GMO Labelling and the Consumer's Right to Know: A Comparative Review of the Legal Bases for the Consumer's Right to Genetically Modified Food Labelling

*Li Du**

Recent sensationalist lobbying campaigns have frequently used the protection of the "consumer's right to know" as a rationale for demanding a mandatory labelling system for genetically modified organisms (GMOs). This article aims to discuss how Health Canada, the Canadian agency responsible for food labelling, is likely to react to the purportedly overwhelming argument of the consumer's right to know and the allegedly strong trend towards mandatory GMO labelling requirements. It begins with a comparative analysis of recent legal practices regarding the legal basis of the consumer's right to know for GMO labelling in the US, the European Union, and

De récentes et sensationnalistes campagnes de lobbying ont invoqué le « droit du consommateur de savoir » comme une raison d'insister sur l'établissement d'un système d'étiquetage obligatoire pour les organismes génétiquement modifiés (OGM). Cet article vise à discuter comment Santé Canada, l'agence canadienne responsable de l'étiquetage alimentaire, risque de réagir au prétendu puissant argument du droit du consommateur de savoir ainsi qu'à la présumée forte tendance vers des exigences d'étiquetage des OGM. L'auteur propose une analyse comparative des récentes pratiques juridiques en ce qui concerne la base légale de l'étiquetage des OGM par raison

* Li Du, LLB, MBBS (Wuhan), PhD (Alberta); Research Associate at the Health Law Institute, Faculty of Law, University of Alberta, Edmonton, AB; PhD Candidate, School of Law, Wuhan University, Hubei, China. I would like to gratefully acknowledge Timothy Caulfield and Linda Reif for assistance and insight in the research and writing of this article. I would also like to thank Christen Rachul, School of Linguistics and Language Studies, Carleton University, Ottawa, for language editing at the early stages of this article. I am very grateful to the editors of McGill Journal of Law and Health for their great assistance throughout the entire publication process.

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China. It subsequently refers to international instruments relevant to GMO labelling, examining how the consumer's right to know is addressed on the level of international law. Based on this review, this paper concludes that the consumer's right to know is currently far from being universally accepted as a justifiable rationale for enacting a mandatory food labelling requirement; consequently, in cases where there is no solid evidence indicating that there are harmful effects of GMOs on human health and preservation of life, Health Canada is unlikely to introduce a mandatory regime based solely on an acknowledgement of the consumer's right to know whether foods are GMOs or contain GM ingredients.

du droit du consommateur de savoir aux États-Unis, dans l'Union européenne et en Chine. Il adresse également les instruments internationaux pertinents à l'étiquetage des OGM, s'interrogeant comment le droit du consommateur de savoir est considéré au niveau du droit international. Cette revue de la littérature permet de conclure que le droit du consommateur de savoir est actuellement loin d'être universellement reconnu comme justification pour la promulgation d'un règlement obligatoire d'étiquetage alimentaire. Par conséquent, dans les cas où il n'existe pas de preuve solide démontrant des effets nuisibles des OGM sur la santé humaine ou la préservation de la vie, il est peu probable que Santé Canada introduise un régime obligatoire d'étiquetage basé exclusivement sur une reconnaissance du droit du consommateur de savoir si des aliments sont des OGM ou s'ils en contiennent comme ingrédients.

Introduction

Genetically modified food (GM food) labelling refers to a statement located on a label of prepackaged food, or written documentation in the case of non-prepackaged food, stating either that a product contains or consists of genetically modified organisms (GMOs) or, conversely, that it is GMO-free.[1] The European Union (EU) was the first legislative body to adopt a traceability and labelling system for the management of GMOs, and today, more than sixty countries have promulgated GMO labelling laws, which vary significantly.[2] In general, GMO labelling schemes can be classified into two categories: mandatory and voluntary. Under a mandatory labelling regime, GM food products have to be labelled to distinguish them from non-GM foodstuffs, while a voluntary labelling regime allows operators to make the decision whether to label GM products (or "GM-free" products) or not. The EU GMO labelling system is representative of a mandatory labelling scheme. It requires that products be labelled if they contain ingredients of

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1 See the definition of "labelling" provided by the Codex Alimentarius Commission; this joint body of the UN Food and Agriculture Association (FAO) and the World Health Organization (WHO), provides a standard for labelling of food products in general, including those that are genetically modified organisms (GMOs) or contain GM ingredients. See Codex Alimentarius Commission, *General Standard for the Labelling of Prepackaged Foods*, Codex STAN 1-1985 (Rev 1-1991). A GMO can be generally understood as an organism whose genetic material has been altered by genetic engineering techniques, although other techniques exist. In this article, I limit the discussion of genetic modification to the genetic engineering techniques. See Health Canada, *Biotechnology and Genetically Modified Foods*, online: HC <www.hc-sc.gc.ca/fn-an/gmf-agm/fs-if/faq_1-eng.php#p4>.

2 In 1997, the first EU instrument to address regulatory issues regarding novel food and food ingredients was adopted; it forms the basis for the EU's mandatory GMO labelling regime. See EC, *Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients*, art 8, [1997] OJ, L 43/1 at 5. See also Colin A Carter & Guillaume P Gruère, "Mandatory Labeling of Genetically Modified Foods: Does It Really Provide Consumer Choice?" (2003) 6:1-2 AgBioForum 68 at 68; Clare B Herrick, "'Cultures of GM': Discourses of Risk and Labelling of GMOs in the UK and EU" (2005) 37:3 Area 286 at 290; Laura Murphy, Jillian Bernstein & Adam Fryska, "More Than Curiosity: The Constitutionality of State Labeling Requirements for Genetically Engineered Foods" (2013) 38 Vt L Rev 477 at 480.

which more than 0.9% are from an authorized GMO.[3] In contrast, the US and Canada use voluntary labelling regimes which permit food producers or retailers to choose to label their food products as GMO or non-GMO, to label them as containing GM or non-GM ingredients, or to provide no labels at all.[4]

Over the decades, there have been debates concerning GMO labelling schemes, and these controversies have never been settled. For example, the California GMO labelling campaign in 2012 – the proposed *California Right to Know Genetically Engineered Food Act*, introduced as a ballot measure under the name Proposition 37 (Prop 37) – reignited debates in the US and Canada about issues such as the possible risks and benefits of GM foods, the transparency of food supply systems, and, in particular, the protection of the consumer's informed choice and the right to know. The California ballot measure insisted that Californian consumers have a right to know whether foods are genetically modified or contain GM ingredients, and had it been successful, would have required that retailers and producers label food products if they were GM or contained GM ingredients.[5]

The current Canadian GMO labelling law does not recognize the consumer's right to know as a determinative factor triggering a special labelling

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3 EC, *Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed*, art 12(2), [2003] OJ, L 268/1 at 11 [*EC Regulation 1829/2003*]. Article 12(2) specifies that the labelling requirement "shall not apply to foods containing material which contains, consists of or is produced from GMOs in a proportion no higher than 0,9 per cent of the food ingredients considered individually or food consisting of a single ingredient, provided that this presence is adventitious or technically unavoidable."

4 See Canadian General Standards Board, *Voluntary Labelling and Advertising of Foods That Are and Are Not Products of Genetic Engineering*, National Standard of Canada CAN/CGSB-32.315-2004 (Ottawa: CGSB, 2004), online: CGSB <www.tpsgc-pwgsc.gc.ca/ongc-cgsb/programme-program/normes-standards/internet/032-0315/documents/commite-commmittee-eng.pdf>. The situation in the US will be discussed in Part I.A.

5 Ballot Measure (Cal), Proposition 37 (2012), *Genetically Engineered Foods. Labeling. Initiative Statute, proposal to adopt The California Right to Know Genetically Engineered Food Act* (defeated), s 1(a) [California Prop 37]. The official text of the proposition is available in California Secretary of State, Elections Division, *California General Election, Tuesday, November 6, 2012: Official Voter Information Guide* at 110-13, online: CSOS <http://vig.cdn.sos.

requirement for GMO foods. Health Canada, the Canadian federal agency responsible for food labelling, takes the position that GM foods are not substantially different from conventional non-GM foods, and that GM foods should be assessed in the same manner as conventional foods.[6] Under this standard, foods that have been approved by Health Canada, whether GM or non-GM, are deemed to be safe for human consumption.[7] GM foods require labelling only if there are changes in the food (e.g. problematic allergens or a significant nutrient or compositional change) that consumers need to be informed of for health and safety reasons.[8] Proponents of mandatory GMO labelling are not satisfied with the current Canadian voluntary labelling of GMOs; they criticize the government's policy in this regard as having kept consumers ignorant about GM foods, citing the rationale of the consumer's right to know.[9] For example, supporters of private member's Bill C-257

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ca.gov/2012/general/pdf/complete-vig-v2.pdf>. For the official analysis and statement of the opposing positions for the information of voters, see *ibid* at 54-57.

6 Health Canada, Health Products and Food Branch, Food Directorate, *Guidelines for the Safety Assessment of Novel Foods* (June 2006), online: HC <www.hc-sc.gc.ca/fn-an/alt_formats/hpfb-dgpsa/pdf/gmf-agm/guidelines-lignesdirectrices-eng.pdf>.

7 See Health Canada, "Genetically Modified (GM) Foods and Other Novel Foods", online: HC <www.hc-sc.gc.ca/fn-an/gmf-agm/index-eng.php>.

8 For GMO labelling, Health Canada operates on the premise that the process behind the product is irrelevant, so the label need only address product traits. See Stan Benda, "It's All about Elmer Gantry … There Is No Frankenstein!!! – Part II" (2003) 16 IPJ 393 at 425; see also Canadian Food Inspection Agency, Factsheet, "Labelling of Genetically Engineered Foods in Canada", online: CFIA <www.inspection.gc.ca/english/fssa/labeti/novnou/novnoue.shtml>.

9 See Shauna Nep & Kieran O'Doherty, "Understanding Public Calls for Labeling of Genetically Modified Foods: Analysis of a Public Deliberation on Genetically Modified Salmon" (2013) 26:5 Society and Natural Resources 506 at 517; Canadian Biotechnology Action Network, "Labeling", online: Canadian Biotechnology Action Network <www.cban.ca/Resources/Topics/Labeling>. For a US example, see Earth Talk, "Should genetically modified food products be labeled for consumer protection?", *About.com* (nd), online: About,com <http://environment.about.com/od/health/a/Should-Genetically-Modified-Food-Products-Be-Labeled-For-Consumer-Protection.htm>, reprinted from *E/The Environmental Magazine* (16 September 2010).

(introduced in the Canadian parliament in 2011)[10] argued that Canadian consumers have the right to be informed about whether or not the food they purchase has been genetically modified.[11]

With this strong push for mandatory labelling, the question of whether the consumer's right to know can provide stand-alone justification for mandatory GMO labelling challenges the Canadian food labelling system. Moreover, as this article will discuss, the labelling of GM foods has already become a global issue, and is of particular relevance to the international trade conflicts of agricultural products due to different GMO labelling methods. Therefore, a timely review of the concept of the consumer's right to know and its legal status as a stand-alone justification for mandatory GMO labelling in different jurisdictions and international instruments relevant to GMO labelling may provide persuasive evidence regarding the legal status of the consumer's right to know under the Canadian regime.

Of note, although the consumer's right to know or to be informed has been put forward by anti-GMO groups as an argument for mandating a GMO labelling regime, the concept of such a right "to know" or "to be informed" has never been clearly defined.[12] In light of relevant claims used in recent GMO labelling campaigns,[13] the concept of the consumer's right

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10 Bill C-257, *An Act to amend the Food and Drug Act (mandatory labelling for genetically modified foods)*, 1st Sess, 41st Parl, 2011 (first reading 23 June 2011) [Bill C-257].

11 See e.g. *House of Commons Debates*, 41st Parl, 1st Sess, No 14 (23 June 2011) at 1010 (Alex Atamanenko), online: Parliament of Canada <www.parl.gc.ca/HousePublications/Publication.aspx?DocId=5112534&Language=E&Mode=1>.

12 R Paul Thompson, *Agro-Technology: A Philosophical Introduction* (New York: Cambridge University Press, 2011) at 42.

13 The GMO labelling legislative campaigns expressing the concept of the consumer's right to know include, in the US, California Prop 37, *supra* note 5; Ballot Measure (Wash), Initiative 522 (2013), *Labeling of Genetically-Engineered Foods*, proposal to adopt *The People's Right to Know Genetically Engineered Food Act* (defeated), online: Washington Secretary of State <http://sos.wa.gov/_assets/elections/initiatives/FinalText_285.pdf> [Washington Initiative 522] (initially proposed as an initiative to the legislature, before being submitted to the electorate); *An Act to Protect Maine Food Consumers' Right to Know about Genetically Engineered Food and Seed Stock*, 126th Leg, Me, 2013 (enacted, will come into effect if five contiguous states adopt similar legislation before 2018 (§ 2(1)-(2)), online: Maine Legislature <www.maine-

to know, for the purposes of this study, shall involve the following elements: (1) consumers, drawing on health risk concerns, argue that they have a right to know what is in their food; (2) consumers specifically want to know or to be informed as to whether foods are GMOs or contain GM ingredients; and (3) consumers believe the implementation of mandatory GMO labelling measures will be effective, thereby assisting them to make informed choices between GM and non-GM food products.

This study is mainly focused on a descriptive exploration of how the consumer's right to know has been addressed in the selected domestic and supranational GMO labelling laws and other instruments. The study also provides a legal analysis of whether the consumer's right to know is accepted as an exclusive justification for a mandatory GMO labelling in selected jurisdictions and international instruments – in particular, under the World Trade Organization (WTO) agreements.

Part I of this article consists of a comparative examination of selected domestic and regional GMO labelling law. Based on considerations of different labelling models and the scales of cultivation and marketing of GM products, the GMO labelling regimes of the EU, the US, and China are reviewed. The three jurisdictions are all major agricultural trade partners with Canada, have different GMO marketing scales, and use varying labelling models.[14] The EU grows only a small amount of GM crops and imposes among the most severe restrictions and regulatory oversight in the world for the approval and labelling of GM foods;[15] these restrictions must

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legislature.org/legis/bills/getDoc.asp?id=29251> [Act to Protect Maine Food Consumers' Right to Know]; and, in Canada, Bill C-257, *supra* note 10.

14 See Agriculture and Agri-Food Canada, *2011-2012 Agriculture and Agri-Food Market Access Report: Re-opening, Maintaining and Expanding Markets* (2012), online: AAFC <www5.agr.gc.ca/resources/prod/doc/pdf/marram_2011-12_eng.pdf>; see also Foreign Affairs and International Trade Canada, *Canada's State of Trade: Trade and Investment Update – 2012*, at 84-85, online: Foreign Affairs, Trade and Development Canada <www.international.gc.ca/economist-economiste/assets/pdfs/performance/SoT_2012/SoT_2012_Eng.pdf>.

15 International Service for the Acquisition of Agri-biotech Applications, *Brief 46-2013: Executive Summary Global Status of Commercialized Biotech/GM Crops: 2013* at Table 1, Fig 1, online: ISAAA <www.isaaa.org/resources/publications/briefs/46/executivesummary/default.asp>; Steve Keane, "Can a Consumer's Right to Know Survive the WTO? The Case of Food Labeling" (2006) 16:1 Transnat'l L & Contemp Probs 291 at 300; Aarti Gupta, "Transpa-

be implemented by all EU member states.[16] In contrast, the US, the world's leading GM crop producer, leans more heavily on a burden of scientific proof of harm in its GMO-related regulations, and has adopted a voluntary labelling regime.[17] China, one of the first countries in the world to introduce GM crops commercially,[18] was the sixth largest producer of biotech crops in 2013.[19]

Part II continues the comparative analysis at the international law level. Several international instruments relevant to GM food labelling are examined. They include the newly approved *Compilation of Codex Texts Relevant to Labelling of Foods Derived from Modern Biotechnology* by the Codex Alimentarius Commission's Committee on Food Labelling (which deals with international food and agricultural law);[20] the *Cartagena Protocol on*

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rency as Contested Political Terrain: Who Knows What about the Global GMO Trade and Why Does It Matter?" (2010) 10:3 Glob Environ Polit 32 at 46, 48.

16 With the accession of Croatia on July 1, 2013, the EU currently has 28 member states: Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, and the United Kingdom. See European Union, "Countries", online: EU <http://europa.eu/about-eu/countries/index_en.htm>; see also *EC Regulation No 1829/2003*, *supra* note 3 at 22 ("[t]his Regulation shall be binding in its entirety and directly applicable in all Member States").

17 Simon Lester & Inu Barbee, "The Challenge of Cooperation: Regulatory Trade Barriers in the Transatlantic Trade and Investment Partnership" (2013) 16:4 J Int'l Econ L 847 at 855.

18 The International Service for the Acquisition of Agri-biotech Applications (ISAAA) in fact names China as the first country in the world to commercialize GM crops. See Clive James & Anatole F Krattiger, *Global Review of the Field Testing and Commercialization of Transgenic Plants: 1986 to 1995; The First Decade of Crop Biotechnology* (ISAAA Brief No 1 – 1996) at 23, online: ISAAA <www.isaaa.org/resources/publications/briefs/01/download/isaaa-brief-01-1996.pdf>; Yu Zhuang & Wenxuan Yu, "Improving the Enforceability of the Genetically Modified Food Labeling Law in China with Lessons from the European Union" (2013) 14:3 Vermont Journal of Environmental Law 465.

19 International Service for the Acquisition of Agri-biotech Applications, *supra* note 15 at Table 1.

20 Codex Alimentarius Commission, *Compilation of Codex Texts Relevant to the Labelling of Foods Derived from Modern Biotechnology*, CAC/GL 76-2-11

Biosafety to the Convention on Biological Diversity (international environmental law);[21] the 1994 *General Agreement on Tariffs and Trade* (the *GATT 1994*);[22] the *WTO Agreement on the Application of Sanitary and Phytosanitary Measures* (known as the *SPS Agreement*);[23] and the *Agreement on Technical Barriers to Trade* (known as the *TBT Agreement*).[24] The concluding section summarizes the legal basis of the consumer's right to know for GMO labelling as explored in the preceding parts, and assesses whether the concept is likely to be accepted by the Canadian food labelling system.

I. Can the Consumer's Right to Know Provide Sufficient Justification for GMO Labelling under Domestic and Regional Legal Regimes?

A. United States

In the United States, the labelling of GM food products is governed by the Food and Drug Administration (FDA). The FDA supports a voluntary labelling requirement for food derived from genetic modification, which allows manufacturers to decide whether or not to label their products as developed using bioengineering.[25] According to the FDA, GM foods and

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(2011), online: CA <www.codexalimentarius.org/> [*Codex Compilation*].

21 *Cartagena Protocol on Biosafety to the Convention on Biological Diversity*, 29 January 2000, 2226 UNTS 208, 39 ILM 1027, online: Convention on Biological Diversity <http://bch.cbd.int/protocol/text> [*Cartagena Protocol*].

22 *General Agreement on Tariffs and Trade 1994*, 15 April 1994, 1867 UNTS 187, 33 ILM 1153 [*GATT 1994*].

23 *Agreement on the Application of Sanitary and Phytosanitary Measures*, 15 April 1994, 33 ILM 1125, online: World Trade Organization <www.wto.org/english/docs_e/legal_e/15sps_01_e.htm> [*SPS Agreement*].

24 *Agreement on Technical Barriers to Trade*, 15 April 1994, 33 ILM 1125, online: World Trade Organization <www.wto.org/english/docs_e/legal_e/17-tbt_e.htm> [*TBT Agreement*].

25 US, Food and Drug Administration, *DRAFT Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering; Draft Guidance* (Docket No 00D-1598), 66 Fed Reg 4839 (January 2001), online: FDA <www.fda.gov/Food/GuidanceRegulation/Gui-

non-GM counterparts do not have material differences, and are therefore subject to the same labelling requirements as other food products specified in sections 403(i) and 201(n) of the *Federal Food, Drug, and Cosmetic Act* (*FDCA*).[26] Accordingly, GM foods must necessarily be labelled differently from their non-GMO counterparts only when they: (1) are significantly different from their traditional counterparts; (2) have changed in usage; (3) have a significantly different nutritional property; or (4) contain new allergens.[27] As a result, in the absence of evidence of one of these four conditions, the implementation of a mandatory labelling regime based solely on consumer demand or on the principle of the consumer's right to know would represent a departure from the Act in its current form. The FDA's position is that production methods are not material factors by which to conclude that GM foods differ from non-GM conventional foods, and thus that special labelling measures should be not applied to GM foods in the absence of material differences between GM and non-GM foods.[28]

However, individual US states, in particular western and northeastern states, have introduced ballot measures or proposals for mandating non-voluntary GMO labelling regimes similar to California's defeated Prop 37,[29] mentioned earlier. For example, Initiative 522 in the State of Washington, which aimed to establish an *Act Relating to Disclosure of Foods Produced through Genetic Engineering* (also known as the *People's Right to Know Genetically Engineered Food Act*), was based on the argument of the consumer's right to know, and would have mandated GMO labelling measures for all GM foods or foods containing a GM ingredient; it was rejected by voters on 5 November 2013.[30] However, in the same year, the Connecticut legisla-

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danceDocumentsRegulatoryInformation/LabelingNutrition/ucm059098.htm> [FDA, *Draft Voluntary Labeling Guidance*].

26 *Federal Food, Drug, and Cosmetic Act*, 21 USC §§ 321(n), 343(i) (1938) [*FDCA*].

27 FDA, *Draft Voluntary Labeling Guidance*, *supra* note 25.

28 *Ibid*.

29 See *supra* note 5 (in the Introduction).

30 Washington Initiative 522, *supra* note 13 at 5. See also Elizabeth Weise, "Washington state voters reject labeling of GMO foods", *USA Today* (6 November 2013), online: USA Today <www.usatoday.com/story/news/nation/2013/11/06/washington-state-voters-reject-gmo-labeing/3450705/>; Jon Entine, "After GMO labeling bill defeat in Washington, will anti-GMO 'witch hunts' escalate in next battleground – Kaua'i?", *Forbes* (7 November 2013),

ture passed *An Act Concerning Genetically-Engineered Food*, becoming the first state to support a requirement for GMO labelling.[31] A month later, in January 2014, Maine joined Connecticut, with the passage into law of a GMO labelling act approved the previous year by its legislature.[32] Nonetheless, by their own terms, the entry into force of these labelling laws depends on five neighbouring states of the northeast region enacting substantially similar statutes.[33] To date, no other contiguous states have passed mandatory GMO labelling laws.

US case law on the subject of the consumer's right to know is also relevant to this discussion. In *Alliance for Bio-Integrity v Shalala*, a coalition of scientists, chefs, civil activists, and religious leaders brought suit in federal court to oppose the FDA's non-labelling policy for GM food. Concerned that GMOs may pose potential risks to human health and the environment or that consuming GMOs infringed individuals' religious beliefs, the plaintiff organization founded its claim on six grounds – *inter alia*, the FDA's failure to observe notice-and-comment procedures, non-compliance with environmental legislation, arbitrary decision-making, and violation of religious freedom.[34] In accepting the counter-motion for summary judgment and dismissing the Alliance for Bio-Integrity's suit, the US District Court for the DC Circuit declined to support a consumer's right to know as a sole and sufficient basis for a food labelling legislation.[35] The Court held that a consumer's right to know can only be considered *after* another material difference has been shown in the product – in other words, that the consumer's

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online: Forbes <www.forbes.com/sites/jonentine/2013/11/07/after-gmo-labeling-bill-defeat-in-washington-will-anti-gmo-witch-hunts-escalate-in-next-battleground-kauai/>.

31 Conn Gen Stat tit 21a, ch 418, § 21a-92c (2014) [*Connecticut GMO Labeling Law*]. See also Reid Wilson, "Maine becomes second state to require GMO labels", *The Washington Post* (10 January 2014), online: WP <www.washingtonpost.com/blogs/govbeat/wp/2014/01/10/maine-becomes-second-state-to-require-gmo-labels/>.

32 Wilson, *ibid*.

33 *Act to Protect Maine Food Consumers' Right to Know*, *supra* note 13, § 2(1)-(2); *Connecticut GMO Labeling Law*, *supra* note 31; see also Wilson, *supra* note 31.

34 *Alliance for Bio-Integrity v Shalala*, 116 F Supp (2d) 166 at 170 (DC Cir 2000) [*Shalala*].

35 *Ibid* at 178-79.

interest in knowing is not material in and of itself under the *FDCA*[36] – and furthermore that the FDA's position that genetic modification did not create a material difference between two products was entitled to deference.[37]

The case of labelling of recombinant bovine somatotropin (rBST)[38]-derived milk products in the US is another instructive example of how the consumer's right to know has been addressed in US juridical practice. The substance in question, 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.[39] In 1993, the FDA approved the use of rBST in animals,[40] and it became one of the first GE products approved by the US government for use in livestock food production.[41] Yet health-related concerns about rBST such as an alleged hindrance to the immune system and increased incidence of ketosis and liver disease resulted in extensive debates in the public sphere.[42] However, safety assessments of

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36 *Supra* note 26.

37 *Shalala*, *supra* note 34 at 178-79; see also Thomas J Moyer & Stephen P Anway, "Biotechnology and the Bar: A Response to the Growing Divide between Science and the Legal Environment" (2007) 22 Berkeley Tech LJ 671 at 697-701.

38 The acronym for recombinant bovine somatotropin may be styled either "rBST" or "rbST." This article uses the form "rBST" except where directly citing a source that uses the alternative styling.

39 Joseph J Molnar, Keith A Cummins & Peter F Nowak, "Bovine Somatotropin: Biotechnology Product and Social Issue in the United States Dairy Industry" (1990) 73:11 J Dairy Sci 3084 at 3085; see also 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 at 525.

40 *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 rbST Guidance*].

41 DE Bauman, "Bovine Somatotropin and Lactation: From Basic Science to Commercial Application" (1999) 17:2-3 Domest Anim Endocrinol 101 at 111.

42 See *ibid* at 111-12; Lee Ann Jackson & Michele T Villinski, "Reaping What We Sow: Emerging Issues and Policy Implications of Agricultural Biotechnology" (2002) 24:1 Review of Agricultural Economics 3 at 12; Guillermo F Gallo & Elliot Block, "Effects of Recombinant Bovine Somatotropin on Nutritional Status and Liver Function of Lactating Dairy Cows" (1990) 73:11 J Dairy Sci 3276 at 3276; see also JK Oldenbroek et al, "Effects of Treatment of Dairy

rBST milk evaluated by authoritative US and Canadian bodies such as the US FDA, the Royal College of Physicians and Surgeons of Canada, etc., all concluded that the use of rBST was unlikely to cause any toxic effect on human health.[43] International organizations such as the World Health Organization (WHO) and the UN Food and Agriculture Organization (FAO) also confirmed that rBST was safe for human consumption.[44]

Despite the lack of evidence proving that the use of rBST is harmful for human consumption, consumers increasingly expressed the desire for rBST labelling to enable them to differentiate between rBST and non-rBST milk products.[45] In February 1994, the FDA issued the *Interim Guidance on the Voluntary Labeling of Milk and Milk Products from Cows that Have Not Been Treated with Recombinant Bovine Somatotropin*.[46] This *Guidance* declined to implement a mandatory model and moreover discouraged the use of "rBST free" labelling, because the FDA was concerned that labelling milk products as "rBST free" might lead to a misunderstanding among consumers that milk products from cows treated with supplemental rBST were different in composition from, or inferior to, those derived from cows not receiving rBST.[47] To avoid this potentially erroneous impression, the *In-*

Cows with Recombinant Bovine Somatotropin over Three or Four Lactations" (1993) 76:2 J Dairy Sci 453 at 465.

43 US, Food and Drug Administration, *Report on the Food and Drug Administration's Review of the Safety of Recombinant Bovine Somatotropin* (updated 23 April 2009), online: FDA <www.fda.gov/animalveterinary/safetyhealth/productsafetyinformation/ucm130321.htm>; Royal College of Physicians and Surgeons of Canada, *Report of the Royal College of Physicians and Surgeons of Canada – Expert Panel on Human Safety of rbST* (prepared for Health Canada, January 1999) at "Conclusions", online: Health Canada <www.hc-sc.gc.ca/dhp-mps/vet/issues-enjeux/rbst-stbr/rep_rcpsc-rap_crmcc_final-a-eng.php>.

44 Seventy-Eighth Meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA), *Toxicological Evaluation of Certain Veterinary Drug Residues in Food*, WHO Food Additives Series, no 69 (Geneva: World Health Organization, 2014) at 143-45, online: WHO <http://apps.who.int/iris/bitstream/10665/128550/1/9789241660693_eng.pdf>.

45 Terence J Centner & Kyle W Lathrop, "Labeling rbST-Derived Milk Products: State Responses to Federal Law" (1997) 45:2 U Kan L Rev 511 at 515.

46 *Interim rbST Guidance*, *supra* note 40.

47 The FDA noted that "[t]here is currently no way to differentiate analytically between naturally occurring bST and recombinant bST in milk, nor are there

terim rbST Guidance adopted the voluntary labelling method for rBST-derived milk products, but encouraged dairy producers to pair production labelling indicating that their milk is "from cows not treated with rbST"[48] with a clarifying statement such as "No significant difference has been shown between milk derived from rbST-treated and non-rbST-treated cows."[49]

Nevertheless, several jurisdictions in the US were not satisfied with the federal rBST labelling guidance, and they attempted to establish a mandatory labelling regime for rBST milk products. In 1994, based on the claim that laws should protect consumer interests and the public's right to know, Vermont implemented a statute mandating the labelling of rBST milk products derived from rBST-treated cows.[50] This requirement was vigorously challenged in court by the International Dairy Food Association (IDFA).[51] The IDFA argued that the statute violated dairy producers' right to freedom of expression as guaranteed under the First Amendment.[52] Vermont's mandatory requirements were rejected by the United States Court of Appeals for the Second Circuit.[53] On the basis of reports from the FDA, which confirmed that dairy products derived from herds treated by rBST were indistinguishable from products from untreated herds, the Court held that

> their [Vermont consumers'] desire is *insufficient* to permit the State of Vermont to compel the dairy manufacturers to speak 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.[54]

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any measurable compositional differences between milk from cows that receive supplemental bST and milk from vows that do not" (*ibid* at 6280).

48 *Ibid*.

49 *Ibid*.

50 Vt Stat Ann tit 6 § 2754 (terminated 30 Mar 1998 by Adj Sess, No 127 § 4 (1993), as amended by No 61 § 272i (1997)).

51 *Int'l Dairy Foods Ass'n v Amestoy*, 92 F (3d) 67 (2d Cir 1996).

52 *Ibid* at 67.

53 *Ibid* at 67, 69-70.

54 *Ibid* at 74 [emphasis added].

The Court concluded that "consumer curiosity" could not provide a sufficient justification for mandating an rBST labelling measure, which it considered a breach of dairy producers' First Amendment right to freedom of expression.[55]

Legislators in other states, on the other hand, have taken the opposite position and attempted to *prohibit* processors from labelling their products as "artificial hormone free" or "rBST-free." In 2007, Pennsylvania, another large dairy-producing state, proposed a draft that aimed to forbid any labelling statements indicating that a milk product was from non-rBST-treated cows.[56] Both dairy industry and consumer protection groups strongly objected to the proposal. They argued that the prohibition of "rBST-free" labelling would frustrate consumers' access to information that was needed to fulfill their interest in being able to choose between rBST-derived and non-rBST-derived dairy products.[57] Pennsylvania Secretary of Agriculture Dennis Wolff contended, on the other hand, that "rBST-free" labels might falsely imply that rBST-treated products were unsafe.[58] After months of controversy, the Governor of Pennsylvania stepped in and the Pennsylvania Department of Agriculture subsequently issued revised milk labelling standards.[59] These standards required that any claim on the label of a dairy product stating that rBST was not used during production, such as "No rbST" or "Free of rbST" be accompanied by a disclaimer, so that the label in its

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55 *Ibid*; see also GL Keel, "Commercial Free Speech Trumps the Politics of Food Labeling: The Legacy of rbST-Free Milk Mandate and Prohibition Cases for Genetic Engineering Disclosure Laws" (2014) 48:1 First Amendment Studies 44 at 49.

56 Mark Scolforo, "Pennsylvania bars hormone-free milk labels, roiling industry", *San Diego Union-Tribune* (13 November 2007), online: SD U-T. <http://legacy.utsandiego.com/news/business/20071113-1350-hormones.html>.

57 *Ibid*.

58 *Ibid*. See also Emily A Kane, "Pennsylvania bans rBGH-free labels on dairy products", *Natural News* (13 December 2007), online: NN <www.naturalnews.com/022379.html>.

59 US, Pennsylvania Department of Agriculture, Bureau of Food Safety and Laboratory Services, *Milk Labeling Standards 2.0.1.17.08*, online: PDA <www.agriculture.state.pa.us/portal/server.pt/gateway/PTARGS_0_2_24476_10297_0_43/AgWebsite/Files/Publications/milk_labeling_standards_new.pdf> [*Pennsylvania Milk Labeling Standards*]. See also Teri Lee Gruss, "Pennsylvania governor rethinks milk labeling rule for rBST", *Natural News* (22 February 2008), online: NN <www.naturalnews.com/022699.html>.

entirety would read, for example, "No rbST was used on cows producing this milk. No significant difference has been shown between milk derived from rbST-treated and non-rBST-treated cows."[60]

Ohio is another state that attempted to prohibit "rBST-free" labelling under a rule adopted by the Ohio Department of Agriculture in 2008 that banned outright composition claims such as "rBST-free" on dairy product labels.[61] The Ohio labelling rule was also adopted on the premise that a label that read "rBST-free" label might create the false or misleading impression that milk products from rBST-treated cows are inferior to those from untreated cows.[62] However, in 2010, in *International Dairy Foods Association v Boggs*, both the IDFA and the Organic Trade Association (OTA) challenged the Ohio rule, claiming that the ban violated their First Amendment right to exercise truthful commercial speech.[63] The US Court of Appeals for the Sixth Circuit upheld the IDFA and OTA appeals and reversed the judgment of the district court, thus ruling against the ban on such labels.[64]

As the above discussion reveals, the current US federal and state food labelling systems provide mechanisms to voluntarily make information available to consumers, but the consumer's right to know has not as yet been sufficient to justify a *mandatory* labelling regime at the federal level for either GMO foods or an analogous foodstuff from the point of view of "right to know" campaigns, namely rBST-derived milk products. Under current federal regulations, mandatory labeling of GMO foods can be demanded only when there are significant public health and safety interests that require special labelling on that basis. Based on the FDA's present findings on GMO safety assessment, as referenced above, it is unlikely for proponents of GMO labelling to succeed in convincing a court to implement or uphold a mandatory labelling requirement for GMO foods on the sole basis of the consumer's right to know.

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60 *Pennsylvania Milk Labeling Standards*, *supra* note 59, para 7(A)(iii).

61 Ohio Admin Code § 901:11-8-01 (rescinded). See also *International Dairy Foods Association v Boggs*, 622 F (3d) 628 at 634 (6th Cir 2010).

62 *Ibid* at 633.

63 *Ibid* at 635.

64 *Ibid* at 643.

B. European Union

The protection of the consumer's right to know has played a significant role in GMO labelling legislation in the European Union. The principle can be traced back to the *Treaty Establishing the European Community,*[65] and is reproduced in Article 169(1) of the current *Treaty on the Functioning of the European Union*. That article reads:

> In order to promote the interests of consumers and to ensure a high level of consumer protection, the Union shall contribute to protecting the health, safety and economic interests of consumers, as well as to promoting their right to information, education and to organise themselves in order to safeguard their interests.[66]

Moreover, the *Charter of Fundamental Rights of the European Union* proclaims, "Union policies shall ensure a high level of consumer protection."[67] Based on these established principles, GMO labelling legislation in the EU has consistently emphasized the protection of the consumer's right to know. The latest GMO labelling regulation, *EC Regulation 1830/2003*, maintains that making information available to consumers does constitute a sufficient legal basis for a mandatory GMO labelling regime.[68]

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65 *Consolidated Version of the Treaty Establishing the European Community*, 2 October 1997, [1997] OJ C 340/173 at 247, art 153 (ex art 129a), as amended by the *Treaty of Amsterdam amending the Treaty on European Union, the Treaties establishing the European Communities and certain related acts*, 2 October 1997, [1997] OJ C 340/1 (entered into force 1 May 1999).

66 *Consolidated Version of the Treaty on the Functioning of the European Union*, 13 December 2007, [2012] OJ C 326/47 at 124, art 169(1) (entered into force 1 December 2009; most recent consolidation 26 October 2012).

67 *Charter of Fundamental Rights of the European Union*, 7 December 2000, [2012] OJ C 326/391 at 403, art 38 (entered into force 1 December 2009, most recent promulgation 26 October 2012). The *Charter* has binding legal effect on EU bodies and on member states only when they are implementing their EU obligations; see the *Treaty on European Union*, 13 December 2007, [2012] OJ C 326/13 at 19, art 6(1) (entered into force 1 December 2009; most recent consolidation 26 October 2012).

68 Paragraph 11 of the preamble of EC Regulation 1830/2003 states: "It is necessary to ensure that consumers are fully and reliably informed about GMOs and the products, foods and feed produced therefrom, so as to allow them to make an informed choice of product." EC, *Regulation (EC) No 1830/2003 of the*

Although the consumer's right to know appears to be an important consideration with respect to GMO labelling legislation in the EU, the availability of GM products is relatively limited in the EU market.[69] Consequently, consumers in the EU are not likely to have a real choice between GM and non-GM products and, as a result, the legislation providing for a right to know *whether* foods are genetically modified may have limited real-world relevance in EU states. Questions about the legislation's supposed focus on consumers have also been raised, with criticisms levelled against some EU members' recent bans on certain GM varieties that had already passed EU safety assessments, on the basis that the policies in question are arbitrary and not based on scientific evidence, but rather are driven by political expediency or protectionist purposes.[70]

One example of GMO policy that was not based on scientific evidence is the Monsanto MON810 corn case. A variety of GM maize, MON810 contains a Bt-derived gene that encodes a protein toxic to certain lepidopteran pest insects, including the European corn borer.[71] To date, no evidence has been established showing that MON810 corn negatively affects non-targeted animals under natural field conditions.[72] Nonetheless, MON810 has been banned for cultivation by the governments of six EU countries (France,

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European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC, [2003] OJ L 268/24 at 25 [*EC Regulation 1830/2003*].

69 Annie H Liu, My Bui & Mark Leach, "Considering Technological Impacts When Selecting Food Suppliers: Comparing Retailers' Buying Behavior in the United States and Europe" (2013) 20:2 Journal of Business-to-Business Marketing 81 at 90 ("most food retailers within the European Union do not sell GMO products…. However, in Iceland, GMO goods are available because of Icelanders' lack of awareness and therefore ambivalence on the issue").

70 William A Kerr, "What Is New in Protectionism? Consumers, Cranks, and Captives" (2010) 58:1 Canadian Journal of Agricultural Economics 5 at 16; Marcel Kuntz, John Davison & Agnès E Ricroch, "What the French Ban of *Bt* MON810 Maize Means for Science-Based Risk Assessment", Correspondence, (2013) 31:6 Nat Biotechnol 498 at 498-99.

71 Agnès Ricroch, Jean Baptiste Bergé & Marcel Kuntz, "Is the German Suspension of MON810 Maize Cultivation Scientifically Justified?" (2010) 19:1 Transgenic Res 1 at 1 [Ricroch, Bergé & Kuntz, "German Suspension"].

72 *Ibid* at 9.

Austria, Greece, Hungary, Germany, and Italy) despite the absence of solid scientific evidence.[73] In France, contiguous cultivation of MON810, which had been grown for several years, was suspended due to political reasons in 2008.[74] The French government replaced two pre-existing science-based GMO committees (the *Commission de génie génétique* and the *Commission du génie biomoléculaire*) with a temporary committee, the *Comité de préfiguration de la Haute Autorité sur les biotechnologies*. After just one meeting, the chairman of the *Comité*, Senator Jean-François Le Grand, indicated that the group "had 'serious doubts' about the safety of MON810."[75] However, his statement was denied by almost all other scientists and economists on the committee, who argued that Senator Le Grand had misinterpreted the committee report, as the document did not use the words "serious doubts," nor did it characterize the new scientific evidence as demonstrating the negative effect of MON810.[76] Similarly, in 2009, the cultivation and marketing of MON810 in Germany was halted by Federal Minister Aigner,[77] whereupon the German Central Commission for Biological Safety challenged the moratorium as being non-scientifically grounded.[78] Related criticisms can be found in a study by Agnès Ricroch, Jean Baptiste Bergé, and Marcel Kuntz. Based on an extensive survey of the scientific literature regarding the possible effects of MON810 on non-target animals under natural field conditions, Ricroch's team argued that the existing meta-knowledge on Bt maize "was ignored by the German government [which] instead used selected individual studies which fit what seems to be a political decision."[79]

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73 John Davison, "GM Plants: Science, Politics and EC Regulation" (2010) 178:2 Plant Sci 94 at 95.

74 Kuntz, Davison & Ricroch, *supra* note at 70 at 498.

75 Davison, *supra* note 73 at 95. (Note that Davison incorrectly refers to Senator Le Grand as "Legrand.")

76 Agnès E Ricroch, Jean Baptiste Bergé & Marcel Kuntz, "Is the Suspension of MON810 Maize Cultivation by Some European Countries Scientifically Justified?", *Information Systems for Biotechnology News Report* (April 2010) at 2, online: ISB <www.isb.vt.edu/news/2010/Apr/Suspension-of-MON810-Maize-Cultivation.pdf>.

77 Davison, *supra* note 73 at 95; Ricroch, Bergé & Kuntz, "German Suspension", *supra* note 71 at 1-2.

78 Kuntz, Davison & Ricroch, *supra* note at 70 at 498.

79 Ricroch, Bergé & Kuntz, "German Suspension", *supra* note 71 at 10.

Under the strict EU GMO approval systems and individual states' non-scientifically-grounded policy-making, GMOs are not cultivated in significant quantities in the EU.[80] As a result, the stringent EU labelling requirements intended to address the consumer's right to know can be considered protectionist measures, because the labelling demands are primarily applied to imported food and feed from GMO-producing countries such as Canada and the US.

C. China

Legislative powers in the People's Republic of China are vested in a number of bodies at the central and local levels.[81] To date, neither of the two highest bodies – namely, the National People's Congress of China and its Standing Committee – has passed a law regarding GMOs or GM ingredients. The Standing Committee's *Food Safety Law of the People's Republic of China*, adopted in 2009, sets out general principles and provisions on food safety, packaging, and labelling of food products. It recognizes the important role of labelling of food products as a means of disclosing information and promoting communication between consumers and producers.[82]

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[80] International Service for the Acquisition of Agri-biotech Applications, *supra* note 15.

[81] In terms of different levels of authority, concepts concerning laws in China can be summarized as follows (in descending order of authority): (1) "laws" are promulgated by the National People's Congress or its Standing Committee; (2) "(administrative) regulations" are issued by the State Council; (3) "(administrative) rules" are issued by the ministries under the State Council; (4) "local regulations" are promulgated by the people's congresses or their standing committees of the provinces, autonomous regions, and municipalities directly under the Central Government; (5) "local rules" are issued by the people's government of the provinces, autonomous regions, and municipalities directly under the Central Government and the comparatively larger cities. See PRC, 3rd sess, 9th National People's Cong, Pres Order No 31, *Legislation Law of the People's Republic of China*, arts 7, 56, 57, 63 (promulgated 29 April 2000). An official English translation is available in the legislative database of the Chinese Government's official website, online: Chinese Government's Official Web Portal <http://english.gov.cn/laws/2005-08/20/content_29724.htm>.

[82] PRC, 7th sess Standing Cttee, 11th National People's Cong, Pres Order No 9, *Food Safety Law of the People's Republic of China*, art 48 (promulgated 28 February 2009) [*Food Safety Law*]. An unofficial English translation is available in the legislative database of the Chinese Procedural Law Network, on-

Although the *Food Safety Law* does not contain any detailed or specific provisions on GMO labelling, it has provided the authority for lower legislative bodies to enact other laws that can be applied to GMOs where applicable, including for the labelling of GMOs.[83] These laws include the *Measures for the Administration of New Resource Food*, issued by the Ministry of Health in 2007;[84] the *Administrative Provisions on Food Labeling*, issued by the State Administration of Quality Supervision, Inspection and Quarantine (QSIQ) in 2007 and amended in 2009;[85] and the *Administrative Measures for Labeling Agricultural GMOs*, issued by the Ministry of Agriculture in 2002 and amended in 2004.[86]

Before the *New Resource Food Measures* came into effect in 2007, there was another administrative rule: the *Administrative Measures for Genetical-*

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line: CPLN <www.procedurallaw.cn/english/law/200903/t20090320_196425.html>.

83 *Ibid*, art 101.

84 PRC, Ministry of Health, Order No 56 (2007), *Measures for the Administration of New Resource Food*, 2007 May-August Falü Qüanshu 560 (promulgated 2 July 2007; effective 1 December 2007; repealed 31 May 2013) [*New Resource Food Measures*]. For an unofficial English translation, see FAOLEX doc no LEX-FAOC073544, online: FAOLEX <http://faolex.fao.org/docs/texts/chn73544E.doc>. The Ministry of Health regulates health concerns associated with GM foods. See Yang Wanghua, "Regulation of Genetically Modified Organisms in China" (2003) 12:1 Reciel 99 at 105.

85 PRC, General Administration of Quality Supervision, Inspection, and Quarantine, Order No 102 (2007), revised by Order 123 (2009), *Administrative Provisions on Food Labeling* (revision promulgated 22 October 2009) [*Administrative Provisions on Food Labeling*]. For an unofficial English translation, see FAOLEX doc no LEX-FAOC082579, online: FAOLEX <http://faolex.fao.org/docs/texts/chn82579.doc>.

86 PRC, Ministry of Agriculture, Order No 10 (2002), revised by Order No 38 (2004), *Administrative Measures for Labeling Agricultural Genetically Modified Organisms*, 2002 January-June Falü Qüanshu 1689 (issued 5 January 2002; effective 20 March 2002; revised 1 July 2004). No English translation of the 2004 revision, either official or unofficial, seems to have been published. However, an unofficial English translation of the 2002 *Measures* is provided by the Chinese Ministry of Environmental Protection's Biosafety Clearing-House, online: BC-H <http://english.biosafety.gov.cn/image20010518/5423.pdf>. Since 1996, the Ministry of Agriculture has established and implemented biosafety regulatory systems that ensure the appropriate use of agricultural bio-

ly Modified Food Hygiene.[87] Issued by the Ministry of Health in 2001, that rule specifically focused on the management of GM foods. It is worth noting that the protection of consumer "awareness" (i.e. right to know) had been recognized as a main rationale for implementing special management rules for GM foods in the 2001 *Measures*.[88] However, the 2007 *New Resource Food Measures* removed the statement regarding "protect[ing] consumers' rights of … awareness" from its rationales for establishing management measures for GM foods. Instead, it emphasized only health concerns to the exclusion of other considerations, thus establishing safety as the sole justification for the application of administrative measures to GM foods.[89]

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technology, from laboratory research to commercialization. See Jia Shirong & Peng Yufa, "GMO Biosafety Research in China" (2002) 1 Environ Biosafety Res 5 at 7.

87 PRC, Ministry of Health, Order No 28 (2002), *Administrative Measures for Genetically Modified Food Hygiene*, 2002 January-June Falü Qüanshu 626 (approved 11 December 2001; promulgated 8 April 2002; effective 1 July 2002; repealed 2 July 2007 by the *New Resource Food Measures*, *supra* note 84, art 28) [*Administrative Measures for Genetically Modified Food Hygiene*]. An unofficial translation is provided by the US Food and Drug Administration Global Agriculture Information Network (GAIN), online: USDA <http://apps.fas.usda.gov/gainfiles/200207/145684140.pdf>.

88 *Administrative Measures for Genetically Modified Food Hygiene*, *supra* note 87, art 1 states:

> Based on the Food Hygiene Law of the People's Republic of China … and Ag GMO Safety Regulations, these measures are established to strengthen the monitoring and administration of genetically modified (GM) food and protect consumers' rights of health and awareness.

(translation of the USFDA GAIN report, *supra* note 87 [reference omitted]).

89 The *New Resource Food Measures*, *supra* note 84, states:

> In order to strengthen the supervision and management of new resource food and protect the physical health of consumers, these Measures have been made in accordance with the Law on Food Hygiene Law of the People's Republic of China (the "Food Hygiene Law").

(translation from the FAOLEX database, *supra* note 84).

With regard to the *Administrative Provisions on Food Labeling* issued by the QSIQ, the protection of consumer interests is one of its rationales for requiring a food to be labelled. Other considerations include standardizing the labelling of foods, preventing fraud with respect to quality, and protecting the legitimate rights and interests of businesses.[90]

II. Can the Consumer's Right to Know Provide Sufficient Justification for a Mandatory GMO Labelling Measure at the Level of International Law?

The preceding comparative analysis indicates that although the consumer's right to know has not been recognized as providing sufficient legal basis for mandatory GMO labelling in the US, Canada, or China, it does provide such a basis in the EU. As a result, conflicts of GM food trade due to different labelling measures are inevitable. Accordingly, the question of whether the consumer's right to know is accepted as a stand-alone justification for mandatory GMO labelling in relevant international instruments is of significance for the settlement of potential GMO-related trade disputes. At the level of international law, the legal instruments that contain provisions applicable to the labelling of GMOs are principally: (1) various international food labelling standards established by the Codex Committee on Food Labelling, a sub-committee of the Codex Alimentarius Commission; (2) the *Cartagena Protocol on Biosafety to the Convention on Biological Diversity*; and (3) the WTO agreements. Each of these is discussed in turn below.

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90 See *Administrative Provisions on Food Labeling*, *supra* note 85, art 1 ("[f]or the purpose of … safeguarding the legitimate rights and interests of enterprises and consumers, these Provisions are formulated …" [translation from the FAOLEX database, *supra* note 85]).

A. The Codex Alimentarius Commission and Codex Committee on Food Labelling

1. 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.[91] It is an international food standards-setting body, the first session of which was held that same year in Rome; around 120 participants from 30 countries and 16 international organizations attended the 1961 session.[92] The US, EU, and Canada were among the first members of the Codex Alimentarius Commission, and China became a member in 1984.[93] Today, the Codex Alimentarius Commission has 186 members (185 countries and the EU) and 224 observers (52 intergovernmental organizations, 157 non-governmental organizations, and 15 UN agencies).[94] Its members comprise 99% of the world's population.[95]

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91 The World Health Organization (WHO), as the United Nations' 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, UK: Routledge, 2009) at 1; World Health Organization, "About WHO", online: WHO <www.who.int/about/en/>; World Health Organization, "World Health Assembly", online: WHO <www.who.int/mediacentre/events/governance/wha/en/>. For more information on the history of the Codex, see Codex Alimentarius, "About Codex: The Foundation History of Codex", online: CA <www.codexalimentarius.org/about-codex/codex-timeline/en/> [Codex Alimentarius, "Foundation History"]; Meredith T Mariani, *The Intersection of International Law, Agricultural Biotechnology, and Infectious Disease* (Leiden: Martinus Nijhoff, 2007) at 62.

92 Codex Alimentarius, "Foundation History", *supra* note 91.

93 Codex Alimentarius, "Members and Observers: Members" (28 August 2014), online: CA <www.codexalimentarius.org/members-observers/members/en/>.

94 Codex Alimentarius, "Members and Observers" (14 May 2014), online: CA <www.codexalimentarius.org/members-observers/en/>; see also Ching-Fu Lin, "Scientification of Politics or Politicization of Science: Reassessing the Limits of International Food Safety Lawmaking" (2013) 15:1 Colum Sci & Tech L Rev 1 at 5.

95 Codex Alimentarius, "About Codex" (31 March 2014), online: CA <www.codexalimentarius.org/about-codex/en/>.

The Codex Alimentarius Commission develops Codex food standards, guidelines, and related texts that aim to protect the health of consumers and ensure fair food trade.[96] GM food labelling is addressed in the *Principles for the Risk Analysis of Foods Derived from Modern Biotechnology*, which were adopted by the Commission in 2003 (followed by amendments in 2008 and 2011).[97] According to the *Principles*, GM food risk assessment is a comprehensive process of science-based analysis and is conducted on a case-by-case basis.[98] Food labelling is regarded by the *Principles* as one of the risk management methods, but it is addressed in the context of marketing approvals and post-market monitoring with the purposes of

> (a) verifying conclusions about the absence or the possible occurrence, impact and significance of potential consumer *health effects*; and (b) monitoring changes in nutrient intake levels, associated with the introduction of foods likely to significantly alter nutritional status, to determine their human *health impact*.[99]

Hence, the health safety issue is the major concern under the Codex's risk assessment guidance for GM foods.

2. The Codex Committee on Food Labelling

The Codex Committee on Food Labelling (CCFL) is the main body under the Codex Alimentarius Commission that prepares drafting provisions on labelling applicable to all foods.[100] Prior to 2011, the CCFL had drafted four documents related to the issues regarding GMO labelling, but none of

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96 *Ibid*.

97 Codex Alimentarius Commission, *Principles for the Risk Analysis of Foods Derived from Modern Biotechnology*, CAC/GL 44-2003 (2003).

98 *Ibid*, s 3.13.

99 *Ibid*, s 3.20 [emphasis added].

100 Codex Alimentarius, "List of Active Codex Committees" (2 April 2014), online: CA <www.codexalimentarius.org/committees-task-forces/en/?provide=committeeDetail&idList=7>.

them achieved consensus.[101] Finally, in May 2011, after almost twenty years of debate, and having at last obtained the agreement of the US that it would not oppose the adoption of a Codex guideline on the voluntary labelling of GMOs, the 39th Session of the CCFL reached a consensus and thereby developed the 2011 *Compilation of Codex Texts Relevant to the Labelling of Foods Derived from Modern Biotechnology*.[102] This newly adopted *Compilation* does not specifically endorse the labelling of GM products, nor create new obligations, but rather requires that any approach implemented by Codex members regarding the labelling of GM foods be consistent with already adopted Codex texts.[103]

From a review of all of these existing Codex texts, it becomes evident that the consumer's right to know has not been considered a rationale that can be used to justify a mandatory labelling requirement for foods derived from modern biotechnology. For example, according to the *General Stan-*

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101 These four drafts of the Codex Committee on Food Labelling (CCFL) included:

(1) *Proposed Draft Recommendations for the Labelling of Foods Obtained through Biotechnology*, ALINORM 97/22A, Appendix VI (Report of the CCFL to the Codex Alimentarius Commission, 25th Sess, Geneva, 1997);

(2) *Proposed Draft Recommendations for the Labelling of Foods Obtained through Certain Techniques of Genetic Modification/Genetic Engineering (Proposed Draft Guidelines for the Labelling of Food and Food Ingredients Obtained through Certain Techniques of Genetic Modification/Genetic Engineering)*, ALINORM 01/22A, Appendix V (Report of the CCFL to the Codex Alimentarius Commission, 24th Sess, Geneva, 2001);

(3) *Proposed Draft Guidelines for the Labelling of Food and Food Ingredients Obtained through Certain Techniques of Genetic Modification/Genetic Engineering: Labelling Provisions*, ALINORM 04/27/22, Appendix VI (Report of the CCFL to the Codex Alimentarius Commission, 27th Sess, Rome, 2004); and

(4) *Draft Amendment to the* General Standard for the Labelling of Prepackaged Foods *(Draft Recommendations for the Labelling of Foods Obtained through Certain Techniques of Genetic Modification/Genetic Engineering): Definitions*, ALINORM 08/31/22, Appendix VI (Report of the CCFL to the Codex Alimentarius Commission, 31st Sess, Geneva, 2008).

102 *Supra* note 20.

103 The *Codex Compilation* states expressly: "The purpose of this document is only to recall and assemble in a single document some important elements of guidance from Codex texts, which are relevant to labelling of foods derived from modern biotechnology" (*ibid*, s 1). Specifically, the *Compilation* "recalls"

dard for the Labelling of Prepackaged Foods, GM food products are required to be labelled only when the presence of an allergen in any food or food ingredients obtained through biotechnology is transferred from any foods or ingredients that are known to cause hypersensitivity, such as peanuts, milk, fish, etc.[104] This indicates that the relevant concerns are still associated with health or safety specifically.

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the following Codex Alimentarius documents:

(1) *General Standard for the Labelling of Prepackaged Foods*, *supra* note 1, particularly ss 3.1-3.2, 4.1.1-4.1.2, 4.2.2, 7.1;

(2) *General Guidelines on Claims*, CAC/L 1-1979, particularly ss 1.2-1.3, 2 (Definition), 3.3, 3.5, 4.1, 5.1(iii)-(vi);

(3) *Guidelines for Use of Nutrition and Health Claims*, CAC/GL 23-1997, "Introduction" and ss 1.1-1.5;

(4) *Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods*, CAC/GL 32-1999, particularly s 1.5;

(5) *General Guidelines for Use of the Term "Halal"*, CAC/GL 24-1997;

(6) *Working Principles for Risk Analysis for Food Safety for Application by Governments*, CAC/GL 62-2007;

(7) *Principles for the Risk Analysis of Foods Derived from Modern Biotechnology*, CAC/GL 44-2003, particularly at para 19;

(8) *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants*, CAC/GL 45-2003;

(9) *Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms*, CAC/GL 46-2003; and

(10) *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals*, CAC/GL 68-2008.

See also Codex Committee on Food Labelling, *Proposed Draft Compilation of Codex Texts Relevant to Labelling of Foods Derived from Modern Biotechnology*, REP 11/FL, Appendix III (Report of the CCFL to the Codex Alimentarius Commission, 34th Sess, Geneva, 2011).

[104] *General Standard for the Labelling of Prepackaged Foods*, *supra* note 1, ss 4.2.1.4, 4.2.2.

B. *The* Cartagena Protocol on Biosafety to the Convention on Biological Diversity

The *Cartagena Protocol on Biosafety to the Convention on Biological Diversity*[105] is the first multilateral treaty that deals exclusively with the safe handling, transport, and use of living modified organisms (LMOs) derived from modern biotechnology. The *Cartagena Protocol* was adopted on 29 January 2000, and entered into force on 11 September 2003.[106] As of 8 August 2014, the *Cartagena Protocol* has 167 contracting parties, including the EU and China.[107] Canada signed the *Protocol* on 19 April 2001, but has not ratified it.[108] The US has not signed or ratified the *Protocol*.[109]

Aside from the establishment of a Biosafety Clearing-House, which is meant to "[f]acilitate the exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms,"[110] the *Cartagena Protocol* also initiated two other kinds of information exchange mechanisms. One is the communication of information, which is provided for mainly through an "advance informed agreement" procedure (AIA);[111] the second is LMO identification, which is primarily based on the

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105 *Cartagena Protocol*, *supra* note 21.

106 Convention on Biological Diversity, "Parties to the Protocol and Signature and Ratification of the Supplementary Protocol" (11 June 2014), online: CBD <http://bch.cbd.int/protocol/parties/>.

107 Secretariat of the Convention on Biological Diversity, "Cartagena Protocol on Biosafety Ratification List" (8 August 2014), online: CBD <www.cbd.int/doc/lists/cpb-ratifications.pdf> ["Cartagena Ratification List"]. For more information on the *Cartagena Protocol*, see Mariani, *supra* note 91 at 18-27.

108 "Cartagena Ratification List", *supra* note 107.

109 *Ibid*.

110 *Cartagena Protocol*, *supra* note 21, art 20.

111 *Ibid*, arts 7-8. 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 to be intentionally introduced into the environment can be exported. See also *ibid*, art 11.1, which specifies that when LMOs are intended for direct use as food or feed, or for processing, the Party that makes a final 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. That Party must make a decision under a domestic regulatory framework that is consistent with the objective of this Protocol and within 270

labelling regime.[112] The labelling requirement is a key component of the information exchange mechanisms under the *Cartagena Protocol*, and is a significant requirement for states parties to implement the *Protocol* as well. Ever since they were first agreed to in 2000, the detailed requirements for labelling LMOs intended for direct use as food or feed or for processing (LMO-FFPs) have undergone debate. Consensus was not fully reached until the seventh meeting of the Convention on Biological Diversity Conference of the Parties serving as Meeting of the Parties (MOP) to the *Cartagena Protocol on Biosafety* held in October 2014.[113] The outcome of that meeting

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days of receipt of the notification (*ibid*, arts 10.3, 11.4).

112 *Ibid*, art 18.2.

113 This issue was discussed repeatedly, from the First Meeting of the Conference of the Parties (COP) to the Cartagena Protocol on Biosafety (2004) up until the Sixth Meeting (2012), but consensus was not fully reached during that period. See e.g. Third Meeting of the Conference of the Parties serving as the Meeting of the Parties to the Cartagena Protocol on Biodiversity (COP-MOP 3), Decision BS-III/10, *Handling, Transport, Packaging and Identification of Living Modified Organisms: Paragraph 2(a) of Article 18* (2006), online: CBD <www.cbd.int/decision/mop/?id=11066> [Decision BS-III/10]; see also Fifth Meeting of the Conference of the Parties serving as the Meeting of the Parties to the Cartagena Protocol on Biodiversity (COP-MOP 5), Decision BS-V/8, *Handling, Transport, Packaging and Identification of Living Modified Organisms: Paragraph 2(a) of Article 18* (2010), online: CBD <www.cbd.int/decision/mop/default.shtml?id=12321>. The issue was also discussed at the Fourth and Sixth Meetings without resolution (Decisions BS-IV/8 and BS-VI/8). But most recently, the COP-MOP 7 meeting held in October 2014 addressed this issue again and came to agreement based on a review of the past eight years of implementation of paragraph 2(a) of Article 18 of the *Cartagena Protocol* and Decision BS-III/10. See United Nations, Press Release, "UN Meeting Agrees on Decisions to Advance the Implementation of the International Agreement on the Safe Use of Living Modified Organisms" (3 October 2014), online: Convention on Biological Diversity <www.cbd.int/doc/press/2014/pr-2014-10-03-bscopmop7-en.pdf> [United Nations, Press Release, "Implementation of the International Agreement"]. For the report by the Executive Secretary accompanying the agenda item at the meeting, see Conference of the Parties serving as the Meeting of the Parties to the Cartagena Protocol on Biodiversity, Seventh Meeting, *Handling, Transport, Packaging and Identification of Living Modified Organisms: Synthesis of Information on Experience Gained with the Implementation of Requirements Related to Paragraph 2(a) of Article 18*, UNEP/CBD/BS/COP-MOP/7/8 (11 August 2014), especially at para 29, online: Convention on Biological Diversity <www.cbd.int/doc/meetings/bs/mop-07/official/mop-07-08-en.pdf>.

was an agreement that the Parties should continue to use measures that can ensure the implementation of requirements under paragraph 2(a) of Article 8 of the *Cartagena Protocol on Biosafety* and paragraph 4 of decision BS-III/10. Accordingly, each party shall clearly identify LMOs by using "may contain" or "contains" labelling and by ensuring they are intended for direct use as food or feed or for processing, but not for intentional introduction into the environment.[114] However, the *Cartagena Protocol* does not address food safety concerns and does not require labelling for consumer products. As expressed in Article 1 of the *Protocol*, the established information exchange system is for

> 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….[115]

Consequently, it can be concluded that under the *Cartagena Protocol*, rationales for mandating labelling requirements on LMOs are not based on protecting the consumer's right to know, but primarily on the considerations of ensuring conservation and sustainable use of biological diversity, as well as protecting human health.

C. The WTO system

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 interstate trade disputes.[116] Currently, the WTO has 160 members, including active global trade players such as Canada, the

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114 United Nations, Press Release, "Implementation of the International Agreement", *supra* note 113; *Cartagena Protocol*, *supra* note 21, art 18.2(a); Decision BS-III/10, *supra* note 113 at paras 4(a)-(b).

115 *Cartagena Protocol*, *supra* note 21, art 1 [emphasis added].

116 World Trade Organization, "What is the WTO?", online: WTO <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* (Oxford: Hart, 2012) at 3.

EU, the US, and China.[117] So far, there has been no complaint about GMO labelling on the WTO level, and within the WTO system there are no agreements that specifically regulate the labelling of GMOs. However, provisions of the WTO *GATT 1994*, the *SPS Agreement*, and the *TBT Agreement* all have some relevance to the issue of GM product labelling, and thus they are applicable to the settlement of potential GMO trade disputes arising from differing GMO labelling regimes. Moreover, the argument of the consumer's right to know has been discussed in several important WTO cases – for example, the *United States—Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna Products* (*US—Tuna II*)[118] and, in particular, the *United States—Certain Country of Origin Labelling (COOL) Requirements* (*US—COOL*).[119] These cases have provided persuasive evidence for determining whether the consumer's right to know can serve as a sole justification for mandatory labelling requirements under WTO rules.

1. *GATT 1994*

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 by all WTO members. Exceptions to the *GATT* obligations are available under Article XX, wherein a member state can justify restrictive measures on imported products in certain defined circumstances.[120] Among these exceptional situations, a demand for mandatory labelling of imported GMO foods could theoreti-

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117 World Trade Organization, "Understanding the WTO: The Organization" (26 June 2014), online: WTO <www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm>.

118 *United States—Measures Concerning the Importation, Marketing and Sale of Tuna and Tuna Products (Complaint by Mexico)* (2012), WTO Doc WT/DS381/AB/R (Appellate Body Report), online: WTO <www.wto.org/english/tratop_e/dispu_e/381abr_e.pdf> [*US—Tuna II*].

119 *United States—Certain Country of Origin Labelling (COOL) Requirements (Complaints by Canada and Mexico)* (2012), WTO Doc WT/DS384/AB/R, WT/DS386/AB/R (Appellate Body Reports), online: WTO <www.wto.org/english/tratop_e/dispu_e/384_386abr_e.pdf> [*US—COOL*].

120 Article XX of *GATT 1994*, *supra* note 22, originates in the original 1947 *GATT* (*General Agreement on Tariffs and Trade*, 30 October 1947, 55 UNTS 194, art XX, Can TS 1947 No 27 (entered into force 1 January 1948)), which is incorporated into the 1994 agreement under the operation of *GATT 1994*, Article

cally fall within exception (b) ("necessary to protect human, animal or plant life or health") and/or exception (g) ("relating to the conservation of exhaustible natural resources if such measures are made effective in conjunction with restrictions on domestic production or consumption").[121] However, the

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1(a). Article XX permits exceptions for 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 Article II and Article 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 … ;
>
> (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 Article XX, which states that the justification of these exceptions is "[s]ubject 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" (*ibid*). See also Jacqueline D Krikorian, *International Trade Law and Domestic Policy: Canada, the United States, and the WTO* (Vancouver: UBC Press, 2012) at 86-87.

121 *GATT 1994*, *supra* note 22, arts XX(b), (g); see also Marie Kreipe, *Genetically Modified Food: Trade Regulation in View of Environmental Policy Objectives* (Hamburg: Diplomica, 2010) at 23-24.

consumer's right to know is not one of the ten exceptions under Article XX.[122] Moreover, much of the language of Article XX is broad and vague. Thus, in situations which are based on the objectives of protecting human and animal health or conserving exhaustible natural resources, the application of Article XX will be heavily dependent on interpretation by the Panel and Appellate Body.[123] To meet the increasing concerns regarding human and animal health, provision of information to consumers, 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.[124] These agreements are discussed in the next two sections.

2. *SPS Agreement*

The *SPS Agreement* acknowledges that WTO members have the right to use certain trade-restrictive sanitary measures where "necessary for the protection of human, animal or plant life or health."[125] Specifically, under the definitions in Annex A of the *Agreement*, these measures include "labelling requirements directly related to food safety."[126] Therefore, a state can use the *SPS Agreement* to justify its labelling requirement if the labelling measure is adopted based on the argument of potential health risk. However, according to Articles 2.2 and 2.3, these labelling requirements must be

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122 See Rüdiger Wolfrum, "Article XX *GATT 1994*: General Exceptions [Introduction]" in Rüdiger Wolfrum, Peter-Tobias Stoll & Anja Seibert-Fohr, eds, *WTO: Technical Barriers and SPS Measures* (Leiden: Martinus Nijhoff, 2007) 61 at 64.

123 See generally Rüdiger Wolfrum, Peter-Tobias Stoll & Anja Seibert-Fohr, eds, *WTO: Technical Barriers and SPS Measures* (Leiden: Martinus Nijhoff, 2007).

124 Simonetta Zarrilli & Irene Musselli, "The Sanitary and Phytosanitary Agreement, Food Safety Policies, and Product Attributes" in Merlinda D Ingco & John D Nash, eds, *Agriculture and the WTO: Creating A Trading System for Development* (Washington, DC: World Bank/Oxford University Press) 215 at 216-17. In the event of a conflict between the *GATT 1994* and an Annex 1A listed agreement such as the *SPS* or *TBT Agreements*, the latter prevails (*ibid* at 220).

125 Saul Halfon, "Confronting the WTO: Intervention Strategies in GMO Adjudication" (2010) 35:3 Sci Technol Human Values 307 at 310; *SPS Agreement*, *supra* note 23, art 2.1.

126 *Ibid*, Annex A, para 1.

"applied only to the extent necessary to protect human, animal or plant life or health," shall not be "maintained without sufficient scientific evidence," and "shall not be applied in a manner which would constitute a disguised restriction on international trade."[127]

Given that the *SPS Agreement* recognizes the Codex Commission as a credible international authority on food related issues,[128] the 2011 *Codex Compilation* is expected to be followed by every WTO member on the basis of Article 3.1.[129] Nevertheless, WTO members can still use more stringent measures than the Codex standards in cases where they consider that the Codex guidelines are not sufficient to protect human, animal, or plant life or health in their jurisdiction, with the proviso that these measures must be justified by sufficient scientific evidence.[130] If the relevant scientific evidence is insufficient, member states can *provisionally* adopt a *SPS* measure to prohibit imports of certain items or require mandatory labelling of products[131] – thus enabling, for example, the labelling of GM foods or foods containing GM ingredients. However, 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."[132] Therefore, the *SPS Agreement* does not appear to be consistent with adopting the consumer's right to know – i.e. a non-risk-based factor – as a rationale for imposing mandatory GMO labelling measures beyond a time-limited, provisional period.

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127 *Ibid*, arts 2.2, 2.3.

128 *Ibid*, Annex A, para 3(a) (defining "[i]nternational standards, guidelines and recommendations" as being, in the area of "food safety, the standards, guidelines and recommendations established by the Codex Alimentarius commission relating to food additives, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice"). See also Peter J Aggett et al, "Nutrition Issues in Codex: Health Claims, Nutrient Reference Values and WTO Agreements: A Conference Report" (2012) 51 Eur J Nutr S1 at S2.

129 "To harmonize sanitary and phytosanitary measures on as wide a basis as possible, Members shall base their sanitary or phytosanitary measures on international standards, guidelines or recommendations, where they exist …" (*SPS Agreement*, *supra* note 23, art 3.1).

130 *Ibid*, art 3.3.

131 *Ibid*, art 5.7.

132 *Ibid*.

3. *TBT Agreement*

If a state argues that its labelling measures are not safety-based – in order to avoid application of the *SPS Agreement*, which is stringent in its requirements of proof – then the *TBT Agreement* would apply instead. The *TBT Agreement* sets up principles for assessing technical barriers to trade, requiring that technical regulations adopted by members not be applied in a manner that would constitute arbitrary or unjustifiable discrimination or a disguised restriction on international trade.[133] In the terminology of the *TBT Agreement*, labelling requirements applied to a GM-based product could be considered either a "technical regulation" (if it is a mandatory labelling regime) or a "standard" (if it is a voluntary labelling regime).[134]

The *TBT Agreement* allows member states to use technical regulations to fulfill a legitimate objective, such as "national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the environment."[135] 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 fulfil a legitimate objective, taking account of the risks non-fulfilment would create.[136]

The use of 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 contribution that the technical regulation in question makes to legitimate objectives.[137]

It is uncertain whether providing consumers with GMO information on labels solely on the basis of a claimed consumer's right to know can be regarded as a legitimate objective under Article 2.2 of the *TBT Agreement*. To date, no analyses from the WTO Panels and Appellate Body have addressed

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133 *TBT Agreement*, *supra* note 24, art 2.1.

134 *Ibid*, Annex 1, paras 1-2.

135 *Ibid*, art 2.2.

136 *Ibid*.

137 See *US—Tuna II*, *supra* note 118 at para 319.

this issue. The WTO Appellate Body in its decision in the *US—COOL* dispute noted that the determination of the "legitimacy" of a measure's objective should be based on an independent and objective assessment that considers the measure's "design, architecture, structure, legislative history, as well as its operation."[138] The Appellate Body also recognized that if the objective of the measure is among those enumerated in Article 2.2 of the *TBT Agreement*, then the objective is legitimate.[139] With regard to the objective of the "country of origin labeling" (COOL) measure, although providing consumers with information as to origin is not among those objectives specifically listed in Article 2.2, the Appellate Body found that the COOL measure was related to the objective of prevention of deceptive practices specified in both Article 2.2 and *GATT 1994*, Article XX(d).[140]

Following the Appellate Body's reasoning in the *US—COOL* case, if the provision of information can fall within the scope of the legitimate objective of prevention of deceptive practices under Article 2.2, the subsequent question should then be whether providing consumers with information on a *specific type of issue* – e.g. whether foods are GMO or contain GM ingredients – can also be linked to the objective of prevention of deceptive practices. To assert this linkage, a member state would have to prove that GM and non-GM products are different, and that deceptive purchases will occur because of confusion arising from the absence of labelling. One approach would be for the member state to demonstrate that the use of GM techniques has had an impact on the quality or properties of the end products sufficient to distinguish GM products from their non-GM counterparts. However, to date, there has been no solid scientific evidence suggesting GM and non-GM food products have material differences that may cause higher risks or major changes for nutritional compositions of GM foods.[141]

Given that there is no established evidence supporting the existence of material differences between GM and non-GM foods, the provision of in-

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138 *US—COOL*, *supra* note 119 at para 395.

139 *Ibid* at paras 370-72.

140 *GATT 1994*, *supra* note 22, art XX(d).

141 When California Prop 37, *supra* note 5, became a nationwide controversy, the American Association for the Advancement of Science (AAAS) issued a formal statement arguing against the misguided assumption by the proposition's proponents that there are harmful risks associated with GM foods. The AAAS argued that "consuming foods containing ingredients derived from GM crops

formation to consumers as to whether their foods are genetically modified or contain GM ingredients is not likely to be deemed a "legitimate objective" under the meaning of Article 2.2 of the *TBT Agreement*. Even if it can be argued that there are scientific uncertainties for GM food risks, the consumer's right to know and/or a state's desire to provide consumers with information are still unlikely to provide sufficient justification for a mandatory GMO labelling measure under the *TBT Agreement*. This is because there is an alternative that can fulfill the same objective but in a less trade-restrictive manner: a voluntary negative (i.e. "GMO-free") labelling requirement.[142] As GM foods have repeatedly been shown to be as safe as non-GM foods for human consumption, the use of voluntary negative labelling by distributors of "GM-free" products could provide the desired level of consumer information, which may assist consumers in making informed choices while preventing trade conflicts from arising through contradictory mandatory labelling requirements.

Concluding Remarks

The evidence presented in the foregoing legal exploration indicates that a universal acceptance of the consumer's right to know in the context of

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is no riskier than consuming the same foods containing ingredients from crop plants modified by conventional plant improvement techniques." See American Association for the Advancement of Science, News Release, "Statement by the AAAS Board of Directors on Labeling of Genetically Modified Foods" (20 October 2012), online: AAAS <www.aaas.org/sites/default/files/AAAS_GM_statement.pdf>. Even in the EU, where GM foods are subject to more stringent regulatory management, the European Food Safety Authority (EFSA) Panel on GMOs published a scientific opinion in 2012 on the safety assessment of genetically modified MON810 maize varieties, a type of GM maize developed by Monsanto that can express the Cry1Ab insect protein isolated from Bacillus thuringiensis (Bt) to control certain Lepidoptera insects. See EFSA Panel on Genetically Modified Organisms (GMO), "Scientific Opinion on an Application (EFSA-GMP-NL-2012-107) for the Placing on the Market of Maize MON 810 Pollen under Regulation (EC) No 1829/2003 from Monsanto" (2012) 10:12 EFSA Journal 3022, online: EFSA <www.efsa.europa.eu/en/efsajournal/doc/3022.pdf>. The report "conclude[d] that 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" (*ibid* at 6). See also Kuntz, Davison & Ricroch, *supra* note 70.

142 See Keane, *supra* note 15 at 324.

GMO labelling legislation has not been achieved, either in domestic law or in relevant international instruments (see the summary presented in Tables 1 and 2). GMO labelling regulations in the US, Canada, and China do not recognize the consumer's interest in knowing whether foods are GMOs or contain GM ingredients as a sufficient, stand-alone rationale for implementing a mandatory labelling measure. Rather, only health safety concerns or compositional differences between GM and non-GM conventional foods would be regarded as determinative factors triggering labelling requirements. Put another way, under GMO labelling laws of these three countries, consumers only have a right to know what could harm them.

In contrast, EU GMO labelling law acknowledges the consumer's right to know as sufficient justification for a mandatory labelling regime. Accordingly, EU consumers are entitled to receive information about the GM status of their foods, regardless of health and safety concerns. This being said, the insistence on the consumer's right to know in EU GMO labelling legislation does not in itself guarantee EU consumers real choice at the point of purchase, because there are limited GM foods available in the EU market in the first place. In addition, an increasing number of challenges by scientists make the case that EU members' policies on the cultivation of authorized GMOs are not scientifically grounded, but rather are politically driven. Furthermore, because of the bans on GMO cultivation in the EU, the mandatory GMO labelling requirement overwhelmingly affects imported foods, a fact that suggests that the consumer's right to know may have been used as an excuse for EU protectionism.

At the international level, although the fragmentation of international law has resulted in different, or even inconsistent, approaches to GMO labelling requirements, applicable international instruments do not recognize the consumer's right to know as a permissible exclusive basis for a GMO labelling regime. The Codex Alimentarius's *Principles for the Risk Analysis of Foods Derived from Modern Biotechnology* and its 2011 *Compilation* regard health and safety concerns as the determinative factors for implementing mandatory GMO labelling. The *Cartagena Protocol*, in keeping with its status as an international environmental treaty, targets conservation and sustainable use of biological diversity, as well as the protection of human health. Thus, it does not provide authority for member states to require a special labelling measure for LMOs exclusively based on the consumer's right to know.

Under the WTO system, the consumer's right to know is not included in the exceptions under Article XX of the *GATT*, which permits special trade measures to be deemed not to violate other *GATT* rules. The *SPS Agreement*

insists on scientific justifications for any sanitary/phytosanitary measures adopted by member states, therefore it will not permit a mandatory GMO labelling regime grounded solely in the consumer's right to know without any supporting scientific evidence. The *TBT Agreement* allows member states to use technical regulations to fulfill a legitimate objective. Nonetheless, to analogize from the Appellate Body's reasoning in the *US—COOL* case, it appears that providing consumers with information about whether foods are GMOs or contain GM ingredients may not be regarded as satisfying a legitimate objective under Article 2.2 of the *TBT Agreement*, because of the lack of scientific evidence confirming that GM foods are either materially different from non-GM foods or pose any known harms or higher risks to human and animal health and safety. Therefore, the consumer's right to know appears to be unavailable under the WTO system as sufficient basis for mandatory GMO labelling as well.

As noted in the Introduction to this paper, Health Canada's current GMO labelling regime relies heavily on scientific rationality, while the EU GMO legislation emphasizes a social protection rationale. Although the Canadian model of scientific, evidence-based policy-making may be challenged for its limited social considerations, the EU model may not actually be more socially responsive; the discussion in Part II regarding some of the policies regarding GMOs adopted by EU countries reveals that the EU's GMO policy-making may in reality be more influenced by consumer and environmental lobby groups and/or protectionist concerns than by respect for consumer interests *per se*.[143] In conclusion, given that there is no established evidence indicating harmful effects of GMOs, and that the legal basis of the consumer's right to know has not been accepted under international instruments, especially in the WTO system, it is highly unlikely that Health Canada will stop using the present voluntary GMO labelling system and instead introduce a mandatory labelling system.

However, the obstacles to a mandatory labelling measure do not necessarily mean that there are no alternative methods for catering to the increasing demand for information about GM foods from consumers and environmental groups. In practice, commercial self-adjustments carried out by many companies in the US and Canada suggest that, even without a mandatory federal GMO labelling regime, greater transparency from manufactu-

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[143] See *supra* notes 70-79 and accompanying text. See also 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 at 61.

rers and retailers can be achieved through voluntary labelling. For instance, the retailer Whole Foods has already adopted an internal policy of voluntarily labelling and advertising the GM status of their products to inform their customers, and also requires their suppliers to provide this information.[144] Accordingly, some consumers' non-GMO preferences that are not scientifically linked to health and safety evidence are increasingly supported under voluntary labelling regimes. In fact, it is in consideration of promoting the consumer's right to make informed choices that the author of this paper advocates for the consistent implementation of a voluntary labelling regime.

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144 Walter Robb & AC Gallo, "Whole Foods Market commits to full GMO transparency – announcement at Natural Products Expo West", News Release/ Corporate Blog Post, *Whole Foods Market* (11 March 2013), online: WFM <www.wholefoodsmarket.com/blog/whole-foods-market-commits-full-gmo-transparency-announcement-natural-products-expo-west>; see also Anton E Wohlers, "Labeling of Genetically Modified Food: Closer to Reality in the United States?" (2013) 32:1 Politics Life Sci 73 at 73.

Table 1. The Consumer's Right to Know in US, Canadian, EU, and Chinese GMO Labelling Legislation

State	Labelling requirements for GMOs	Can the consumer's right to know provide the sole basis for mandatory labelling?	If not, what rationales can justify mandatory labelling?
US	Voluntary	No	A material difference between GM foods and their non-GM counterparts.
Canada	Voluntary	No	Health and safety concerns
EU	Mandatory	Yes	
China	Mandatory	Generally no	Health and safety concerns

Table 2. The Consumer's Right to Know in International Instruments Relevant to GMO Labelling

Instrument	Labelling requirements for GMOs	Can the consumer's right to know provide the sole basis for mandatory labelling?	If not, what rationales can justify mandatory labelling?
Cartagena Protocol on Biosafety	Mandatory	No	Conservation and sustainable use of biodiversity, human health
Codex CCFL	Not specified	No	Health and safety concerns
WTO Agreements	Not specified	Probably no	*GATT 1994*: Article XX exceptions *SPS Agreement*: Scientific evidence of health risks *TBT Agreement*: Measures that do not constitute unnecessary obstacles to international trade