of Business-to-business Marketing 81.

[56] Art. 1 of *Regulation 1830/2003/EC*, *supra* note 26.

[57] Ralf Wiljelm, Lutz Berbner & Joachim Schiemann, *Concept for the Realization of a GMO Monitoring in Germany*, online: <http://www.biosicherheit.de/pdf/dokumente/bba_monitoring.pdf>.

This idea that GMO labels could facilitate health monitoring and traceability of products sold on the market seems logical and reasonable, but there are difficulties in the implementation of and compliance with this regulation. First, this traceability and labeling system would be time-consuming and it would drastically delay the EU approval system. As traceability follows at all stages of GM food production and distribution, all producers in the line, including companies, farmers, purchasers and other stakeholders, have to provide and be given information on the GM nature of the crop and implement a discriminating traceability system. The combination of this long and complex information transmission chain and the process of pre-validating and validating detection methods, along with the development of certified reference material, has made the whole system very costly, inefficient and time-consuming.[58] Another problem is that the generic label language, as I will explore in detail in Chapter Six, such as a label that says: "this product contains genetically modified organisms", does not actually provide traceability to a source. The ability to trace the source of the product depends on accurate information being provided at every link in the information transmission chain. A mere statement of identification of the crop is impossible to satisfy a retrospective safety investigation and precise withdrawal of products.[59] Moreover, in cases of some highly processed products, such as highly refined oil or flour produced from GM maize, the GM ingredient may not be detectable because of the high purity of the product or due to its degradation during processing. For these kind of products, labels are just partial paper trails that cannot provide any information for tracing the origin of the products.[60]

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[58] John Davison, Yves Bertheau, *EU Regulations on the Traceability and Detection of GMOs: Difficulties in Interpretation, Implementation and Compliance*, online: CAB International <http://www.prodinra.inra.fr/prodinra/pinra/data/2008/07/PROD2008c17b92d_20080707114922058.pdf>.

[59] Gary E. Marchant, Guy A. Cardineau, & Thomas P. Redick, *Thwarting Consumer Choice: The Case Agaist mandatory Labeling for Genetically Modified Foods* (Washington. D.C.: The AEI Press, 2010) at 46; See also Christophe Charlier, *Traceability and Labeling of GMOs as A Framework for Risk Management in European Regulation*, online: 2005 Paper prepared for presentation at the 99th seminar of the European Association of Agricultural Economists <http://ageconsearch.umn.edu/bitstream/24700/1/pp05ch01.pdf>.

[60] John Davison, Yves Bertheau, *EU Regulations on the Traceability and Detection of GMOs: Difficulties in Interpretation, Implementation and Compliance*, online: CAB International

Therefore, the EU regulations on the traceability and labeling of GMOs may not function practically in the protection of human health and environment.

3.3 Precautionary Principle

The traceability and labeling of GMOs, as noted, is considered to be a tool for managing risk associated with GM foods and feeds. The underlying theme of this risk management is that where the unforeseen adverse effects on human health and environment are established, the GMO product can be detected and withdrawn from the market. This kind of precautionary notion is in accordance with the precautionary principle[61] that is proclaimed throughout the entire EU GMO legislation.[62] The precautionary principle, which was once applied by the EU only to the environmental area, has been expanded by the EU to apply also to the area of public health.[63] With its application, the EU has taken a relatively proactive role in enacting strict legislation to control the spread of GMOs, dictating that GMOs should not be adopted until they can be proven definitely safe to the environment and human health.

<http://www.prodinra.inra.fr/prodinra/pinra/data/2008/07/PROD2008c17b92d_20080707114922058.pdf>.

[61] Art. 15 of 1992 *Rio Declaration on Environment and Development* [hereinafter 1992 Rio Declaration] defines the precautionary approach as follows: "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." *United Nations Conference on Environment and Development (UNCED), Rio de Janeiro*, 13 June 1992, 31 ILM 847, online: Earth Summit <http://www.un.org/geninfo/bp/enviro.html>; In a Communication from the Commission on the Precautionary Principle /*COM/2000/0001 final*/, "the precautionary principle may be invoked where urgent measures are needed in the face of a possible danger to human, animal or plant health, or to protect the environment where scientific data do not permit a complete evaluation of the risk. It may not be used as a pretext for protectionist measures. This principle is applied mainly where there is a danger to public health. For example, it may be used to stop distribution or order withdrawal from the market of products likely to constitute a health hazard", *Communication from the Commission on the Precautionary Principle, Commission of the European Communities, Brussels, February 2, 2000 COM (2000)1*, online: Europa <http://ec.europa.eu/dgs/health_consumer/library/pub/pub07_en.pdf>.

[62] From *Directive 2001/18/EC* the EU has adopted a legislative framework on the deliberate release of GMOs into the environment and the placing of GMOs on the market in accordance with the precautionary principle. This principle has been continually adopted in the Regulations 1829/2003/EC and 1830/2003/EC. See Deliberate release of GMOs, online: Europa <http://europa.eu/legislation_summaries/agriculture/food/l28130_en.htm>.

[63] The concept of the precautionary principle was first set out in a Commission communication adopted in February 2000 on recourse to the precautionary principle, in which it defined this concept and envisaged how it would be applied. See the Precautionary Principle, online: Europa <http://europa.eu/legislation_summaries/glossary/precautionary_principle_en.htm>.

The precautionary approach or precautionary principle has been inserted in a number of international environmental instruments, such as the CBD framework.[64] At the broadest level of generality, the approach is unobjectionable: it is always better to be safe than sorry.[65] However, when it comes to decision-making faced with scientific uncertainty, the role of the precautionary principle is hotly debated. Its advocates, for example, affirm the principle's guiding role, and request a formal "precautionary" approach when uncertain risk to public health and the environment might occur (e.g., risk associated with GM foods and feeds). In terms of rationales, the use of the precautionary approach results in the better protection of human well-being and the environment.[66] But its opponents strongly oppose its use in the decision making process. They argue that the precautionary principle is not a sound basis for public policy, and that it provides no meaningful guidance to pressing policy questions and forbids all courses of action, including regulation.[67] In the context of GMOs, the precautionary principle is applied as the basis for the EU's GMO safe approval and management system. The adoption of the precautionary principle has made the EU GMO laws the most stringent in the world. Undoubtedly, the complexity concerning the concept of the precautionary approach or principle and its application in risk assessment and management is far beyond what I address here. I will undertake an in-depth examination of its legal status and role in risk assessment and management in Chapter Five.

B. Canada

[64] Convention on Biological Diversity, *Convention on Biological Diversity*, 5 June 1992, 1760 UNTS 79, 31 ILM 818, online: <http://www.cbd.int/>.
[65] Michael L. DeKay, Dalia Patino-Echeverri & Paul S. Fischbeck, *Better Safe Than Sorry: Precautionary Reasoning and Implied Dominance in Risky Decisions*, online: <http://www.cbdr.cmu.edu/papers/pdfs/cdr_060.pdf>.
[66] Jonathan H. Adler, *The Problems with Precaution: A Principle without Principle*, online: The American <http://www.american.com/archive/2011/may/the-problems-with-precaution-a-principle-without-principle>.
[67] Cass R. Sunstein, "Beyond the Precautionary Principle" (2003) 149 John M. Olin Law and Economics Working Paper.

In 2012, Canada ranked as the fourth largest producer of GM crops in the world.[68] A total of 11.8 million hectares of land was devoted to growing four main varieties of GM crops: GM canola, maize, soybean and sugarbeet.[69] The herbicide tolerant canola, which grew by 8.4 million hectares in 2012, has been reported as Canada's largest canola crop (adoption rate is 97.5%).[70] In Canada, foods that have been modified by genetic manipulation are defined as novel foods in the Novel Foods Regulation under the *Food and Drug Act* of 1985.[71] A novel food is allowed to enter the Canadian marketplace only if it is assessed as being as safe and nutritious as foods already in the domestic food marketplace. Under the *Food and Drug Act*, Health Canada is responsible for ensuring all foods, including novel foods, are safe for consumption before they are approved to enter the food market.[72] The pre-market notification system, which requires companies who want to sell GM food to submit a notification to the Health Products and Food Branch, permits Health Canada to conduct a thorough safety assessment of all GM foods.[73] To date, over 81 types of genetically modified foods have been approved for sale in Canada.[74]

1. Regime review

Health Canada and the Canadian Food Inspection Agency (CFIA) are responsible for regulatory issues concerning the labeling of all food, including food containing GMO ingredients.[75] Under the *Food and Drug Act*, Health Canada is "responsible for developing polices and setting

[68] *Top Ten Facts about Biotech / GM Crops in 2012 A New Overview of Biotech Crops in 2012*, *supra* note 11
[69] *Genetically Modified Organisms*, online: Environment Canada <http://www.ec.gc.ca/inre-nwri/default.asp?lang=En&n=E8A9C49D-1>.
[70] *Global Status of Commercialized Biotech / GM Crops: 2012*, *supra* note 11.
[71] *Frequently Asked Question – Biotechnology and Genetically Modified Foods*, online: Health Canada <http://www.hc-sc.gc.ca/fn-an/gmf-agm/fs-if/faq_1-eng.php>. *Food and Drug Act*, R.S.C., 1985, c. F-27, s.5.
[72] Health Canada, *Guidelines for the Safety Assessment of Novel Foods*, online: Health Canada <http://www.hc-sc.gc.ca/fn-an/legislation/guide-ld/nf-an/guidelines-lignesdirectrices-eng.php>.
[73] *Frequently Asked Question – Biotechnology and Genetically Modified Foods*, *supra* note 71.
[74] *Ibid.*
[75] The authority of Health Canada the CFIA to regulate food labeling derives from the Food and Drug Act of 1985, *Genetically Modified Organisms*, online: <http://www.ec.gc.ca/inre-nwri/default.asp?lang=En&n=E8A9C49D-1>.

standards related to the health and safety aspects of labeling,"[76] e.g., allergens. By determining the information required on food labels, it seeks to ensure the food is safe to use.[77] The role of the CFIA is to apply "these labeling policies and enforce the regulations", and to prescribe basic food labeling and advertising requirements, protecting consumers from misrepresentation and fraud regarding food labeling, packaging and advertising.[78] With respect to GM food, Canada has a similar position to the US policy on GMO labeling. Health Canada takes the position that GM foods should be assessed in the same manner as conventional foods.[79] Using this standard, the GMO foods that have been approved by Health Canada have been deemed safe.[80] Food must be labeled only if there are changes in the food (e.g. problematic allergens or a significant nutrient or compositional change), and consumers need to be informed of such changes for health and safety concerns.[81] Based on this premise, Canada has implemented a voluntary labeling regime for GM products. Under this labeling system, any food producers or retailers can label their food products as either GM or non-GM, or they can state nothing at all.[82] The CFIA inspects a food product and calls it "GMO-free" only if it is to be exported to a country that requires such a label.[83] But GM products sold within Canada are not required to be labeled.

1.1 *Food and Drug Act*

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[76] *Frequently Asked Question – Biotechnology and Genetically Modified Foods*, *supra* note 71.
[77] *Ibid.*
[78] *Ibid.*
[79] Health Canada, *Guidelines for the Safety Assessment of Novel Foods*, online: Health Canada <http://www.hc-sc.gc.ca/fn-an/legislation/guide-ld/nf-an/guidelines-lignesdirectrices-eng.php>.
[80] See *Genetically Modified (GM) Foods and Other Novel Food*, online: Health Canada <http://www.hc-sc.gc.ca/fn-an/gmf-agm/index-eng.php>.
[81] For GMO labeling, Health Canada operates on the premise that the process behind the product is irrelevant; so the label need only address product traits. See S. Benda, "It's all about Elmer Gantry ... There is no Frankenstein!!! -- Part II" (2003) 16 I.P.J. 393; also see *supra* note 3; and also see *Labeling of Genetically Engineered Foods in Canada*, online: Canadian Food Inspection Agency <http://www.inspection.gc.ca/english/fssa/labeti/novnou/novnoue.shtml>.
[82] *Voluntary Labeling and Advertising of Foods That Are and Are Not Products of Genetic Engineering National Standard of Canada CAN/CGSB-32.315-2004*, online: <http://www.tpsgc-pwgsc.gc.ca/cgsb/on_the_net/032_0315/standard-e.html>.
[83] See *Labeling of Novel Food Derived Through Genetic Engineering*, online: Health Canada <http://www.hc-sc.gc.ca/fn-an /gmf-agm/index-eng.php>.

The authority of Health Canada and the CFIA to regulate food labeling derives from the *Food and Drug Act* of 1985. According to subsection 5(1) of the Act, a food shall be considered misbranded if it is labeled "in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety."[84] Section 7 of the *Consumer Packaging and Labeling Act* of 1995 also dictates that all labeling and advertising of foods must be accurate and not misleading.[85] Based on this principle of labeling, the CFIA developed several rules to facilitate avoidance of misleading health claims. For example, the claims should provide clear, understandable, truthful, and meaningful information to the consumer[86] and the claims should "be based on science and supported by adequate scientific evidence."[87] Therefore, in Canada, labels may be placed on foods that are or are not products of genetic modification provided that "such claims are truthful, not misleading, not deceptive, and not likely to create an erroneous impression of a food's character, value, composition, merit or safety."[88]

However, a lot of research has suggested that mandatory labeling "[m]ight give consumers the impression that existing measures to ensure food safety are not adequate."[89] This negative attitude towards GM labels was also affirmed by the 2002 report on GM food labeling by the Standing Committee on Agriculture and Agri-Food.[90] This impression, therefore, was considered

[84] *Food and Drug Act*, *supra* note 71.
[85] *Consumer Packaging and Labeling Act*, R.S.C., 1985, c. C-38, s.7.
[86] *General Principles for Health Claims*, online: Canadian Food Inspection Agency <http://www.inspection.gc.ca/english/fssa/labeti/guide/ch8e.shtml>.
[87] *Ibid.*
[88] *Chapter 4.9 Novel Foods Which are Products of Genetic Modification of Guide to Food Labeling and Advertisin*g, online: Canadian Food Inspection Agency <http://www.inspection.gc.ca/english/fssa/labeti/guide/ch4ae.shtml#a4_9>.
[89] Charlene Elliott, "Commentary Unlabeled: Law, Language and Genetically Modified Foods in Canada" (2006) 31:1 Canadian Journal of Communication 247.
[90] The Standing Committee on Agriculture and Agri-Food, *Labelling of Genetically Modified Food and Its Impacts On Farmers* (Government of Canada Publication, 2002).

to be in accordance with the meaning of "misleading" under the *Food and Drug Act*,[91] and was held to be one piece of the supporting evidence for adoption of a "voluntary labeling policy".[92]

1.2 Voluntary labeling of GMOs

As stated above, Canada uses a voluntary labeling system with respect to approved GM products. To promote the application of such voluntary labeling, the Government of Canada adopted the National Standard for Voluntary Labeling and Advertising of Foods That Are and Are Not Products of Genetic Engineering (the Labeling Standard) in 2004.[93] This Standard was supported by the Canadian government and developed by the Canadian General Standards Board (the CGSB). With the establishment of a multi-stakeholder committee – composed of "representatives of food producers, manufacturers, distributors, consumers, general interest, and government groups"[94] – the CGSB aimed to integrate the will of the public into the process of policy making.

In terms of the Standard, food producers and manufacturers are allowed to decide whether to label their GM products. Even when a label is not needed under the *Food and Drug Act*, the label is permitted provided that the voluntary positive or negative labeling (i.e., "does contain" or "does not contain") is not misleading or deceptive and the claim itself is factual.[95] Accordingly, a product can be labeled as "GMO free" where it has "no significant health, safety or compositional change."[96] Moreover, the Labeling Standard also established the threshold for GM

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[91] Elliott, *supra* note 89.
[92] *Ibid.*
[93] *Voluntary Labeling and Adverting of Foods That Are and Are Not Products of Genetic Engineering* (the 2004 Labeling Standard), *supra* note 82.
[94] *Introduction of National Standard for Voluntary Labeling and Adverting of Foods That Are and Are Not Products of Genetic Engineering*, online: Public Works and Government Services Canada <http://www.tpsgc-pwgsc.gc.ca/ongc-cgsb/programme-program/norms-standards/internet/032-0315/index-eng.html>.; Chris MacDonald, Melissa Whellams, "Corporate Decisions about Labeling Genetically Modified Foods" (2007) 75 Journal of Business Ethics 181.
[95] *Labeling of Genetically Engineered Foods in Canada*, *supra* note 81.
[96] *Ibid.*

ingredients. It mandates that a single-ingredient food can claim to be a genetically modified product only when "more than 95 percent of the source of the single ingredient" is a genetically modified product.[97] In addition, when GM-related claims are made, the label must contain a reference to an external, readily accessible source of further information (e.g. a toll-free telephone number or a website) if the process used to engineer the food has not been described on the label.[98] It is believed that the extra information obtainable through websites or toll-free numbers can provide consumers with enough knowledge to make informed purchasing decisions.

2. Rationales for the voluntary label approach

2.1 Promoting the consumer's informed choice

The Canadian GMO regulatory regime was primarily designed to provide a satisfactory protection for consumer health and safety, and the environment.[99] The Labeling Standard was intended to provide consumer choice. The label does not imply that any health or safety concerns exist for the products as these concerns are already addressed by the *Food and Drug Act* and *Regulations*.[100] Only food, including GM food, proved to be safe can be allowed to enter the domestic food marketplace. The function of the current GMO voluntary labeling system was claimed as providing a consistent policy to verify the truthfulness of labels[101] and to promote the consumer's informed choice.

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[97] Art. 5 of *National Standard of Canada CAN/CGSB-32.315-2004*, *supra* note 82.
[98] Art. 4.1.1 of *National Standard of Canada CAN/CGSB-32.315-2004*, *ibid.*
[99] *Frequently Asked Question – Biotechnology and Genetically Modified Foods*, *supra* note 71.
[100] *Ibid.*
[101] *The regulation of genetically modified food*, online: Health Canada <http://www.hc-sc.gc.ca/sr-sr/pubs/biotech/reg_gen_mod-eng.php>.

However, since the adoption of the Standard in April 2004, few labels indicating genetic modification have appeared on food products.[102] This is not surprising. Some scholars have pointed out that, in terms of the Canadian public attitude towards GM food products, it is unlikely that producers and manufacturers will want to risk a voluntary communication of the presence of GMOs in their products.[103] As a result, as surveys indicate, Canadians have been left in the dark about whether the foods they buy are derived from GM plants.[104] Given this reality, it is not surprising that survey research has shown that a significant portion of the Canadian public is not satisfied with this labeling regime. The public believes that they have rights to know what they are eating[105] and they want a clearer labeling of genetically modified ingredients and foods.[106]

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[102] *National Standard of Canada CAN/CGSB-32.315-2004*, *supra* note 82.

[103] Elliott, *supra* note 94; Chris MacDonald, Melissa Whellams, "Corporate Decisions about Labeling Genetically Modified Foods" (2007) 75 Journal of Business Ethics 181.

[104] See Drew Halfnight, *Canadian Consumers in Dark about Genetically Modified Food*, online: July 07, 2011 <http://www.guelphmercury.com/news/local/Art./559315--canadian-consumers-in-dark-about-genetically-modified-food>. Canadian Biotechnology Advisory Committee, *Improving the Regulation of Genetically modified Foods and Other Novel Foods in Canada* (Canada: CBAC Publication 2001) at 38. It is reported that: "the typical Canadian kitchen is likely to contain many ingredients or foods that have been genetically modified. Everything from bread to tomatoes, corn and soya oil has been produced from altered food organisms. Some estimates are that as many as 30,000 different products on grocery store shelves are 'modified.' That is largely because many processed foods contain soy. Half of North America's soy crop is genetically engineered."

[105] "An overwhelming majority of Canadians think that the government has provided insufficient information about genetically modified organisms (GMO) in food and believes that all foods containing GMOs should be labeled as such.", see Oliver Moore, *Poll Shows Huge Support for GMO Labeling) Globe and Mail Website December 3, 2003*, online: <http://www.healthcoalition.ca/archive/cac-dec2003.pdf>; "Consumers clearly believe that the Federal Government has failed in its job in providing Canadians with adequate information about genetically modified foods. The poll indicated that 80% of the surveyed people considered that the Government of Canada has provided inadequate information about genetically modified foods.", see *Consumers Want Mandatory Labeling of Genetically Modified Foods Canada Newswire December 3, 2003*, online: <http://www.healthcoalition.ca/archive/cac-dec2003.pdf >; *Non-GMO Project Promises Clarity for Consumers 29 June 2010*, online: <http://communities.canada.com/vancouversun/blogs/greenman/archive/2010/06/29/non-gmo-project-promises-clarity- for-consumers.aspx >.

[106] A vote, calling for implementation of mandatory labeling of GMO food, was held on May 5, 2008: 83% of people were in favor of mandatory labeling for genetically modified foods, see *Bill on Labeling GMOs in Canada Voted Down*, online: Celsias <http://www.celsias.com/Art. /bill-on-labelling-gmos-in-canada-voted-down/>; A study published in 2007 by Union des consommateurs also indicated that the Canadian consumers thought that the food labels left them confused and ill-informed. See Union des consommateurs, "Les nouvelles tendances de consommation et l'information alimentaire: comment satisfaire le consommateur?" (April 2007); online: < http://www.consommateur.qc.ca/union-des-consommateurs/docu/agro/etiquet_alim.pdf>; "Nearly nine out of 10 Canadians want Ottawa to force companies to disclose whether any food they sell contains genetically modified ingredients, a new poll suggests.", see Steven Chase, *Canadians Want GM Foods Labeled, Poll Finds Globe and Mail December 4, 2003*, online: <http://www.healthcoalition.ca/archive/cac-dec2003.pdf>. According to a 1999 Environics poll, 80 percent of Canadians want GM foods to be labeled. Greenpeace Canada says that number is closer to 95 percent, see *supra* note 3; *GM Food Labeling Initiatives Move Forward at National and State Levels 24 April 2008*, online: <http://newhope360.com/gm-food-labeling-initiatives-move-forward-national-and-state-levels>; *Canada's GMO Free Label Project 06 July 2010*, online: GreenMuze <http://www.greenmuze.com/nurture/gmos/2801-canadas-gmo-free-labeling-project -.html>.

2.2 Substantial equivalence

In Canada, the safety assessment approach of all novel foods is based on the concept of "substantial equivalence". This term appeared in a 1993 Organization for Economic Co-operation and Development (OECD) publication in 1993, and it embodies the idea that existing traditionally produced foods can serve as a reference to assess the safety of GM foods.[107] The concept requires that an assessment of a GM food should indicate that: "the food is as safe as its traditional counterpart."[108] The substantial equivalence concept has also been adopted by the Food and Drug Administration of the US (FDA)[109] and recognized by other international organizations such as the FAO and the WHO.[110]

By comparing the GM food to its traditional counterpart which has a long history of safe use, Health Canada will value nutrition and composition of the GM food.[111] In addition, it will "review existing data to check for the presence of toxicants or anti-nutrients, and for the potential allergenicity of any proteins introduced into the food product."[112] If a GMO is substantially equivalent to a non-GMO food that has a history of safe use, the GMO should not be regulated any more stringently than the non-GM food simply because it is a product of biotechnology. Thus, when a GM food product has been estimated equivalent to its traditional counterpart based on the

[107] Harry A. Kuiper, et al., "Substantial Equivalence – An Appropriate Paradigm for the Safety Assessment of Genetically Modified Foods?" (2002) 181-182 Toxicology 427.
[108] *Definition of Substantial equivalence*, online: OECD <http://stats.oecd.org/glossary/detail.asp?ID=2604>.
[109] The US FDA held that "since no material difference in nutrition, composition, or safety exists between the modified commodities and their traditional counterparts…Moreover, by virtue of the technology employed, genetically modified plants are safer than their traditional counterparts in light of the precision and specificity that can be accomplished with current genetic technology. There is no reason to label the commodities in any way that would distinguish them from their traditional counterparts." See Frederick H. Degnan, "The Food Label and the Right-To-Know" (1997) 52 Food & Drug LJ 49.
[110] Harry A. Kuiper, *et al*, "Substantial Equivalence – An Appropriate Paradigm for the Safety Assessment of Genetically Modified Foods?" (2002) 181-182 Toxicology 427.
[111] Health Canada, The Regulation of Genetically Modified Food, online: Health Canada <http://www.hc-sc.gc.ca/sr-sr/pubs/biotech/reg_gen_mod-eng.php>.
[112] Frédéric Forge, *Genetically Modified Foods*, online: <http://publications.gc.ca/Collection-R/LoPBdP/BP/prb9912-e.htm>.

substantial equivalence concept, Health Canada is ready to accept that it poses no different risks, including the risk of long-term adverse effects.[113]

The EU used to implement the substantial equivalence norm as a "simplified procedure"[114] for approving novel food products, including GM foods. But since the late 1990s, substantial equivalence was subjected to widespread criticism.[115] "It was highly controversial, primarily because it sidestepped the need for a scientific risk assessment."[116] Regulation (EC) 1829/2003 did not continue to use this concept, and the "simplified procedure" was abandoned in respect of GM food, on the basis that "the substantial equivalence principle is not a safety assessment in itself, but it is a pragmatic tool used as a guide in the safety assessment of novel foods.[117] The substantial equivalence approach remains available as a risk assessment tool in Regulation (EC) 1829/2003, but it cannot be used as a shortcut for the GM food approval. As a result, the test methods for GM food have become subject to more stringent demands and argumentation in the current EU regulatory procedure.[118]

C. China

As a developing country, China was one of the first countries in the world to introduce GM crops commercially. It has been ranked as the sixth largest producer of biotech crops based on total

[113] *Ibid.*
[114] The "simplified procedure" means a national authority need not carry out a risk assessment for a GM food which had "substantial equivalence" with a non-GM counterpart regarded as safe. See Les Levidow & Susan Carr, *GM Food on Trail Testing European Democracy* (UK: Taylor & Francis 2010) at 144.
[115] *Ibid*.
[116] Maria Lee, *EU Regulation of GMOs* (UK: Edward Elgar Publishing Limited 2008) at 73. Critics pointed out that food regulators should not rely on the doctrine of substantial equivalence and bypass the need for extensive testing. See Frederick H. Degnan, "The Food Label and the Right-To-Know" (1997) 52 Food & Drug LJ 49.
[117] Maria Lee, *ibid*.
[118] See Levidow & Carr, *supra* note 114 at 144.

acreage (4.0 million hectares) in 2012 according to ISAAA,[119] and is currently the largest producer of GM cotton (Bt-cotton) in the world according to Reuters.[120] Facing an already huge and growing population, limited arable land and water supply, and environmental challenges, Chinese scientists have been motivated to develop new technologies, such as GM biotechnology, to help secure the national food supply and improve the quality of life for people in China.[121] With the help of the National High-tech R&D Program (commonly known as National 863 Program), National Basic Research Program of China (973 Program)[122] and special programs for transgenic technology research, Chinese scientists have made significant progress on GM technology since 1996.[123] By developing GMOs with independent intellectual property rights, China has been striving to break Western seed monopolies.[124] To date, according to newspaper reports, China has made great progress with some GMOs, e.g., GM cotton and rice.[125]

In terms of different levels of authority, concepts concerning laws in China can be summarized as follows (authority from high to low): (1) Laws: promulgated by the National People's Congress or its Standing Committee; (2) Regulations: issued by the State Council; (3) (Administrative)

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[119] *Global Status of Commercialized Biotech / GM Crops: 2012*, *supra* note 11.

[120] *China Mulls GMO Food Law, Grain Law Ready in 2011*, online: Reuters <http://www.reuters.com/Art. /2010/12/27/us-china-food-gmo-idUSTRE6BQ0VV20101227>.

[121] It is estimated that China will lose its position of self-sufficiency in wheat, rice and corn by around 2010, unless it increases productivity drastically. See Michael Howlett & David Laycock ed, *Regulating Next Generation Agri-Food Biotechnologies Lessons from European, North American, and Asian Experiences* (Oxon: Routledge 2012) at 120; "China will accelerate development of its own genetically modified (GMO) crops, seeking to secure food security and international competitiveness", see Chris Buckley and Niu Shuping, *China Says Has not Allowed Imported GMO Grain Seeds in for Planting*, online: Reuters <http://www.reuters.com/Art. /idUSTOE62109P20100303>.

[122] The National High-tech R&D Program (863 Program) and National Basic Research Program of China (973 Program) are two national S&T program held by the Ministry of Science and Technology of the Peoples Republic of China. online: Ministry of Science and Technology of the People's Republic of China <http://www.most.gov.cn/eng/programmes1/200610/t20061009_36225.htm>.

[123] *How do Chinese develop the first GM Bt Cotton and What's the Application Status of Bt Cotton in China?*, online: Ministry of Agriculture <http://www.moa.gov.cn/ztzl/zjyqwgz/zswd/201007/t20100717_1601251.htm>. Also see Jianke JIANG, "'Yi jian duo diao' Bt Cotton", 2002 8 13 People's Daily.

[124] Jianke JIANG, "The Overall Chinese Agricultural Biotechnology Has Leaped to the World Leading Level" 2007 January 9 People's Daily.

[125] *Ibid.*

rules: published by Ministries; (4) Local regulations: promulgated by local people's congresses; and (5) Local rules: issued by local governments.[126] The Ministry of Agriculture of The People's Republic of China (Ministry of Agriculture) is responsible for the management of agricultural GMOs. It has established and implemented a biosafety system that covers agricultural GMO laboratory and greenhouse experimentation, field evaluation, and commercialization since 1996.[127] With regard to food safety concerns, the Ministry of Health of The People's Republic of China (Ministry of Health) regulates GMO foods.[128]

To date, China has issued seven GM plant bio-safety certifications (i.e., GM cotton, tomatoes, sweet peppers, petunias, papayas, rice, and corn) and China has also approved four biotech products for import as processing materials (i.e., soybeans, corn, canola and cotton).[129] However, obtaining a bio-safety certification does not mean the approved GM crops can be commercially grown in China. In fact, so far, the Chinese government has not approved any GM staple food crops for commercialization even though it has made a significant investment in research and development of agricultural biotechnology in this area (e.g., Huahui No.1, Bt Shanyou 63).[130] Yet, the safety approval for two kinds of GM strains of rice and one type of corn, given by the Bio-safety Committee of the Ministry of Agriculture in November 2009,[131] has led to a great debate

[126] See *A Brief Introduction of the Legal System of China*, online: <http://faculty.cua.edu/fischer/ComparativeLaw2002/bauer/China-main.htm>.
[127] Jia Shirong & Peng Yufa, "GMO Biosafety Research in China" (2002) 1 Environ. Biosafety Res. 5.
[128] Yang Wanghua, "Regulation of Genetically Modified Organisms in China" (2003) 12:1 RECIEL 99.
[129] Ministry of Agriculture GMO 30 Years Practice. at36.
[130] "Huagyu No.1" and "Bt Shanyou 63" are two anti-insect GM rice varieties developed by Huazhong Agricultural University. They are the first two types of GM rice that obtained bio-safety certifications from the Ministry of Agriculture. Security Certification for Two Anti-insect GM Rice Varieties Obtained, online: Huazhong Agricultural University News <http://news.hzau.edu.cn/showArt.php?aid=27617>.
[131] *Breaking Chinese-style Fallacies and Rumors about GMOs*, online: Ministry of Agriculture <http://www.moa.gov.cn/ztzl/zjyqwgz/zjyxwbd/201108/t20110801_2074206.htm>.

in the country about whether genetically modified rice, the staple food for the majority of Chinese, is safe for consumption.[132]

The Chinese government has been attempting to promote development of GM technology and also establish a sound regulatory framework for GMOs. The State Council promulgated the Regulation on Safety Administration of Agricultural GMOs on May 23, 2001 (the 2001 Agricultural GMOs Safety Regulation), and later on January 5, 2002, the Ministry of Agriculture issued three supporting regulations to facilitate bio-safety regulation of GMOs.[133] In 2004, the State Administration of Quality Supervision, Inspection and Quarantine issued Administrative Measures for Entry/Exit Inspection and Quarantine of GM Products (the 2004 Measures).[134] In addition, China has established a bio-safety management system for agricultural GMOs. This system is created by the Ministry of Agriculture and is composed of the Inter-ministerial Joint Conference System for Bio-safety Management (seven concerned national ministries) and the National Agricultural GMO Bio-safety Committee.[135] Within this framework, the Chinese government has placed great importance on the bio-safety management of agricultural GMOs.

1. Regime review

[132] *China Shuts Down GE Rice?*, online: The Diplomat <http://the-diplomat.com/china-power/2012/02/29/china-shuts-down-ge-rice/>.

[133] Administrative Measures for Safety Assessment of Agricultural GMOs, Administrative Measures for Safety of Imported Agricultural GMOs, and Administrative Measures for Labeling Agricultural GMOs. Hua FENG, "The Key of Safety Management for GMOs is Safety Evaluation" 2005 6 28, People's Daily.

[134] The State Administration of Quality Supervision, Inspection and Quarantine issued Administrative Measures for Entry/Exit Inspection and Quarantine of GM Products 2004, online: The Central People's Government of the People's Republic of China <http://www.gov.cn/gongbao/content/2005/content_63203.htm>.

[135] See *Second National Agricultural GMOs Biosafety Committee Was Established*, online: The Central People's Government of the People's Republic of China < http://www.gov.cn/gzdt/2005-06/22/content_8611.htm>.

The newly adopted *Food Safety Law of the People's Republic of China* 2009 (the Food Safety Law)[136] sets out general principles and provisions on food safety, packaging and labeling of food products. It was promulgated by the National People's Congress and has the highest level of authority. The *Food Safety Law* recognizes the important role that a label, labeling, or/and instruction of a food product can play in information disclosure and communication between consumers and producers. It requires that labels and instructions on food products should be clear and understandable. They should be not written in a manner that is false, misleading or deceptive or is likely to create an impression regarding their healing powers.[137] The *Food Safety Law* does not have any detailed and specific provisions on GMO labeling, but it authorizes other laws, where applicable, that can be applied to GMOs, including the labeling of GMOs.[138] These laws include: the *Administrative Measures for New Resources Food* issued by the Ministry of Health in 2007;[139] the *Administrative Measures for Food Labeling* (amended in 2009) issued by the State Administration of Quality Supervision, Inspection and Quarantine (QSIQ) originally in 2007;[140] and the *Administrative Measures for Labeling Agricultural GMOs* (amended in 2004) issued by the Ministry of Agriculture in 2002.[141]

1.1 Partial mandatory labeling for agricultural GMOs

Under the current Chinese labeling system, the labeling of agricultural GMOs is supervised by the Ministry of Agriculture while the labeling of GM food is managed by the QSIQ. The 2004

[136] *The Food Safety Law of the People's Republic of China*, 28 February 2009 (2009).
[137] *Ibid*, Art. 48.
[138] *Ibid*, Art. 101.
[139] *The Administrative Measures for New Resources Food* was issued by Ministry of Health in July 2nd, 2007 and came into effect on December 1st, 2007. online: The Central People's Government of the People's Republic of China <http://www.gov.cn/ziliao/flfg/2007-07/18/content_688929.htm>.
[140] *The Administrative Measures for Food Labeling*, online: The Central People's Government of the People's Republic of China <http://www.gov.cn/gongbao/content/2008/content_970333.htm>.
[141] *The Administrative Measures for Labeling Agricultural GMOs* (has been amended in 2004) was issued by Ministry of Agriculture originally in 2002 and came into effect on March 20th, 2002. Online: Ministry of The People's Republic of China <http://www.moa.gov.cn/ztzl/zjyqwgz/zcfg/201007/t20100717_1601302.htm>.

Administrative Measures for Labeling Agricultural GMOs has listed the types of agricultural GMOs that should be labeled.[142] They include seventeen kinds of five major categories of GMOs: (1) GM soybean seed, soybean, soybean meal, soybean oil, and soybean meal; (2) GM corn seed, corn, corn oil, and corn flour (including corn flour with tax No. 11022000, 11031300, and 11042300) (3) GM rape seed, canola, rapeseed oil, and oil rapeseed meal; (4) GM cotton seed; and (5) GM tomato seeds, fresh tomatoes, and tomato sauce.[143] According to the Ministry of Agriculture, except for the GM cotton (labels on GM cotton can help to ensure the authenticity of GM cotton seed sold on the market), requiring labels for the other four categories of GMOs was implemented to provide consumers with information and enable them to make informed choices.[144] The 2009 *Administrative Measures for Food Labeling* and the 2007 *Administrative Measures for New Resources Food* do not directly deal with the issue of GM food labeling. They do not form a list indicating which types of GM food must have mandatory labels, nor set out provisions applying specially to GMOs. Only Article 16(3) of the 2009 *Administrative Measures for Food Labeling* provides that the food has to be labeled if it is a GM food or contains GM ingredients.[145] Based on Article 11(3), it may be concluded that highly processed food whose GM ingredients cannot be detected need not be labeled, and that GM flavorings and additives, and food produced with GMOs, such as milk, do not need to be labeled.

In terms of the labeling requirement, agricultural GMOs must be labeled as "Genetically modified XX", "Genetically modified XX processed", or "Processed material has been

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[142] *The Administrative Measures for Labeling Agricultural GMOs* (has been amended in 2004), *ibid*.
[143] Affix of he *Administrative Measures for Labeling Agricultural GMOs*, Catalog: The First Batch of the Agricultural GMOs need to be labeled. *The Administrative Measures for Labeling Agricultural GMOs* (has been amended in 2004), Online: Ministry of The People's Republic of China <http://www.moa.gov.cn/ztzl/zjyqwgz/zcfg/201007/t20100717_1601302.htm>.
[144] *Ministry of Agriculture GMO 30 Years Practice*, *supra* note 129 at 36.
[145] *The Administrative Measures for Food Labeling*, online: The Central People's Government of the People's Republic of China <http://www.gov.cn/gongbao/content/2008/content_970333.htm>.

genetically modified", "This product is produced from GMOs but it contains no GM ingredient", or "The processed material of this product has been genetically modified, but it has no GM ingredient".[146] However, the labeling of GM foods are only required to be written in Chinese. There are no specific rules for the labeling format, which means the producers can decide which methods to use to label the GM foods as long as they are in accordance with the requirements of the 2009 *Administrative Measures for Food Labeling* and the 2007 *Administrative Measures for New Resources Food*.

1.2 No provisions on threshold of GM content and allergenic labeling

Current Chinese laws do not have provisions on the threshold of GM content and on the requirement of allergenic warning. The labeling requirement is based on the final product. Namely, if GMOs can be detected in the final product it must be labeled accordingly. But there is no traceability requirement throughout the entire food chain and no requirement for segregated operations during the cultivation, production, transportation, and sales process of GM food and feed. Without a specific regulation on the threshold of GM content, it is impossible for non-GM food to be safely labeled as "non-GMO" or "not GM". Another flaw in the current GMO labeling regime is that it does not have any provision on allergenic labeling. The allergenic notice used to be required under the Hygiene Administrative Measures for Genetically Modified Foods issued by the Ministry of Health in 2002, but the later adoption of the 2007 Administrative Measures for New Resources Food covered the former Measures and it did not contain provisions on allergenic labeling. Without a mandatory labeling requirement, consumers may not be informed when an allergic material is present in a GM food.

[146] Art. 6 of 2004 *Administrative Measures for Labeling Agricultural GMOs*, *The Administrative Measures for Labeling Agricultural GMOs* (has been amended in 2004), *supra* note 141.

2. Rationales for the labeling requirements

2.1 Protecting the consumer's right to know

In China, the consumer's right to know is protected under the 1993 *Consumer Protection Law of the People's Republic of China* (1993 Consumer Protection Law).[147] According to Article 8, consumers have the right to obtain accurate information on the products they purchase.[148] This "accurate information" on a product includes its "prices, origin, manufacturers, usage, functions, standards, grades, [and] main ingredients…"[149] The 2004 Administrative Measures for Labeling Agricultural GMOs insists on this principle, stating that protecting the consumer's right to know is one of reasons why the Measures were developed and established.[150] The Ministry of Agriculture has considered the labeling of GMOs as a means of risk communication, holding that by information disclosure, consumers have chances to know about agri-biotech which would facilitate their acceptance of the risk rationally.[151]

2.2 Precautionary notion

Though the precautionary principle is not explicitly expressed in any of China's laws on GMO safety management, it is embodied in a number of GMO laws. Article 3 of the 2001 *Agricultural GMOs Safety Regulation* explains that ensuring the safety of agricultural GMOs is done to prevent danger or the potential risk of agricultural genetically modified organisms from the human, animal and plant, microorganism and ecological environment.[152] It is based on this objective that relevant GMO safety management systems have been developed and established,

[147] *The People's Republic of China Consumer Protection Law*, 31 October 1993 (1993).
[148] *Ibid*, Art. 8
[149] *Ibid.*
[150] Art. 1 of 2004 *Administrative Measures for Labeling Agricultural GMOs*, *The Administrative Measures for Labeling Agricultural GMOs* (has been amended in 2004), *supra* note 141.
[151] *Ministry of Agriculture GMO 30 Years Practice*, *supra* note 129 at 38.
[152] Art. 3 of the 2001 *Agricultural GMOs Safety Regulation*, *Regulation on Administration of Agricultural Genetically Modified Organisms Safety*, 23 May 2001 (2001).

such as the GMO licensing system, safety evaluation management mechanism, and labeling system.[153]

The Chinese Ministry of Agriculture has defined the precautionary principle as one of the principles for risk assessment. It held that the precautionary principle could be adopted when scientific uncertainties were discovered during the process of risk assessment.[154] Perhaps the Ministry had a different understanding of the precautionary principle. However, classifying the precautionary principle as one of the guiding principles in risk assessment is not in accordance with some scholars' opinions. For instance, Bernard D. Goldstein[155] defined risk assessment as "[a]ctivities [that] involve the use of all available scientific information, interpreted with the best currently available scientific judgment, to both identify and characterize the potential hazard that a substance may pose, and to quantify the probability of some harm to an individual or a population as a result of exposure to that substance."[156] Yann Devos[157] et al. also held that risk assessment was only based on scientific evidence.[158] The precautionary principle, on the other hand, has been widely accepted as a method of risk management.[159] The precautionary principle decisions are not only based on scientific information but also on other factors such as political,

[153] These systems are regulated by the *Administrative Measures for Safety Assessment of Agricultural GMOs*, *Administrative Measures for Safety of Imported Agricultural GMOs*, and *Administrative Measures for Labeling Agricultural GMOs*.
[154] *Ministry of Agriculture GMO 30 Years Practice*, *supra* note 129 at 20.
[155] Bernard D. Goldstein was assistant administrator for research and development U.S. Environmental Protection Agency Washington, DC. *Faculty Bio*, online: <http://www.eoh.pitt.edu/directory/bios/goldstein.asp>.
[156] Bernard D. Goldstein, "Risk Assessment and Risk Management" (2009) 4:1 Environmental Toxicology and Chemistry 1.
[157] Dr. Yann Devos services at the GMO Unit, European Food (2012.3). online: Center for Critical Philosophy <http://www.criticalphilosophy.ugent.be/index.php?id=36&type=content>.
[158] Yann Devos, Karine Lheureux & Joachim Schiemann, "Regulation Oversight and Safety Assessment of Plants", *Biotechnology in Agriculture and Forestry 64 Genetic Modification of Plants*, (London: Springer, 2010) at 557-567.
[159] According to Bernard, a risk management decision include evaluation of the results of the risk assessment, as well as considerations of technological alternatives, other approaches to resolution permitted under a given statute, and the various social, economic and political factors relevant to the situation. Goldstein, *supra* note 155.

social, cultural and economic considerations. That is the reason why some scholars consider the precautionary principle to be a political rather than a scientific decision-making tool.[160]

D. Comparison between EU, Canadian, and Chinese GMO labeling regimes

1. Similarities between three GMO labeling regimes

Each of the three labeling regimes is developed to protect consumer health. Under the EU labeling regime, all foods and feeds that are, consist of, contain or are made from GMOs are subject to compulsory labeling.[161] In Canada, GM food does not need to be labeled if it is substantially equivalent to its traditional counterparts, but if changes concerning health and safety in the food are established, such as problematic allergens or a significant nutrient or compositional change, the food must be labeled to indicate the difference. The Chinese labeling laws require that parts of agricultural GMOs for consumers' food consumption must be labeled. The current Chinese labeling laws unintentionally missed a requirement for allergenic labeling. But, based on the underlying value of the entire food safety legal framework, it is reasonable to believe that the current Chinese labeling regime has taken consumer health seriously.

All of the three labeling regimes set protection of the consumer's right to know as one of its objectives, claiming their systems enable consumers to make an informed choice. However, none of them in fact accomplishes this goal. In Europe, the mandatory labeling regime guarantees consumers with information but they have no choice, since only non-GM products can be found on the shelf. In Canada, where a voluntary labeling system is used, consumers have a potential choice between GMO and non-GMO food. But this choice is limited because consumers get

[160] Paul Pechan et al, *Safe or Not Safe Deciding What Risks to Accept in Our Environment and Food*, (London Springer, 2011) at 111.

[161] Europa, *Traceability and Labeling of GMOs*, Online: Europa <http://europa.eu/legislation_summaries/environment/nature_and_biodiversity/l21170_en.htm>.

informed about food GM information only if producers or distributers choose to label and only to the degree the label is accurate. In China, under the partial mandatory labeling mechanism, GM soybean oil is almost the only GM food product that is labeled and provided by Chinese supermarkets, so consumers actually do not have too many choices between GMO and non-GMO foods.

2. Differences between three GMO labeling regimes

The three labeling regimes are different in many ways. The EU and a number of its member states have enacted stricter labeling requirements, while Canada's labeling requirements are more modest, only requiring the labeling of products when they are different from their non-GM counterparts or where other health and safety concerns are established, such as allergenic ingredients. In China, on the other hand, using a partial mandatory labeling mechanism, the special labeling requirements only cover 17 kinds of five major categories of agricultural GMOs.

Some features, however, are unique to the EU GMO labeling regime. It has the widest scope of application of labeling requirements. Food or feed which is a GMO, containing, and produced from or containing ingredients produced from GMOs must be labeled.[162] It also establishes a considerably low labeling threshold for GM ingredients. Only if authorized GMOs do not exceed a 0.9 percent threshold and their presence is adventitious and technically unavoidable, are the foods exempt from the labeling obligation.[163] In addition, the EU carries out "measures for the inspection and monitoring of products, including sampling and quantitative and qualitative

[162] Art. 4 of *Regulation 1829/2003/EC*, *supra* note 26.
[163] Art. 12(2) of *Regulation 1829/2003/EC*, *ibid.*

analyses of food and feed. These measures entail the Member States being able to withdraw from the market a product that does not meet the conditions laid down in regulations."[164]

The precautionary principle applies broadly in the EU, and it is an important principle of the EU regulation of GMOs.[165] The traceability and labeling requirements for GM food and feed were developed to facilitate the implementation of risk management measures in accordance with the precautionary principle.[166] Canada does not use the precautionary principle in the GMO food approval and marketing process. It stresses the importance of scientific evidence-based regulation and objects to the application of precautionary measures to the bio-safety management of GMOs.[167] In terms of Chinese practice, although the precautionary principle is not explicitly stated in any of China's GMO laws, the precautionary principle is indeed embodied, in spirit, in a series of GMO laws. Based on this precautionary notion, the GMO licensing system, safety evaluation management mechanism and labeling system has been developed and established. It is worth noting that both China and the EU adopt the precautionary principle but they use it in different ways. The EU has applied the precautionary principle as a legal basis for justifying its stringent GMO approval procedures and the rigorous requirement for the marketing of GMO food, such as mandatory labeling. In contrast, the Chinese government takes the position that GM technology should be developed and that GM crops will be beneficial to the country if they are developed under a sound regulatory framework.[168]

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[164] Europa, *Traceability and Labeling of GMOs*, Online: Europa <http://europa.eu/legislation_summaries/environment/nature_and_biodiversity/l21170_en.htm>.
[165] Lee, *supra* note 116 at 43.
[166] Preamble (3) of *Regulation 1830/2003/EC*, *supra* note 26.
[167] *Frequently Asked Question – Biotechnology and Genetically Modified Foods*, *supra* note 71.
[168] See Jianke Jiang, Jie Ding, "GM Technology It Is Relating to Food Security" 2008 November 27 People's Daily; Yi Zhang, "Promoting Scientific Research and Application of GM Technology by Law" 2010 March 3 People's Daily; Qifeng Hu, "No Evidence To Date can Prove the Approved GM Food Is Harmful to Human and Animals" 2010 June 11 Guamgming Daily. Also see Zhouzi Fang, "Re-discuss the Safety of GM Corps" 2010 April 5 Guangming Daily.

Consequently, the different labeling regulations result in conflicts in trade over GMOs/GMO products between countries as we have explored in Chapter Three, and, further, it will have a significant impact on the international production choices. The voluntary labeling regime, used by Canada, is a market driven system that allows farmers and producers to independently decide whether or not to use GM crops. The EU mandatory labeling regulation, however, mandates that every exporter of food products located in countries inside and outside the EU must abide by the stringent labeling requirements, which subsequently affects decisions of farmers and producers in countries exporting to the EU on the cultivation of GM crops. In terms of both developing and developed countries, a decision to introduce GM crops into their food production may trigger a ban by the EU on imports from these countries. This is extremely difficult for developing countries in particular, since the GM techniques can help improve crop yields and provide environmental benefits which eventually assists them in solving food security problems. However, at the same time the use of GM crops may also block their food exports to the EU market. A simple field trial of a GM crop in a developing country, according to Guillaume P. Gruere's study, may result in the EU's suspensions of that crop variety, as they do not believe the developing country can strictly follow the segregation and identity preservation requirements, which will lead to the mingling of GM and non-GM crops in cargos of products imported into the EU.[169] Hence, the EU's mandatory labeling regime will influence choices whether or not to adopt GM techniques on an international scale.

3. Explaining differences

[169] Guillaume P. Gruere, "A Preliminary Comparison of the Retail Level Effects of Genetically Modified Food Labeling Policies in Canada and France" (2006) 31:2 Food Policy 148.

Different countries have different experiences regarding food consumption and food safety. Such differences have a direct influence on the domestic regulatory frameworks for the labeling of GMOs, making them markedly different. I will explore three sets of explanations here: the first one focuses on different policy-making models for the different labeling regimes, the second is based on producer interests, and the third addresses the distrust of government. I will examine other contributing factors in Chapter Five.

3.1 Different policy-making models

As we have seen, the current Canadian GMO labeling regime relies heavily on scientific rationality while the EU GMO legislation concentrates on social protection rationality. The Canadian model, namely the scientific evidence-based policy-making, has been challenged for its limitation of public participation. Gutteling et al., have argued that regimes that focus on scientific evidence commonly use state-centered methods to control the public input in a policy-making process while ones that are based on social considerations are more open to and accepting of public consultations.[170] However, lots of anti-science decisions regarding GMOs made by EU countries indicate that the social-rationality-oriented model may be more susceptible to political factors.[171]

The anti-science political policy-making surrounding GMOs can be witnessed in the Monsanto MON810 corn case. The MON810 is a variety of GM maize, which consists of a Bt-derived gene that can produce Cry1Ab toxin targeting some of lepidopteran pest insects, including the

[170] J. Gutteling, et al., "Trust in Governance and the Acceptance of Genetically Modified Food in the Netherlands" (2006) 15 Public Understanding of Science 103.

[171] Political factors mainly refer to the pressures from the consumer and environmental groups activism. It is argued that the consumer and environmental groups have played an important role in shaping the EU public opinion about GM technique and GM crops and have greatly influenced GMO policies of the EU and member states. See Jonathan P. Doh & Terrence R. Guay, "Corporate Social Responsibility, Public Policy, and NGO Activism in Europe and the United States: An Institutional-Stakeholder Perspective" (2006) 43:1 Journal of Management Studies 47.

European Corn Borer.[172] In 2012, the European Food Safety Authority (EFSA) Panel on GMOs, the EU agency composed of scientific exports for the safety inspection of GMOs, published a scientific opinion on the safety assessment of MON 810 maize varieties. The opinion concluded that: "the MON810 corn the genetic modification in maize MON 810 does not constitute an additional health risk if maize MON 810 pollen were to replace maize pollen from non-GM maize in or as food."[173] However, the opinion of the EFSA has been ignored arbitrarily by many EU member states, which results in an outcome that MON810 has been banned, without reference to good supporting scientific data, for cultivation by governments of six EU countries (France, Austria, Greece, Hungary, Germany and Italy).[174] Scholars argue that political rather than scientific factors have played determinative roles in the final decision for disapproval.[175] For example, in France, MON810, which had been grown for several years, was suspended for contiguous cultivation by the French government in 2009.[176] Two pre-existing science-based GMO committees (*Commission de Génie Génétique*, *Commission du Génie Biomoléculaire*) were replaced by the French government, and the new temporary committee (*Comité de préfiguration de la Haute Autorité sur les biotechnologies*) issued a report in which, according to the Chairman of the Committee, Senator Legrand, the "committee had serious doubts about the safety of MON810."[177] Twelve scientists and two economists on the Committee rejected Senator Legrand's statement, arguing that he had misinterpreted the report and abused it for political reasons.[178] Similarly, in Germany, the cultivation and marketing of MON810 was halted in 2009

[172] Agnès Ricroch, Jean Baptiste Bergé & Marcel Kuntz, "Is the German Suspension of MON810 Maize Cultivation Scientifically Justified?" (2010) 19:1 Transgenic Res 1.
[173] Marcel Kuntz, John Davison & Agnès E Ricroch, "What the French Ban of Bt MON810 Maize Means for Science-based Risk Assessment" (2013) 31 Nature Biotechnology 498.
[174] John Davison, "GM Plants: Science, Politics and EC Regulation" (2010) 178(2) Plant Science 94.
[175] See Germma Masip, et al, "Paradoxical EU Agricultural Policies on Genetically Engineered Crops" (2013) 18:6 Trends in Plant Science 312; Kuntz, Davison & Ricroch, *supra* note 173; Ricroch, Bergé & Kuntz, *supra* note 172.
[176] *Ibid.*
[177] *Ibid.*
[178] *Ibid.*

by Federal Minister Aigner.[179] The German Central Commission for Biological Safety challenged the moratorium as being non-scientifically grounded.[180] Agnès Ricroch et al., based on an extensive survey of the scientific literature regarding possible effects of MON810 under natural field conditions on non-target animals, argued that the existing well-established risk assessment methods on Bt maize "[were] ignored by the German government who instead used selected individual studies which fit what seems to be a political decision."[181] As a result, GMOs are not cultivated in significant quantities in the EU, and hence the stringent labeling requirements are actually applied to imported food and feed from the GMO producing countries, such as Canada and the US.

3.2 Interests of manufacturers

The interests of manufacturers could be one major factor that secures a more permissive regulatory system or, vice versa, a prohibitive framework.[182] The agricultural biotech industry in North America is the leader in the world's GM seeds production. The data indicate that, from 1982-2002, North American inventors received 3,035 patents for "ag-biotech and crop genetics" while European inventors were granted 774 patents.[183] Another study reveals that the US alone accounted for 48 percent of the new patents in 2001-2009, while China made up 12.5 percent.[184] The US companies Monsanto and DuPont together shared thirty-eight percent of the global proprietary seed market in 2009.[185] Because Canada is geographically in close proximity to the

[179] *Ibid.*
[180] *Ibid.*
[181] Ricroch, Bergé & Kuntz, "Is the German Suspension of MON810 Maize Cultivation Scientifically Justified?" (2010) 19(1) Transgenic Res 1.
[182] Pablo A. Pellegrini, "What Risks and fro Whom? Argentina's Regulatory Policies and Global Commercial Interests in GMOs" (2013) 35:2 Technology in Society 129.
[183] Pollack & Shaffer, *supra* note 20 at70.
[184] Tao Tan, et al., "The Impact of GMO Safety Regulations on Chinese Soybean Exports" (2013) 3:3 J Basic Appl Sci Res 164.
[185] *The World's Top 10 Seed Companies*, online: <http://www.gmwatch.org/gm-firms/10558-the-worlds-top-ten-seed-companies-who-owns-nature>.

US and both are parties to the North American Free Trade Agreement (NAFTA)[186] that allows products to flow relatively freely from the US to Canada and vice versa, it not surprising that Canada has a similar food culture and approximately the same standards as the US regarding GMO regulation. Compared with the North American development, European biotechnology in agriculture is lagging behind. On the other hand, however, European biotech firms are among the world's leaders in GM enzyme manufacture. Enzymes are widely used in the EU in the producing process for bread, cheese, beer, and fruit juices,[187] while GM enzymes are regarded as "processing aids" which are exempted from the EU's GMO approval and labeling requirements.[188] Similarly, imported GM soy and corn are commonly used in animal feeds in the EU, but the resulting meat is not covered by labeling requirements under current EU GMO legislation. Accordingly, it can be argued that such labeling exceptions under the current EU labeling regime are, to some extent, aimed at benefiting the EU's local biotech corporations while prejudicing the North American's GM foods and seeds companies.

Farmer interests also play an important role in forming domestic and regional GMO legislation. Since the introduction of GMO crops in 1996, GM seeds have been commercially grown in the US and Canada, and spread around world quickly in the past decades.[189] Once GM varieties were in the ground in large quantities, farmer interests in turn became a significant source of support for GM crops and foods.[190] However, in Europe, local biotech companies failed to convince

[186] In 1994, the *North American Free Trade Agreement* (*NAFTA*) came into effect, creating one of the world's largest free trade zones and laying the foundations for strong economic growth and rising prosperity for Canada, the United States, and Mexico. *North American Free Trade Agreement*, 17 December 1992, 32 ILM 289, Online: <http://www.naftanow.org/>.
[187] *Enzymes: the Hidden Extras*, Online: Foods Master <http://www.foodsmatter.com/allergy_intolerance/miscellaneous/Art.s/enzymes.html>.
[188] Jaime Aguilera, Ana R. Gomes & Irina Olaru, "Principle for the Risk Assessment of Genetically Modified Microorganisms and Their Food products in the European Union" (2012) 167:1 International Journal of Food Microbiology 2.
[189] Michael Stumo, "Anticompetitive Tactics in Ag Biotech Could Stifle Entrance of Generic Traits" (2010) 15 Drake J. Agric. L. 137.
[190] Pollack & Shaffer, *supra* note 20 at70.

farmers to grow GM crops in the late 1990s.[191] Since then, given the increasingly strict EU regulations on the planting and marketing of GM foods as well as the public's already negative attitude to GM foods, farmers in Europe have been unwilling to grow GMO crops because of the fear that GM foods might not sell well due to negative responses in the European food marketplace. From 1997 to 2002, only one crop variety – Bt Maize – had been planted in the EU, and over a very tiny surface area.[192] Only five EU member states have grown GM crops: Spain, France, Germany, Portugal, and Czech Republic.[193] Further, France and Germany have decreased their planting acreages, while Portugal abandoned cultivation after one year.[194] On the other hand, the EU's anti-GMO stance has spread quickly to other countries and regions.[195] In the context of this anti-GMO trend, the EU farmers, in turn, have benefited from the strict EU GMO labeling regulations because their North American competitors grow GM varieties or because North American non-GM varieties may be inadvertently mixed with GM varieties as a result of their indiscriminate grain distribution system.[196]

3.3 Distrust of government

Public distrust of government is another contributing factor for the establishment of a stringent GMO labeling regime. Philippe Aghion et al. found that "individuals in low trust countries want more government intervention."[197] Canadian consumers are reported to be confident in the Canadian food supply system.[198] This trust in the national food agencies is regarded as a reason

[191] *Ibid*.
[192] The EU Moratorium – More than a Trade Barrier, online: <http://www.sustainabilitynz.org/docs/EU%20Moratorium%20on%20GMOs.pdf>.
[193] *GM Crops: Growing around the World*, online: GMO Compass <http://www.gmo-compass.org/eng/home/>.
[194] ISAAA Global Review of Commercial Transgenic Crops 1998, 1999, 2000, 2001 and 2002.
[195] See Valery Federici, "Genetically Modified Food and Informed Consumer Choice: Comparing US and EU Labeling Laws" (2010) 35 Brooklyn J Int'L 515.
[196] Pollack & Shaffer, *supra* note 20 at 71.
[197] Philippe Aghion, et al, "Regulation and Distrust" 2009 125(3) The Quarterly Journal of Economics 1015.
[198] CFIA, Safe Food for Canadians, online: CFIA <http://www.inspection.gc.ca/about-the-cfia/acts-and-regulations/regulatory-

that may explain the relatively higher acceptance of GM foods by Canadian consumers.[199] That being said, however, in the context of EU food regulation, as Valery Federici argued, distrust of regulators was one of the factors that led European consumers to have an increased demand for harsher regulations.[200] According to Valery, the strong distrust of government and opposition to GMOs in Europe are the result of regulatory failures in a series of food safety crises.[201] These failures "severely undermined public trust in EU food safety regulations and the scientific expertise on which they were based."[202] European consumers are not confident in their national and supranational regulators' abilities to ensure the safety of the food supply. This general distrust also applies to GM foods: a majority of Europeans do not support GM foods.[203] As a result, the EU has to improve the regulatory framework "to strengthen European consumer protection standards as the lack of public confidence in the European food supply threatens the functioning of the single market."[204] Therefore, European regulators adopted the precautionary principle and laid down the most stringent requirements for GMO approval and marketing.

A similar situation also exists in China. Chinese consumers have serious doubts about the government food safety system standards and their enforcement. The food scandals that broke out

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initiatives/sfca/brochure/eng/1338950776168/1338950907678>.

[199] Huanguang Qiu et al, "Consumers' Trust in Government and Their Attitudes Towards Genetically Modified Food: Empirical Evidence from China" (2012) 10:1 Journal of Chinese Economic and Business Studies 67.

[200] Federici, *supra* note 195.

[201] These crises include: "the Sang Contaminé (contaminated blood) scandal, contamination of eggs and meat with the highly carcinogenic industrial chemical dioxin in Belgium, and, most memorably, the Bovine Spongiform Encephalopathy ("BSE" or "mad cow disease") scare in the United Kingdom. The strongest driver of the intensely negative consumer reaction to the BSE scare was not the fact that humans contracted the disease, or that some died, but the anger over E.U. regulators' "belated failure to recognize" the health hazards of BSE…Both the government of Britain and the European Commission denied the validity of consumer concerns and placed no restrictions on the sale of British beef until there had been a significant number of human deaths." *Ibid.*

[202] *Ibid.*

[203] Darren Abrahams, *GM Food and Feed Traceability and Labeling*, online: <http://www.steptoe.com/assets/attachments/2318.pdf>.; see also Council of New Zealand*, GM Free Food Producer*, online: <http://www.sustainabilitynz.org/docs/NZGMFreeFoodProducer.pdf>.

[204] Diahanna Lynch & David Vogel, *The Regulation of GMOs in Europe and the United States: A Case-Study of Contemporary European Regulatory Politics*, online: <http://www.cfr.org/genetically-modified-organisms/regulation-gmos-europe-united-states-case-study-contemporary-european-regulatory-politics/p8688>. The "single market" also called the internal market is the EU project to create free trade within the EU and to cast the Europe into a single economy, see *European Single Market*, online: CIVITAS EU Facts <http://www.civitas.org.uk/eufacts/FSECON/EC1.htm>.

in the past decade have impressed on consumers that the Chinese food regulatory system is incomplete, inspection is weak, and regulations are not strictly enforced.[205] Although these food safety incidents do not involve GM food, they can negatively influence consumers' attitude towards GM foods, causing most of the consumers to easily trust rumors about GM food safety and refuse to consume GM food. The Ministry of Agriculture of China claimed that rumors that GM food is dangerous to eat are due to the public's ignorance about biotechnology and the loss of confidence in government authority.[206] Recent research by Huanguang Qiu et al. found that "consumers' trust in government is found to have a significantly positive impact on their acceptance of GM food."[207] They suggested that any government that wants to pursue the development of GM food should first improve its food safety system to strengthen the public's trust in the government approach to the food system.[208]

Conclusion

This Chapter has explored the sources of international conflict over GMO labeling on the domestic and regional level. It finds that EU consumers have the most critical attitudes toward GM techniques, and that the EU and most EU countries have established the most stringent traceability and labeling regimes for GMOs. On the basis of the precautionary approach, the EU uses a process-based mandatory labeling scheme that requires any products that contain more than 0.9 percent of authorized GM content to be labeled.[209] Canada, in contrast, uses a product-based voluntary labeling regime that allows producers to decide whether or not to label their

[205] Some big events of food safety crises include: in April 2008 more than 100 kindergarteners got sick at a school in Zhuhai, Guangdong province after drinking bacteria infected milk; in September, 2008 thousands infants became sick and developed kidney stones from powder-milk poisoning (produced by Sanlu) causing 4 deaths. Tainted Milk and Poisoned Children in China, online: <http://factsanddetails.com/china.php?itemid=1685&catid=11&subcatid=73>.

[206] *Breaking Chinese-style Fallacies and Rumors about GMOs*, online: Ministry of Agriculture <http://www.moa.gov.cn/ztzl/zjyqwgz/zjyxwbd/201108/t20110801_2074206.htm>.

[207] Qiu et al, *supra* note 199.

[208] *Ibid.*

[209] *Regulation 1830/2003*, *supra* note 26.

products as GM or non-GM.[210] Canada adopts the substantially equivalent principle for risk assessment of GMOs, and only mandates that GMOs be labeled when nutritional or compositional changes, or other health related concerns, such as allergens, have been verified.[211] China, as a representative of developing countries, has been active in promoting the development of GM-based agriculture on the one hand, and has shown cautious attitude towards marketing GMOs, in particular, the commercialization of GM rice and other staple foods, on the other hand.[212] China applies the precautionary approach and claims that all GM products in China must be labeled no matter how much GM content is contained within the products (zero tolerance).[213]

The labeling regulatory frameworks, thus, differ dramatically in jurisdictions, and the reasons for these differences are much more complicated and profound than the different GMO labeling regimes per se. This Chapter discusses three contributing factors that have played a significant role in shaping the EU and domestic GMO labeling regimes: (1) different GMO labeling policy-making models; (2) different marketing demands and different producer interests; and (3) different levels of trust in government management of food supply system. However, putting all these complex factors aside, in general, the primary purpose for labeling, regardless of jurisdiction, is to provide consumers with material information that helps them to make meaningful informed choices.[214] Accordingly, the statements of labeling should be accurate and

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[210] *Voluntary Labeling and Advertising of Foods That Are and Are Not Products of Genetic Engineering National Standard of Canada CAN/CGSB-32.315-2004*, *ibid.*

[211] Health Canada, *Guidelines for the Safety Assessment of Novel Foods*, online: Health Canada <http://www.hc-sc.gc.ca/fn-an/legislation/guide-ld/nf-an/guidelines-lignesdirectrices-eng.php>; *Voluntary Labeling and Advertising of Foods That Are and Are Not Products of Genetic Engineering National Standard of Canada CAN/CGSB-32.315-2004*, online: <http://www.tpsgc-pwgsc.gc.ca/cgsb/on_the_net/032_0315/standard-e.html>.

[212] *"Twelfth Five" National Strategic Emerging Industry Development Plan*, online: the Central People's Government of China <http://www.gov.cn/zwgk/2012-07/20/content_2187770.htm>.

[213] Kou Jianping, an official from China's Ministry of Agriculture said: "China adopted mandatory 'zero threshold' identification. It must be marked as long as the product contains genetically modified ingredients." See *China Most Strict on Genetically Modified Organisms*, online: Guangming Daily, August 24, 2011 <http://english.people.com.cn/90882/7578858.html>.

[214] For example, Preamble (11) of *Regulation 1830/2003/EC*, *supra* note 26; Introduction part of Voluntary Labeling and Advertising of Foods That Are and Are Not Products of Genetic Engineering National Standard of Canada, *Voluntary*

must disclose material information for the identification of one category product. Therefore, it comes down to two fundamental questions, which are included in all debates about GMO labeling requirements: are GMOs substantially different from the non-GM conventional crops? If scientific uncertainty over the answer to this question exists, is a mandatory labeling measure an appropriate approach to manage relevant risk? In the next Chapter, I will address these questions in depth and explore the evidence to argue against a mandatory GMO labeling regime.

Labeling and Advertising of Foods That Are and Are Not Products of Genetic Engineering National Standard of Canada CAN/CGSB-32.315-2004, *supra* note 87; Art. 1 of the Administrative Measures for Labeling Agricultural GMOs of China, *The Administrative Measures for Labeling Agricultural GMOs* (has been amended in 2004), *supra* note 141.

Chapter 5 Critique of Rationales for Mandatory Labeling Requirements

As discussed in previous chapters, current food labeling laws, in general, require that labeling of types of products should provide consumers with accurate and material information that helps them make informed choices. In the context of labeling GM foods and foods containing GM ingredients, if GMOs are proved to be not substantially different from conventional crops, it may not be necessary to label them. This reasoning is exemplified by the position taken by both Health Canada and the US Food and Drug Administration (FDA). Both agencies have adopted a policy that embraces the idea that GM foods have been proven to be safe for consumption before they are commercially grown and sold on the market. They are not compositionally different from non-GM foods and, as a result, there is no special need for the labeling of GMO products.[1]

However, political groups and environmental and consumer protection organizations have put forward arguments in favor of the mandatory labeling of GMOs. In this Chapter, I will analyze and critique these arguments, finding that most are not based on solid scientific evidence and that some of them are misleading. I start with a brief review of the rationales for mandatory labeling of GMOs. The evidence gathered in this review indicates a need to have a scientific inspection of GM techniques and GMO safety concerns. Such a scientific probe could clarify some facts about GMO safety concerns and fundamentally collapse several arguments for mandatory labeling measures. Following my call for rationales that are more scientifically sound, I turn to discuss risk assessment and management of GMOs, with a particular focus on the precautionary principle,

[1] Canadian Food Inspection Agency (CFIA), *Novel Food which are Products of Genetic Modification*, online: CFIA Guide to Food Labeling and Advertising <http://www.inspection.gc.ca/english/fssa/labeti/guide/ch4ae.shtml>. U.S. Food and Drug Administration (FDA), Statement of Policy – Foods Derived from New Plant Varieties, online: FDA <http://www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/Biotechnology/ucm096095.htm>.

the implementation of which has resulted in mandatory requirements for all GM products. I find that there are many controversies over the precautionary principle/approach. For example, there are criticisms of the definition of the principle per se, and there exists different opinions over whether the precautionary principle or approach is a legally binding international norm. Based on the exploration of these controversies and the scientific exploration and risk assessment and management discussion, I argue that the precautionary principle cannot provide sufficient justification for a mandatory labeling regime for GMOs. The last section of this chapter will look at the argument of the "consumer's right to know". I will argue that although the consumer's right to know sounds undefeatable, it cannot stand up to deep scrutiny. My analysis will prove that the consumer's right to know alone cannot justify a mandatory labeling requirement for GMOs.

A. Review of rationales for mandatory labeling

Arguments by proponents of a mandatory GMO labeling regime can be summarized according to the following two perspectives or concerns: (1) informed decision making: protecting the consumer's right to know or right to be informed, i.e., providing consumers with information that helps them to make informed choices,[2] and (2) environmental protection concerns: avoiding GMOs' potential contaminations of other traditional crops and local biodiversity.[3]

[2] "Consumer's right to know" or "right to be informed" has been discussed extensively in the literature. Some representative works include: Lara B. Winn, "Special Labeling Requirements for Genetically Engineered Food: How Sound Are the Analytical Frameworks Used by FDA and Food Producers?" (1999) 54 Food & Drug LJ 667; Diane T. Vasquez, "Genetic Engineering and Food Labeling: A Continuing Controversy" (2000) 10 San Joaquin Agric L Rev 77; J. Teel "Regulating Genetically Modified Products and Processes: An Overview of Approaches" (2000) 8 NYU Envtl LJ 649; F. X. Perrez "Taking Consumers Seriously: the Swiss Regulatory Approach to Genetically Modified Food" (2000) 8 NYU Envtl LJ 585; Alicia T. Simpson, "Buying and Eating in the Dark: Can the Food and Drug Administration Require Mandatory Labeling Of Genetically Engineered Foods? Alliance for Bio-Integrity v. Shalala, Et Al., 116 F. Supp.2d 166 (2000)" (2001) 19 Temp Envtl L & Tech J 225; S. L. Kirby, "Genetically Modified Food: More Reasons to Label Than Not" (2001) 6 Drake J Agric L 351; Taiwo A. Oriola, "Consumer Dilemmas: The Right to Know, Safety, Ethics and Policy of Genetically Modified Food" (2002) 2002 Sing J Legal Stud 514; Andrew J. Nicholas, "As the Organic Food Industry Gets Its House in Order, the Time Has Come for National Standards for Genetically Modified Foods" (2003) 15 Loy Consumer L Rev 277; E. Robertson, "Finding A Compromise in the Debate over Genetically Modified Food: An Introduction to A Model State Consumer Right-To-Know

1. Informed decision-making

The proponents of mandatory labeling of GMOs have frequently emphasized consumers' right to know and their willingness to choose foods based on GMO labels placed on the products. Common arguments used to support a informed choice justification for GMO mandatory labeling include health risk concerns, religious considerations, vegetarian preferences, and even the "yuck factor."[4]

Advocates declare that transgenic technology has unnaturally changed the genes of crops and made the GM varieties substantially different from crops produced by traditional crossbreeding.[5] Using this "natural-artificial" dichotomy, critics of GMOs argue that the labeling of GMOs should be mandatory in order to facilitate the consumer's informed choice of either taking on the potential risk or shunning the consumption of GM foods. Moreover, proponents of mandatory labeling also warn that potential health risks, such as toxicity and allergies caused by GM foods and GM ingredients is life-threatening to vulnerable consumers,[6] because the introduced gene,

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Act" (2003) 9 BU J Sci & Tech L 156; Graham M. Wilson, "A Day on the Fish Farm: FDA and the Regulation of Aquaculture" (2004) 23 Va Envtl LJ 351; M. Gihooley, "Reexamining the Labeling for Biotechnology in Foods: The Species Connection" (2004) 82 Neb L Rev 1088; Jamie E. Jorg Spence, "Right to Know: A Diet of the Future Presently Upon US" (2005) 39 Val U L Rev 1009; Comment, "A Tale of Two Systems: A Comparison Between US and EU Labeling Policies of Genetically Modified Foods" (2006) 15 San Joaquin Agric L Rev 193; David A. Nauheim, "Food Labeling and the Consumer's Right to Know: Give the People What They Want" (2009) 4 Liberty U. L. Rev. 97; Valery. Federici, "Genetically Modified Food and Informed Consumer Choice: Comparing U.S. and E.U. Labeling Laws" (2010) 35 Brook J Int'l L 515.

[3] Stuart Smyth and Peter W. B. Philips, "Labeling to Manage Marketing of GM Foods" (2003) 21(9) Trends in Biotechnology 389; Jr. C. Neal Stewart, *Genetically Modified Planet: Environmental Impacts of Genetically Engineered Plants* (New York: Oxford University Press, 2004); Jacques-Henry Weil, "Are Genetically Modified Plants Useful and Safe?" (2005) 5794-5) IUBMB Life 311; Alison Peck, "The New Imperialism: Toward and Advocacy Strategy for GMO Accountability" (2008-2009) 21 Geo. Int'l Envtl. L. Rev. 37; Marguerite A. Hutchinson, "Moving Beyond the WTO: A Proposal to Adjudicate GMO Disputes in an International Environmental Court" (2008-2009) 10 San Diego Int'l L.J. 229;

[4] H.Siipi & S. Uusitalo, "Consumer Autonomy and Sufficiency of GMF Labeling" (2008) 21 Journal of Agricultural and Environmental Ethics 353; Also see P. Markie, "Mandatory Genetic Engineering Labels and Consumer Autonomy", in P. Weirich ed, *Labeling Genetically Modified Food: the Philosophical and Legal Debate* (Oxford: Oxford University Press, 2007) at 88-105.

[5] Cyrus Martin, "The Psychology of GMO" (2013) 23:9 Current Biology 356.

[6] A food allergy is defined as the "adverse reaction to foods where an immune mechanism is involved." Montserrat Fernández-Rivas & Ricardo Asero, "Chapter two – Which Foods Cause Food Allergy and How is Food Allergy Treated?" in Chalotte Madsen, et al., *Risk Management for Food Allergy* (UK, Oxford: Elsevier, 2014) at 26.

which has already been known for its sensitization to patients, has the potential to produce an allergen in its final product.[7] Consequently, it is argued that the labeling of GM foods can help food-allergic consumers to avoid consuming these foods and thereby improve their qualities of life.[8] Furthermore, some consumers think that unlabeled GM foods could negatively affect them, because GM ingredients transferred from certain animals or other sorts of species would conflict with their particular faiths.[9] They insist on their right to know and ask for mandatory labels for the GM content of the foods.

2. Environmental considerations

Proponents of mandatory labeling also argue that GMOs might negatively influence traditional crops. This claim, gradually formed since the late 1980s, is based on the fact that plants became resistant to chemical insecticides due to increased insecticide usage.[10] Critics purported that herbicide-tolerant GM crops could spread the tolerance trait to related plants, thereby leading to increased consumption of herbicides and eventually even to "superweeds".[11] Recently, environmental pressure groups have conceptualized GMOs' negative impact on traditional crops as "gene flow" or "genetic pollution", conceptions that indicate undesirable movements of genetic material from GM to non-GM crops as a result of uncontrolled spreads of genetic

[7] M.C. van Putten, et al, "Novel Foods and Allergy: Regulations and Risk-benefit Assessment" (2011) 22:2 Food Control 143.

[8] Michael A. Whittaker, "Reevaluating the Food and Drug Administration's Stand on Labeling Genetically Engineered Foods" (1998) 35 San Diego L Rev 1215; J. E. Beach, "No 'Killer Tomatoes': Easing Federal Regulation of Genetically Engineered Plants" (1998) 53 Food & Drug LJ 181; Karen A. Goldman, "Labeling of Genetically Modified Foods: Lagal and Scientific Issues" (2000) 12 Geo Int'l Envtl L Rev 717; H. N. Ellison, "Genetically Modified Organisms: Does the Current Regulatory System Compromise Consumer Health?" (2002) 10 Penn St Envtl L Rev 345; Stan Benda, "It's all about Elmer Gantry ... There is no Frankenstein!!! — Part II" (2003) 16 IPJ 393; Javier Guillem Carrau, "Lack of Sherpas for a GMO Escape Route in the EU" (2009) 10 German L.J. 1169; Rita Batista and Maria Margarida Oliveira, "Facts and Fiction of Genetically Engineered Food" (2009) 27(5) Trends in Biotechnology 277.

[9] P. Markie, "Mandatory Genetic Engineering Labels and Consumer Autonomy", in P. Weirich ed, *Labeling Genetically Modified Food: the Philosophical and Legal Debate* (Oxford: Oxford University Press, 2007) at 88-105.

[10] David Chandler, et al., "The Development, Regulation and use of Biopesticides for Integrated Pest" (2011) 366 (1573) Phil Trans R Soc B 1987.

[11] Les Levidow & Susan Carr, "GM Crops on Trail: Technological Development As A Real-world Experiment" (2007) 39:4 Futures 408.

information.[12] Both these conceptions have created the negative image for the public that GMOs might damage the natural environment. They sounded an alarm against the development of GM crops, and gave a negative image to consumers about GM foods. This negative perception, in turn, increased the public's desire for the mandatory labeling of GM foods.

The above review of arguments for mandatory labeling measures reveals that the public's anxiety about GM food safety and GMOs' impact on the environment are the major factors that underline every rationale. In particular, all arguments are based on a presupposition that GM foods may have short/long-term negative impacts on human health due to the unnatural change of crop gene, and hence steps need to be taken to avoid harms arising from GMOs. But is this presupposition supported by solid scientific evidence? Therefore, to start my arguments against mandatory labeling regimes, in the next sections I explore what the scientific evidence tells us about GMO safety concerns, aiming to provide objective information and clarify some facts about GMOs and GM techniques.

B. Scientific evidence and the mandatory labeling regime

> In May 2012, France's attempt to ban the planting of Monsanto GM maize was rejected by the EU's food safety agency. The European Food Safety Authority ruled that "there is no specific scientific evidence, in terms of risk to human and animal health or the environment to support the French ban.[13]
>
> The American Medical Association (AMA) formally gave an opinion on special labeling of bioengineered foods that stated: "Our AMA believes that as of June 2012, there is no scientific justification for special labeling of

[12] Richard M. Twyman, et al, "Plant Biotechnology: the Importance of Being Accurate" (2009) 27:11 Trends in Biotechnology 609.

[13] Adam Vaughan, *French Ban of Monsanto GM Maize Rejected by EU*, online: the Guardian <http://www.guardian.co.uk/environment/2012/may/22/french-ban-gm-maize-rejected>.

> bioengineered foods, as a class, and that voluntary labeling is without value unless it is accompanied by focused consumer education."[14]…

News concerning GMO safety, like the quotations above, has been frequently reported over the last decades. Indeed, concerns about GMO safety are fundamental to the origin of the debates around GMO labeling regimes. Within the scientific community, where questioning is an intrinsic property of science and challenges have always been welcomed in scientific research, debates around GMO safety assessment are either a part of, or motivate, the progress of GM technology-related research. However, in cases where scientific studies concerning GMO safety are conducted based on poor experimental designs and their results show certain risks of GMOs are published in academic journals, the public will easily get confused about whether GMOs are safe for consumption. In particular, when such scientific research is interpreted by the public/media as uncertainty or even a hazard for human health, the chances that the public will misunderstand GM techniques and the cultivation of GM crops are very high. Therefore, a review of scientific research regarding GM technology and GMOs is necessary in order to examine whether GM crops are as safe as conventional foods and whether they need special treatment i.e., mandatory labeling measures based on their safety uncertainty.

1. GM techniques

As previously addressed in Chapter One, a GMO discussed in this dissertation is limited to an organism whose genes have been altered by biotechnological methods that aim to produce desirable traits. Emphasizing this limitation is due to the fact that moving genes into a host

[14] *AMA: No Scientific Justification for Special Labeling of Bioengineered Foods*, online: BIOtechNOW <http://www.biotech-now.org/food-and-agriculture/2012/06/ama-no-scientific-justification-for-special-labeling-of-bioengineered-foods?utm_source=rss&utm_medium=rss&utm_campaign=ama-no-scientific-justification-for-special-labeling-of-bioengineered-foods>.

organism to modify the genome of the organism can be exercised in different ways. Some methods for genetically changing plants have been used for thousands of years. Many people think that conventional breeding, which has been used in traditional agriculture to cultivate a plant with a desired trait, is a natural way of hybridization.[15] However, a history of artificial breeding extending over a century has shown that a crossbreed has never been exercised without human interference.[16] Selective breeding is always based on agronomists' reviews of selection experiments that aim to choose the most positive response for a trait of interest.[17]

Compared with modern agricultural techniques, the limit of traditional breeding techniques is evident. Selective process is time-consuming. Finding a plant that manifests the maximum value for a desirable trait is considered the biggest weakness of selective breeding technique.[18] When a potential wild plant is selected, a large quantity of genes will be exchanged during the breeding process. However, some of those genes manifest useful while others manifest unwanted traits in the offspring.[19] In some situations, these unwanted traits are not safe for human health. For example, an over-safety-for-consumption level of glycoalkaloids[20] can be detected in some new potato varieties produced by using conventional plant breeding.[21] Poisoning symptoms of glycoalkaloids, including nausea, vomiting, diarrhoea, stomach cramps, headache and, in some

[15] Yutaka Tanaka, "Attitude Gaps Between Conventional Plant Breeding Crops and Genetically Modified Crops, and Psychological Models Determining the Acceptance of the Two Crops" (2013) 16:1 Journal of Risk Research 69.
[16] Adrianne Massey, "Crops. Genes, and Evolution" (2001) 1:3 The Journal of Food and Culture 20.
[17] Trygve Gjedrem, "Genetic Variation in Quantitative Traits and Selective Breeding in Fish and Shellfish" (2011) 33:1-4 Genetics in Aquaculture 51.
[18] R. Paul Thompson, *Agro-Technology A Philosophical Introduction* (New York: Cambridge University Press, 2011) at 15.
[19] Genetically Modified Organisms, online University of California San Diego <http://www.bt.ucsd.edu/gmo.html>.
[20] Many plants in the *Solanaceae* family contain glycoalkaloids, and they are considered to be natural toxins. They are active as pesticides and fungicides and are produced by the plants as a natural defense against animals, insects and fungi that might attack them. Clycoalkaloids, online: Food Safety Watch the Science of Safe Food, <http://www.foodsafetywatch.com/public/154.cfm>.
[21] Clycoalkaloids, online: Food Safety Watch the Science of Safe Food, <http://www.foodsafetywatch.com/public/154.cfm>.

serious cases, neurological problems, might occur when the uptake of new potato varieties contain a high level of glycoalkaloids.[22]

With the development of genetic engineering techniques, agronomists are able to carry out sophisticated levels of breeding in more accurate and efficient ways. The selections of desirable genes need no longer be limited within the same species, because engineering techniques enable the desired genes to transfer not only between the same or related species, but also between unrelated species or genera.[23] Public worries about such "wide crosses" are unnecessary, as the "[d]ifferences between species arise mainly from how the genes are organized on the chromosomes, and how the gene sequences regulated the activity of the protein coding genes."[24] Thus, a transformation of a fish gene to a tomato gene would not turn a tomato into a fish.[25] Moreover, these "wide crosses" actually occurred in conventional breeding a long time ago. Agricultural professionals have carried out a wide range of crosses, from different species, or even different genera, in selective processes.[26] One example is bread wheat. It has been "crossbred with more than ten different species in four different genera."[27] Although these "wide crosses" are not new in plant breeding, genetic engineering techniques can make the process of genetic modification more accurate.[28] They enable scientists to identify a particular DNA sequence of a selected gene that expresses the desired trait. As well, they allow scientists to excise the selected gene segment and physically move or add it to a new plant, thereby enhancing

[22] *Ibid.*
[23] Batista & Oliveira, *supra* note 8.
[24] Massey, *supra* note 16.
[25] Alan McHughen & Robert Wager, "Popular Misconceptions: Agricultural Biotechnology" (2010) 27:6 New Biotechnology 724
[26] Massey, *supra* note 16.
[27] *Ibid.*
[28] Henry-York Steiner, "Editor's Choice: Evaluating the Potential for Adverse Interactions within Genetically Engineered Breeding Stacks" (2013) 161:4 Plant Physiology 1587.

one of the plant's desirable traits.[29] In general, the genetic engineering techniques enable the genetic improvement of crops to be carried out in a more precise and controllable fashion.

2. Health concerns

Health-related concerns about GM technology and GM foods have resulted in numerous scientific studies conducted by scientific groups from different countries. There has been plenty of research from industrialized countries, such as the US and Canada, where GMOs have been widely grown and sold, as well as a large amount of studies from developing countries, such as Brazil and China, where GM crops were introduced for the purposes of improving national nutrition and securing food supplies.[30] Even in the EU, where the planting of GM foods has been prohibited in some EU member states, and the public has been strongly against GM foods, scientific groups have engaged in a variety of high-quality scientific research in regards to GMO health concerns.[31] For the over twenty-five years of GMO biosafety research, the EU has not established any scientific evidence that shows GM crops are more risky than crops genetically improved by traditional methods.[32]

The most common health concerns associated with GMOs that have been frequently posed by scientific research include (but are not limited to) the potential transmission of foreign DNA through GM food, the marker gene into human,[33] unintended nutritional composition changes,[34]

[29] Barbara Bordogna Petriccione, *Introduction to GMO: Technique and Safety*, online: <http://www.ruiggian.org/ressources/Brochure1GMO.pdf?ID=190&FILE=/ressources/Brochure1GMO.pdf>; Genetically Modified Organisms, online University of California San Diego <http://www.bt.ucsd.edu/gmo.html>.

[30] Hossein Azadi & Peter Ho, "Genetically Modified and Organic Crops in Developing Countries: A Review of Options for Food Security" (2010) 28:1 Biotechnology Advances 160

[31] John Davison, "GM Plants: Science, Politics and EC Regulations" (2010) 178: 2 Plant Science 94.

[32] Germma Masip, et al, "Paradoxical EU Agricultural Policies on Genetically Engineered Crops" (2013) 18:6 Trends in Plant Science 312; McHughen & Wager, *supra* note 25; Alessandro Nicolia et al., "An Overview of the Last 10 Years of Genetically Engineered Crop Safety Research" (2013).

[33] Yves Tourte, *Genetic Engineering and Biotechnology Concepts, Methods and Agronomic Applications* (Enfield: Science

and potential toxicity.[35] The following section, however, will show that scientists have raised these health-related questions but there is no firm data to indicate that there exists real human harm from the GMO foods.

2.1 Toxicity

A prior health-related concern with GM crops was whether new inserted genes would create unintended toxicity that is harmful for human and animal health. In the US, where GM food has been sold to consumers for decades, over 70 percent of some foods sold on shelves currently contain GMOs, yet there has been no authoritative reports published to confirm that the consumption of GMOs has caused serious illness or death.[36] In contrast, organic foods, which have been considered as healthier than conventional foods by most consumers (but a 2012 Stanford research indicated that little evidence demonstrated that organic foods are healthier than conventional foods from a nutritional point of view),[37] were reported to be the cause of a multistate outbreak of shiga toxin-producing escherichia coli 157:H7 infections in the US in 2012.[38]

We have seen lots of experiment-based study results supporting the argument that GM foods pose no more risk than non-GM counterparts, yet challenges have never stopped in the scientific

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Publishers, Inc., 2005) at 168; Batista & Oliveira, *supra* note 8.

[34] Batista & Margarida Oliveira, *ibid.*

[35] Claudia Peoletti, et al., "GMO Risk Assessment around the World: Some Examples" (2008) 19 Trends in Food Science & Technology S70.

[36] Ademola A Adenle, "Response to Issues on GM Agriculture in Africa: Are Transgenic Crops Safe?" (2011) 4: 338 BMC Research Notes.

[37] Michelle Brandt, *Little Evidence of Health Benefits from Organic Foods, Stanford Study Finds (September 3, 2012)*, online: Stanford School of Medicine <http://med.stanford.edu/ism/2012/september/organic.html>.

[38] Centers for Disease Control and Prevention, Multistate Outbreak of Shiga Toxin-producing Escherichia Coli O157:H7 Infections Linked to Organic Spinach and Spring Mix Blend (Final Update), online: CDC <http://www.cdc.gov/ecoli/2012/O157H7-11-12/index.html?utm_source=feedburner&utm_medium=feed&utm_campaign=Feed%3A+CdcOutbreakRss+(CDC+Outbreak+RSS)>; see also Ivana Vinković et al., "A Comparison of the Nutritional Value and Food Safety of Organically and Conventionally Produced Wheat Flours" (2014) 143 Food Chemistry 522.

research field.[39] Ewan and Pusztai's test in 1990s is the most controversial report on this issue of GMOs leading to health concerns. Their study claimed that rats fed with transgenic potatoes were found to have several injurious results in the gastrointestinal tract.[40] These potential dangers of transgenic potatoes sparked a global media and rumor frenzy.[41] But in the scientific societies, the study has been castigated and retracted. The main criticism concerns the flaws in the design of the experiment. For instance, Harry A Kuiper et al., criticized Pusztai's results and argued that the experiment was incomplete: too few animals per diet group were included, the chemical composition between GE and non-GE potatoes varieties was not clear, and the statistical techniques applied to the analysis of results were inappropriate.[42]

A similar situation in which a toxicity study on GM food was criticized by the scientific community can also be observed in Aziz Aris and Samuel Leblanc's research publication.[43] In this paper, the authors claimed they had detected traces of glyphosate (GLYP) and gluphosinate (GLUF), 3-methylphosphinicopropionic acid (3-MPPA), and the insecticidal protein Cry1Ab in the blood of women, pregnant or not pregnant, and in umbilical cords, in the Eastern Townships of Quebec, Canada.[44] The GLYP and GLUF were used on herbicide tolerant GM plant varieties and 3-MPPA was their major metabolite. The Cry1Ab was produced by certain varieties called

[39] The very recent one is from the Morten Poulsen research team. They conducted an experimental study on the compositional and toxicological analysis of a GM potato line with reduced α-solanine content. Based on a 90-day feeding study in the Syrian Golden hamster, the authors claimed that the GM potato used in the experiment did not appear to be more risky to human or animal health than the non-GM counterparts (Desiree wild-type potato). See Morten Poulsen et al., "Compositional and Toxicological Analysis of A GM Potato Line with Reduced α-solanine Content – A 90-day Feeding Study in the Syrian Golden Hamster" (2012) 64:1 Regulatory Toxicology and Pharmacology 177.

[40] See Steve Connor, Arpad Pusztai: *the Verdict GM Food: Safe or Unsafe?*, online: The Independent-London <http://www.mindfully.org/GE/Arpad-Pusztai-Potato.htm>.

[41] See Martin Enserink, "Institute Copes with Genetic Hot Potato" (1998) 281 Science 1124.

[42] Harry A Kuiper, Hub PJM Noteborn & Ad ACM Peijnenburg, "Adequacy of Methods for Testing the Safety of Genetically Modified Foods" (1999) 354:9187 The lancet 1315.

[43] Aziz Aris & Samuel Leblanc, "Maternal and Fetal Exposure to Pesticides Associated to Genetically Modified Foods in Eastern Townships of Quebec, Canada" (2011) 31:4 Reproductive Toxicology 528.

[44] *Ibid.*

Bt-resistant insect pests. A few months later, however, comments from other scientific groups appeared in the same journal that criticized the Aris and Leblanc study:

> …disappointingly the authors of this paper do not present any convincing data to link the consumption of GM food with detectable levels of agricultural pesticides/metabolites in the blood. Instead their approach is to quantify three pesticides in the sera of pregnant and non-pregnant women and newborn infants without defining the food intake of the subjects beyond saying that it was a representative food market-basket.[45]

Agnes E. Ricroch et al., recently published a literature review on the "assessment of the health impact of GM plant diets in long-term and multigenerational animal feeding trials."[46] The study is convincing because the authors systematically reviewed 12 long-term studies and 12 multigenerational studies concerned with the effects of 5 types of GM foods on animal health. Their review of the collected data demonstrated that: "[n]o sign of toxicity in analyzed parameters has been found in long-term studies," and that "[n]o sign of toxicity in parameters has been found in multigenerational studies."[47]

2.2 Transmission of foreign DNA

Another health concern with GM crops is the horizontal gene transfer (HGT). The HGT is biology terminology that describes a transformation of "genetic material directly to a living cell or an organism followed by its expression."[48] One of the questions often posed is whether the newly inserted genes, or marker gene, are incorporated into a consumer's genetic makeup and

[45] Utz Mueller & Janet Gorst, "Comment on "Maternal and Fetal Exposure to Pesticides Associated to Genetically Modified Foods in Eastern Townships of Quebec, Canada" by A. Aris and S. Leblanc [Reported. Toxicol. 31(2011)528-533]" (2012) 33(3) Reproductive Toxicology 401.

[46] Agnes E. Ricroch et al., "Assessment of the Health Impact of GM Plant Diets in Long-term and Multigenerational Animal Feeding Trails: A Literature Review" (2012) 50:3-4 Food and Chemical Toxicology 1134.

[47] *Ibid.*

[48] G. van den Eede, et.al, "The Relevance of Gene Transfer to the Safety of Food and Feed Derived from Genetically Modified GM) Plants" (2004) 42:7 Food and Chemical Toxicology 1127.

thereby impose threats to human beings.[49] These worries are based on some experimental reports that food DNA fragments may transfer to human beings through the micro-organisms living in the digestive tract of human beings from the oral cavity to the colon.[50] These micro-organisms are believed to be potential recipients for the transmission of DNA ingested and released through GM food. Such worries are intensified when dealing with the marker genes because many of the first generation GM crops used the resistance to antibiotics marker genes.[51] Thus, the risk that a resistance to antibiotics could be transferred to human beings has been commonly raised as an issue.[52]

The FDA published a guidance document for industry entitled *Use of Antibiotic Resistance Marker Genes in Transgenic Plants* in 1998.[53] It held the following view on the issue of potential transfer of foreign genes to microorganisms:

> The likelihood of transfer of an antibiotic resistance marker from plants to microorganisms in the gut or in the environment is remote and that, such transfer, if any, would likely be insignificant when compared to transfer between microorganisms, and in most cases, would not add to existing levels of resistance in bacterial populations in any meaningful way…The potential transfer of antibiotic resistance genes from foods derived from transgenic plants to cells lining the gastrointestinal tract does not raise a safety concern. Most DNA is degraded in the gut and thus, would be unavailable for transfer, and even if some DNA survived and was available for transfer into these cells, it would not be integrated and expressed due to lack of selective pressure. Additionally, because these cells are continuously sloughed off and replaced by new cells, a cell that incorporated an antibiotic

[49] Tourte, *supra* note 33 at 168.
[50] Report of the EFSA GMO Panel Working Group on Animal Feeding Trails, "Safety and Nutritional Assessment of GM Plants and Derived Food and Feed: The Role of Animal Feeding Trails" (2008) 46 Food and Chemical Toxicology S2.
[51] FAO, *Health and Environmental Impacts of Transgenic Crops*, online: FAO Corporate Document Repository <http://www.fao.org/docrep/006/Y5160E/y5160e10.htm>.
[52] Tourte, *supra* note 33 at 169.
[53] FDA, *Use of Antibiotic Resistance Maker Genes in Transgenic Plants*, online: FDA <http://www.fda.gov/food/guidancecomplianceregulatoryinformation/guidancedocuments/biotechnology/ucm096135.htm>.

> resistance gene would not be long-lived and present a safety hazard with respect to compromising therapy with antibiotics.[54]

In order to address the issue of potential transfer, a special European working group linked to the EU project on safety evaluation of horizontal gene transfer from GMOs to the microflora of the food chain and human gut (GMOBILITY) was established to investigate HGT in terms of food and feed safety concerns from 2000.[55] Based on the comprehensive data analysis, the research result made some clarification about the myth of HGT. It emphasized that gene transfer was a common phenomenon in the natural environment and could occur at different stages along the food chain.[56] After the inserted DNA was introduced to the recipient organism, the new DNA did not show any physical and chemical differences from the host DNA.[57] Even if such a gene transfer was possible, only a very small amount of transgenic DNA would actually reach the colon. Since most foods are processed before eating, and since the heat-processed food often contains very small sized DNA the possibility of foreign DNA transmission is accordingly decreased.[58] In addition, most of the DNA fragments would be degraded through the digestion process in the gastrointestinal tract. Thus, the acquisition of foreign genes is a rare event. The GMOBILITY authors concluded that: "HGT is at the origin of the variety of life itself and there is very little reason to assume that consumption of transgenic food or feed adds any particular generalized risk…there is so far no evidence that such DNA may end up in germ line cell as a consequence of the consumption of food."[59]

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[54] *Ibid.*
[55] van den Eede, et.al, *supra* note 48.
[56] *Ibid.*
[57] *Ibid.*
[58] *Ibid.*
[59] *Ibid*. In the Nicolia et al research, they concluded that as confirmed by all the studies so far, "HGT of transgenic DNA to gastrointestinal bacteria of human and animal is estimated to be an extremely rare event." Alessandro Nicolia, et al., "An Overview of the Last 10 Years of Genetically Engineered Crop Safety Research" (2013) Crit Rev Biotechnol; also see Bo Lin, et al., "Qualitative Observation on Persistence and Microbial Transformation of Recombinant DNA from Transgenic Rice Biomass Incubated in in vitro Rumen System" (2013) 41:1 Journal of Applied Animal Research 14.

In 2005, Mazza et al. published research on the potential transmission of diet-derived DNA from GM feed to animal tissues.[60] They fed piglets with GM and non-GM maize for 35 days, and reported that both maize and GMO-derived sequences were detected in blood, muscle and different organs.[61] Maize sequences were found in all tissues except for muscles, while fragmented transgenic sequences were detected in the blood and organs of the piglets.[62] However, the authors pointed out that the uptake of foreign DNA might be a natural process, and that the occurrence of genetic transfer associated with GM plants was almost the same as with conventional plants. Namely, they shared the same risk.[63]

2.3 Changes of nutritional compositions

Concerns about changes to the nutritional compositions of the final products of GM foods are actually based on one of the potential benefits of GM crops: the increase in nutritional crop value, especially in comparison to conventional crops, through GM technology. People are afraid that unintended changes of nutritional compositions might occur along with the improvement of certain nutritional components.

Melina C. McCann et al. conducted comparative research on compositional change between GM and conventional soybeans.[64] The soybean samples were from glyphosate-tolerant soybeans (GTS) and conventional varieties. The date analyses were based on three years – 2001, 2002,

[60] Mazza R, et al, "Assessing the Transfer of Genetically Modified DNA for Fee to Animal Tissues" (2005) 14(5) Transgenic Res. 775.
[61] *Ibid.*
[62] *Ibid.*
[63] *Ibid.*
[64] Melina C, McCann, et al, "Glyphosate-Tolerant Soybeans Remain Compositionally Equivalent to Conventional Soybeans (Glycine max L.) during Three Years of Field Testing" (2005) 53 J. Agric Food Chem 5331.

2003 – of field testing, and the results indicated that the "[c]omposition of commercial GTS over the three years of breeding into multiple varieties remains equivalent to that of conventional soybeans."[65] A similar conclusion is also shown in the Yan Wang et al. experiment.[66] They analyzed the proteomic profiles and nutritional composition of transgenic rice seeds that contained the Cry1Ab/Ac and non-GM rice seeds, and the comparative analyses of the two data sets indicated that the "[n]utritional quality of the rice from the transgenic lines was equivalent to that of its non-transgenic counterparts and that the effect of growth environment on the rice was no less than that of the single gene insertion."[67]

Besides GM soybeans and rice, other commercial GM crops, such as GM maize and potatoes have also been assessed to compare their nutritional content with conventional varieties. Results have confirmed that GM varieties were of equivalent composition to the non-transgenic varieties.[68]

This preceding summary of scientific research on GMO safety issues highlights that to date there is no established scientific evidence showing that GM crops are more risky than non-GM counterparts. A few studies that have shown harm from GMO consumption have been retracted or severely criticized by the scientific community for underscoring the lack of evidence to support claims of harm.[69] Thus, a mandatory labeling requirement based on the argument that

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[65] *Ibid.*

[66] Yan Wang, et al, "Comparative Analysis of the Proteomic and Nutritional Composition of Transgenic Rice Seeds with Cry1ab/ac Genes and Their Non-transgenic Counterparts" (2012) 55:2 Journal of Cereal Science 226.

[67] *Ibid.*

[68] Batista & Oliveira, *supra* note 8.

[69] A very latest example is the Gilles-Eric Séralini et al. research paper. This paper was published in the journal *Food and Chemical Toxicology* in 2012 claiming that a GM maize variety causes serious disease in rats. After the publication, near-universally scientists criticized their paper for the lack of scientific evidence. The journal retracted this paper in 2013. See Barbara Casassus, *Study Linking GM Maize to Rat Tumours is Retracted*, online: Nature <http://www.nature.com/news/study-linking-gm-maize-to-rat-tumours-is-retracted-1.14268>. This paper was republished (without peer-viewed) in Environmental

GM foods are harmful for human and animal health is not likely to be justified on the basis of solid scientific evidence.

C. The precautionary approach and mandatory labeling regimes

As the above scientific exploration of GM techniques has indicated, GMOs are unlikely to have higher risks of near-term adverse effects than those already identified non-GM food products on human safety and health, and the environment. At the same time, it is scientifically inappropriate to declare that of GMOs pose "zero" long-term (i.e., fifty or hundred years or longer) adverse effects. However, opponents of GMOs argue that the cultivation and marketing of GM crops should be allowed only when GM crops have been proven to be of no harm to human and animal health, or the environment. Such a strong argument is based on the precautionary notion that appears to carry an undefeatable reasoning that "it is better to avoid problems now than regret them in the future."[70] The EU, as I have explored in Chapter Four, is the supporter of the precautionary approach. It elaborates the precautionary notion as the "precautionary principle", on which it bases the implementation of stringent GMO regulations that enforce mandatory labeling measures and a traceable system throughout the entire food supply chain.[71] Canada and the US, however, using the substantial equivalence principle, do not regard GM crops as a special category of food products, and have thereby implemented a policy of voluntary labeling measures.

Sciences Europe (June 2014). See Gilles-Eric Séralini et al., "Republished Study: Long-term Toxicity of A Roundup Herbicide and A Roundup-tolerant Genetically Modified Maize" (2014) 26:14 Environmental Science Europe.

[70] Pablo A. Pellegrini, "What Risk and For Whom? Argentina's Regulatory Polices and Global Commercial Interests in GMOs" (2013) 35:2 Technology in Society 129.

[71] Erik P. Bucy, "Biology, Precaution, and Consumption" (2013) 32:1 Politics and the Life Sciences 1; Jaime Costa & Concepcion Novillo, "Regulatory Approvals of GM Plants (Insect Resistant) in European Agriculture: Perspectives from Industry" in Guy Smagghe & Isabel Diaz, *Arthropod-plant Interactions Novel Insights and Approaches for IPM*, Vol. 14 (UK, London: Springer, 2012) at 204.

When analyzing risk management approaches to GMOs, L.F. Clark concluded that there are two predominant risk management frames in the world of GMO regulations: proof of harm and precautious risk. The former frame is primarily based on scientific evidence that uses the prevention principle, which is defined as "preventing the creation of risk at the source, rather than trying to counteract its effects at the point of impact," to access potential hazards arising from the use of agri-biotechnology.[72] This risk frame can been found in risk governance structures in Codex and CCFL, the WTO system, and domestic risk management frameworks, such as those used by Canada and the US. Meanwhile, the precautious risk frame does not view science-based evidence as the authoritative source of knowledge over the safety and potential hazard associated with GM food products. It uses the precautionary approach to emphasize the need to avoid any future unknown risks and unanticipated harms trigged by the use of GMOs rather than prevent or limit relevant risks by conducting scientific tests. Generally, this risk frame can be identified in environmental protection frameworks, for example, the CBD and Cartagena Protocol, and it has also been represented in the EU GMO regulatory framework as the "precautionary principle".[73] Since the precautionary principle has been frequently argued as one of the bases for mandatory GMO labeling regimes, the following section will provide an in-depth analysis of this "principle". I will argue that the "precautionary principle" or "precautionary approach" has not been accepted as a principle of customary international law or a general principle of law recognized by nations, and that a risk management frame that heavily relies on the precaution notion is not an appropriate approach for managing risks. Accordingly, the precautionary principle supported by EU law cannot provide sufficient legal justification for a mandatory labeling regime.

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[72] Lisa F. Clark, "Framing the Uncertainty of Risk: Models of Governance for Genetically Modified Foods" (2013) 40:4 Science and Public Policy 479.

[73] Marjolein B. A. van Asselt & Ellen Vos, "EU Risk Regulation and the Uncertainty Challenge" in Sabine Roeser et al., *Handbook of Risk Theory Epistemology, Decision Theory, Ethics, and Social Implications of Risk* (Germany, Berlin: Springer, 2012) at 1122.

1. The precautionary principle and its role in GMO legislation

1.1 Background and concept

The precaution stance is regarded as a strategy for managing risk.[74] It is primarily used in policies and law related to environmental protection when scientific uncertainties exist, and functions to avert, where applicable, irreversible environmental hazards.[75] Originally, the formal concept of precaution was considered to have evolved out of a German socio-legal tradition in the 1930s.[76] Later in the early 1970s, Germany initiated the development of an air pollution control concept known as *Vorsorgeprinzip*, which translates into English as "precaution principle."[77] So far, a popular and comprehensive definition of the precautionary principle was formulated in a January 1998 meeting at Wingspread, headquarters of the Johnson Foundation in Racine, Wisconsin.[78] The Wingspread Statement on the Precautionary Principle summarizes the principle as:

> When an activity raises threats of harm to the environment or human health, *precautionary measures* should be taken even if some cause and effect relationships are not fully established scientifically.
> In this context the proponent of the activity, rather than the public, should bear the burden of proof.[79]

According to the private sector Johnson Foundation's definition of the precautionary measure, key elements include:

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[74] James Crawford, *Brownlie's Principles of Public International Law*, 8ed (UK, Oxford: Oxford University Press, 2012) at 357.
[75] Edward Elgar, *Finding Solution for Environmental Conflicts Power and Negotiation* (UK, Cheltenham: Edward Elgar Publishing Limited, 2008) at 182-183
[76] John Barry, *Rethinking Green Politics: Nature, Virtue and Progress* (UK, London: SAGE Publication Ltd, 1999) at 137.
[77] Scott LaFranchi, "Surveying the Precautionary Principle's Ongoing Global Development: The Evolution of an Emergent Environmental Management Tool" (2005) 32 B.C. Envtl Aff L Rev 679.
[78] See The Science and Environmental Health Network, *The Precautionary Principle A common Sense Way to Protect Public Health and the Environment*, online: Mindfully.org <http://www.mindfully.org/Precaution/Precautionary-Principle- Common-Sense.htm>; Also see, I. M. Goklany, "Precaution Without Perversity: A Comprehensive Application of the Precautionary Principle to Genetically Modified Crops" (2001) 20 Biotech L Report 377.
[79] N. J. Myers & C. Raffensperger, *Precautionary Tools for Reshaping Environmental Policy* (Cambridge, Mass.: MIT Press, 2006) at 94 (emphasis added).

1) Taking precaution in the face of scientific uncertainty;

2) Exploring alternatives to possibly harmful actions; and

3) Placing the burden of proof on proponents of an activity rather than on victims or potential victims of the activity.[80]

1.2 The role of the precautionary principle in GMO Management.

In the context of GMO management as discussed in Chapter Four, the EU and many EU member states have made the precautionary principle an important rule in approving GMO safety during the authorization process.[81] The EU enacted *Directive 2001/18 on Deliberate Release* in an effort to establish a comprehensive GMO approval process based on the precautionary principle that would do the utmost to protect human health and the environment.[82] According to *Directive 2001/18*, each GMO applicant has to make an environmental assessment based on the precautionary principle before submitting a notice of intent to deliberately release a GMO or place it on the EU market.[83] This assessment requires an evaluation of risks, whether direct or indirect, immediate or delayed, the deliberate release or placing on the market of the GMO may pose to human health and the environment.[84] However, the result of applying this precautionary principle oriented stringent approval process is a series of delays for approving GM varieties for cultivation and marketing.[85] Moreover, the EU implemented a very strict mandatory labeling and traceability system along with the food supply chain based on the application of the precautionary

[80] See the Science and Environmental Health Network, *supra* note 83.
[81] Jale Tosun, "How the EU handles Uncertain Risk: Understanding the Role of the Precautionary Principle" (2013) 20:10 Journal of European Public Policy 1517.
[82] See Art. 1 and Annex II of *Directive 2001/18/EC* of the European Parliament and of the Council on the Deliberate Release into the Environment of Genetically Modified Organisms and Repealing Council Directive 90/220/EEC (Directive 2001/18/EC), EC, *Directive 2001/18 of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC*, [2001] O.J. L106/1.
[83] Art. 6 of *Directive 2001/18/EC*, *ibid.*
[84] Art. 2 (8) and Art. 16 of *Directive 2001/18/EC*, *ibid.*
[85] Davison, *supra* note 31.

principle. The application of the precautionary principle in GMO management has been criticized for being non-scientific evidence oriented and ignoring the WTO rules with no supporting evidence.[86]

2. Legal status of the precautionary principle under international law

The legal status of the precautionary principle/approach is still under debate. Whether the precautionary approach has formed as a customary international law principle or a general principle of law remains unresolved. Therefore, the following sections will analyze the current status of the precautionary notion in international law, evaluating whether it has evolved into a new rule of customary international law or a general principle of law recognized by nations.

2.1 Whether the precautionary principle has been recognized as a customary international law?

Article 38 (1)(b) of Statute of the International Court of Justice (ICJ) defines customary international law as "evidence of general practice accepted as law."[87] The ICJ statements in the *North Sea Continental Shelf* case[88] clarify two distinct requirements of customary international law: 1) the rule must be followed by states in an extensive and virtually uniform manner (state practice) and 2) it must be accepted as a matter of law by those states (*opinio juris*).[89] With regard to the state practice, the decision of the ICJ in the *Anglo-Norwegian Fisheries* case requires "substantial uniformity", emphasizing the importance of consistency of state practice.[90] To

[86] Alan Raybould & Guy M. Poppy, "Commercializing Genetically Modified Crops Under EU Regulations: Objectives and Barriers" (2012) 3:1 GM Crops and Food: Biotechnology in Agriculture and the Food Chain 9.
[87] Art. 38 of *Statute of the International Court of Justice*, the customary international law is defined as the general practice of states accepted as law, *Statute of the International Court of Justice*, 3 Bevans 1179; 59 Stat. 1031; T.S. 993; 39 AJIL Supp. 215 (1945).
[88] *Case North Sea Continental Shelf (Federal Republic of Germany/Netherlands)*, ICJ Judgment of 20 February 1969.
[89] *Ibid*, paragraphs 43-44.
[90] *Anglo-Norwegian Fisheries Case (United Kingdom v. Norway)*, ICJ Judgment of 18 January 1951.

examine the precautionary principle under these two components, state domestic law, international instruments, the international court/tribunal decisions, the writings of publicists etc. all have to be taken into account to evaluate whether a customary norm has yet formed.

2.1.1 References to precautionary principle/approach in domestic law and international environmental practice

The precautionary notion is used in some domestic environmental law and policy of European countries, such as Germany, Norway, and France.[91] For example, Article 5(2) of the German *Federal Emission Control Act (Bundes-Immisionsschutzgesetz)* states that: "precautions are taken to prevent harmful effects on the environment, in particular by such emission control measures as are appropriate according to the state of the art."[92] In 2008, the Norwegian Ministry of Finance published a White Paper entitled "Norway's Strategy for Sustainable Development."[93] It claimed that Norway's environmental policy is based on the precautionary principle, which requires that "if there is uncertainty about the outcome, environmental considerations must be given priority."[94] In France, the precautionary principle was added to the "Environment Charter" of the French Constitution, and the precautionary principle is treated as a constitutional principle in French domestic law.[95]

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[91] Nicolas de Sadeleer ed, *Implementing the Precuationary Principle: Approaches from the Nordic Countries, the EU and USA* (UK: Cromwell Press, 2007) at 29, 229, 320,

[92] Art. 5(2) of *Federal Emission Control Act (Bundes-Immisionsschutzgesetz)*, Vom 15. Maerz 1974 (BGBl I S. 721, 1193).

[93] Norwegian Ministry of Finance, Norway's Strategy for Sustainable Development, online: <http://www.regjeringen.no/upload/FIN/rapporter/R-0617E.pdf>.

[94] *Ibid* at 16.

[95] Art. 5 of *Charte de I'environnement de 2004*: "Lorsque la réalisation d'un dommage, bien qu'incertaine en l'état des connaissances scientifiques, pourrait affecter de manière grave et irréversible l'environnement, les autorités publiques veillent, par application du principe de précaution et dans leurs domaines d'attributions, à la mise en oeuvre de procédures d'évaluation des risques et à l'adoption de mesures provisoires et proportionnées afin de parer à la réalisation du dommage." Charte de I'environnement de 2004, online: Legifrance <http://www.legifrance.gouv.fr/Droit-francais/Constitution/Charte-de-l-environnement-de-2004>. See also "Precaution Versus Principles" (2004) 429 Nature 585; Gabriel Calzada, Cécile Philippe & Xavier Mera, "The Precautionary Principle: A High-Risk Principle" (2005) 25:3 Economic Affairs 60.

The precautionary notion is also found in domestic law and policy of countries outside the EU jurisdictions. For example, in Canada, the precautionary principle has been incorporated into a variety of provincial law and federal laws relevant for environmental protection. For example, the Preamble of the *Canadian Environmental Protection Act*[96] states that:

> the Government of Canada is committed to implementing the *precautionary principle* that, 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.[97]

Similar statements of the precautionary notion can also found in the Preambles of the Canadian *Oceans Act*[98] and *Species at Risk Acts*.[99] In Australia, the 1992 National Strategy for Ecologically Sustainable Development includes the precautionary notion as one of the guiding principles.[100]

At the regional level, the precautionary principle has been introduced as a basis of EU environmental policies.[101] Article 191(2) of the Treaty on the Functioning of the European Union states that:

> Union policy on the environment ... shall be based on the *precautionary principle* and on the principles that preventive action should be taken, that environmental damages should as a priority be rectified at source and that the polluter should pay.[102]

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[96] *Canadian Environmental Protection Act*, 1999, S.C. 1999, c.33.
[97] *Ibid*, Preamble.
[98] Preamble of *Oceans Act* acknowledges that: "Canada promotes the wide application of the precautionary approach to the conservation, management and exploitation of marine resources in order to protect these resources and preserve the marine environment." *Oceans Act*, S.C. 1996, c. 31.
[99] Preamble of *Species at Risk Act* recognizes that: "the Government of Canada is committed to conserving biological diversity and to the principle that, if there are threats of serious or irreversible damage to a wildlife species, cost-effective measures to prevent the reduction or loss of the species should not be postponed for a lack of full scientific certainty." *Species at Risk Act*, S.C. 2002, c. 29.
[100] Part 1 of National Strategy for Ecologically Sustainable Development states: "where there are threats of serious or irreversible environmental damage, lack of full scientific certainty should not be used as a reason for postponing measures to prevent environmental degradation". The Council of Australian Governments, National Strategy for Ecologically Sustainable Development, online: Australian Government <http://www.environment.gov.au/node/13029#Principles>.
[101] See Ulrich Beyerlin & Thilo Marauhn, *International Environmental Law* (UK, Oxford: Hart Publishing Ltd, 2011) at 48.
[102] European Union, *Consolidated version of the Treaty on the Functioning of the European Union*, [2007] 26.10.2012, O.J. C326/47.

At the international level, the precautionary stance has been enshrined in many international environment instruments. It was set forth in Principle 15 of the non-binding *Rio Declaration on Environment and Development* (Rio Declaration) in 1992.[103] It reads as follows:

> 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.[104]

The Convention on Biological Diversity (CBD) includes the precaution notion in the Preamble, that "where there is a threat of significant reduction or loss of biological diversity, lack of full scientific certainty *should* not be used a reason for postponing measure to avoid or minimize such a threat."[105] The Preamble of the Cartagena Protocol on Biosafety reaffirms the "precautionary approach" claimed in the Rio Declaration without, however, providing a precise formulation of the approach.[106] The precaution notion is recognized by the *1992 United Nations Framework Convention on Climate Change* as one of its guiding principles by stating that:

> The Parties *should* take *precautionary measures* to anticipate, prevent or minimize the causes of climate change and mitigate its adverse effects. Where there are threats of serious or irreversible damage, lack of full scientific certainty *should* not be used as a reason for postponing such measures, taking into account that policies and measures to deal with climate change should be cost-effective so as to ensure global benefits at the lowest possible cost. To achieve this, such policies and measures *should* take into account different socio-economic contexts, be comprehensive,

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[103] The 1992 *United Nations Conference on Environment and Development (UNCED) Rio de Janeiro* is a set of 27 legally non-binding principles designed to commit governments to ensure environmental protection and responsible development and intended to be an Environmental Bill of Rights, defining the rights of people to development, and their responsibilities to safeguard the common environment, see *UN Conference on Environment and Development (1992)*, online Earth Summit :<http://www.un.org/geninfo/bp/enviro.html >; See *United Nations Conference on Environment and Development (UNCED), Rio de Janeiro*, 3-14 June 1992, 31 ILM 874 (1992).

[104] *Ibid*, Principle 15 (emphasis added).

[105] Preamble of the *Convention on Biological Diversity*, *Convention on Biological Diversity (CBD)*, 5 June 1992, 1760 UNTS. 79, 31 ILM 818, online: <http://www.cbd.int/>.

[106] Preamble of the *Cartagena Protocol on Biosafety*, *The Cartagena Protocol on Biosafety*, 29 January 2000, 2226 UNTS 208, 39 ILM 1027, online: <http:// bch.cbd.int/protocol/>.

> cover all relevant sources, sinks and reservoirs of greenhouse gases and adaptation, and comprise all economic sectors. Efforts to address climate change may be carried out cooperatively by interested Parties.[107]

As explored above, the precautionary notion has been addressed in domestic law and international multilateral agreements related to environmental protection. However, precaution, a frequently used "term" is still a fairly new concept in environmental policy and law.[108] So far, a clear and uniform legal definition of the precautionary approach or principle has not been reached.[109] The precautionary notion has been mainly used in legal instruments on the environment and, in most cases, it is addressed in the preamble of a domestic act or a treaty as the "precautionary approach/measure" and not the "precautionary principle."[110] It is worth noting that: (1) a preamble has little legal force in a treaty and also most of the preambles consider that the precautionary approach "should" apply, as opposed to "shall" to situations where the scientific uncertainty occurs; (2) domestic acts and treaties that have adopted the expression of the "precautionary principle" are less common than acts and treaties that have used the "precautionary approach" or "precautionary measure;"[111] and (3) the "precautionary principle" has been used in domestic acts and regional legislation, i.e., the EU GMO legislations rather than international instruments.[112] The result of all these concerns leads to a conclusion that both

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[107] Art. 3.3 of *1992 United Nations Framework Convention on Climate Change*, *1992 United Nations Framework Convention on Climate Change* 09 May 1992, 1771 UNTS 107, 31 ILM 849 (emphasis added).

[108] Søren Løkke & Per Christensen, "The Introduction of the Precautionary Principle in Danish Environmental Policy: The Case of Plant Growth Retardants" (2008) 21:3 Journal of Agricultural and Environmental Ethics 229.

[109] Phillippe Sands, *Principles of International Environmental Law*, 3rd ed (UK, Cambridge: Cambridge University Press, 2012) at 218.

[110] For example, Preamble of the Convention on Biological Diversity and Preamble of the Cartagena Protocol on Biosafety, *supra* notes 105, 106.

[111] "In the negotiations of international declarations, the United States has opposed the use of the term 'principle'. It considers the precaution as an approach but not a principle, because the 'principle' has special connotations in legal language. Due to the fact that a 'principle of law' is a source of law, it means that it is compulsory, so a court can quash or confirm a decision through the application of the precautionary principle. In this sense, the precautionary principle is not a simple idea or a desideratum but a source of law. This is the legal status of the precautionary principle in the European Union. On the other hand, an 'approach' usually does not have the same meaning. A precautionary approach is a particular 'lens' used to identify risk that every prudent person possesses." See Miguel A. Recuerda, "Dangerous Interpretations of the Precautionary Principle and the Foundational Values of European Union Food Law: Risk Versus Risk" (2008) 4 J Food L & Pol'y 1.

[112] The "precautionary principle" has been consistently used in EU GMO regulations. For example, Art. 7 of Regulation (EC) No

domestic law and international instruments have acknowledged the fundamental value of the precautionary approach in the development of environmental law, but the precautionary notion has not been applied in a virtual or consistent manner by states.

2.1.2 Decisions of international courts and tribunals

In the 1995 ICJ case concerning *Nuclear Test*,[113] the dissenting opinions of Judge Weeramantry and Judge *ad hoc* Palmer canvassed the precautionary notion, considering the precautionary principle to be an *emerging* customary norm.[114] In the 2006 *Pulp Mills on the River Uruguay (Argentina v. Uruguay)* case brought before the ICJ, the precautionary principle question was raised in the context of assessing the scientific evidence and the burden of proof.[115] Argentina contended that the precautionary principle should be applied to reverse the burden of proof.[116] The Court mentioned the precautionary approach only once in the final judgment by stating that: "while a *precautionary approach* may be relevant in the interpretation and application of the provisions of the Statute [a bilateral treaty between Argentina and Uruguay], it does not follow that it operates as a reversal of the burden of proof."[117] However, the Court used "precautionary approach" to refer to the "precautionary principle" claimed by both parties. Moreover, the Court took a position that the precautionary approach "may be", rather than "is", relevant in the

178/2002 specifically addresses when the "precautionary principle" should be applied. See EC, *Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety*, [2002] O.J. L031. The "precautionary principle" is also adopted in Regulation (EC) No 1829/2003 and Regulation (EC) No 1830/2003. See EC, *Regulation No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labeling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (Regulation (EC) No 1830/2003)*, [2003] O.J. L268/24, and EC, *Regulation 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, O. J. Legislation (2003) No L268*/1, [2003] O.J. L268/1.

[113] *Request for an Examination of the Situation in Accordance with Paragraph 63 of the Court's Judgment of 20 Decemeber 1974 in the Nuclear Tests (New Zealand v France) case*, ICJ Order of 22 September 1995.

[114] See Christopher Weeramantry, *Dissenting Opinion of Judge Weeramantry*, online: <www.**icj**-cij.org/docket/files/97/7567.pdf> (emphasis added); *Geoffrey Palmer, Dissenting* Opinion of Judge Sir Geoffrey Palmer, online: <www.icj-cij.org/docket/files/97/7571.pdf>; see also Beyerlin & Marauhn, *supra* note 101 at 51.

[115] *Case Concerning Pulp Mills on the River Uruguay (Argentina v. Uruguay)*, ICJ Judgment of 20 April 2010.

[116] *Ibid*, paragraph 55.

[117] *Ibid*, paragraph165.

interpretation of the treaty. Furthermore, the Court placed much more importance on what the precautionary approach cannot do, i.e., "operates as a reversal of the burden of proof."[118] Therefore, the ICJ did not address whether the precautionary principle is a binding principle of customary international law.

A more explicit reference of the precautionary principle can be found in the recent decision of the International Tribunal for the Law of the Sea (ITLOS) in the 2010 *Responsibilities and Obligations of States Sponsoring Persons and Entities with Respect to Activities in the Area*.[119] In this Advisory Opinion, the ITLOS Seabed Disputes Chamber noted that regulation 31, paragraph 2 of the *Regulations on Prospecting and Exploration for Polymetallic Nodules in the Area* of 2000 (Nodules Regulation), and regulation 33, paragraph 2 of *Regulations on Prospecting and Exploration for Polymetallic Sulphides in the Area* of 2010 (Sulphides Regulation) state that sponsoring States (as well as the Authority) "shall apply a precautionary approach, as reflected in Principle 15 of the Rio Declaration" in order "to ensure effective protection of the marine environment from harmful effects which may arise from activities in the Area."[120] The Chamber pointed out that the non-binding precautionary approach in the Rio Declaration had been transformed by the Nodules Regulation and Sulphides Regulation into a binding obligation pursuant to a treaty commitment, and that the precautionary approach is "an integral part of the general obligation of due diligence of sponsoring States, which is applicable even outside the scope of the Regulations." The Chamber recognized that there was a "*trend* towards making this

[118] Cançado Trindade, *Separate Opinion of Judge Cançado Trindade*, online: <http://www.icjcij.org/docket/files/135/15885.pdf >; Dire Tladi, *Principles of Sustainable Development in the Case Concerning Pulp Mills on the River Uruguay*, online: <http://www.idlo.int/Documents/Rio/01.%20Pulp%20Mills%20on%20the%20River%20Uruguay.pdf>.

[119] *Responsibilities and Obligations of States Sponsoring Persons and Entities with Respect to Activities in the Area*, ITLOS case 17, ITLOS Advisory Opinion of 1 February 2011.

[120] *Ibid*, paragraph 130.

approach part of customary international law, "[121] which means the Chamber did not hold that the precautionary approach was a formed, binding customary norm.

In the context of bio-agricultural product international trade, the precautionary principle has been raised as a defense to trade restrictive measures in a number of WTO cases, particularly in *European Communities – Measures Concerning Meat and Meat Products (Hormones)* (*EC – Meat Hormones*) and *European Communities – Measures Affecting the Approval and Marketing of Biotech Products* (*EC – Biotech*).[122] In the *EC – Meat Hormones* case (1998), the EU argued that its ban on the importation of hormone-fed beef produced in the US and Canada could be justified by non-WTO rules of international law, i.e., the precautionary principle regulated in the CBD and Cartagena Biosafety Protocol.[123] The EU also argued that the precautionary principle was already a principle of customary international law binding on all countries.[124] The US and Canada vigorously opposed these arguments. They refuted the use of "precautionary principle" and denied the principle represented a principle of customary international law.[125] Both the Panel and the AB avoided making any explicit statements on the normativity of the precautionary principle. The AB stated:

> The status of the precautionary principle in international law continues to be the subject of debate among academics, law practitioners, regulators and judges. The precautionary principle is regarded by some as having

[121] *Ibid*, paragraph 135 (emphasis added). See also Tim Stephen, "Climate Change adaptation and Marine and Coastal Law" in Jonathan Verschuuren ed, *Research Handbook on Climate Change Adaptation Law* (UK, Cheltenham: Edward Elgar Publishing Limited, 2013) at 417.

[122] Report of the Appellate Body, *European Communities – EC Measures Concerning Meat and Meat Products (Hormones) (EC – Meat Hormones)*, (1998) WT/DS26/AB/R, WT/DS48/AB/R; Report of the Panel, *European Communities – Measures Affecting the Approval and Marketing of Biotech Products (EC – Biotech)*, (2006) WT/DS291/R, WT/DS292/R, WT/DS293/R; also see G. C. Shaffer, M. A. Pollack, "Hard Vs. Soft Law: Alternatives, Complements, and Antagonists in International Governance" (2010) 94 Minn. L. Rev. 706.

[123] Report of the Appellate Body, *EC – Meat Hormones*, *ibid*, paragraph 16; Report of the Panel, *EC – Biotech*, *ibid*, paragraph 7.45

[124] *Ibid*.

[125] Report of the Appellate Body, *EC – Meat Hormones*, *ibid* at paragraphs 40, 43; Report of the Panel, *(EC – Biotech)*, *ibid*, paragraph 7.80.

> crystallized into a general principle of customary international environmental law. Whether it has been widely accepted by Members as a principle of general or customary international law appears less than clear. We consider, however, that it is unnecessary, and probably imprudent, for the Appellate Body in this appeal to take a position on this important, but abstract, question. We note that the Panel itself did not make any definitive finding with regard to the status of the precautionary principle in international law *and that the precautionary principle, at least outside the field of international environmental law, still awaits authoritative formulation*.[126]

In *EC – Biotech* (2006), the WTO Panel rejected the argument that a treaty that was not binding on all parties to the dispute should be dispositive. Since the US was not a party to the Cartagena Biosafety Protocol, the precautionary principle as expressed in that agreement could not be used to interpret WTO rules in these disputes.[127] However, the Panel did not provide an analysis on the legal status of the precautionary principle. Rather, it stated that the: "legal status of the precautionary principle remains unsettled ... and if it is not necessary to do so ... we need not take a position on whether or not the precautionary principle is a recognized principle of general or customary international law."[128]

2.1.3 Opinions of publicists

In addition, publicists have not reached consensus on whether the precautionary principle has formed as a customary norm. Sands argues that, although the ICJ and a WTO Panel have declined to recognize that the principle has a customary international law status, there is sufficient evidence of state practice to justify the argument that the precautionary approach, as elaborated in the Rio Declaration, the Climate Change Convention regime and the CBD, has

[126] Report of the Appellate Body, *EC – Meat Hormones*, *ibid*, paragraph 123 (emphasis added).
[127] Report of the Panel, *EC – Biotech*, *supra* note 123, paragraph 7.68
[128] *Ibid* paragraph 7.89.

received sufficient broad support so that it reflects a principle of customary law.[129] However, based on the argument that the precautionary approach has not gained a uniform definition and its application is inconsistent in state and international practice, Birnie, Boyle and Redgwell disagree that the precautionary approach can be recognized as a formed customary norm.[130]

As discussed above, the precautionary notion is much used as the precautionary approach/principle in domestic law and international instruments relevant to environmental protection. However, its concept is still undefined, and no legal instruments have stipulated the concrete conditions and workable steps for practical applications of precautionary action. All these concerns leave the precautionary approach/principle being debated in the literature. In particular, the ICJ and the WTO Panel/AB were reluctant to apply the precautionary notion as a legal principle for interpreting treaties and settling disputes, and they refused to acknowledge that the precautionary principle has a customary international law status.[131] Opinions of publicists remain controversial regarding the legal status of the precautionary approach. Thus, currently, the precautionary approach has not formed into a binding customary international law principle.

2.2 Whether the precautionary principle has been accepted as a general principle of law?

According to Article 38 (1)(c) of the ICJ Statute, the precautionary principle can be considered to be a general principle of law if it is "recognized by civilized nations".[132] As explored in the above section, the recognition of the precautionary principle has been expressed in EU laws and EU

[129] Sands, *supra* note 109 at 228.

[130] Patricia Birnie, Alan Boyle & Catherine Redgwell, *International Law & the Environment*, 3rd ed (New York: Oxford University Press Inc., 2009) at 161-162.

[131] In the *whaling in the Antarctic (Australia v. Japan: New Zealand Intervening)* (2014) case, the ICJ did not use the precautionary approach, which was proclaimed by Australia and New Zealand, to interpret the provision in dispute. See Whaling in the Antarctic (Australia v. Japan: New Zealand Intervening), ICJ Judgment of 31 March 2014; see also Cançado Trindade, *Separate Opinion of Judge Cançado Trindade*, online: ICJ <http://www.icj-cij.org/docket/files/148/18146.pdf> paragraph 60. Beyerlin & Marauhn, *supra* note 101 at 52.

[132] Art. 38(1)(c) of the *Statute of the International Court of Justice*, *supra* note 87.

member state laws concerning the environmental protection and food safety issues.[133] However, the precautionary principle is still not formed in a single and agreed formulation, and it has not been consistently and generally used in domestic legal systems and state practice. The US, in the WTO *EC – Biotech* case, has strongly argued that the precautionary principle cannot be recognized as a general norm of international law as claimed by the EU.[134] Also in the WTO *EC – Hormones* case, Canada just states that the precautionary principle is an emerging principle of law and does not recognize it as a principle of public international law.[135] Although, in the *Pulp Mills* ICJ case, Judge Trindade in his separate opinion argues that the precautionary principle is a general principle of international law, it is only his individual view.[136] The ICJ as a tribunal as well as the WTO Panels and AB have never made any statements on whether the precautionary principle has formed into a general principle of law. Accordingly, the precautionary principle cannot be acknowledged as a general principle of law.

The above analysis indicates that the legal status of the precautionary principle/approach continues to evolve. It is not yet a binding customary international law norm in the international environmental law and international food safety law areas. Also, it has not been accepted as a general principle of law. Even if the precautionary approach may have gained recognition as a principle of environmental protection law, its application in other areas such as food security and safety is far from universally accepted.[137] In terms of this conclusion, the EU's mandatory

[133] Miguel A. Recuerda, "Dangerous Interpretations of the Precautionary Principle and the foundational Value of European Union Food Law: Risk versus Risk" (2008) 4 J Food L & Pol'y 1.
[134] Report of the Panel, *EC – Biotech*, *supra* note 123, paragraphs 4.540-4.541.
[135] Report of the Appellate Body, *EC – Meat Hormones*, *supra* note 123, paragraph 122
[136] Cançado Trindade, *supra* note 131.
[137] Judge Charlesworth pointed out in the separate opinion of the judgment of *Whaling in the Antarctic* case that the precautionary principle was used in instruments that deal with a wide range of issues, but these subject matters were still limited to the areas of the conservation and management of environmental resources. See Charlesworth, *Separate Opinion of Judge ad hoc Charlesworth*, online: ICJ <http://www.icj-cij.org/docket/files/148/18158.pdf>.

labeling requirement based on the precautionary principle is unlikely to be supported by the WTO system.

3. Critiques of the application of the precautionary principle in GMO management

Except for the non-uniform definitions and clear application of the precautionary principle/approach as explored above, some of the critics focusing on the concept of the precautionary principle/approach per se, argue that expressions of the precautionary principle as stated in relevant legal instruments cannot withstand scrutiny. As Per Sandin explains:

> there are always some cause-and-effect relationships that are not fully established scientifically. And every action might raise threats to human health and the environment, if possibilities that are remote enough are taken into consideration. If the precautionary principle is understood as prohibiting those courses of action that might lead to harm, then the precautionary principle will prohibit every action, including the action of taking precautionary measures, since any action, in a sense, might have unforeseen harmful consequences.[138]

In addition to the problematic definition of the precautionary principle, other questions commonly asked are: on what criteria can a technique or technology be considered threatening, and who makes that decision?[139] In terms of criteria, there always exist contradictions between scientific studies on safety assessments of a new technology, and the uncertainty that is an unavoidable part of risk assessment and management. Hence, if risk management is based on the precautionary principle rather than oriented around scientific evidence, the determination of a threshold for the criteria could be very subjective: it can be very high, i.e. causing serious or irreversible harm, or lower, i.e. causing some harm to human and animal health as well as the

[138] Tim Lewens, *Risk Philosophical Perspectives* (London and New York: Routledge, 2007) at 101.
[139] Alan Randal, "Innovation, Risk, Precaution, and the Regulation of GM Crops" in Colin A. Carter, GianCarlo Moschini & Ian Sheldon ed, *Genetically Modified Food and Global Welfare* (UK: Emerald Group Publishing Limited, 2011) at 340.

environment. Accordingly, in the case of GM agricultural techniques, as explored in the previous section, controversy associated with the safety assessment of GMOs continues within the scientific research field. Even though the scientific studies that prove GMOs exhibit no special risk are generally considered to have more validity than those studies that warn against GMOs, GM techniques have nonetheless been perceived as a threatening technology in some jurisdictions.[140] As a result, some policy-making scenarios have been influenced by an emphasis on public input and the advocacy of political and environmental groups instead of scientific evidence. The example in Chapter Four that the EU member countries banned cultivation of several GM varieties shows that the approval decisions are not made based on scientific evidence but on other social factors.

As well, in the context of risk assessment, studies have shown that humans are not particularly adept in understanding risk assessments.[141] Studies have identified many different features of how individuals assess risk and their levels of acceptance of these risks.[142] For example, most people pay more attention to qualitative aspects of risks, perceiving them as either acceptable or unacceptable, and hence fail to understand or appreciate the probabilities of risk. They tend to focus too much attention on potential consequences of risks and overestimate the possibilities of extremely improbable ones.[143] The Table below shows more examples of differences in risk perception. It indicates differences between experts and the lay public in ranking risk perception.

[140] Eurobarometer's 2010 survey indicated that on average fifty-four percent of Europeans considered that GM food is not good for themselves and their family. Eighty percent of respondents in Latvia and seventy-eight percent in Greece agreed that GM food is not good. See Special Eurobarometer, *Biotechnology Report*, online: <http://ec.europa.eu/public_opinion/archives/ebs/ebs_341_en.pdf > at 20.

[141] Lynn J. Frewer, "Risk Perception, Communication and Food Safety", in Hami Alpas, Madeleine Smith & Asylbek Kulmyrzaev ed., *Strategies for Achieving Food Security in Central Asia*, (Dordrecht: Springer, 2012) at123.

[142] Sean Caulfield & Timothy Caulfield, *Imagining Science Art, Science and Social Change* (Edmonton: The University of Alberta Press, 2008) at 3-4.

[143] *Ibid.*

Table 1: Differences between experts and the lay public in ranking in risk perception[144]

Activity	Expert rank	Lay rank
Motor vehicles	1	2
Smoking	2	4
Alcoholic beverages	3	6
Surgery	5	10
Motorcycles	6	5
X-rays	7	22
Non-nuclear electric power	9	18
Nuclear power	20	1

Similar to these differences in risk perceptions, no matter the big benefits and high level of bio-safety represented by GMOs, when asked about their attitude towards GMOs, consumers still express distrust of and hesitation to consume GM foods. According to a survey on cognition of GM food safety among residents of Shenzhen City in China, the majority of people surveyed still feel that GM foods are of high risk. Most respondents (83.33%) do not support GM foods, and, in relation to consumption, consider the safety of GM food (50.93%) to be the most important concern. European citizens have also repeatedly expressed their opposition to GMOs.[145] Official polls indicated that an average of nearly 60% of European consumers oppose GMOs while only around 20% support them. In Slovenia, Cyprus, Greece, Scandinavia, Germany, France, Latvia and Hungary 70-80% of people are reported as being against GMOs. The consumers' rejection of GMOs has resulted in very few, or even no, GMO products being sold on European supermarket shelves.[146]

[144] R. Wennig, "Threshold Values in Toxicology – Useful or not?" (2000), 1131-3 Forensic Science International 323.

[145] "The percentage of awareness and acceptance to GM food were 36.3% and 16.67% respectively, only 2.68% of the respondents known well GM food. 50.6%of the respondents considered GM food is not related with their lives. 66.29% of the respondents wished to get more information about the health and safety of GM food, and GM food safety was considered the most important information (50.93%)." See Yang Yongcun et al., "Investigation on Cognition and Demand for Food Health and Safety Knowledge about Genetically Modified Food among Residents of Shenzhen City" (2007) 23 Chin J Public Health 488.

[146] Eurobarometer 295, *Report: Attitudes of European Citizens towards the Environment*, online: European Commission <http://ec.europa.eu/public_opinion/archives/ebs/ebs_295_en.pdf> at 64-66.

4. Risk perception and the precautionary principle

In terms of scientific risk assessment, risk is understood as standard risk assessment procedure that reports the probability of a harm occurring as a result of a human activity, technology, or a natural process.[147] However, the above section has shown that consumers do not assess risks in this way. Psychological studies have found that, because of how individuals perceive risk, he or she frequently fails to make an objective judgment about the nature, likelihood and magnitude of risks.[148] Humans are prone to use personal preference for likelihood to judge risk. The biases in their perceptions of likelihood result in their limited ability to assess risk in an objective manner.[149] Sunstein explored a number of theories to explain why individual tends to subjectively assess risks.[150] He found that many of the reasons are rooted in human behavior. For instance, ordinary people are likely to:

> 1) make some risks seem especially likely to come to fruition whether or not they actually are; (availability heuristic); (2) concentrate people's attention on worst case scenarios, even if it is highly improbable (probability neglect); (3) make man-made decisions and processes seem especially suspect (a belief in the benevolence of nature); (4) unable to see that risks are part of systems, and that interventions into those system can create risks of their own (system neglect); (5) judging risks on the basis of emotional responses (affect heuristic); (6) move to extreme views when engaging in group discussions (group polarization).[151]

[147] Jennie S. Popp et al., *The Role of Biotechnology in A Sustainable Food Supply* (New York: Cambridge University Press, 2012) at 148.
[148] Jermoe S. Legge Jr & Robert F. Durant, "Public Opinion, Risk Assessment, and Biotechnology: Lessons from Attitude toward Genetically Modified Foods in the European Union" (2010) 27:1 Review of Policy Research 59.
[149] Ortwin Renn, "Three Decades of Risk Research: Accomplishments and New Challenges" (1998) 1:1 Journal of Risk Research 49.
[150] See Cass R. Sunstein, *Risk and Reason: Safety, Law, and the Environment* (Cambridge: Cambridge University Press, 2002) at 35.
[151] *Ibid* at 99-103.

Pursuant to Sunstein's theories, when taking the increasing involvement of public input in policy-making as a symbol of democratic progress, public policy-makers and risk managers should be aware of the public's understanding of risk assessment. Renn summarized four semantic images that govern ordinary people's perception, outlined in the Table below. According to Renn, the public's risk perception in the "slow killers" category was formed not based on people's personal experience or knowledge but on information from others. He further insisted that: "[t]hese risks pose a major demand for trustworthiness in those institutions that provide information and manage the hazard."[152]

Table 2: The four semantic images of risk in public perception[153]

1. Pending danger
• artificial risk source
• large catastrophic potential
• inequitable risk-benefit distribution
• perception of randomness as a threat
2. Slow Killers
• (artificial) ingredient in food, water, or air
• delayed effects; non-catastrophic
• contingent on information rather than experience
• quest for deterministic risk management
• strong incentive for blame
3. Cost-benefit ratio
• confined to monetary gains and losses
• orientation towards variance of distribution rather than expected value
• asymmetry between risks and gains
• dominance of probabilistic thinking
4. A vocational thrill
• personal control over degree of risk
• personal skills necessary to master danger
• voluntary activity
• non-catastrophic consequences

[152] Renn, *supra* note 149.
[153] *Ibid.*

In the context of GMOs, people's risk perception regarding bio-agriculture is that GMO foods are "slow killers" as described in the section 2 of the Table above. Therefore, providing the public with accountable and adequate information is helpful for enabling people to assess risks of GMOs in a more objective and rational way. However, if the precautionary principle is blindly applied to the management of GMOs, ill-advised approaches will be implemented since the application of the precautionary principle cannot provide much more accountable information. Rather, it just highlights the precaution with respect to the use of GM techniques without telling us the "right" amount of precaution or what a reasonable cost for the precaution might be.[154]

One example is Australia's precautionary-based Weed Risk Assessment (WRA) measures in 1997 as regulatory means to reduce the flow of new weeds inside its boundaries.[155] Under the WRA, some new plants were banned because of the perceived possibility that they might become weeds.[156] During 2002-2003, 320 plant species were refused entry into Australia.[157] No one doubted the effect that the WRA had kept out weeds, including agricultural and environmental weeds. But studies indicated that these benefits might not be large in most situations, particularly since there had already been many weeds blighting farms and forests, and extra species might not significantly increase costs or harms.[158] As Cheryl Gordon pointed out, "[A] precautionary approach to plant introductions ensures the prevention of irreversible harm, but promotes the likelihood that species which offer substantial benefits to society will be denied import

[154] See Lea B. Vaughn, "A Few Inconvenient Truths about Michael Crichton's State of Fear: Lawyers, Causes and Science" (2010) 20 Seton Hall J Sports & Ent L 49; also see Sunstein, *supra* note 150 at 26.
[155] *Development of the Weed Risk Assessment System*, online: Australian Government Department of Agriculture <http://www.daff.gov.au/ba/reviews/weeds/development>.
[156] *Ibid*; Rosie Cooney & Barney Dickson, *Biodiversity and the Precautionary Principle: Risk and Uncertainty in Conservation and Sustainable Use* (London: Earthscan, 2005) at 141.
[157] *Ibid* at 141-142.
[158] *Ibid* at 146.

access."[159] From a very basic perspective, the precautionary principle offers no guidance but forbids all courses of action, including management regulation.[160]

D. The consumer's right to know and informed choice

Another core argument for requiring mandatory labeling measures is the consumer's right to know. The consumer's right to know, an evident argument, is probably accepted and asserted by every consumer. In the context of food consumption, where relevant issues such as food safety and quality are very important to consumers, most consumers would believe that they have a right to know what is in their food. Critics of GM food have popularized this right as a part of consumer freedom of choice or a part of "health freedom."[161] In light of this argument, all safety or risk concerns become less relevant and the purported "right" has been portrayed as a key value for the need for mandatory labeling of GM foods.

1. The "right to know" in international instruments related to GMO management

As we have seen in Chapters Two and Three, there is no overarching inter-governmental organization that can effectively address all of the trade, environmental, and food safety issues under one umbrella in relation to the labeling of GMOs. The Codex CCFL (agricultural food safety regime) has abandoned its attempt to formulate a special international labeling standard, and has approved the guidance that regulates the labeling of GMOs under existing Codex texts,

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[159] *Ibid* at 148.

[160] See Sunstein, *supra* note 150 at 26.

[161] Christophe Chao-Hung Chen holds that "the first theory of regulating and labeling GM food is based on the consumer's right to know, and at the core of this theory is the notion that the public has a basic right to know any fact it deems important about food or commodity before making a purchasing decision". See Christophe Chao-Hung Chen, "Labeling Genetically Modified Food – Comprehensive Law Studies from Consumer's Perspective (2006) 1 Nat'l Taiwan U L Rev 1. David Alan Nauheim holds that the consumer's right to know is a part of a larger concept of health freedom. He holds that according to the US Constitution, the government should protect the consumer's right to receive accurate non-misleading information that they reasonable desire. See David Alan Nauheim, "Food Labeling and Consumer's Right to Know: Give the People What They Want" (2009) 4 Liberty U L Rev 97.

which are based on health-related concerns. The Cartagena Protocol on Biosafety (environmental regime) mainly focuses on potential adverse or harmful effects of LMOs that may impact the conservation and sustainable use of biological diversity. The WTO system (trade regime) is in favor of promoting international trade of GMOs by setting up a science-based regulatory framework. The fragmentation of international law leads to inconsistent and, in some cases, incompatible approaches to GMO labeling requirements, but none of these approaches recognize the consumer's right to know as the exclusive basis for a GMO labeling regime.

Table 3: the consumer's right to know (CRK) in international instruments

	Labeling requirements for GMOs	Can the CRK solely justify a mandatory labeling?	If not, what rationales can justify?
Cartagena Protocol on Biosafety	Mandatory	No	Conservation and sustainable use of bio-diversity, human health
Codex CCFL	Not specified	No	Health and safety concerns
WTO Agreements	Not specified	Probably No	SPS: Scientific evidence of health risk TBT: Shall not constitute unnecessary obstacles to international trade

2. The "right to know" in domestic and regional legislation

As previously explored in Chapter Four, in terms of the three selected jurisdictions, the EU is the only authority that regards the consumer's right to know as a sufficient basis for a mandatory labeling regime. Canada and China consider health safety concerns as a determinative rationale for requiring a mandatory labeling measure for foods. Although the consumer's right to know appears to play an important role in EU GMO labeling legislation, it is difficult to find GM products in the EU market. This means that consumers in the EU are not likely to have a real

choice between products and, as a result, the right to know does not play a big role.[162] Moreover, criticisms of some EU members' recent arbitrary bans on certain GM varieties, which have passed EU authoritative safety assessment, reveal that relevant GMO policies in EU member countries are not based on scientific evidence.[163] Hence, it is reasonable to doubt whether the current stringent EU GMO labeling legislation is based on a consideration of protecting the consumer's right to know or is simply due to political stress from environmental interest groups.[164]

Table 4: the consumer's right to know (CRK) in Canada, the EU and China GMO labeling legislation

	GMO Labeling Models	Can the CRK solely justify a mandatory labeling?	If not, what rationales can justify?
Canada	Voluntary	No	Health safety concerns
EU	Mandatory	Yes	
China	Mandatory	No	Health Concerns

3. The "right to know" has not gained support from voters

In Canada, the "consumer's right to know" is also a common justification argued by Canadian environmental groups for filing petitions with governments arguing that they should introduce mandatory labeling requirements for GM foods. In 2011, a network of Quebec environmental organizations – the Réseau Québécois Contre les OGM – proposed a report entitled "Food safety: A challenge for society and responsibility of all the stakeholders in the food system," that sent a

[162] Louise Gray, *Can We Buy Genetically Modified Crops in Our Supermarket Shelves?*, online: The Telegraph <http://www.telegraph.co.uk/foodanddrink/8278156/GM-food-QandA.html>; Annie H. Liu, My Bui & Market Leach, "Considering Technological Impact When Selecting Food Suppliers: Comparing Retailers' Buying Behavior in the United States and Europe" (2013) 20:2 Journal of Business-to-business Marketing 81.

[163] Marcel Kuntz, John Davison & Agnès E Ricroch, "What the French Ban of Bt MON810 Maize Means for Science-based Risk Assessment" (2013) 31 Nature Biotechnology 498.

[164] Jonathan P. Doh & Terrence R. Guay, "Corporate Social Responsibility, Public Policy, and NGO Activism in Europe and the United States: An Institutional-Stakeholder Perspective" (2006) 43:1 Journal of Management Studies 47; Masip, et al, *supra* note 32. Davison, *supra* note 31.

request to the provincial government to establish obligatory labeling of GM foods in grocery stores.[165] Charles Tanguay, director of communications for a non-profit Quebec union – Union des Consommateurs stressed that "We want to be a leader, to convince the rest of Canada it's time for GMO labeling. It is a basic right of consumers to know."[166] In 2008, Gilles-A. Perron, MP, introduced *Bill C-517: An Act to Amend Food and Drugs Act (Mandatory Labeling for Genetically Modified Foods)* which would have amended Section 2 of the *Food and Drugs Act* by adding a definition of GMOs, and called for the implementation of a mandatory labeling regime for GMO food.[167] It read:

> No one may sell this food or a food product containing this food in a package unless a label is affixed to the package containing the following notice: This product or one or more of its components has been genetically modified (Ce produit ou un ou plusieurs de ses composants ont été génétiquement modifies). In addition, no one may sell this food or a food product containing this food in a package unless a poster in the prescribed form has been placed near the food containing the following notice: Genetically modified (Génétiquement modifié)[168]

This Bill was debated in the House by members of all parties in 2008, but was not passed by the Canadian Parliament.[169] But the effort has not stopped. A similar proposal, *Bill C-257: An Act to Amend Food and Drugs Act (Mandatory Labeling for Genetically Modified Foods)*, was introduced by Alex Atamanenko, MP in 2011. He said that "[t]he time is coming [when] we will

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[165] Jordan Venton-Rublee, *Petition Circulating to Label All Genetically Modified Foods*, online: the McGill Daily <http://www.mcgilldaily.com/2011/10/petition-circulating-to-label-all-genetically-modified-foods/>.
[166] *Ibid.*
[167] *Bill C-517*, online: Parliament of Canada, <http://parl.gc.ca/HousePublications/Publication.aspx?Language=E&Mode=1&DocId=3314855&File=19>.
[168] *Ibid.*
[169] *Status of the Bill*, online: Parliament of Canada LEGIS info <http://www.parl.gc.ca/LegisInfo/BillDetails.aspx?Mode=1&billId=3293171&Language=E>.

have the right to know that we are eating genetically modified food."[170] The Bill he proposed was aimed at promoting the choice of Canadians to decide what they want, and do not want, to eat.[171]

In the US, where GMOs are labeled on a voluntary basis, environmental groups, consumer organizations, and politicians in states such as Vermont and California have launched a series of campaigns requesting clear labels on any food containing GM ingredients, based on the consumer's right to know.[172] So far, no bills have passed. The sensational California campaign, *the California Right to Know Genetically Engineered Food Act*, otherwise known as the Californian *Proposition 37* (Prop 37), a state-wide initiative that would have mandatorily required food retailers and producers to label food products if they were GMOs or GM ingredients, was defeated on November 7, 2012 by California voters by a margin of 51.4 to 48.6 percent after a multi-year campaign.[173]

4. A consumer's interest or desire should not solely justify a mandatory GMO labeling

4.1 Should labeling material information only

The proposed acts or petitions calling for mandatory labeling of GMOs contain no explanation or definition about what and how information should be delivered. Given that commercialized GM varieties are approved to be safe for consumption, arguments such as "to know what's in their foods" are more likely to be based on the consumer's curiosity and can be applied to any food

[170] Rrandy Shore, *Richmond Poised to Join Other Non-GMO B.C. Municipalities*, online: Vancouver Sun <http://www.vancouversun.com/technology/Richmond+poised+join+other+municipalities/6440309/story.html>.

[171] *Alex Atamanenko on Food and Drugs Act*, online: Openparliament.ca <http://openparliament.ca/debates/2011/6/23/alex-atamanenko-1/only/>.

[172] Gilles-A. Perron, *An Act to Amend the Food and Drugs Act (Mandatory Labeling for Genetically Modified Foods)*, online: openparliament.ca <http://openparliament.ca/politicians/226/>.

[173] See Robert Haselkorn, "Hard to Swallow: Do Foods Containing 'Genetically Modified Organisms' (GMOs) Need Warning Labels?" (2013) 27:7 The FASEB Journal 2531; Amy Westervelt, *With California Prop Defeated, GMO Labeling Proponents Look to Farm Bill*, online: <http://www.forbes.com/sites/amywestervelt/2012/11/13/with-california-prop-defeated-gmo-labeling-proponents-look-to-farm-bill/>.

consumption. However, consumers always have endless requirements for information because of their curiosity. If policy is to satisfy consumers' desire for information, then a lot of products may be unnecessarily labeled, or misinform consumers as to the safety of the product. In this light, mandatory labeling requirements that provide information of no importance, or warnings for ingredients with little or no health risk, render the primary function of labels useless, since information overload would otherwise let the more important information become lost within crowded labels.[174]

However, the argument that only material information should be mandatorily labeled does not necessarily mean that some consumers' concerns about GMO foods that are not related to health and safety will be ignored. In fact, it is based on the consideration of these consumers' rights to make informed choices that I encourage to use a voluntary labeling regime of GMOs to provide them with information that is essential to making an informed choice.

4.2 The labeling of rBST-derived milk products: a case study

The labeling recombinant bovine somatotropin (rBST)-derived milk product case in the US is an instructive example of how to establish a proper labeling law that can protect the consumer's right to know what could harm them and as the same time avoid misleading information disclosure as results of inappropriate labels and labeling models.

[174] Carl R. Galant, "Labeling LIMBO: Why Genetically Modified Foods Continue to Duck Mandatory Disclosure" (2005) 42 Hous L Rev 125.

rBST is a genetically engineered hormone. It is an artificial variant of bovine somatotropin, a hormone naturally produced by all milk cows that regulates a cow's milk production.[175] rBST was the first GE product approved by the US government for use in livestock food production. Milk from rBST treated cows did not show any difference in composition with the non-rBST treated cows,[176] and somatotropin is "species limited", which means that BST can only bind to a specific receptor located on the cell surface in bovine species. That a receptor in non-bovine species is not able to bind to BST will block BST from having any biological effect on these other species, including humans.[177] Yet, health-related concerns about rBST such as obstacles to the immune system,[178] and the incidence of ketosis and liver disease, have resulted in extensive scientific research.[179] These studies found no significant risk to dairy cows and humans because of the use of rBST.[180] Therefore, the FDA, in 1993, approved the use of rBST in animals.[181] Other countries and international organizations, such as the WHO and FAO, have also confirmed that BST is safe for human consumption.

Despite the FDA's conclusion that the use of rBST is safe for human consumption, consumers have expressed their increasing desire to have information on milk products to enable them to choose between rBST and non-rBST milk products. In February 1994, the FDA issued the

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[175] Joseph J. Molnar et al., "Bovine Somatotropin: Biotechnology Product and Social Issue in the United States Dairy Industry" (1990) 73 J DAIRY Sci 3084; David A. Martin, "Crying over Spilt Milk: A Closer Look at Required Disclosures and the Organic Milk Industry" (2011) 18 Mo Envtl L & Pol'y Rev 524.

[176] D.M. Barbano et al., "Effect of a Prolonged-Release Formulation of N-Methionyl Bovine Somatotropin (Sometribove) on Milk Composition" (1992) 75 J DAIRY Sci 1775.

[177] Congress of the United States Office of Technology Assessment, *U.S. Dairy Industry at a Crossroad: Biotechnology and Policy Choices*, online: <http://www.princeton.edu/~ota/disk1/1991/9142/9142.PDF>.

[178] J. K. Oldenbroek et al., "Effects of Treatment of Dairy Cows with Recombinant Bovine Somatotropin over Three or Four Lactations" (1992) 76 J DAIRY Sci 354.

[179] D. E. Bauman et al., "Somatotropin (bST): International Dairy Federation Technical Report" (1994) 293 BULL IN'L DARIY FED'N 2.

[180] Terence J. Centner & Kyle W. Lathrop, "Labeling rBST-Drived Milk Products: State Responses to Federal Law" (1997) 45 U Kan L Rev 515.

[181] *Interim Guidance on the Voluntary Labeling of Milk and Milk Products from Cows that have not been Treated with Recombinant Bovine Somatotropin*, 59 Fed Reg 6279 (1994).

"Interim Guidance on the Voluntary Labeling of Milk and Milk Products from Cows that Have Not Been Treated with Recombinant Bovine Somatotropin" (Interim rBST Guidance).[182] It stated that labeling milk products as "rBST free" might lead to a false image that milk products from cows receiving supplemental rBST was compositionally different from cows not treated with rBST.[183] To avoid this potentially misleading information, the FDA declined to implement a mandatory model and adopted the voluntary labeling method for rBST-derived milk products. According to the Interim rBST Guidance, when products are labeled as "This milk is from cows not treated with BST," the following statement must also be used: "No significant difference has been shown between milk derived from BST-treated and non-BST-treated cows."[184]

Nevertheless, several jurisdictions in the US have attempted to establish a mandatory labeling regime for rBST milk products. In 1994, Vermont implemented a statute mandating the labeling of rBST milk products derived from rBST-injected cows. This statute was based on the claim that laws should protect consumer interests and the public's right to know.[185] This requirement had been strongly argued against by the International Dairy Food Association (IDFA). The IDFA countered that the statute violated dairy producers' First Amendment right not to speak. The Vermont mandatory requirements were rejected by the US Court of Appeals for the Second Circuit.[186] Relying on the reports from the FDA that there was no scientific evidence to support the claim that rBST was harmful to human health, the Court held that the Vermont consumers' "desire is insufficient to permit the State of Vermont to compel the dairy manufacturers to speak

[182] *Ibid.*
[183] The FDA noting that "[t]here is currently no way to differentiate analytically between naturally occurring bST and recombinant bST in milk, nor are there any measurable compositional differences between milk from cows that receive supplemental bST and milk from vows that do not." *Ibid* at 6280.
[184] *Ibid.*
[185] VT. STAT. ANN. Tit. 6, § 2754 (terminated by 1993, Adj. Sess., No. 127, 4, as amended by 1997, No. 61 § 272i, (eff. Mar. 30, 1998).
[186] *Int'l Dairy Foods Ass'n v. Amestoy*, 92F.3d 67 (2d Cir. 1996).

against their will. Were consumer interest alone sufficient, there is no end to the information that states could require manufacturers to disclose about their production methods…"[187] The Court ruled that consumer curiosity was an *insufficient* justification to infringe upon the First Amendment rights of dairy producers.[188]

In 2007, another large dairy-producing state, Pennsylvania, drafted a proposal that aimed to forbid any labeling statements that demonstrated that a milk product was from non-rBST-derived cows.[189] The proposal was intensely debated by both the dairy industry and consumer protection groups. Several dairy producers and consumer groups argued that the prohibition of rBST-free labeling would cut off consumers' access to information which was essential to making an informed choice.[190] Consumers would no longer be allowed to distinguish between dairy products derived from rBST-treated cows and non-rBST-treated cows. Dennis Wolff, the Pennsylvania Agriculture Secretary, contended that "rBST" labels provided misleading information, implying that rBST-treated products were unsafe.[191] After six months of wide discussion, the Pennsylvania Department of Agriculture issued revised milk labeling standards in 2008.[192] It required a claim and disclaimer accompanied with "No rBST" or "Free of rBST", i.e., "No rBST was used on cows producing this milk. No significant difference has been shown between milk derived form rBST-treated and non-rBST-treated cows."[193]

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[187] *Ibid* at 67
[188] *Ibid* at 67, 69-70
[189] Mark Scolforo, *Pennsylvania Bars Hormone-Free Milk Labels, Roiling Industry*, online: San Diego <http://legacy.utsandiego.com/news/business/20071113-1350-hormones.html>.
[190] *Ibid*.
[191] Teri Lee Gruss, *Pennsylvania Governor Rethinking Milking Labeling Rules for rBST*, online: NaturalNews <http://www.naturalnews.com/022699.html>; also see Emily A Kane, *Pennsylvania Bans rBGH-Free Labels on Dairy Products*, online: NaturalNews <http://www.naturalnews.com/022379.html>.
[192] *Milk Labeling Standards 2.0.1.17.08*, online: <http://www.idfa.org/files/exhibit_016.pdf>.
[193] *Paragraph 7 (A) (iii) of Milk Labeling Standards*, *ibid*.

Conclusion

This Chapter explored arguments against the rationales for the mandatory labeling of GMOs proclaimed by critics of GM techniques and GM food products. It was found that these rationales were largely based on the assumption that manipulating the genes of organisms was not a precise process, thereby challenging GMOs might have unpredictable and uncontrollable harmful effects on human and animal health as well as the environment. Thus, this chapter first explored scientific research on GM techniques and GMO safety concerns. It clarified that genetic engineering technology vis-à-vis traditional plant hybrid methods enabled the genetic improvement of crops in a more precise and controllable pattern, and that there was no established evidence to date supporting the assumption that GM foods posed higher risks than conventional counterparts. Moreover, the clarification of GMO safety does not mean the application of biotechnology in agricultural production is risk-free. "Zero risk" is statistically impossible, and current scientific studies never guarantee that GMOs are one hundred percent safe. Therefore, a real challenge behind controversies over GMO labeling is how to use legal techniques to deal with scientific uncertainty.

To cope with the scientific uncertainty regarding GMOs, the precautionary approach has been adopted by domestic law and international legal instruments related to environmental protection, such as the CBD and Cartagena Biosafety Protocol. The EU introduced a mandatory GMO labeling regime oriented around the precautionary principle and a stringent labeling and traceability system has been required throughout the entire EU food supply chain. However, there were many controversial concerns surrounding the use of a precautionary notion as a risk management approach in a GMO regulatory system. This Chapter found that the precautionary principle has not become a general customary international law norm and it has not become a

general principle of international law recognized by nations. The international community has acknowledged the value of the precautionary principle to international environment law, but a uniform definition of the precautionary principle/approach has not been established and its application results in disputes concerning the environmental protection, food safety and international trade is still unclear. Moreover, this Chapter found that the application of the precautionary principle is not a proactive attitude to deal with problems. This is because it does not provide much accountable information, and emphasizes precaution in the use of GM techniques while not making clear the "right" amount of precaution or what a reasonable cost for the precaution might be. Therefore, the precautionary principle should not be considered a justification for mandatory labeling measures.

The evidence gained in this chapter also found that the legal basis of the consumer's right to know for mandatory GMO labeling is far from universally accepted in both relevant international legal instruments and domestic GMO labeling laws. It was found that the EU GMO labeling law is the only legislation that recognized the consumer's right to know as a sufficient justification for a mandatory labeling regime. However, the combination of the EU stringent GMO labeling system and the increasing number of challenges against EU member state policies on cultivation and marketing of safety-approved GMOs were found to be politically driven, and this makes it reasonable to suspect that the consumer's right to know is being used as an excuse by anti-GMO groups against the development of GMOs in Europe.[194] Health risk concerns have been widely accepted as the rationale for a food labeling law, and hence the purported consumer's unlimited right to know is insufficient either to invalidate the current labeling approach or to justify a

[194] Doh & Guay, *supra* note 164; Davison, *supra* note 31.

special mandatory GMO labeling law.[195]

Therefore, this chapter reveals that rationales for the mandatory labeling of GMOs cannot withstand scrutiny. In the next chapter, I will continue to explore challenges to the implantation of a mandatory labeling regime, focusing on practical problems for implementing special labeling of GMOs.

[195] Galant, *supra* note 174.

Chapter 6 Arguments against Implementation of A Mandatory GMO Labeling Regime

In the last chapter, I reviewed rationales for mandatory labeling of GMOs and argued that rationales such as: irreversible harm to human and animal health; the precautionary principle; and the consumer's right to know do not, on their, stand as sufficient justifications for mandating special labeling requirements for GMOs. It is worth noting that such rationales are proclaimed mainly from consumers' perspectives and very much focus on: health concerns; risk management when confronting scientific uncertainty; and rights to know in order to make informed choices. I am of the opinion that we should put priorities on protecting consumer's health and rights, but when there is little scientific justification for mandatory labeling, we should consider stakeholders other than consumers in the entire GMO industry such as farmers, producers, distributors, and even authorized laboratories. Their interests will also be impacted by the GMO regulatory regime, perhaps significantly. With this consideration at the forefront, this chapter progresses from the discussion on labeling law rationales as laid out in Chapter Five to an exploration of the pragmatic challenges and costs issues arising from the implementation of mandatory labeling GMO regimes – which are not trivial.[1] Such problems include: the increased cost of GM products; inaccurate and misleading statements on the labeling of GMOs; uncertain labeling threshold regulations due to inaccurate terminologies adopted by GMO labeling laws; and nonconformity with WTO rules.

A. The cost of labeling

[1] Discussing practical concerns about the implementation of a mandatory GMO labeling regime is based on a premise that there is little scientific justification for the labeling. I recognize that if labeling could be justified on scientific grounds, these practical concerns would need to be overcome. They likely would not, on their own, stand as a justification against labeling.

Advocates for mandatory labeling of GMOs frequently argue that labeling GMOs is nearly costless – all that is needed is to stick a label on a product.[2] However, few mandatory regulatory requirements come with no costs, particularly when applied to something as complex as GMO labeling. Any types of food labeling requirements will inevitably increase the cost of production, as can be exemplified by the US *Nutrition Labeling and Education Act* (NLEA), which has powerfully changed the nutrition labels on prepackaged food sold on the US markets.[3] It requires that every food sold in the US market provide a mandatory "Nutrition Facts" label, which lists calories, fat, saturated fat, cholesterol, sodium, fiber, sugar, protein, and vitamin and mineral content.[4] Mandatory nutritional labeling aims to provide consumer information concerning food nutritional content at the point of sale in order to help the consumer make healthier food choices.[5] Meanwhile, the cost to apply these new rules is huge. It was reported that the US food industry spent a one-time cost of $2 billion related to implementation of the nutrition-labeling regime in 2003, combined with a small amount of extra on-going cost.[6]

Similar to the nutrition labeling requirements, most of the GMO labeling regulations have formulated provisions on specified labeling format, location, size and statement.[7] Differently, the implementation of a mandatory GMOs labeling regime would be much more complicated than

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[2] Stuart Smyth & Peter W. B. Philips, "Labeling to Manage Marketing of GM Foods" (2003) 21:9 Trends in Biotechnology 389.

[3] *Nutrition Labeling and Education Act*, 1990, 21U.S.C. 301.

[4] *Guide to Nutrition Labeling and Education Act (NLEA) requirements*, online: U.S. Food and Drug Administration <http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074948.htm>.

[5] *Nutrition Labeling*, online: Health Canada <http://www.hc-sc.gc.ca/fn-an/label-etiquet/nutrition/index-eng.php>.

[6] Bruce A. Silverglade, "The Nutrition Labeling and Education Act: Progress to Date and Challenges for the Future" (1996) 15:1 Journal of Public Policy & Marketing 149; Wallace E. Huffman, *Consumer Acceptance of Genetically Modified Foods: Traits, Labels and Diverse Information*, online: <http://www.econ.iastate.edu.login.ezproxy.library.ualberta.ca/sites/default/files/publications/papers/p11835-2010-08-10.pdf>; see also Factsheet on the New Proposed Nutrition Facts Label, online: FDA <http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm387533.htm>.

[7] The NLEA have specifically stipulated the "location of nutrition facts panel", "general format and print size", "serving size", and "nutrient declaration" etc. See *Guide to Nutrition Labeling and Education Act (NLEA) requirements*, online: U.S. Food and Drug Administration <http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074948.htm>.

compulsory nutrition labeling requirements, because the mandatory GMO labeling scheme not only refers to detection of the varieties and amounts of GMO materials in end food products, but also requires a segregation and identity preservation system for GMO products.[8] The economic considerations can have clear legal relevance, as highlighted in *US – Country of Origin Labels (US – COOL)* case[9], to the creation of limitations on access to markets, when require mandatory labeling measures are required for exporters of GM food products.[10]

1. Increased cost from segregation and identity preservation

Under the current EU process-based labeling system, a mandatory GMO labeling requirement would demand testing, segregation and identity preservation of GMO products in the entire food supply chain, i.e. from crops harvesting equipment to barns, from farms to markets, and from food distributors to the final end consumers.[11] Consequently, a dual market has to be created to accommodate these requirements.[12] An estimation of such increased cost resulting from this segregation and identity reservation system could be observed in the WTO *US – COOL* case.

In the *US – COOL* case, the WTO Panel reviewed the costs of compliance with the COOL measure to decide whether they would be higher for imported compared to for domestic

[8] According to PG Economics, "both segregation and IP essentially refer to any system of crop or raw material management that segregates or preserves the identity of the source or nature of the materials. At a general level segregation is synonymous with 'keeping crops, products etc. apart' whilst IP is more widely considered to apply where there is a positive desire to preserve the identity or source of a crop or product." House of Commons, *Agriculture – Third Report*, online: <http://www.publications.parliament.uk/pa/cm199900/cmselect/cmagric/71/7103.htm#note7>.

[9] Report of the Panel, the *United States – Certain Country of Origin Labeling (the US – COOL)*, (2011) WT/DS384/R. WT/DS386/R.

[10] Joseph A, McMahon & Melaku Geboye Desta, *Research Handbook on the WTO Agriculture Agreement New and Emerging Issues in International Agricultural Trade Law* (UK: Edward Elgar Publishing Limited, 2012) at 171.

[11] Martin Henseler, et al., "On the Asynchronous Approvals of GM Crops: Potential Market Impacts of A Trade Disruption of EU Soy Imports" (2013) 41 Food Policy 166.

[12] Marion Desquilbet & David S. Bullock, "Who Pays the Cost of Non-GMO Segregation and Identity Preservation?" (2009) 91:3 Amer J Agr Econ 656.

livestock.[13] The WTO Panel found that although the COOL measure did not explicitly require the segregation of domestic and imported livestock, it called for an unbroken chain of reliable information on the country of origin. When put in practice, this chain of information required the segregation of meat and livestock according to origin as defined by the COOL measure.[14] By exploring segregation costs under different business scenarios,[15] the Panel found that business scenarios involving imported livestock, including exclusively and partially imported livestock, are overall more costly than the exclusively domestic livestock due to the COOL measure.[16] As a result, the requirement of labeling the country of origin creates an incentive for participants to process domestic rather than imported livestock because, under the COOL measure, processing meat from exclusively domestic livestock is less costly than other business scenarios.[17] The Panel also reviewed economic studies submitted by Canada to verify whether the costs of the COOL measure were as significant as Canada proclaimed, or remained as small as the US contested. Based on two economic studies on the segregation costs of the COOL measure – one prepared by Informa Economics in June 2000, and the other one conducted by Professor Sumner's economic simulation model published in June 2010[18]– the Panel acknowledged that the COOL measure had led to a significant and negative impact on imported livestock due to the increased cost.[19]

In the context of labeling GMOs, however, a complete segregation of GM products from non-GM counterparts is not only a matter of cost, for some large GMO producers, such as the US and

[13] *Ibid.*
[14] *Ibid* paragraph 7.336.
[15] In terms of whether the livestock being processed has domestic or imported origin, there are five possible business scenarios under the COOL measure: (a) processing domestic and imported livestock and meat irrespective of origin and solely according to price and quality; (b) processing meat from exclusively domestic livestock; (c) processing meat from exclusively imported livestock; (d) processing exclusively domestic and exclusively imported livestock at different times; or (e) processing both domestic and imported meat by commingling the two on the same production day. Panel of the Report, *ibid* paragraph 7.333.
[16] *Ibid* paragraph 7.402.
[17] *Ibid* paragraphs 7.403-7.404
[18] *Ibid* paragraph 7.488.
[19] *Ibid* paragraph. 7.548.

Canada, it is practically unachievable. Ever since GM crops have been commercially grown and sold in North America, non-GM and GM crops have coexisted within the entire food supply system.[20] Establishing a segregated food supply system in the US and Canada to meet the requirements of mandatory labeling of GM products will necessitate the construction of a new duplicate system specifically for GM products. This new system in turn necessitates replacement or cleanup at every link of the existing food supply chain, from cultivation, to storage, to transportation, to end sale, to segregate GM from non-GM products. Such a giant project would be difficult for the US and Canadian governments to approve, especially since commercialized GMO products have been shown, by the best available evidence, to be safe for human and animal consumption by domestic and international authorities.

2. Increased cost for detecting GMO content

To date, a widely used method for detecting quality and quantities of GMO contents is a real-time polymerase chain reaction (PCR) assay, which is operated on a molecular level to quantify a targeted DNA molecule.[21] By labeling a fluorescent reporter to sequence specific

[20] Gary E. Marchant, Guy A. Cardineau, & Thomas P. Redick, *Thwarting Consumer Choice: The Case Against Mandatory Labeling for Genetically Modified Foods* (Washington. D.C.: The AEI Press, 2010) at 54.

[21] Suchitra Kamle &Sher Ali, "Genetically Modified Crops: Detection Strategies and Biosafety Issues" (2013) 522:2 Gene 123. PCR amplification with subsequent sequencing of the PCR products has been used to sequence the genetic inserts. Strachan T & Read AP give an explanation about the mechanism of the standard PCR reaction:

> PCR is a rapid and versatile *in vitro* method for amplifying defined target DNA sequences present within a source of DNA. Usually, the method is designed to permit *selective amplification* of a specific target DNA sequence(s) within a heterogeneous collection of DNA sequences (e.g. total genomic DNA or a complex cDNA population). To permit such selective amplification, some prior DNA sequence information from the target sequences is required. This information is used to design two oligonucleotide primers (amplimers) which are specific for the target sequence and which are often about 15–25 nucleotides long. After the primers are added to denatured template DNA, they bind specifically to complementary DNA sequences at the target site. In the presence of a suitably heat-stable DNA polymerase and DNA precursors (the four deoxynucleoside triphosphates, dATP, dCTP, dGTP and dTTP), they initiate the synthesis of new DNA strands which are complementary to the individual DNA strands of the target DNA segment, and which will overlap each other.

T. Strachan & AP. Read, "Chapter PCR, DNA Sequencing and in vitro Mutagenesis" in Strachan T. & Read, *Human Molecular Genetics*, 2nd ed (New York: Wiley-Liss, 1999).

oligonucleotides, the amplified products can be detected as the reaction advances.[22] The PCR analysis can test whether the transgene has been successfully inserted into the plant genome, as well as the number of copies of the inserted gene in the host genome.[23] However, using this laboratory methodology in a real life scenario to detect GM materials in tons of crops would require considerably large numbers of dedicated laboratories that possess sophisticated equipment and professionally trained personnel. Also, in order to meet the strict labeling requirement, the testing would have to be administered at every point of the food supply chain by different operators, including importers, local GM crops growers, distributors and finally foodstuff producers. Thus, the cost of analysis would result in increased prices for both GMO and non-GMO products.

In 2006, a Chinese research team made an economic analysis of the cost of applying requirements of labeling under the Cartagena Protocol on Biosafety.[24] Their results indicated that the most expensive testing was quantitative analysis for GMO materials.[25] Such types of detection were nearly two times the amount of the cost for a qualitative examination based on the same sample of GMOs. Moreover, when testing a GMO with many varieties, such as maize, the cost for that testing is more expensive than a GMO with fewer varieties. Therefore, it can be concluded that the more stringent the labeling regime (e.g., foods with 0.9 percent of GM ingredients have to be labeled), the higher the costs for the detection of GMO contents. It is worth noting that this economic study was only an estimation of parts of cost for testing GMO

[22] Kamle & Ali, *ibid*.
[23] Laura S. Privalle, "Development of an Agricultural Biotechnology Crop Products: Testing from Discovery to Commercialization" (2012) 60 J Agric Food Chem 10179.
[24] *The Cost of Implementing the Biosafety Protocol – A Look at China*, online: International Food & Agricultural Trade Policy Council <http://www.agritrade.org/Publications/IssueBriefs/China_BSP.pdf>.
[25] *Ibid.*

materials. It only calculated the cost for testing at ports and did not include the cost for later tests at other points along the domestic food supply chain.

Table 5: Compliance cost: estimated LMO testing costs and other fees of exporting soybean and maize from the USA at the border in China in 2005[26]

	"May contain LMOs"	"Identifies LMOs"	"Quantifies LMOs"
Soybeans			
Cost per sample (US $)	216	216	324
Cost per ton (US$)	0.30	0.30	0.44
Export price in Jan 2006 (US$/ton)	245	245	245
Share of FOB price (%)	0.12	0.18	0.18
Total cost (million US$)	**8.33**	**8.33**	**12.5**
Maize			
Cost per sample (US$)	465	792	1536
Cost per ton (US$)	0.67	1.16	2.26
Export price in Jan 2006 (US$)	105	105	105
Share of FOB price (%)	0.64	1.14	2.15
Total cost (million US$)	**34.2**	**59.3**	**115.1**

Data Source: Reported in Huang et al., 2006[27]
Note: costs include laboratory testing costs (about 80%) and other service charges (about 20%)

3. Consumers' willingness to pay (CWP) for the labeling of GMOs

The increased cost is initially paid for by the food producers, but would eventually be passed onto consumers. As discussed earlier, labeling requirements are not for safety concerns: if a GMO variety is not safe for human and animal consumption, then food safety authorities would not let it be offered for sale on the market. The label is purported to provide consumers with information, thereby facilitating more choices. But once this mandatory label is applied, problems arise: do consumers really care about GM labels? And are consumers willing to pay a premium for this additional information?

[26] *Ibid.*
[27] Jikun Huang, et al, "Will the Biosafety Protocol Hinder or Protect the Developing World: Learning from China's Experience" (2008) 33 Food Policy 1.

Indeed, many consumer surveys have shown that consumers do demand a GM label. However, most recent consumer survey results were based on a certain amount of respondents and used questionnaires designed for particular experimental purposes. When putting in a wide range of population and real shopping circumstances, it is difficult to estimate if "GMO" labels really do matter to consumers, because there are too many factors other than "GMOs" that determine the consumers' choices.[28] Just as Stuart Smyth and Peter W. B. Phillips observe in their 2003 research about consumers' attitude to food labeling:

> …Consumers, when asked in polls, express a high level of desire to have these products labeled so that they can be differentiated but when the purchasing decisions are taking place within grocery stores the perceived value of this kind of labeling rapidly diminishes. This might be because the majority of consumers want to go into a grocery store and purchase their food products as quickly as possible. Produce and meats are purchased based on appearance and processed foods based on brand recognition. Within North America at least, labeling for GM content is largely irrelevant and, as such, will do little to support post-market monitoring and surveillance of GM foods.[29]

With regard to the consumer's willingness to pay a premium for the labeling of GMOs, plenty of consumer attitude surveys and economic analyses on this issue have been made in many different countries.[30] Stuart Smyth and Peter W.B. Phillips undertook a literature review on the willingness of consumers to pay for the GMO labels in some selected countries, including the US, UK,

[28] Cyrus Martin, "The Psychology of GMO" (2013) 23:9 R356; Fanny Rolin, Jean Kennedy & Josephine Wills, "Consumers and New Food Technologies" (2011) 22:2-3 Trends in Food Science & Technology 99.

[29] Smyth & Phillips, *supra* note 2.

[30] Benjamin Onyango, et al., "U.S. Consumers' Willingness to Pay for Food Labeled 'Genetically Modified'"(2006) 35:2 Agricultural and Resouce Economics Review 299; Wallace E. Huffman, et al., "The Effects of Prior Beliefs and Learning on Consumers' Acceptance of Genetically Modified Foods" (2007) 63:1 Journal of Economic Behavior & Organization 193; Jane Kolodinsky, "Affect or Information? Labeling Policy and Consumer Valuation of rBST Free and Organic Characteristics of Milk" (2008) 33:6 Food Policy 616; H. De Steur, et al., "Willingness-to-accept and Purchase Genetically Modified Rice with High Folate Content in Shanxi Province, China" (2010) 54:1 Appetite 118; Aylin Ayaz, et al., "Consumer Acceptance, Knowledge and Attitudes towards Organic and Genetically Modified Foods: A Cross-sectional Study among Turkish University Students" (2011) 5 HealthMED 1014;

Canada, and New Zealand.[31] They found that consumer attitudes toward GM products and non-GM conventional food were located on a spectrum: in every market, based on the review of collected surveys, there was always a small percentage of consumers on one end of the spectrum who refused to consume GMO products, while the main middle section of the spectrum was represented by consumers who did not care very much either way whether they consumed GM or non-GM foods.[32] This large middle group, according to Smyth and Phillips, was the most meaningful in the labeling policy decision-making process. As well, the same survey did not suggest that the "willingness to pay" in this main group had a strong correlation with the demands of labeling GMOs.[33]

Consumer surveys in China also show a similar result. Using consumer surveys from two Chinese cites, Beijing and Xianyang, Rong Zhao et al. analyzed how Chinese consumers reacted to traceable food products. They discovered that a consumer's awareness of the relationship between the food traceability system and food safety would impact on his or her willingness to buy the traceable food.[34] According to the data collected by the Rong Zhao team, as consumers become increasingly aware of the correlation between ensured safe food consumption and food traceability systems, their likelihood of consuming traceable food also increases.[35] On the other hand, Rong Zhao et al. also found that the higher food prices caused by the traceability system

[31] Smyth & Phillips, *supra* note 2.
[32] *Ibid*. A similar result was also shown in a consumer survey carried out by Agricultural Biotechnology Council in 2009. The data indicated that in the UK the largest proportion of respondents (54%) neither supported nor opposed GM products. See Agricultural Biotechnology Council, *GM Crops and Consumers 2009*, online: <www. abcinformation.org>; "...so when your typical American soccer mom scrutinizes that box of corn flakes on the supermarket shelf, she will see mention of 'milled corn, malt flavoring, and sugar' but not genetically modified organisms (GMO)." Martin, *supra* note 28.
[33] Smyth & Phillips, *supra* note 2.
[34] Rong Zhao, et al., "Influencing Factors of Consumer Willingness-to-buy Traceable Foods: An Analysis of Survey Data from Two Chinese Cities" (2010) 1 Agriculture and Agricultural Science Procedia 334.
[35] *Ibid*.

decrease consumer willingness to buy.[36] According to their study, Chinese consumers were not willing to pay a premium for the traceability system if the food has already proved to be safe for consumption.[37]

4. Causing unfair competition

Aside from survey studies on consumers' willingness to pay, some recent economic studies on consumer preference for GM versus non-GM food products has indicated that labeling of GMOs may cause unfair competition in the food sale market. Consumer survey studies indicated that respondents more highly valued "non-GM products" or "GMO free" products than their "genetically modified" counterparts,[38] and that "GMO free" or "GMO" labels lead to negative impacts on the sales of GM products and products with no labels.[39] Some scholars argued that such effect would lead to unfair competition in both upstream and downstream markets.[40] A special research project on the relationship between downstream labeling and upstream price competition conducted by Oliver Bonroy and Stephenane Lemarie revealed that labels could influence price competition through "a different effect and a ranking effect."[41] According to their research, due to the EU regulations on GMOs and other factors, consumers lowered the ranking

[36] *Ibid.*
[37] *Ibid.*
[38] Astrid Dannenberg et al. conducted an economic experiment on consumers' attitude towards GM labeling. Their analysis showed that compared with GM products, the residents of Mannheim, Germany, who participated in the experiment, were more supportive of non-GM products than GM counterparts, and participants required an average discount of 47-59% to perchance GM products. See Astrid Dnnenberg, Sara Scatasta & Bodo Sturm, "Mandatory Versus Voluntary Labeling of Genetically Modified Food: Evidence from An Economic Experiment" (2011) 42 Agricultural Economics 373. Benjamin Onyango et al. in their survey of "US consumer's willingness to pay for food labeled genetically modified" found that "compared with cornflakes that have no labels information, cornflakes labeled "contains no genetically modified corn" have a value of 10 percent more." See Onyango et al., *supra* note 30; Wanki Moon et al research also showed the UK consumers' continuing negative attitude to GM foods, 46 percent of respondents stated that they would never buy GM food at any discount. See Wanki Mooon, Siva K. Balasubramanian & Arbindra Rimal, "Willingness to Pay (WTP) a Premium for non-GM Foods versus Willingness to Accept (WTA) a Discount for GM Foods (2007) 32:2 Journal of Agricultural and Resource Economics 363.
[39] An economic experiment conducted by Astrid Dannenberg et al., has shown that "GMO" and "GMO free" will create a degree of uncertainty about the quality of products that do not carry a label. See Astrid Dnnenberg, Scatasta & Sturm, *ibid.*
[40] In the context of the GMO industry, the upstream market includes GMO seeds companies; the downstream market includes food producers, retailers, and consumers. Oliver Bonroy & Stephane Lemarie, "Downstream Labeling and Upstream Price Competition" (2012) 56:3 European Economic Review 347.
[41] *Ibid.*

of the cost-saving GE technology, which led to GMOs being sold at a lower price.[42] As a result, farmers would have to consider the cost-saving advantage of GM seeds as well as the fact that GM products were worth less in the market when compared to other products that did not have "GMO" labels on them.[43] Thus, the labeling in the downstream market would have an indirect consequence on the unfair competition in the upstream market.

The preceding exploration of relevant economic studies associated with the labeling of GMOs has illustrated that a mandatory labeling regime would increase the cost of food products, impair sales of products without labels, and hence lead to unfair price competition in the upstream market. Moreover, the increased cost of satisfying special labeling requirements will ultimately be borne by consumers. People with higher incomes can afford to buy labeled-GM foods with higher prices, but most consumers with average incomes do not care too much about additional information on whether or not foods have been GM-treated, and hence are unlikely to pay extra for non-GM products or they simply cannot/could not afford the increased prices. The food affordability issue for poor persons becomes urgent in developing countries, where the supplementation of affordable foods is a crucial factor for food security. GM foods were invented to decrease the cost of global food production, but a mandatory GMO labeling requirement increases costs substantially for both producers and consumers. In particular, higher prices for GMO-labeled foods make such foods prohibitively expensive for many of the population in developing countries and low-income families in industrialized countries. Therefore, a mandatory labeling requirement can hardly be justified on the basis of economic considerations.

[42] *Ibid.*
[43] *Ibid.*

B. Inaccurate and misleading information disclosure

The truth-telling requirement is embodied in a number of legal instruments concerning food labeling on both domestic and international levels. For example: Article 5(1) of the *Canadian Food and Drug Act* and Article 14 to 16 of the *Canadian Consumer Packaging and Labeling Act* mandate that all information on food must be true: "[n]o person shall label, package, treat, process, sell or advertise any food in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character, value, quantity, composition, merit or safety."[44] The main piece of EU legislation concerning food labeling, Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labeling, presentation and advertising of foodstuffs (Directive 200/13/EC), outlined the truthful information disclosure requirement, and requested that information provided on food must be accurate and not mislead the consumer in terms of the food's properties.[45] The Codex General Standard for the Labeling of Prepackaged Foods also recognized that "prepackaged food shall not be described or presented on any label or in any labeling in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect."[46] However, the following discussion will indicate that regulations on the labeling statement for the labeling of GMOs are not accurate and sufficient. They are misleading to consumers. They do not provide any accurate information on the health consequences of consuming GMO products but instead imply that food products labeled as GMOs may be qualitatively inferior to their traditional non-GM counterparts.

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[44] Art. 5(1) of *Canadian Food and Drug Act* and Arts. 14 to 16 of *Canadian Consumer Packaging and Labeling Act*, *Consumer Packaging and Labeling Act*, R.S.C., 1985, c. C-38, s.7.

[45] Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labeling, presentation and advertising of foodstuffs. (Directive 2000/13/EC), EC, *Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labeling, presentation and advertising of foodstuffs*, [2000] O.J. L109/29.

[46] Art. 3.1 of *Codex Standards General Standard for the Labeling of Prepackaged Foods*, *Codex Standards General Standard for the Labeling of Prepackaged Foods*, Codex STAN 1-1985.

1. The Cartagena Protocol on Biosafety and "May contain LMOs"

1.1 "May contain"

Under the Cartagena Protocol, in the case of trans-boundary shipments of living modified organisms (LMOs) intended for food, feed, or processing between contracting parties, the exporters are required to provide information about the LMOs, including the types of LMOs that are or probably are present in the cargo's crops. Specifically, the information should indicate that the cargo crops "may contain" LMOs, and are intended for food, feed and processing, and are not for international introduction into the environment for planting.[47] Of all the types of mandatory labeling, the "may contain LMOs" label may be the most accurate disclosure, because it covers almost every possibility of occurrence of all types of LMOs. On the other hand, however, this vast coverage of all possibilities also shows the inaccuracy and inefficiency of the statements on labels.

To begin with, a list of all possible LMOs does not provide any precise and useable information to an importing country. When cargoes of LMOs are about to enter a country, an inaccurate "may contain" declaration does not reveal any precise information to an importing country.[24] In cases where the domestic GMO regulations are very stringent, such as the mandatory GMO labeling requirements in the EU, the importing countries would have to test and record types of LMOs contained in bulk shipment and transported by themselves without any other crops. Otherwise, the mere declaration of "may contain (types of LMOs)" provided by the exporting countries would not be able to meet the procedural and substantive requirements of domestic GMO

[47] Art. 18 of the *Cartagena Protocol*, *the Cartagena Protocol on Biosafety*, 29 January 2000, 2226 UNTS 208, 39 ILM 1027, online: <http:// bch.cbd.int/protocol/>.

management.[48] Thus, the "may contain" labeling statement under the Cartagena Protocol does not produce any positive effect on protecting the importing countries and their consumers. Instead, such types of labeling increase costs for both exporters and importers, and their local food processors as well. As a result, the "may contain" labels could become responsible for delaying an acceptance of bulk shipments of GMO crops, leading to agricultural trade restrictions.

From the consumer perspective, the "may contain GMOs" is also not a preferred statement compared to other types of labeling. A consumer experiment conducted by Onyango et al., which examined consumers' attitudes towards different labeling statements, indicated that consumers viewed the statement of "may contain GMOs" as "not providing any meaningful information to the consumer".[49] In their experiment, consumers appeared to prefer labels that clearly stated that this product was not a GMO or did not contain GM ingredients.[50] Therefore, the "may contain" labeling language is not a confident signal to consumers and, hence, is not suggested as a good choice for labels.

1.2 "Contain"

"This shipment contains" is another suggested option for the labeling of LMOs. It was proposed in the MOP-2 meetings of the Cartagena Protocol and had been widely discussed in the later MOP-3 meetings in March of 2006 in Brazil.[51] The proposal for a "this shipment contains" label aimed at providing clearer and more detailed labeling information. It suggested that identified

[48] Carl R. Galant, "Labeling LIMBO: Why Genetically Modified Foods Continue to Duck Mandatory Disclosure" (2005) 42 Hous L Rev 125.
[49] Onyango, *et al*., *supra* note 30.
[50] *Ibid*.
[51] *Decisions Adopted by the Conference of the Parties Servicing as the Meeting of the Parties to the Cartagena Protocol on Biosafety at Its Second Meeting, Montreal, 30May-3 June 2005*, online: CBD <http://www.cbd.int/doc/decisions/mop-02/full/mop-02-dec-en.pdf>. *Decisions Adopted by the Conference of the Parties to the Convention on Biodiversity at Its Third Meeting Servicing as the Meeting of the Parties to the Cartagena Protocol on Biosafety, Curitiba, Brazil, 13-17 March 2006*, online: CBD <http://www.cbd.int/doc/decisions/MOP-03/full/mop-03-dec-en.pdf>.

types of LMOs should be declared when a LMO in a particular cargo is known through identity preservation systems. The "shipment contains" option had gained an interim agreement by delegates at the MOP-3 meetings.[52] However, actual practice in the years since the agreement has shown that such "shipment contains" labeling options, namely "identifies GMO" labeling, are not easy to fulfill.

As previously discussed, the current operational system of agricultural commodity trade is not ready for the actual implementation of such information disclosure schemes. Disclosing more detailed information, such as which LMO varieties are present in a particular cargo, would require mandatory segregation of LM varieties, segregation of LM varieties from non-LM counterparts, and testing and recording at various points along the entire chain of agricultural commodity trade. However, at present, the comingling of GMOs and non-GMOs is still maintained in the domestic food supply and distribution systems of the major GMO-producing countries, such as the US, Canada and Brazil. Hence, accurate information about the identities of types of LMOs would be difficult to be realized on a practical level. Without accurate records at each point in the commodity chain, the labeling of a cargo shipment of crops that reads as "contain a type(s) of LMO(s)" would be difficult.

2. "Genetically Modified X" or "This product contains GMOs" or "This product contains genetically modified [name of organism(s)]"

In China, the GMO labeling regulation has listed possible labeling contents that can be used for labeling GM products, such as: "Genetically modified XX;" "Genetically modified XX

[52] *Decisions Adopted by the Conference of the Parties to the Convention on Biodiversity at Its Third Meeting Servicing as the Meeting of the Parties to the Cartagena Protocol on Biosafety, Curitiba, Brazil, 13-17 March 2006*, online: CBD <http://www.cbd.int/doc/decisions/MOP-03/full/mop-03-dec-en.pdf>.

processed;" "Processed material has been genetically modified;" "This product is produced from GMOs but it contains no GM ingredient;" or "The processed material of this product has been genetically modified, but it has no GM ingredient."[53] In the EU, "This product contains genetically modified organisms" and "This product contains genetically modified [name of organism(s)]" are the two specified labeling contents under the current EU GMO labeling laws.[54]

However, some of the above noted labeling statements have been criticized for being misleading and inaccurate.[55] Under a strict mandatory labeling system, such as the EU GMO regulatory regime, all GM products have to be labeled. For this reason, all GM products carry the same generic stickers. These identical and simple labels only notify consumers of the fact that such labeled products are different from non-labeled ones. They do not provide any detailed information, neither about what types of genetic modification have been made and why nor about any differences within the same categories of GM products. For example, a "genetically modified potato" label is used for all potatoes that have been genetically modified, but the simple label could not tell readers which potatoes, as a class, were bio-engineered for anti-drought and which ones were engineered for pesticide resistance. More importantly, this missing information as to why GM techniques were used or what improved traits were gained as a result of genetic modifications – would both increase the information adequacy of GM labels and increase positive consumer attitudes to GM products.[56] Thus, applying the same label to all GM foods does not

[53] Art. 6 and Art. 1 of the 2004 *Administrative Measures for Labeling Agricultural GMOs*. *The Administrative Measures for Labeling Agricultural GMOs* (has been amended in 2004), Online: Ministry of The People's Republic of China <http://www.moa.gov.cn/ztzl/zjyqwgz/zcfg/201007/t20100717_1601302.htm>.

[54] EC, *Directive 2001/18 of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC*, [2001] O.J. L106/1.

[55] Jagadeesan Premanandh, "Global Consensus –- Need of the Hour for Genetically Modified Organisms (GMO) Labeling" (2010) 17:1 Journal of Commercial Biotechnology 37.

[56] Brian Roe & Mario F. Teisl, "Genetically Modified Food Labeling: The Impacts of Message and Messenger on Consumer Perceptions of Labels and Products" (2007) 32:1 Food Policy 49.

provide accurate information, but leads to an implication that GM foods are inferior to foods created without biotech engineering.[57]

Moreover, claims that a particular food either contains GMOs or is "GMO-free" are misleading, because most foods do not contain "organisms" at all.[58] For example, labeling a bottle of canola oil as "this product contains GMO" or "GMO Canola Oil" is misleading, because canola oil is not an organism, or does not contain organisms. Both Health Canada and the US FDA uphold this point of view. For this reason, such types of statements are not allowed in Canada and the US.[59] In addition, negative labels, such as "GMO-free," or "this product contains no genetically modified ingredients," may be inaccurate and misleading when the product is a multi-ingredient food and the ingredients cannot be verified for their origins, or cannot be guaranteed against unintentionally comingled unapproved genetically modified products.[60] In some cases, such negative labeling is misleading, indicating that there is a benefit to purchase products that contain no genetically modified ingredients.[61]

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[57] Mikael Klintman, "Arguments Surrounding Organic and Genetically Modified Food Labeling: A Few Comparisons" (2002) 4:3 Journal of Environmental Policy & Planning 247.

[58] *Voluntary Labeling and Advertising of Foods That Are and Are Not Products of Genetic Engineering National Standard of Canada CAN/CGSB-32.315-2004*, online: <http://www.tpsgc-pwgsc.gc.ca/cgsb/on_the_net/032_0315/standard-e.html>.

[59] Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering; Draft Guidance, online: US FDA <http://www.fda.gov/food/guidancecomplianceregulatoryinformation/guidancedocuments/foodlabelingnutrition/ucm059098.htm>.

[60] B1.3 of Voluntary Labeling and Advertising of Foods That Are and Are Not Products of Genetic Engineering National Standard of Canada, *Voluntary Labeling and Advertising of Foods That Are and Are Not Products of Genetic Engineering National Standard of Canada CAN/CGSB-32.315-2004*, online: <http://www.tpsgc-pwgsc.gc.ca/cgsb/on_the_net/032_0315/standard-e.html>. Nicholas Kalaitzandonakes et al summarized four possible ways that unapproved GM varieties may be inadvertently presented in the food/feed supplies of one or more countries: "(a) experimental biotech crops that have received authorization for contained use in laboratories, greenhouses or field trials (e.g. Bt 10 maize, Prodigene maize, Liberty Link rice, Event 32 maize, Bt rice, FP 967 flax) but have not yet received regulatory approval for commercial use in any country; (b) biotech crops (e.g. Starlink maize) that have received regulatory approval for some commercial uses (e.g. feed) but not for others (e.g. food); (c) biotech crops that have been approved for all possible commercial uses (e.g. DAS 59122-7 maize) in one or more countries (e.g. US, Japan, S. Korea) but not yet in others (e.g. European Union), a case of asynchronous approvals; (d) biotech crops that have received time-limited regulatory approvals for commercial uses, which may have expired." See Nicholas Kalaitzandonakes, James Kaufamn & Douglas Miller, *Potential Economic Impacts of Zero Thresholds for Unapproved GMOs: the EU Case*, online: Food Policy (2013) <http://dx.doi.org/10.1016/j.foodpol.2013.06.013>.

[61] Jane Kolodinsky, "Affect or Information? Labeling Policy and Consumer Valuation of rBST Free and Organic Characteristics of Milk" (2008) 33:6 Food Policy 616.

3. Result of inaccurate labeling

From the perspectives of importers and exporters, inaccurate labels or statements of imported bulk shipments of GMO crops may lead to additional costs for importers due to labor inputs. Importers have to test all GM contents and document relevant information according to their domestic GMO traceability and labeling requirements. Exporters will also suffer significant economic losses if they offer insufficient information to importers about the shipments of GMO crops, because insufficient information may cause importers to postpone the shipment.[62]

Within a domestic market of GM foodstuff the existing negative image of GM agricultural techniques has already placed GM food products on an unfair status in the food market. Inaccurate labeling statements will further deepen consumers' misunderstanding of GM foods, damage the sale of GM foodstuff and lead to unfair competition in both upstream and downstream markets as discussed above. Also, domestic consumer interests will be impaired as a result of the inaccurate labeling. They may be confused or misled by the inaccurate information, and it may be difficult to make meaningful informed choices based on inaccurate labeling statements.

C. Challenges for specifications of labeling threshold

In the EU, GMO regulations have established a labeling threshold value of 0.9 percent of adventitious or technically unavoidable EU-authorized GMO contamination for GM food and

[62] Gemma Masip, et al., "Paradoxical EU Agricultural policies on Genetically Engineered Crops" (2013) 18:6 Trends in Plant Science 312.

feed.[63] If products contain more than 0.9 percent of GMOs they must be labeled. Labeling is still required if the GMO has not been authorized, or when the detection is below 0.9 percent but is avoidable and not adventitious.[64] For non-authorized GMOs that have received a favorable opinion from the European Food Safety Authority, the labeling threshold is established as low as 0.5 percent when the presence of GMOs is adventitious or technically unavoidable.[65] The EU is not the only authority setting out the labeling threshold for GM products. Other countries, such as Japan, South Korea, Australia and New Zealand have enacted similar regulations on GMO tolerance for labeling of GM products, ranging from 0.1 percent to 5 percent.

Countries	**The labeling threshold for GM products**
European Union	0.9 (%)
Brazil	1
China	0
Japan	5
China (Taiwan)	5
China (Hong Kong)	5
Chile	2
South Korea	3
Malaysia	3
Thailand	5
Mexico	3
Russia	0.9
Australia and New Zealand	1
Switzerland	0.9
United Kingdom	0.9
Turkey	None
Canada	5
United States	N/A

[63] Art. 12(2) of *Regulation No 1829/2003*, EC, *Regulation 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, O. J. Legislation (2003) No L268*/1, [2003] O.J. L268/1.
[64] *Ibid.*
[65] *Ibid*, *Regulation (EC) No 1829/2003*, Art. 47.

Table 6: Labeling thresholds in different regions and countries[66]

Since it is technically and practically impossible to guarantee zero percent of GM ingredients in food and feed, countries introduced a certain value of labeling threshold for GM ingredients.[67] However, ever since the establishment of labeling thresholds, especially the EU's nearly 1 percent tolerance, the value of a labeling threshold has been the subject of critiques. Opponents argue that there is no clear justification for setting a labeling threshold for approved GMO varieties since they have passed rigorous assessments for safe human consumption,[68] and that the EU's less than one percent threshold requirement is unnecessarily costly, time-consuming and scientifically unjustified.[69] If a closer examination of this threshold regulation is undertaken, it is not difficult to find the gaps between the regulation and interpretation as well as implementation of the regulation.

1. Interpretation of threshold

The first difficulty in applying the threshold regulation is determining how to interpret the different labeling threshold levels. For example, the latest EU legislation on specifying a labeling threshold for GMOs, Regulation (EC) 1829/2003, reads as "…foods containing material which contains, consists of or is produced from GMOs in a proportion no higher than 0.9 percent of the

[66] Kamle & Ali, *supra* note 20; Yu Zhuang & Wenxuan Yu, "Improving the Enforceability of the Genetically Modified Food Labeling Law in China with Lessons from the European Union" (2013) 14 Vt J Envtl L 465; Duillaume P. Gruere & S.R. Rao, "A Review of International Labeling Policies of Genetically Modified Food to Evaluate India Proposed Rule" (2007) 10:1 The Journal of Agrobiotechnology Management & Economics 6; Virginia Kimani & Gullaume Gruere, "Implications of Import Regulations and Information Requirements under the Cartagena Protocol on Biosafety for GM Commodities in Kenya" (2010) 13:3 The Journal of Agrobiotechnology Management & Economics 2; T., Demeke, D.J. Perry & W.R. Scowcroft, "Adventitious Presence of GMOs: Scientific Overview for Canadian Grains" (2006) 86 Can J Plant Sci 1; Maria Regina Branquinho, Renata T.B. Ferreira & Paola Cardarelli-Leite, "Survey of Compliance with Labeling legislation in Food Containing GMOs in Brazil" (2010) 23:3 Journal of Food Composition and Analysis 220.

[67] Florian Weighardt, "European GMO Labeling Thresholds Impractical and Unscientific" (2006) 24 Nature Biotechnology 23.

[68] Perry & Scowcroft, *supra* note 66.

[69] Mark A. Pollack & Gregory C. Shaffer, *When Cooperation Fails the International Law and Politics of Genetically Modified Foods* (New York: Oxford University Press, 2009) at 242-243.

food ingredients considered individually or food consisting of a single ingredient, provided that this presence is adventitious or technically unavoidable."[70] The term "ingredient" is defined in Paragraph 4(a) of Article 6 of Directive 2000/13/EC as "any substance including additives used in the manufacture and preparation of a food product and still in the final product even if changed."[71] Accordingly, in the context of GMOs, the labeling threshold of 0.9 percent requires that the weight of GM ingredients should not exceed a proportion of 0.9 percent of the total weight of raw materials (ingredients), otherwise the product has to be labeled as containing GMOs.

While regulators are using mass/mass ratios of GMOs to non-GMOs for defining labeling thresholds, the current method for detecting and quantifying the amount of GM ingredients in food and feed, as I explained earlier, is PCR, a molecular-level analytical methodology made in DNA/DNA ratios. The DNA/DNA ratio measurement can be precisely determined, but the following conversion of mass/mass units suffers from a lot of practical difficulties. Hence, such an analytical measurement would increase the uncertainty of and errors in GMO detection.[72]

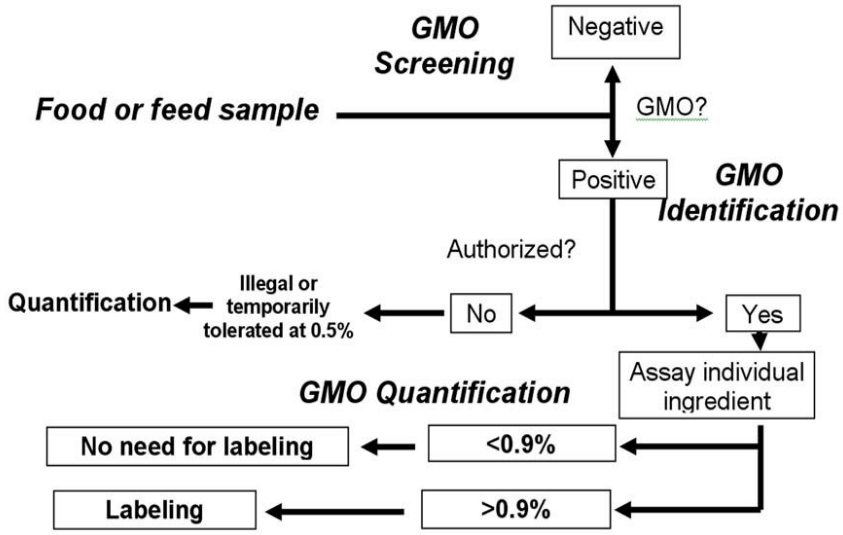
2. Challenges in qualifying and quantifying GMOs

In practice, the actual procedure for detecting GMOs can be summarized in Figure 3. To get a quick conversion of mass/mass ratio it is advantageous to use the certified reference materials (CRMs),[73] or sets of samples where certain levels of GMO concentration have been precisely

[70] Art. 12.2 of *Regulation (EC) 1829/2003*, *supra* note 63.
[71] Paragraph 4(a) of Art. 6 of *Directive 2000/13/EC*, *supra* note 45.
[72] Arne Holst-Jensen, "Testing for Genetically Modified Organisms (GMOs): Past, Present and Future Perspectives" (2008) 27:6 Biotechnology Advances 1071.
[73] David Lee, et al, "Quantitation Using Informative Zeros (QUIZ): Application for GMO Detection and Quantification Without Recourse to Certified Reference Material" (2010) 118:4 Food Chemistry 974.

determined.[74] This being said, there have been challenges in using this method to test GM content.[75]

Figure 1: Decision tree for GMO detecting and labeling[76]



2.1 The percentage of GM DNA

A lot of criticism has been aimed at how the percentage of GM DNA has been defined.[77] The EU Commission Recommendation of 4 October 2004 on technical guidance for sampling and detecting of genetically modified organisms and materials produced from genetically modified organisms as or in products in the context of Regulation (EC) No 1830/2003 (Recommendation

[74] The quantification of GM contents in food or feed is relying on "comparing the relative amount of a genetically modified organism (GMO)-specific target to a reference target or 'normaliser' using real-time polymerase chain reaction. The determination of GMO content depends primarily on the availability of certified reference materials (CRMs), a set of samples where the GMO concentration has been accurately determined. The amplification from DNA extracted from unknown samples in rt-PCR can be compared with amplification from DNA from CRMs which acts as calibrators both for the behavior of the samples in rt-PCR and to determine the copy number of the targets in the DNA extracts under investigation." See David Lee, et al, "Quantitation Using Informative Zeros (QUIZ): Application for GMO Detection and Quantification Without Recourse to Certified Reference Material" (2010) 118:4 Food Chemistry 974. Also see David Rodriguez-Lazaro, et al, "Trends in Analytical Methodology in Food Safety and Quality: Monitoring Microorganisms and Genetically Modified Organisms" (2007) 18:6 Trends in Food Science & technology 306.

[75] Weighardt, *supra* not 66; Arne Holst-Jensen, et al., "Coherence between Legal Requirements and Approaches for Detection of Genetically Modified Organisms (GMOs) and Their Derived Products" (2006) 54:8 J Agri Food Chem 2799.

[76] Rodriguez-Lazaro, et al., *supra* note 74.

[77] Maher Chaouachi, Aurélie Bérard & Khaled Saïd, "Relative Quantification in Seed GMO Analysis: State of Art and Bottlenecks" (2013) 22:3 Transgenic Research 461.

(EC) 2004/787) provides a proposal on defining percentages of GM DNA, i.e., "the percentage of GM-DNA copy numbers in relation to target taxon specific DNA copy numbers calculated in terms of haploid genomes."[78] Voices from the science fields did not support this new definition, with opponents arguing that the terminology, "haploid genome," would result in uncertainty when quantifying GM contents.[79] As Arne Holst-Jensen argued, the use of haploid genomes:

> leaves too much room for interpretation because it is not clear if the reference to haploid genome shall be understood as the monoploid or holoploid genome. The question is not just of academic interest because most food crops are polyploid derivatives of ancestral wild plant species. For example, the holoploid genome of wheat ($n = 3x = 21$) is composed of three monoploid genomes ($n = x = 7$). Consequently, the interpretation of the term "haploid genome" will have a highly significant impact on how GM is quantified.[80]

2.2 Mechanism for converting mass/mass to DNA/DNA

The use of CRMs to convert mass/mass to DNA/DNA is based on a presumption that there is a direct proportionality between the weight of the ingredient and the total number of genes or genomes contained in it. However, this presumption has been challenged.[81] Studies indicate that the factual molecular dosage of GM content could be higher or lower than 0.9 percent of the food ingredients.[82] Florian Weighardt has provided four possible reasons for this variation:

> First, no data are available on whether different lines of the same plant species exhibit a conserved ratio between the weight of what is considered an

[78] EU Commission Recommendation of 4 October 2004 on technical guidance for sampling and detection of genetically modified organisms and material produced from genetically modified organisms as or in products in the context of Regulation (EC) No 1830/2003 (Recommendation 2004/787/EC), *EU Commission Recommendation of 4 October 2004 on technical guidance for sampling and detection of genetically modified organisms and material produced from genetically modified organisms as or in products in the context of Regulation (EC) No 1830/2003, O. J. (2004) No L348*, [2004] O.J. L348.

[79] Holst-Jensen, et al., *supra* note 75.

[80] *Ibid.*

[81] S. Trapmann et al., *The Certification of Reference Materials of Dry-mixed Soya Powder with Different Mass Fractions of Roundup Ready soya*, online: European Commission IRMM Information Reference Materials <https://irmm.jrc.ec.europa.eu/refmat_pdf/ERM-BF410_report.pdf>.

[82] Weighardt, *supra* not 66.

> ingredient and the number of genomes contained in it...; Second, it is well known that some species of cultivated plants, like maize, show significant intraspecies variation in nuclear DNA content…; Third, if we consider diploid organisms, both the genetic modification and the species-specific reference marker could be found in homozygosis or in heterozygosis…; Finally, the ploidy of the tissue that the ingredient is derived from could vary from the usual diploid asset of organisms.[83]

Furthermore, since the adoption of this analytical measurement, the CRMs have become the key and determinative medium in the process of GMO detection. As a result, any changes to CRMs would cause errors or even differences in qualifying and quantifying GMOs. The CRMs are produced by the EU-based institute: the Institute of Reference Materials and Measurements (IRMM) of the EU's Joint Research Centers (JRC).[84] Under ideal conditions, CRMs should be standardized in certified proportion to specific mixtures of GM and non-GM materials, and should be used directly for GMO testing. However, in practice there are shortcomings for using CRMs to examine GM content. One such limit is that CRMs are only available for detecting GMO varieties that have been authorized and commercialized by the EU authorities.[85] This limit poses a practical problem for operators: when some types of GM varieties have received regulatory approval in an exporting country but have not been authorized in an importing country, the importers are then unable to use the CRMs to test those unapproved GMO varieties. For example, because of the technical difficulty in testing unauthorized GMOs, an experimental Chinese insect-resistant rice, Xianyou63 (Bt63), has been reported as having been detected in rice noodles within the chain of world food supplies.[86] Moreover, CRMs cannot be used to test GM varieties that are no longer commercially grown or are very newly approved for

[83] *Ibid*.
[84] Perry & Scowcroft, *supra* note 66.
[85] Rodriguez-Lazaro, et al., *supra* note 74.
[86] John Davison, "GM Plants: Science, Politics and EC Regulations" (2010) 178:2 Plant Science 94.

commercialization. [87] Therefore, it is suggested that the testing methods need further developments to make the detection of GM materials more accurate and efficient.[88]

2.3 Sampling

It is widely accepted that the sampling errors have been considered as the most significant factor in producing false measurements and uncertainty for GMO detection.[89] Any sampling errors will impact the mass/mass ratio of GM to non-GM content in raw material. Since these errors are unavoidable in practice, they will subsequently reduce the accuracy of CRM standards and impair the reliability of final testing results. With regard to sampling methods, some international organizations have developed international standards for sampling. For example, the International Organization for Standardization (ISO) has established several standards for sampling oilseed for quality and quantity assessment,[90] This said, harmonized international standards have not been formed worldwide to date. In Recommendation (EC) 2004/787, the EU's Commission proposed detailed guidelines for sampling methods, these guidelines suggest that operators take into account existing standards established by ISO, and require that in cases where lot sizes are larger than 500 tones, incremental samples should be at 100 collections.[91] However, a larger number of incremental samples would mean a more time-consuming and expensive testing process.

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[87] Rodriguez-Lazaro, et al., *supra* note 74.

[88] *Ibid*; Lutz Grohmann, "Detection of Genetically Modified Plants in Seeds, Food and Feed" (2010) 64 Genetic Modification of Plants Biotechnology in Agriculture and Forestry 117.

[89] Holst-Jensen, *supra* note 71; also see T. Allnutt, et al., "Sampling and Modeling for the Quantification of Advantitious Genetically Modified Presence in Maize" (2008) 56:9 J Agric Food Chem 3232.

[90] ISO 542:1990, ISO 664:2008 online: ISO <http://www.iso.org/iso/catalogue_detail.htm?csnumber=4619>.

[91] Recommendation 2004/787/EC, *EU Commission Recommendation of 4 October 2004 on technical guidance for sampling and detection of genetically modified organisms and material produced from genetically modified organisms as or in products in the context of Regulation (EC) No 1830/2003, O. J. (2004) No L348*, [2004] O.J. L348.

Therefore, the practical operational problems caused by the lack of coherence in defining the labeling threshold for GM content and real laboratorial methods for GMO detection has inadvertently contributed to factors that create uncertainty when implementing GMO labeling rules. In addition to these practical concerns, there are other fundamental questions behind the issue of an uncertain labeling threshold: that is, do the GMO labeling thresholds have any useful value in toxicology? And do they delineate the maximal permissible proportion of GM materials in food or feed beyond which they would be harmful or toxic to human and animals? The answer to both questions is probably no. As explored previously, although there is no established universal authority that assesses and approves GM varieties internationally as of today, all authorized GMOs go through the rigorous assessments by a country's authority before they are commercially grown and sold on the market. This means they have been approved to be safe for human and animals based on the current established scientific evidence. Thus, the value of 0.9 percent or even lower does not mean that products containing more than 1 percent of GM materials are toxic for human and animal consumption.[92] Therefore, the establishment of labeling thresholds for GM content is not a health-related tolerance, but an "authority developed" safety limit that is non-toxicologically relevant, because the risk associated with GMOs is low in real life. For this reason, threshold regulations should be developed with great care. As R. Wenning analyzed in his study:

> The philosophy behind these threshold values must be well understood and they should only be applied to real cases by persons with enough toxicological background. The bad use of these numbers in toxicology can have dramatic consequences. Especially in regulatory toxicology, the use of thresholds should be made with greater care.[93]

D. It is unlikely that mandatory labeling can be upheld under the WTO rules

[92] R. Wenning, "Threshold Values in Toxicology – Useful or Not" (2000) 113:1-3 Forensic Science International 323.
[93] *Ibid.*

Based on all the analysis in this chapter and the scientific exploration in Chapter Five, the questions I asked at the end of Chapter Three, i.e., whether a mandatory labeling measure is consistent with the WTO rules, can be answered at this stage of my research. According to my analysis in Chapter Three, under the WTO system, provisions of the GATT 1994, the SPS Agreement, and the TBT Agreement are applicable for the determination of whether a mandatory labeling measure is in violation of WTO rules. In the following section, I will examine mandatory labeling measures under each applicable WTO agreement and reach conclusions on their conformity with the WTO rules.

1. Article XX(b) of the GATT 1994

As previously discussed, in order to justify a labeling measure without violating Article XX(b) of the GATT 1994, the member state has to prove that: 1) there exists well-established evidence that shows GM products are more harmful than conventional counterparts to human and animal health and life; 2) there are no alternative non-trade restricting measures available for achieving the same objectives of protecting human and animal health; and 3) the measure does not constitute arbitrary or unjustifiable discrimination, or a disguised restriction in international food trade. However, my exploration found that there was no solid evidence indicating that GM crops pose higher risks than conventional foods to human and animal health and safety. As well, in comparison to mandatory labeling, voluntary labeling remains an alternative that is less trade-restrictive measure, and has been used in North America for decades with no cases pertaining to health safety issues being reported as a result of voluntary labeling regimes. Also of note is that the EU does not cultivate and sell large amounts of GMOs, and hence its mandatory labeling requirements and the 0.9 percent GM content threshold is not aimed at local EU GM product producers, but is particularly targeted at imported GM foods and feeds from GMO exporting

countries, such as the US, Canada and Brazil.[94] Thus, the increased costs due to implementation of labeling give a price advantage to non-GM products, and trigger the effect of arbitrary or unjustifiable discrimination against imported GM products.[95] Therefore, mandatory labeling cannot find a justification under Article XX(b) of the GATT 1994.

2. The SPS Agreement

Under the SPS Agreement, if a member state wants to use mandatory labeling demands for imported GM products, it has to provide evidence that the labeling measure is based on scientific evidence and risk assessment. Again, since there is no established evidence to support GMOs' harmful effect on human and animal health and safety, the member's mandatory labeling measures cannot be supported under the SPS Agreement. Even if the member argues that relevant scientific evidence regarding GMO safety is not sufficient, it has to seek additional information necessary for a more objective assessment of risk associated with GMOs within a reasonable period of time. Otherwise, if it cannot provide supplementary evidence on time, the member state cannot insist on long-term requirements for mandatory labeling of imported GMOs.

3. The TBT Agreement

If a WTO member state intends to justify its mandatory labeling measures exclusively based on the argument of providing consumers with information, the TBT Agreement can be applied and the member state has to prove the following conditions to make its labeling measures justifiable under the TBT Agreement. To prove its mandatory GMO labeling measures are in accordance with Article 2.1 of the TBT Agreement, the member state has to verify: 1) GM products are not

[94] Davison, *supra* note 86.
[95] *Ibid.*

"like products" vis-à-vis their conventional counterparts, and 2) the mandatory labeling measures do not result in less favorable treatment of the imported product compared to the like domestic product. To meet the requirements of Article 2.2, the member state has to explain that 1) providing consumers with information as to whether foods have been genetically modified is a legitimate objective within the meaning of Article 2.2; 2) the measure has fulfilled the objective of the measure; and 3) the measure is not trade-restrictive; and 4) there are no alternative non-trade restricting measures that can achieve the same objectives (i.e., providing consumers with information) and is not more trade-restrictive than necessary to fulfill a legitimate objective.

As explained in Chapter Three, the "like product" issue is significantly crucial in the GMO labeling case, because if GM and non-GM foods are deemed to be "like products" under the TBT Agreement, the mandatory labeling requirement applied to GM products is a violation of the TBT Agreement. This issue has been so controversial and complex that even the WTO Panel did not give a clarification in the *EC-Biotech* case. However, based on the scientific review of GM techniques and GMO safety considerations in Chapter Five, my research found that there are no material differences between GM and non-GM foods in relation to: 1) properties, nature and quality; 2) the end-use in a market; and 3) tariff classifications. The evidence gained in consumer survey studies indicates that the consumer preference for GM and non-GM foods should not be taken as a determinative factor, since studies on consumer preference can be affected by many factors and study results are varied. Accordingly, I conclude that GM foods can be recognized as "like products" to non-GM foods, and that the mandatory labeling measure is unlikely to be upheld under Article 2.1 of the TBT Agreement based on this conclusion.

With regard to the determination of whether a mandatory labeling measure is more trade-restrictive than necessary to fulfill a legitimate objective, i.e., requirements under Article 2.2 of the TBT Agreement, I have argued in Chapter Three that the mandatory GMO labeling measures are trade-restrictive under Article 2.2 of the TBT Agreement. In consideration of whether the provision of GMO information can be considered a legitimate objective, the evidence gained in scientific review of GM techniques reveals that GM techniques have not caused quality or property changes of the end products and that, as a production method, the use of GM techniques does not trigger health or environmental risks that can be accepted as the human safety and environmental conservation exceptions under Article XX of the GATT. Accordingly, providing consumers with GMO information should not be linked to the objective of prevention of deceptive practices listed under Article 2.2, and hence it should not be deemed to be a legitimate objective under Article 2.2. Since the provision of GMO information is not considered to be a legitimate objective, the conclusion that the mandatory labeling measures are not consistent with Article 2.2 of the TBT Agreement can be made without further inquiries into other conditions.

Even if a WTO Panel/AB regards providing consumers with GMO information to be a legitimate objective under Article 2.2, discussions in this Chapter indicate that the GMO labeling measures have not achieved a certain degree of contribution to the legitimate objective. This is because most current uses of GMO labeling are not only confusing but have also been challenged for being inaccurate and inadequate in the disclosure of information.[96] As previously discussed in Chapters Five and Six, vague labels cannot provide consumers with accurate and useful GM information when making choices between GM and non-GM products. Instead, mandatory

[96] As I have discussed in this chapter, there have been a lot of challenges for the statement of the labeling of GMOs, such as "may contain GMO" or "this product contain GMOs".

positive GMO labels (e.g., "This product has been genetically modified") may even aggravate the misconception that GMO foods threaten human health.[97] It may be argued that negative GMO labeling such as "This product is not GMO" or "This products do not contain GM ingredients" are more accurate than those positive labeling statements. However, the above noted examination of GM content testing methods demonstrates that, due to the increased number of new GM varieties and the limitation of testing methods, products that are labeled as GMO free may also contain unauthorized GM ingredients. Thus, a mandatory GMO labeling measure should not be considered to be a contribution to the objective of providing consumers with information on whether the foods they buy have been genetically modified or contain GM ingredients.

Moreover, in terms of the last condition, namely that there be no alternative non-trade restricting method, my research indicates that voluntary labeling, which is not more trade-restrictive than the necessary patterns, can take the place of the mandatory labeling to achieve the same objective of providing consumers with GM information. Therefore, in general, mandatory labeling is unlikely to be recognized as permitted under Article 2.2 of the TBT Agreement by a Panel or the AB.

Conclusion

Given there is little scientific justification of mandatory labeling regimes, it is necessary to examine practical challenges and costs associated with the implementation of the regime, because they are important components of the evaluation of a system. Accordingly, in this chapter, I focused on three perspectives that relate to the enforcement of a mandatory GMO labeling scheme, including the cost of labeling, accurate information disclosure, and the establishment of

[97] Scientific American's Board of Editors, "Fight the GM Food Scare" (2013) 10 Scientific American 1.

labeling thresholds for GM content. I also reached the conclusion in this chapter that a mandatory labeling regime is likely to violate WTO rules.

Based on the literature reviewed, I found that a mandatory labeling regime would increase the cost of both GM and non-GM food products. It was estimated that an additional cost of up to thirty percent would be added to a product's price for providing a simple GMO label.[98] Although survey studies have indicated that consumers are interested in knowing whether their food has been genetically modified, and most of them prefer to buy food that is labeled as "non-GM," there is also survey evidence showing that most consumers are not willing to pay the premium for such labeling. As a result, economic costs for implementation of a mandatory labeling regime need to be considered carefully especially when this price increase is related to providing the public with affordable foods.

Moreover, I also found that most of the current regulated labeling statements do not provide accurate and sufficient information on GM products. The inaccuracy of such statements could lead to heavy economic burdens for both importers and exporters. In order to meet the different domestic GMO labeling requirements, importers and exporters would have to distinguish, segregate, and preserve GM products from non-GM varieties. The inaccurate and inadequate information disclosure may also mislead consumers. Survey studies have revealed that statements of GMO labeling result in a common misunderstanding that GM products are qualitatively inferior to non-GM products. Therefore, the labeling statements need improvements to provide much more accurate and non-misleading information.

[98] Stuart Smyth & Peter W. B. Philips, "Product Differentiation Alternatives: Identity Preservation, Segregation, and Traceability" (2002) 5 AgBioForum 30.

Furthermore, my investigation into the establishment of thresholds for labeling GM products indicated that there exists a gap between the legal definitions of labeling thresholds, percentage of DNA and the real laboratorial methods for GMO detection, i.e., PCR and CRMs. The gap has resulted in uncertainty when fulfilling GM content threshold legislation. In addition, since detection methods for GM content have limitations per se, the confusion and uncertainty of implementation would be unavoidable in the technical operational context. Therefore, the regulation of labeling thresholds cannot be scientifically justified. Furthermore, threshold labeling does not have any useful values in toxicology, but rather expresses "political" safety limits that are non-toxicologically relevant.

Lastly, based on the analysis in this chapter as well as scientific study review in Chapter Five, I argue that the implementation of mandatory labeling measures cannot find any justifications under the applicable WTO rules, because these measures: (1) are neither based on a risk assessment nor sufficient scientific evidence, (2) exceed the level of protection of a relevant international (Codex) standard without scientific justification, and (3) the provision of GMO information may not be recognized as a legitimate objective. In addition, it can be argued that such regulatory restrictions are more trade-restrictive than necessary and have the effect of creating unnecessary obstacles to international trade because less trade-restrictive alternatives (e.g. voluntary labeling) are available. Therefore, member states that demand long-term mandatory labeling measures on imported GM products would face challenges before WTO Panels and the AB for violation of WTO rules.

In conclusion, the implementation of mandatory labeling of approved GMOs cannot find its justification from either theoretical or practical perspectives. Truth in labeling is a method of risk management. But in cases where there is no evidence indicating harmful effects of GMOs and the labeling statement is not accurate, the labeling of GM food produces little benefit, while leading to much more negative impacts. It results in not only increased food costs, but also a widespread misunderstanding about the safety consumption of GM foods, and can eventually impair the entire GM food industry. Regulations that are not based on solid scientific evidence, such as the threshold requirement, are demonstrated to be more harmful than helpful for consumer protection and the development of GM technology. Therefore, law and policy makers should abandon the mandatory labeling method for GMOs and place much more weight on promoting a uniform traceability system for GMOs on a international level, thereby aiming at accessing and managing GMO risks on human, animal health, and the environment.

Chapter 7 Conclusion: Lessons of GMO Labeling Conflicts, A Harmonized International System for the GMO Risk Assessment and GM Content Testing, and Indications for the Improvement of the Canadian GMO Labeling Regime

Regulation of GMO labeling, and GM foods in particular, will continue to be a subject of agricultural trade disputes, given that GMO global trade is irreversible and changes of positions by the two giant economies, EU and North America, is unlikely. The trade collision of different labeling requirements indicates that the discussion of GMO labeling is no longer limited within one or several jurisdictions. In fact it represents a more profound and complex controversy over socio-political-related concerns, agricultural biotechnology, international trade, and environmental protection. Thus, to give a full landscape of GMO labeling conflicts and possible solutions to the settlement of this collision, this dissertation has undertaken a comprehensive analysis of current GMO labeling laws on the international, domestic and EU levels. As well, this dissertation has explored arguments against rationales for mandatory labeling regimes, and has examined pragmatic issues around the enforcement of labeling measures widely adopted in current labeling legislation. In the first section of this chapter, I offer a set of concluding remarks, revisit different labeling regimes and their relevant underpinning factors, and restate arguments that criticize mandatory labeling regimes. In the second section, I draw lessons from my analysis of labeling conflicts and conflicts within GMO management, and outline a few points worth noting for future discussions of regulation of agricultural biotechnology. The third section chooses Canada as an example of domestic law to explain recommendations for improving the domestic regulatory framework of GMO labeling.

A. Concluding remarks

1. Challenges for multilateral regimes in settling conflicts of GMO labeling regimes

1. 1 Challenges

As stated by Gilbert R. Winham, multilateral regimes are able to provide states with a cooperative mechanism for managing varied interests.[1] In the case of conflicts regarding GMO labeling, we indeed find that cooperative treaty regimes have produced some positive outcomes by creating a multilateral forum for negotiating, exchanging scientific risk assessments, and clarifying parties' international legal obligations through dispute settlement.[2] For example, I have shown how the CBD and Cartagena Protocol have reached an agreement on the adoption of an advanced information agreement and the precautionary approach for the protection of environmental safety in the area of biodiversity. As well, the Codex CCFL has endeavored to provide a relatively nonpolitical and scientific evidence-based international forum that enables states to communicate and negotiate more independently. All their effort has eventually established the final CCFL guidance for GMO labeling given the US's compromise.

However, I have also found that these multilateral treaty regimes confront challenges in ways that may impair their functions and applicability when it comes to settling agricultural biotechnology controversies. A main challenge comes from the complex plurality of international regimes for agricultural biotechnology. As we have seen, there are a handful of international legal instruments that have relevant rules that are applicable to GMOs, but they apply to different areas due to the fragmented nature of these regimes. The CBD framework (environmental regime) focuses more on the potential adverse or harmful effects of living modified organisms (LMOs),

[1] Gilbert R. Winham, "International Regime Conflict in Trade and Environment: The Biosafety Protocol and the WTO" (2003) 2:2 World Trade Review 1.

[2] Mark A. Pollack, *When Cooperation Fails the International Law and Politics of Genetically Modified Foods* (New York: Oxford University Press, 2009) at 284.

which have the potential to impact on the conservation and sustainable use of biological diversity. The Cartagena Protocol, which is grounded in the precautionary approach, allows the state party to make decisions on the import of LMOs,[3] whilst the WTO system (trade regime) is in favor of promoting trade of GMOs by setting scientific evidence-based regulatory frameworks. The Codex CCFL (food safety regime), which aims to provide coordination between food safety and international food trade, has abandoned its attempts to formulate a special international labeling standard for GMOs, and has, rather, approved the *Compilation* that regulates GMO labeling under existing Codex texts. One problem here is that among these regimes there is no overarching inter-governmental organization that can effectively address all of the trade, environmental and food safety issues and reconcile the subsequent conflicts under one umbrella. The fragmentation of international law has led to inconsistent and, in some cases, even incompatible, approaches to different GMO regimes, and has resulted in an unclear inter-regime hierarchy.[4]

1.2. Solving GMO labeling conflicts under the WTO system

Amongst the multilateral regimes, the CBD framework also contains applicable mechanisms for settling GMO labeling disputes. This being said, its capability for dispute settlement is limited. First of all, it only applies to *living* modified organisms that are intended for direct use as foods and feeds, or for processing. This limitation has excluded a large part of GMO foods from the CBD coverage since a majority of GM foods and food ingredients including GMOs are no longer living organisms. Moreover, the US and Canada, which are the major global developers and producers of GMOs, have not become contracting parties to either the Cartagena Protocol on

[3] See Daniel Wuger & Thomas Cottier, *Genetic Engineering and the World Trade System* (UK: Cambridge University Press, 2008) at197. See also Francesco Francioni & Tullio Scovazzi, *Biotechnology and International Law* (USA, Portland: Hart Publishing, 2006) at 245.
[4] Pollack, *supra* note 2 at 285.

Biosafety or the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress. Canada is a contracting party to the CBD, but the CBD is not a prohibitionist instrument, and its obligations are in weak or soft forms. Accordingly, it is extremely unlikely that Canada and the US will file trade complains under the dispute settlement mechanisms provided by the CBD framework, as neither of them are legally bound by the Protocol and Supplementary Protocol.

The WTO system has been challenged for its excessive consideration of evidence-based assessments that rule out entire categories of ethical, social, and religious values. Consequently, their competence for properly resolving conflicts concerning agricultural biotechnology has come under scrutiny.[5] However, based on my analysis of existing multilateral regimes in settling GMO labeling regime conflicts**,** I argue that the WTO dispute settlement system is the only multilateral regime that can help manage conflicts, monitor compliance, and clarify members' legal obligations towards GMO labeling related disputes. The supportive reasons include:

1) The major players of GMO/non-GMO trade – US, EU, China and Canada are all WTO members and they are bound by the treaty obligations;

2) The WTO has applicable rules for GMO labeling measures and such rules are legally binding on all member states;

3) It has a relatively efficient and legalistic dispute settlement mechanism;

4) Its dispute settlement procedure recruits and relies on scientific experts as a credible source of decision-making related to risk assessment in the dispute settlement process, and hence strengthens its scientific evidence-based trade discipline;[6]

[5] Ian M. Sheldon, "Regulation of Biotechnology: Will We Ever 'Freely' Trade GMOs?" (2002) 29:1 Eur Rev Agric Econ 155.

[6] In the *EC – Biotech* case, the panel mobilized scientific expertise in the dispute resolving process over the risk issues associated with biotech products in question. The input from experts is argued as being "in line with the 'science-based trade discipline' discourse that backed the creation of the WTO and enhanced its legitimacy." See Christophe Bonneuil & Les Levidow, "How Does the World Trade Organization Know? The Mobilization and Staging of Scientific Expertise in the GMO Trade Dispute"

5) The WTO Agreements have referred the Codex standards (soft law) as international standards (turning Codex standards to hard law), and the EU, US, China and Canada are all Codex Committee members. As a result, many social and ethical concerns regarding GMO labeling, which are less likely to be addressed under the WTO system, can be discussed in the Codex forum, and the resulting standards must be adhered to by all WTO member states;

6) In the socio-politically sensitive context of GMO disputes, although the WTO system may not settle the labeling conflicts of GMOs by addressing substantive GMO risk issues, it can indeed facilitate the management of the conflicts and the settlement of disputes through review of the respondent's regulatory procedures; and

7) It is practically difficult to create another new multilateral treaty regime that has both the same number of members as the WTO as well the capacity for dealing with conflicts between GMO safety issues and international trade.

As we have seen in the WTO *EC-Biotech* case, because of the socio-political concerns, the Panel did not make any substantive justification as to whether the EU's measures on biotech products in question were contrary to WTO agreements, or to put it another way, whether the EU measures were based on scientific risk assessments, but it did provide clarification on each side's procedural obligations.[7] These clarifications included the decision that the "undue delays" were inconsistent with the SPS Agreement and that the EU should act in a timely manner in respect of the approval of GM varieties in dispute.[8] Moreover, the Panel also made relative comprehensive analyses on controversial issues that could provide persuasive legal interpretation for future WTO dispute settlement. Such issues include, for example, whether the protection of the consumer's

(2012) 42 Social Studies of Science 75.

[7] *Ibid.*

[8] See Report of the Panel, *European Communities – Measures Affecting the Approval and Marketing of Biotech Products (EC – Biotech)*, (2006) WT/DS291/R, WT/DS292/R, WT/DS293/R.

interest in information is consistent with WTO rules in the context of food products trade, and what criteria can be used to determine "like products."[9] Therefore, even though a WTO decision may not completely resolve disputes over GMO labeling, nor guarantee the full exercise of member obligations under the WTO laws, the dispute settlement process can indeed provide opportunities to let two disputants solve their differences through a legal process, and can facilitate negotiation and communication platforms to promote greater mutual accommodation.[10]

2. Sources of international conflicts of GMOs labeling

The sources of conflict surrounding GMO labeling in international law stem from the different approaches of domestic systems to GMO labeling and the diverse attitudes of national authorities toward GMO and GM technology. The EU and most EU countries have the most critical attitudes toward GM techniques and have established the most stringent traceability and labeling regimes for GMOs. The EU espouses the precautionary approach, uses a process-based mandatory labeling scheme that requires any products that contain more than 0.9 percent of authorized GM content to be labeled.[11] In contrast, Canada adopts a substantially equivalent principle for the assessment of GMO safety concerns, and only mandates that GMOs be labeled when nutritional or compositional changes, or other health related concerns, such as allergens, have been verified.[12] Canada uses a product-based voluntary labeling regime that allows producers to decide

[9] *Ibid*; Report of the Panel, Report of the Panel, the *United States – Certain Country of Origin Labeling (the US – COOL)*, (2011) WT/DS384/R. WT/DS386/R.

[10] Pollack, *supra* note 2 at 290.

[11] Regulation 1830/2003, EC, *Regulation No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labeling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (Regulation (EC) No 1830/2003)*, [2003] O.J. L268/24.

[12] Health Canada, *Guidelines for the Safety Assessment of Novel Foods*, online: Health Canada <http://www.hc-sc.gc.ca/fn-an/legislation/guide-ld/nf-an/guidelines-lignesdirectrices-eng.php>; *Voluntary Labeling and Advertising of Foods That Are and Are Not Products of Genetic Engineering National Standard of Canada CAN/CGSB-32.315-2004*, online: <http://www.tpsgc-pwgsc.gc.ca/cgsb/on_the_net/032_0315/standard-e.html>.

whether or not to label their products as GM or non-GM.[13] On the one hand, China, as a representative of developing countries, has actively joined the GM-based agriculture trend. The Chinese government has given priority to the promotion and development of GM-based agriculture in its twelfth five-year national strategic development plan.[14] On the other hand, China is also very cautious when it comes to marketing GMOs, and is especially so in its commercialization of GM rice and other staple foods. China adopts the precautionary approach and claims that it will use the strictest regulatory framework for GMOs to secure safe food for consumption by the Chinese people. These decisions locate China closer to the EU in terms of GMO management. Although there are no specified rules on a labeling threshold in its mandatory labeling scheme, the Chinese government has declared that all GM products in China must be labeled no matter how much GM content is contained within the products (zero tolerance).[15]

These different GMO labeling regimes can be tracked back to two major contributing factors: (1) different influence of various collective groups on GMO related policy-making, and (2) different marketing demands and different producer interests. In light of the first factor, conventional theories hold that collective groups, i.e., consumer and environmental groups, have significant influence on law and policy making because they encompass large and divergent levels of participation.[16] However, my exploration of the EU and selected domestic labeling frameworks found that the capacity of consumer and environmental groups to influence policy-making in GMO-related management varied dramatically from jurisdiction to jurisdiction. One reason for

[13] *Voluntary Labeling and Advertising of Foods That Are and Are Not Products of Genetic Engineering National Standard of Canada CAN/CGSB-32.315-2004*, *ibid.*

[14] *"Twelfth Five" National Strategic Emerging Industry Development Plan*, online: the Central People's Government of China <http://www.gov.cn/zwgk/2012-07/20/content_2187770.htm>.

[15] Kou Jianping, an official from China's Ministry of Agriculture said: "China adopted mandatory 'zero threshold' identification. It must be marked as long as the product contains genetically modified ingredients." See *China Most Strict on Genetically Modified Organisms*, online: Guangming Daily, August 24, 2011 <http://english.people.com.cn/90882/7578858.html>.

[16] Thomas Bernauer & Erika Meins, "Technological Revolution Meets Policy and the Market: Explaining Cross-national Differences in Agricultural Biotechnology Regulation" (2003) 42:5 European Journal of Political Research 643.

this variation can be derived from the public's different levels of trust in governments.[17] As I explored in Chapter Four, the EU public lost confidence and trust in its governments during the food safety scandals of the 1990s, because the domestic and EU authorities failed to appropriately manage the crises and did not take seriously the public's concerns about food safety.[18] China also has a similar story. This lack of governmental concern thereby increased the public's fear of uncertain risks in both China and EU member states.[19] Accordingly, the public in the EU and China became cautious about the uncertainty risks associated with GM products, and became very skeptical about agricultural biotechnology. As a result, the EU has to develop increasingly stringent regulations of GMOs to improve and strengthen the domestic consumer and environmental groups' confidence in their governments.[20] It adopted the precautionary principle and implemented strict traceability and labeling systems regardless of whether such rules were practically operable. Similarly, the Chinese government claims the position of zero tolerance on food safety issues and requires GM foods to be mandatorily labeled if they have GM contents. The attitudes of the EU and Chinese authorities, and their corollary rigorous regulations, in turn made the public believe there were high risks in consuming GM foods, and as a consequence they became more firmly entrenched in their anti-GMO attitude.

The other reason for the different consumer and environmental groups influence on policy-making related to GMO labeling is due to different policy-making models. EU GMO policy-making places more emphasis on the social concern rationality, while Canada sticks to the

[17] Diane M. Phillips & William K. Hallman, "Consumer Risk Perception and Marketing Strategy: The Case of Genetically Modified Food" (2013) 30:9 Psychology & Marketing 739.
[18] Valery Federici, "Genetically Modified Food and Informed Consumer Choice: Comparing US and EU Labeling Laws" (2010) 35 Brooklyn J Int'L 515.
[19] Bente Halkier & Lotte Holm, "Shifting Responsibility for Food Safety in Europe: An Introduction" (2006) 47:2 Appetite 127.
[20] Thomas Heberer, et al., "Aero Tolerances in Food and Animal Feed-Are there Any Scientific Alternatives?: A European Point of View on An International Controversy" (2007) 175:1-3 Toxicology Letters 118.

scientific evidence based policy-making model. The social consideration oriented model is more accessible for public participation and deliberation, but it is also more susceptible to anti-science mobilization and the impact of protectionism. The Chinese GMO labeling related policy-making model is located between Canada's and the EU's. The Chinese policy-makers have not strictly relied on the scientific evidence as Canadian policy-makers do, nor have they been as open as the EU in terms of the public consultation inputs. Hence, China uses a product-based mandatory labeling system that targets seventeen kinds of five major categories of GM agricultural products.

With regard to the second contributing factor, my research found that marketing demands and producer interests have played a significant role in establishing national labeling systems for GMOs. In terms of the EU GMO industry, it is argued that EU member states' rejection of GM techniques was not based on scientific evidence or purported potential risks (since the EU authorities had clarified several times that the authorized GM crops were not harmful to human and animal health[21]), but rather on the lack of benefits brought about by the application of GM techniques and cultivation of GMOs.[22] The EU exports large amounts of agricultural products, and it does not suffer from food supply shortages and starvation problems. European farmers are able to produce considerably high quantity and quality of foods at reasonable prices using conventional agricultural cultivation techniques.[23] On the other hand, pursuant to the public's support of "natural foods" that occurred during the anti-GMO trend, European farmers did not suffer from the stringent GMO regulatory framework but, rather, took advantage of the EU GMO mandatory labeling system since the North American food producers grew huge amounts of GM crops with no established segregation and identification systems. As a result, it is not surprising

[21] John Division, "GM Plants: Science, Politics and EC Regulations" (2010) 178:2 Plant Science 94.
[22] *Ibid*; Fanny Rolin, Jean Kennedy & Josephine Wills, "Consumers and New Food Technologies" (2011) 22:2-3 Trends in Food Science & Technology 99.
[23] Robert Paarlberg, "GMO Foods and Crops: Africa's Choice" (2010) 27:5 New Biotechnology 609.

to find that most European farmers support EU polices and want to continue with the current or even stricter GMO regulations.

With regard to Canada, as a NAFTA party, it has a strong economic connection with its neighbor, the US. Although some of Canada's agricultural trading partners have administered various types of mandatory labeling regimes, more than fifty percent of Canada's GM crops are exported to the US and Mexico, countries that do not have mandatory labeling requirements.[24] It is reported that the value of agricultural food trade between Canada and the US was about CAN $38.6 billion in 2011 ($19.5 billion in Canadian exports to the US, and $19.1 billion in US exports to Canada).[25] The US has been Canada's largest agricultural trading partner.[26] The US alone has accounted for more than one-half of all Canadian annual agri-food exports.

As a developing country, China faces more complicated problems than the EU and Canada do. For example, the unbalanced development between the eastern and western parts of the country, limited arable land, a huge population and water and air pollution. Having enough food for the public (self-sufficiency) is the most important mission for Chinese food security. Since the advanced seed companies in Western countries have preemptively occupied the seed supply market, the Chinese government has targeted GM technology as a priority industry for support, on the one hand, and the establishment of GMO biosafety regulatory frameworks, on the other, to

[24] According to Agriculture and Agri-Food Canada 2012 report, the US is Canada's largest export destination. Mexico ranked fourth. The two countries together account for more than half of all Canadian agri-food exports. See Agriculture and Agri-Food Canada, *2011-2012 Agriculture and Agri-Food Market Access Report*, online: Government of Canada <http://www.agr.gc.ca/eng/industry-markets-and-trade/market-access/2011-2012-agriculture-and-agri-food-market-access-report/?id=1352240788033 >; See also Foreign Affairs, Trade and Development Canada, *Canada's State of Trade: Trade and Investment Update 2012,* online: <http://www.international.gc.ca/economist-economiste/performance/state-point/state_2012_point/index.aspx?lang=eng >; Government Response to the Standing Committee on Agriculture and Agri-Food Report Labeling of Genetically Modified Food and Its Impact on Farmers, online: Parliament of Canada <http://www.parl.gc.ca/HousePublications/Publication.aspx?DocId=540075&Language=E&Mode=1>.

[25] Foreign Affairs, Trade and Development Canada, *Ibid*.

[26] See also Foreign Affairs, Trade and Development Canada, *Canada's State of Trade: Trade and Investment Update 2012,* online: <http://www.international.gc.ca/economist-economiste/performance/state-point/state_2013_point/index.aspx?lang=eng>.

fundamentally improve China's food production, lower seed prices, and secure Chinese food supplements. The Chinese government has adopted the precautionary approach and has implemented a mandatory labeling regime to control the contamination of domestic biodiversity by imported GMOs. More importantly, some recent food safety scandals have dramatically impaired consumer trust in the government and forced the Chinese government to proclaim its ambitions to administer the strictest supervision of GM foods safety assessments and the implementation of GMO labeling (zero tolerance). Commentators argue that the Chinese government's ambition is scientifically impracticable and it has resulted in unsatisfactory enforcement of the labeling regime.[27]

The conflicts between North America and the EU eventfully challenged the multilateral regimes for resolving controversies over GMO labeling regimes. Both North America and the EU are giant economic entities in the global market, and both tried to impose their own standards on global regulatory standards. We have seen that the EU encouraged the Codex Committees to adopt mandatory GMO labeling and use the precautionary approach when approving and marketing GMOs, and that the EU's recommendations to the Codex were based on integrated ethical and social values rather than scientific evidence. In contrast, Canada and the US have advocated their position of voluntary labeling of GMOs and have proclaimed that the regulatory framework of GMOs should primarily be based on scientific evidence. As I have discussed in Chapters Two and Three, the science based principles proclaimed by Canada and the US have been supported by the Codex and WTO systems. Accordingly, it is not unusual to see the EU, Canada and the US using approaches in different regimes that most benefit their own interests to

[27] Yu Zhuang & Wenxuan Yu, "Improving the Enforceability of the Genetically Modified Food Labeling Law in China with Lessons from the European" (2013) 14 Vt J Envtl L 465.

legally justify their arguments and trade measures, such as in the WTO *EC-Biotech* and *EC-Hormones* cases. As a result, the disagreement between the two economic entities hinders the process of establishing a new multilateral binding regime to solve disputes due to different GMO labeling regimes.

3. Arguments against rationales for a mandatory labeling regime on GMOs

My analysis found that popular rationales for GMO mandatory labeling demands were primarily based on a presumption that GMOs might pose severe and/or irreversible harm to human and animal health. However, this presumption is claimed without solid evidence and merely stands on a hypothesis that GM foods are deemed to be unhealthy and unsafe due to the "unnatural" processes of genetic modifications. In fact, my exploration found that this presumption, along with the "unnatural" argument, has been proven to be scientifically incorrect: some of the presumptions were groundless allegations, while others were based on false research results due to bad or poor experimental designs. Therefore, it is important to clarify that, to date, most scientific authorities assert that there has been no established evidence showing that approved GM crops are more risky than conventional counterparts for human and animal consumption.

Clarifications on GMO safety issues from scientific authorities do not necessarily mean that GMOs are risk-free. Scientifically speaking, every technology, including GM techniques and GMOs, may pose certain levels of risk. However, instead of using science and technology to ascertain uncertain risks associated with GMOs, anti-GM groups have insisted on the implementation of the precautionary approach, and have demanded that a mandatory labeling regime be used to satisfy the requirements of the precautionary principle. Discussions in previous chapters indicate that the concept of precaution has been embedded in many environmental

protection-related legal instruments, but most of the existing international instruments use the expression of "precautionary approach" in the international environmental context. There is even less application of the precautionary approach/principle in the international food safety law context. The ICJ and WTO Panels/AB have not recognized the precautionary principle/approach as a customary international law principle, and it has not been recognized as a general principle of law recognized by nations in the food safety contexts. Even as an emerging principle, the precautionary approach has been challenged for its inappropriate risk assessment and management, because, in its strongest version, the principle would preclude any actions at all, including the risk management regulations themselves. Moreover, given that no uniform and precise concept exists, when applying this principle, another uncertainty arises: which standards should be applied to determine whether a technique or technology is a high-risk performance and who can decide that? Accordingly, in the context of international GM agricultural products trade disputes, use of the precautionary approach to justify a special labeling requirement creates difficulties and complexities in distinguishing this type of a measure from a protectionist measure.[28] Therefore, it is not only difficult to successfully address the precautionary principle under the WTO system but, in addition, this principle cannot provide sufficient legal justification for a country's GMO mandatory labeling demand.

With regard to another popular argument in support of mandatory labeling – the consumer's right to know – my research found that this right is not accepted as a sole legal justification for mandatory GMO labeling in either domestic law or in related international instruments. Within the legal frameworks I examined, the EU was the only jurisdiction in which GMO labeling

[28] Christiane Gerstetter & Matthias Leonhard Maier, Risk Regulation, Trade and International Law: Debating the Precautionary Principle in and Around the WTO (May 19, 2005), online: SSRN <http://ssrn.com/abstract=1568363 or http://dx.doi.org/10.2139/ssrn.1568363>.

legislation recognized a sufficient justification of the consumer's right to know for mandatory GMO labeling. Labeling frameworks used by Canada and China, and all related international instruments, generally consider the health-related concerns as the determinative factor for launching a mandatory labeling requirement for food products. The EU emphasizes the protection of the consumer's right to know, but there are very few GM-labeled foods sold on the EU market. Moreover, some recent EU members' bans on marketing authorized GMO varieties were found to be based not on scientific evidence, but on political concerns. Therefore, the purported consumer's right to know is suspected of being used as an excuse by the EU for protectionist purposes and strategic plans related to limiting the development of GMO marketing in the EU.

My analysis of the consumer's right to know also argues that consumers' desire for information cannot sustain a labeling requirement. This is partly because too much information on labels, written with the intention of satisfying all consumers' desire for information, may ultimately confuse consumers at the point of food purchase, so that the material information will be overlooked. Moreover, meaningful consumer choices will be made only if consumers are fully informed and know the facts about GMO information. However, my exploration found that a simple "GMO" label cannot provide ample and accurate information, and that a survey has indicated that the majority of consumers wanted GM foods to be labeled so they can avoid purchasing products with GM labels (they function as warning sign). Therefore, the consumer' right to know is not a rigorous argument and cannot provide a sufficient justification for the implementation of the mandatory labeling regime for GMOs.

4. Challenges for the enforcement of the mandatory labeling regime

In addition to discussing how rationales for mandatory labeling regimes are controversial, my research also revealed that design flaws cause pragmatic issues to arise when current mandatory labeling requirements are enforced. First of all, labeling statements are often found to be inaccurate, inadequate and misleading. My research indicated that neither positive labeling (i.e., "This product has been genetically modified") nor negative labeling (i.e., "This product is GMO free"), nor "may contain" labeling are accurate or meaningful. In terms of possible labeling, without further explanatory information about genetic modification in particular, a statement such as "This product has been genetically modified," does not disclose any accurate and adequate information, and on this basis cannot disguise different genetic modifications within a same-food variety. Negative, or "GMO free," labeling, on the other hand, may convey sufficient information, but because of the limitations of current GMO detection methods and the absence of international uniform standards for the detection of GM content in the global food supply chain, such labeling may actually obscure certain levels of authorized or even unauthorized GMO content. While "may contain" labeling statements are truthful, they also reference the large possibility of GMO content and this in turn makes such labeling very non-informative. Accordingly, consumers cannot make any real meaningful choices based on these labels, even though they are burdened with the increased costs these labels entail.

Because of better yields and less pesticide use, one benefit associated with GMOs is the decrease in food costs. However, my research found that the implementation of mandatory GMO labeling would demand the establishment of a domestic segregation and identification food supply chain system. This requirement means huge financial and other resource commitments for each country, especially countries such as the US and Canada, which have commingled GM and non-GM crops from the beginning of the commercialization of GM products. Investment in segregation and

identification systems will inevitably increase GM food costs, which will eventually be paid by consumers. Nonetheless, many studies have indicated that GM information, compared to other food attribute information, plays an important but not determinative role in consumers' purchasing decisions,[29] and that most consumers are not willing to pay the premium for labeling.[30] Since GM foods have been rigorously assessed to be safe and healthy for human and animal consumption, they should be treated like conventional food products. Accordingly, the increased food costs caused by labeling GM content are unnecessary for the majority of the public.

Asking the majority of the public to bear the unnecessarily increased food prices may trigger anther food security problem, i.e., the affordability of foods for average-income and low-income families in industrialized and developing countries. People with higher incomes can afford to buy labeled foods easily (whether they are labeled as GMOs, GMOs free, or Organic certification) of higher prices, but most consumers with average incomes are sensitive to food price, and food price is often perceived to be the major factor in the purchase of foods. In particular, food price has more significant impact on people's life in developing countries where the supplementation of affordable foods is a crucial factor for local food security. GM foods were invented to decrease the cost of global food production, but highly priced GMO-labeled foods have offset this benefit, and thus limited the availability of low-price safe foods for the populations in developing countries.

[29] David Castle, "Labeling Policies for Genetically Modified Foods" in Nola M. Ries & Jacob J. Shelley ed, *Food, Health and Biotechnology: Consumer and Social Issues in Canada's New Food and Health Product Industries*. (Advanced Foods and Materials Network, 2007) at11.

[30] Stuart Smyth & Peter W.B.Phillips, "Labeling to Manage Marketing of GM Foods" (2003) 21:9 Trends in Biotechnology 389.

In terms of testing GM contents, most mandatory labeling regimes have set forth a certain level of threshold for GM contents, beyond which the products have to be labeled as GM products. The different provisions on thresholds for GM contents make the GMO detection between food trading parties complex and time-consuming. More importantly, gaps exist between legal definitions of GM content threshold and real laboratorial methods for GMO detection. In other words, the thresholds expressed in legal instruments cannot be understood and applied by bio-scientists in a scientific manner. Therefore, in some cases, threshold requirements, whether they be 3 percent or even 0.5 percent of GM content, cannot actually be tested by bio-specialists. Based on this research, I suspect that all GM content thresholds do not in fact possess any meaningful values in toxicology, but are established as policy limitations, since all approved GM varieties have been deemed to be safe after strict and complex safety assessment procedures.

When we examine the pragmatic issues that arise from implementing mandatory labeling regimes and scientific understandings of GM techniques and GMOs are examined, such mandatory labeling measures violate the WTO rules (GATT 1994, the SPS Agreement and the TBT Agreement). This means that WTO member states may face challenges from Panels and the AB for their mandatory GMO labeling measures when bio-agricultural food trade disputes occur due to different labeling requirements, thereby resulting in the labeling measure not being permitted.

In general, the evidence as set out in this research suggests that law and policy-making surrounding GMO labeling should be primarily based on rational, science-based health and safety-related concerns, such as allergen, compositional and nutritional changes etc. Consumer preferences should also be considered when formulating a labeling framework, but the rules should guarantee that consumers are fully informed about GMOs so that they can make

meaningful choices. However, based on the comparative analysis between the two current widely-used labeling models, i.e., the mandatory and voluntary labeling regimes, from the legal, economic, and customer-behavior studies, my research has found that mandatory labeling measures for GMOs have triggered a number of difficult problems that are actually contrary to existing laws and the public's general interests. For example, the misleading information disclosure goes against truth in advertising requirements in food labeling and advertising laws; increased food costs may affect the affordability of foods for middle-income and low-income families for healthy living in both industrialized and developing countries; and mandatory-labeling measures may trigger legal and institutional conflicts in global agricultural trade due to different domestic labeling systems. Therefore, the insistence on implementing mandatory labeling regimes without solid scientific evidence may have the following outcomes: (1) consumers in fact will not have choices at all since there will be no GM foods available on the market or they will be unaffordable for most persons; (2) the development of biological agricultural technology, which is suggested to be the most promising technique for the sustainable development of agriculture, will be impeded by the overwhelming anti-GM trend; and consequently (3) the food security of millions of persons in developing and even industrialized nations will be deterred.

My research, therefore, suggests that in order to mitigate the chaos of different domestic and regional labeling regimes, the real initiatives that countries should devote their efforts to are: the establishment of a globally harmonized risk assessment and procedure for a GMO approval process, the formation of uniform domestic labeling threshold regulations; and the development of effective detection methods for GM materials. Without such uniform global mechanisms, the labeling regimes, either mandatory or voluntary, are not helpful for the supervision of (authorized

and unauthorized) GMOs on both domestic and international dimensions and for the future development of GMOs. The development of GM techniques and GMO cultivations without uniform global mechanisms may eventually cause trouble for public health and safety, as well as the environmental monitoring of the importing country.

B. Lessons from the conflicts of GMOs labeling

Controversies around agricultural biotechnology will not end with the debates over current GM crops. Other emerging products that use new technology, such as the next generation of GM crops, nanotechnology products, foods derived from cloned animals, and GM animals will also confront similar challenges. In the context of the GMO labeling debates, we have seen that many concerns that do not involve scientific evidence have been raised, and that these concerns have created intractable disputes and have caused controversies to become more complicated or even politicized. One possible outcome of these engagements is that particular mandatory labeling laws and policy-making practices will not follow an evidence-based process. In the following section, I intend to draw some lessons from the current GMO labeling controversies for the better management of future GMO labeling conflicts and regulation of new agricultural biotechnology.

Lesson one: Endeavor to balance discussion when discussing any newly emerging technologies

As an emerging new technology, GM techniques and commercially grown GMOs have attracted a huge amount of discussion from both the scientific community and public groups. However, most of their attention, especially from political and environmental groups, has been focused on potential risks rather than the scientific evidence of GMO safety and concrete benefits of GMOs. The anti-GM campaigners usually deride the benefits of GMOs while focusing solely on

suspicions about their safety. In most cases, they have exaggerated the risks associated with GMOs by using inflammatory statements [31] Given such unbalanced discussion and misrepresented stories, most of the lay public is not easily able to gain objective information about GMOs, and persons are therefore prone to question and judge the safety of GMOs in a subjective manner. The public thereby joins the anti-GM complainers and opposes the cultivation of GMOs, even though they are informed that some varieties of GMOs can solve the food shortage problem in certain countries and save millions of lives.

Similarly, an unbalanced discussion has also occurred in relation to controversies over GMO labeling. Proponents of mandatory labeling regimes have always based their arguments on potential harmful risks associated with GMOs and the consumer's right to know. However, given that existing evidence tells us that there are no negative health issues associated with GMOs, I would argue for an unique regulatory treatment for GMOs, in which not only the consumer's interest, but also humanity's food security, environmental values, and the interests of farmers, producers, and other relevant parties are all respected and protected. The implementation of mandatory labeling measures will directly and/or indirectly negatively impact the interests of most stakeholders, which will eventually turn out to be more harmful than helpful.[32] Thus, during the process of formulating a GMO labeling system, in order to ensure that the final labeling regime benefits consumer protection, sustainable agricultural development and global food security, we must strive toward balanced and informative disclosures and discussions.

[31] Bjorn Lomborg, "The Unintended Consequence of the Anti-GMO Movement: Blind Children" 2013, Feb 25, National Post. See also, *GMO Foods*, online: <http://www.greenpeace.org/canada/en/campaigns/ge/>.

[32] For example, Kathy Fairbanks, attorney and spokeswoman for the Coalition Against the Costly Food Labeling Proposition, warned that the mandatory labeling measure "allows lawyers to file shakedown lawsuits against retailers, against food companies, and against family farmers…and many people could lose out if it passes." Conan Milner, *Proposed Law Calls for GMO Labeling*, online: <http://www.theepochtimes.com/n2/united-states/proposed-law-calls-for-gmo-labeling-300937.html>.

Lesson two: It is important that the information provided to the public is accurate in language that the non-scientist can understand

Consumers are the main subject of information disclosure, and their opinions may affect policy-shaping through democratic policy-making procedures. For this reason, delivering accurate information of an emerging technology becomes crucial for cultivating consumers' attitudes to the new technology. In the context of GMOs, survey evidence states that the public attitudes to GM technology do indeed impact consumer perceptions of GMOs, and will subsequently influence consumer purchase intentions for GM foods.[33] It is observed that a positive attitude to GM technology appears to lead to an increased perception of the benefits of GM foods as well as a higher degree of positive GM food purchase intention, while a negative attitude increases the perceived risks of GM products and results in a decreased percentage of GM consumption intention.[34] Therefore, it can be speculated that accurate information about GM technology and GMOs will substantially influence consumers' choices on GM food.

However, as demonstrated in preceding chapters, many scientific words have been given to different and unscientific meanings by various news reports and mandatory labeling campaigns when mainstream language is used. For example, "Genetic pollution" is a neutral term to describe a phenomena in which "[g]ene flows from a nonnative or invasive species to an indigenous population."[35] However, it has been commonly misused by anti-GM groups to give the public the impression that gene pollution is the result of an "uncontrolled spread of genetic information into the genomes of organisms in which such genes are not present in nature."[36] Similarly, "threshold,"

[33] Macario Rodriguez & Melania Salazar-Ordonez, "Influence of Scientific-technical Literacy on Consumers' Behavioural Intentions Regarding New Food" (2013) 60:1 Appetite 193.
[34] *Ibid.*
[35] *Ibid.*
[36] Richard M. Twyman, et al, "Plant Biotechnology: the Importance of Being Accurate" (2009) 27:11 Trends in Biotechnology

a term used in toxicology, has been misconceived as a certain level of toxic content above which the food becomes unsafe to eat.[37]

These inappropriate usages of scientific words, along with their consequentially common misconceptions, create negative connotations regarding GM technology and GMOs, and hence engender problems for consumer acceptance of GMOs and agricultural biotechnology.[38] As we have seen, consumer choices between GM, non-GM foods, and organic foods are based more on personal preferences, and these preferences have been heavily impacted by information from mass media, stories spread amongst the public and, ultimately, the fears of the unknown. Due to the misunderstanding of scientific words, it is not a surprise to see that a majority of the public would choose conventional or organic food products instead of GM-based products when faced with GM or non-GM labels.[39] A more crucial problem is that if these scientific words are inaccurately used in regulatory guidelines, it could potentially make the regulations practically unenforceable (i.e., threshold regulations and the increased problems of unapproved GMOs detection)[40] or, even worse, could lead policy-makers in a wrong direction (e.g., a scenario in which a Third World country bans GM crops while thousands of its people die from starvation).[41]

Therefore, it is important to educate the public about the scientific meanings of terms related to new emerging technologies. Scientists and government authorities should take responsibility for

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609.

[37] *Ibid*.

[38] Montserrat Costa-Font, Jose M. Gil & W. Bruce Trail, "Consumer Acceptance, Valuation of and Attitudes towards Genetically Modified Food: Review and Implications for Food Policy" (2008) 33:2 Food Policy 99.

[39] Federici, *supra* note 18; Maria L Loureiro & Susan Hine, "Preference and Willingness to Pay for GM Labeling Policies" (2004) 29(5) Food Policy 467.

[40] Richard M. Twyman, et al, "Plant Biotechnology: the Importance of Being Accurate" (2009) 27(11) Trends in Biotechnology 609.

[41] Margaret Wilson & Roger Highfield, Starving Zambia Rejects America's GM Maize, online: The Telegraph <http://www.telegraph.co.uk/news/worldnews/africaandindianocean/zambia/1411713/Starving-Zambia-rejects-Americas-GM-maize.html>.

educating the public, and should make this effort before the informational disclosure has been controlled by pressure groups, and before catchy phrases from media and other organizations influence public perceptions.

Lesson three: Promoting global transparency of genetic modification information and establishing a worldwide-harmonized body of standards for GMO testing

As previously discussed, a real challenge in implementing a labeling system, whether this system be mandatory or voluntary, are the restrictions of current detection methods for testing GM materials. Given the increasing number of new GM varieties, the lack of global transparency for exchanging genetic modification information, and the absence of harmonized worldwide testing standards, the detection of unauthorized GMOs is becoming more difficult than ever. Meanwhile, as a result of different tolerance levels for GM presences in food products as specified by divergent domestic legislation, is the inevitable presence of GM (authorized or unauthorized) materials in the supply chains of crops (GM or non-GM). In recent years, the adventitious presence of unauthorized GMOs has been identified in food products in both Canada and US.[42]

Since the cultivation of GM crops keeps expanding, and global trade in GMOs is continuously growing, the development of analytical methods for detecting authorized and non-authorized GM content is still in demand. To meet this demand, putting labeling models aside, two mechanisms are suggested for development: an internationally harmonized sampling and detection method, and an information exchange system on genetic modification. It is widely recognized that an international harmonized sampling and detection method will assist the development of efficient

[42] *Adventitious Presence of Soy in Grain Products*, online: Canadian Food Inspection Agency <http://www.inspection.gc.ca/food/labelling/core-requirements/ingredients/allergen-labelling/adventitious-presence-of-soy-in-grain-products/eng/1360691333452/1360691654497>; T. Demeke, D.J. Perry & W.R. Scowcroft, "Adventitious Presence of GMOs: Scientific Overview for Canadian Grains" (2006) 86:1 Can J Plant Sci 1

and reliable approaches for the detection of GM materials.[43] This progress is very important for global and regional biosafety control, and is of significant value for developing countries, particularly since they are more likely to be the sites where limited budgets and capacity for scientific research may frustrate the domestic detection of GMO varieties. With regard to the genetic modification information exchange, a reliable information collection and distribution system is important for the global food quality control and plant protection.[44] It is hoped that the Codex and the International Plant Protection Convention managed by the FAO could contribute to global transparency in this area and formulate a harmonized sampling and detection method.[45]

C. Recommendations for the Canadian GMO labeling regime

Recommendation 1: Continue using a voluntary labeling regime, encourage negative labeling

Based on the previous analysis, the implementation of mandatory GMO labeling appears to be more harmful than helpful. Thus, Canada should keep its current voluntary labeling model for GM foods and foods containing GM ingredients. Meanwhile, if labeling is used voluntarily, producers and retailers would be better off using negative labeling rather than positive labeling, because the negative labeling statements are more precise and, as shown by consumer survey studies, more accountable than the positive labeling when providing GM information.

With regard to the potential GMO agricultural products trade conflicts between the EU and Canada due to the EU's stringent GMO approval procedures and different labeling requirements,

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[43] Arne Holst-Jensen, et al., "Detecting Un-authorized Genetically Modified Organisms (GMOs) and Derived Materials" (2011) 30:6 Biotechnology Advances 1318; T. Demeke, D. J. Perry & W. R. Scowcroft, *ibid.*

[44] FAO, *FAO Helping the Consumer and Protecting the Environment Through Food Quality Control and Plant Protection: Codex Alimentarius / international Plant Protection Convention*, online: <http://www.fao.org/worldfoodsummit/sideevents/papers/y6823e.htm>.

[45] Arne Holst-Jensen, et al., *supra* note 43.

communication and negotiations can be carried out through bilateral regimes and the Dispute Settlement Body under the WTO system. In terms of bilateral regimes, it is worth noting that, in May 2009, Canada and the EU launched negotiations toward a Comprehensive Economic and Trade Agreement (CETA).[46] On October 18, 2013, a key agreement in principle on the major elements of the CETA was reached based on rounds of negotiations. This new agreement is estimated to remove ninety-nine percent of tariffs on foods in EU – Canada trade.[47] However, the disagreement over bio-agricultural products trade still remains unsettled, and further negotiations concerning GMO trade will be continued.[48] One positive outcome is that, from December 2011, the EU has approved the "low level presence" of three GM canola varieties, which are no longer authorized in the EU, in Canadian grain shipments.[49] It is reported that this EU decision alone helped Canada save over CAN$1.5 billion in 2011 in terms of Canadian grain, pulse, and oilseed exports to the EU.[50]

Recommendation 2: Improving allergenicity assessments for GM foods

According to Canada's labeling requirements for GMOs, GM foods are classified as one category of novel foods and must be labeled only when "a health or safety concern, i.e., allergens or a significant nutrient or compositional change" is identified.[51] Consequently, allergenicity is an important part of the GMO risk assessment and approval process, as well as a decisive factor for triggering mandatory labeling requirements in Canada. However, the current Canadian regulatory

[46] European Commission, Trade Policy Countries and Regions: Canada, online: europa <http://ec.europa.eu/trade/policy/countries-and-regions/countries/canada/>.
[47] *Ibid*.
[48] Parliament of Canada, Negotiations toward A Comprehensive Economic and Trade Agreement (CETA) between Canada and the European Union, online: <http://www.parl.gc.ca/HousePublications/Publication.aspx?DocId=5431905&Language=E&Mode=1&Parl=41&Ses=1&File=87>.
[49] See Agriculture and Agri-Food Canada, *supra* note 24.
[50] *Ibid*.
[51] *Labeling of Genetically Engineered Foods in Canada*, online: Canadian Food Inspection Agency <http://www.inspection.gc.ca/food/labelling/other-requirements/method-of-production/ge-factsheet/eng/1333373177199/1333373638071>.

framework of GMOs does not indicate how novel food allergenicity should be assessed in specific terms.[52] The current conclusion of safety assessments of GM food is to use a "likelihood" to demonstrate any potential allergenicity caused by the GM food. However, the "likelihood" itself may suggest that there is still uncertainty as to whether the GM food is an allergen.[53]

Since allergen labeling is crucial for food-allergic consumers, a specialized assessment framework for GM foods allergenicity should be developed and incorporated into the current Canadian GMO labeling regime. It is suggested that a specific guidance for assessing the allergenicity of GM food should be developed and a post-market monitoring system should be established to oversee any allergic reactions caused by approved GM foods. As well, where applicable, monitoring systems should give feedback for further adjustments to those organizations responsible for the safety assessment of GM foods.[54]

Recommendation 3: Educating the public on GM techniques and GMOs

Health Canada and the Canadian Food Inspection Agency have indeed provided some information about GM foods and foods containing GM ingredients on their website. However, as we have seen, an information asymmetry still exists. Most Canadians are still not familiar with GM techniques and concepts of GMOs. In the context of vague labeling statements, without a clear notion about what constitutes a GMO, why it has been made, and their safety for consumption, it is hard to make any meaningful informed choice between GM and non-GM products. Therefore, further education about the basic health and safety, environmental, and nutritional aspects of GM food by a credible source, such as Health Canada, provincial health

[52] M.C. van Putten, et al., "Novel Foods and Allergy: Regulations and Risk-benefit Assessment" (2011) 22:2 Food Control 143.
[53] *CFIA Authorization of SmartStax Corn,* online: Canada News Centre <http://news.gc.ca/web/Art.-eng.do?m=%2Findex&nid=469209>.
[54] van Putten, et al., *supra* note 52.

departments and scientist groups is necessary.[55] It would be extremely useful to disseminate accessible definitions of some scientific terms to the public, such as gene flow, genetic pollution, and deliberate release etc. correcting those unscientific understandings emanating from pressure groups. Safety certifications and some of the potential benefits of GM foods including their role in reducing "starvation in developing countries, environmental degradation, and harm to agricultural workers from continued use of chemical fertilizers and pesticides,"[56] should also be made available to the public to give them the full story about GM techniques and GMOs. It is hoped that all this information can be provided more accurately to the lay public.

Recommendation 4: Contribute to the establishment of an international harmonized GMO approval procedure and GMO detection standards

As previously discussed, most industrialized countries have established GMO legal approval procedures, albeit with much variation, while developing countries are in the process of developing or adopting relevant laws on GMOs. So far, there has been no formation of a global, harmonized GMO risk assessment and approval procedure, and new GM varieties are authorized by each country's system independently. Consequently, the continued international expansion of the development and cultivation of GM crops combined with the increased number of new GM varieties created by other countries, will persistently engender the adventitious presence of unauthorized GM material in the supply chains of Canadian crops. Therefore, in the long-term, Canada should actively work with other countries and organizations in the Codex forum to promote an internationally recognized GMO biosafety assessment and harmonized standards of

[55] José I. Rojas-Méndez, et al., "Acceptance of Genetically Modified Foods with Health Benefits: A Study in Germany" (2012) 18:3 Journal of Food Products Marketing 200.
[56] Federici, *supra* note 18.

detection methods to realize a transparent exchange of GM information and accountable testing results.

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