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POLICYCHOICES FOR BIOTECH LEGISLATIVE ENACTMENTS: GENETIC MODIFICATIONS IN THE FOOD CHAIN

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Abstract

Perhaps the highest impact advancements from science over the last half a century are the applications of biology and computer sciences. However, the regulatory aspect of biotechnology is contentious, and it is at a stage of development. This paper covers the current issues on regulatory aspects of genetically modified (GMO) foods, and it examines the regulation of the nations who have biotechnological ability and a history of GMOs for both food and other product crops.

There are some fundamental jurisdictional differences between GMOs and non-GM foods. GMOs are patentable in many jurisdictions, whereas the path to patent for conventional crops is more difficult as many have been in production for decades. A patent gives exclusive rights to a GMO patentee, whereas others do not have this right. Non-GM seeds typically can be planted, replanted, saved, or sold by farmers, but farmers do not have these same rights with GM seeds. GM plants or crops have cross-pollination effects and some say that they contaminate non-GM crops (foods too), which is not usually an issue with non-GM plants.

This paper critically examines regulation on the risk assessment and commercialization process of genetically modified crops/foods in Canada, US and EU. It further looks at related cross-cutting issues such as precautionary principle, labelling GM foods, public participation and transparency in the decision making process and other cross-cutting issues such as co-existence between GM crops and non-GM crops, AP, liability, GM animal; and it discusses policy choices for legislative enactments focusing

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Canada. It has comparative approach and it offers biotech policy choices.

Keywords: Regulation of Genetically Modified Organisms, Risk and Commercialisation Processes, Legislative Policy Choices

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INTRODUCTION

Genetically modified (GM) food[1]is one of the categories of foods available in the market. Over the last 30 years, the field of genetic engineering has progressed tremendously. "The term genetic engineering is used to describe the process by which the genetic makeup of an organism can be altered using 'recombinant DNA technology'"(International Service for the Acquisition of Agri-Biotech Applications [ISAAA], 2012).With the use of recombinant DNA technology (rDNA), scientists are able to produce GM crops and GM foods and companies are able to bring GM crops and GM foods into the market. Despite the benefits of GM foods, such as high yield, higher nutritional value, and resistance to pests and viruses, many people have expressed health concerns over consuming GM foods. The main "concern is that the transfer of genes from one organism to another may result in the transfer of allergens," and it may make GM foods

[1] Genetically modified (GM) is a commonly used tem to describe organisms that have been developed using recombinant DNA technologies. Even though in some sense all today's crops have been 'modified' through breeding over centuries, the common usage is adopted in this paper.

allergenic to certain persons(Fernandez, 2006, pp. 336-337). Particularly from health and environment perspectives, GM crops and GM foods are contentious from the very beginning of their introduction to present.In India the introduction of GM crops has been highly contentious. In this paper we seek to outline the experience of other nations that have a relatively long history of GM use for both food and other product crops.

In Canada, GM foods have been available in the market since 1995(Canadian Biotechnology Advisory Committee [CBAC], 2001). "The phrase 'GM foods' refers generally to food produced from genetically engineered plants and animals using recombinant DNA technology"(CBAC, 2001, p. 2).In Canada, GM foods are part of the broader types of novel foods. Novel foods include foods produced by means of genetic engineering as well as other means such as mutagenesis, cell fusion or conventional cross breeding(CBAC, 2001).In general, the Canadian regulatory system focuses on products that come within the broader categories of novel foods and plants with novel traits. Despite safety assessments, the Canadian regulatory system does not focus on GM foods (United States Department of Agriculture [USDA], 2012).

The Canadian Food and Drug Regulations[2] defines "novel food" as being one that does not have a history of being safely used as a food.[3]In 2012, Canada cultivated biotech crops at about 11.8 million hectors, and as one of the biotech crop-producing countries, it ranked fourth in the world after the US, Brazil and Argentina (Clive, 2013). Major cultivated biotech crops approved for food uses in Canada are canola, corn and soybeans (USDA, 2012). Other types of GM crops approved for food uses in Canada include flax, potato, tomato, squash, sugar beet and others. "The genetic modifications introduced into these crops include herbicide tolerance, resistance to insect pests and to diseases caused by plant viruses, improved shelf life (in the case of tomatoes) and modified oil composition"(USDA, 2012, p. 13).

GM foods play a big role in Canadian import and export trade. The US, Japan, Mexico and China import approximately 85% of Canadian canola, seed, oil and meal(USDA, 2012).Canola is typically a Canadian crop invented by Canadians. The name "canola" stands for Canadian oil, low erucic acid. It is estimated that canola alone contributes $13 billion CAD annually to the Canadian economy(USDA, 2012). Canada also imports GM foods and crops such as corn and soybeans from the US(USDA, 2012).

[2]CRC, c 870 [*Food/Drug Reg*].
[3]*Ibid* at s B.28.001.

The Canadian regulatory system differs from the European Union (EU) system. The EU has biotechnology-specific rules and regulations that allow the cultivation of GM crops and GM foods after authorisation. But in practice, GM-labelled foods are not available in the market and the cultivation of GM crops is temporarily banned in many EU member countries. General consumers are hostile toward GM foods, and retailers are hesitant to sell foods with GM labels. In the United Kingdom (UK), GM crops are temporarily banned from being cultivated in the fields and consumers cannot find GM-labelled foods in the supermarket. In all the big economies of Europe, i.e., Germany, Italy and France, GM-labelled foods are not available in the supermarket. This is the general trend in Europe. In contrast, there is no specific biotechnology law regarding GM foods in the US and Canada; cultivation of GM crops occurs, GM foods are available in the market, GM foods are not required to be labelled and there is no strong opposition from the public. The EU system requires scientific risk assessments and authorisation before GM crops and foods can be brought into the environment or into the market, whereas in the US, there is no need for scientific risk assessments if the GM food is not potentially harmful to public health.

The infamous bovine spongiform encephalopathy (BSE) was first detected in cattle in the UK in 1982.Its massive outbreak in 1989-1990 and again in 1996 in the UK, the widely criticised use of asbestos in France during the 1990s,the'Le sang contamine' scandal in France, and the dioxin contamination of food products produced in Belgium in 1999 severely undermined public trust in the EU food safety regulation(Lynch & Vogel, 2001). These events occurred at the same time when GM foods were first being introduced in Europe, and they impacted the attitude of the European public toward GM foods(Lynch & Vogel, 2001). "In this context it is significant that while many scientists on both sides of the Atlantic, though perhaps more in Europe, regard the most important risks associated with GMOs as environmental, and the risks to human health as ranging from minimal to non-existence, it is the latter which have dominated public discourse in Europe. This is a direct response to mad-cow disease, which has heightened European anxiety over food safety"(Lynch & Vogel, 2001).

These two systems of GMO regulations collided at the WTO Dispute Settlement Body, and many times in agricultural trade negotiations between North America and Europe. Even now, GM agricultural products are the main issue in the proposed US-EU free trade agreement as well as in the Canada-EU free trade agreement. In the EU, GM products including GM foods were not approved for sale from 1998 to 2003(Rosenthal, 2004). In August, 2003, the United States, Canada, and Argentina brought a complaint before the World Trade Organisation (WTO) Dispute Settlement

Body against the EU.[4]They asked for a ruling on the failure of the EU to grant approval on the marketing of a number of GM crops, and they also challenged the imposition of national-import and marketing bans of GM crops by individual EU member states(Sheldon, 2004). This restriction was imposed due to widespread consumer concerns over the health safety and environmental impacts of GM crops(Sheldon, 2004). In this case, i.e., *European Communities - Measures Affecting the Approval and Marketing of Biotech Products*,[5] the WTO Panel considered the measures affecting the approval and marketing of biotech products in Europe.

In *EC-Biotech*, the Panel found that the European Communities applied a general de facto moratorium on the approval of biotech products between June 1999 and August 2003. The Panel found that the European Communities had acted inconsistently with its obligations under Annex C(1)(a), first clause, and Article 8 of the SPS Agreement in respect of the approval procedures concerning 24 out of 27 biotech products because there were undue delays in the completion of the approval procedures for each of these products. However, the Panel found that the European Communities had not acted inconsistently with its obligations under any provisions raised by the complaining parties, including Art. 5.1, 5.5, and 2.2 of the SPS Agreement. The Panel also found, with regard to the European Communities Member State safeguard measures, that the European Communities acted inconsistently with its obligations under Art. 5.1 and 2.2 of the SPS Agreement with regard to all of the safeguard measures at issue, because these measures were not based on risk assessments satisfying the definition of the SPS Agreement (World Trade Organization a). In this dispute, the WTO Panel focused on the procedural aspects and it did not rule anything based on the merits of the case or GMOs.

The EU lifted the 5-year (1998-2003) moratorium on GM foods only after the US, Canada, and Argentina filed a submission against it in the WTO Dispute Settlement Body. Subsequently, the EU made it possible to sell GM foods in the EU by adopting the GM Food and Feed Law (Regulation (EC) No 1829/2003 of the European

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[4] See *European Communities - Measures Affecting the Approval and Marketing of Biotech Products (Complaint by the United States)* (20 May 2003), WTO Doc WT/DS291/1 (Request for Consultations), online: WTO <https://docs.wto.org>; *European Communities - Measures Affecting the Approval and Marketing of Biotech Products (Complaint by Canada)* (20 May 2003), WTO Doc WT/DS292/1 (Request for Consultations), online: WTO <https://docs.wto.org>; *European Communities - Measures Affecting the Approval and Marketing of Biotech Products (Complaint by Argentina)* (21 May 2003), WTO Doc WT/DS293/1 (Request for Consultations), online: WTO <https://docs.wto.org>.

[5] *(Complaint by the United States, Canada and Argentina)* (2006), WTO Doc WT/DS291/R, WT/DS292/R, WT/DS293/R (Panel Report) online: WTO <https://docs.wto.org> [*EC-Biotech*].

Parliament and of the Council of 22 September 2003on genetically modified food and feed[6]) and GMO Traceability and Labelling Law (Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC[7]), which came into force on 18 April 2004.

In Canada, regulations cover the risk assessment aspects of GM foods. Accordingly, GM foods are subject to risk assessment before they are commercialised. However, many issues relating to GM foods are not addressed by regulation. GM foods produced by GMOs are covered by regulation, but conventional or organic foods contaminated by GMOs are not. Issues such as risk assessment of foods containing GMOs or GMO-contaminated foods, applicability of the Precautionary Principle if there is a need to protect public health, and labelling are not addressed by regulation in Canada. What happens if honey (food) is contaminated by GMOs? Is it marketable as organic honey or GM honey? Should we consider it as GM honey (food) and subject it to risk assessment? North American laws are silent on this issue. In Europe, the European Court of Justice (ECJ) in *Karl Heinz Bablok and Others v Freistaat Bayern*[8] ruled that honey and food supplements containing pollen derived from a GMO are foodstuffs produced from GMOs which can not be marketed without prior authorisation.[9]The ECJ also ruled that GMOs for food use, foodstuffs containing or consisting of GMOs, or foodstuffs produced from ingredients produced using or containing GMOs must be authorised before being placed on the market.[10]This case was referred to the ECJ by the Bavarian Higher Administrative Court of Germany. This law suit was brought before the court in Germany in 2005 when a beekeeper found MON810 maize DNA and genetically modified proteins in his beehives situated 500 meters from the land where GM crops were cultivated.[11]

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

[7] EC, *Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC* [2003] OJ, L 268/24 [*Regulation 1830/2003*].

[8] Case C-442/09 *Karl Heinz Bablok and Others v.Freistaat Bayern* [ECJ, 6 Sept. 2011] [*Bablok*].

[9] *Ibid* at para 109.

[10] *Ibid* at paras17, 109.

[11] *Ibid* at para 36.

Very small amounts of MON810 maize DNA were detected in a number of samples of honey.[12]

Further issues arise over whether such contaminated foodstuffs should be GM-labelled. Again, law in North America is silent on this. In Europe, honey that contains pollen from authorised GM plants has to be labelled as such if the GM pollen accounts for more than 0.9 per cent of the total pollen content.[13]Whether consumers have the freedom to choose between GM foods and non-GM foods and whether they have the right to know about GM and non-GM foods are also not addressed in Canada.

1. REGULATION OF GM FOODS

(A) Commercialisation and Scientific Risk Assessment in Canada, US and EU

In Canada, there is no specific biotechnology law. The Federal Regulatory Framework for Biotechnology (1993)(Government of Canada, 1993) is the main governmental policy that addresses biotechnology and it specifies that existing legislation and regulatory institutions be used to deal with biotechnology. Hence, the subject matter of biotechnology has been regulated by various existing relevant laws in Canada.

Part 6 of the Canadian Environmental Protection Act,[14]addresses the regulation of animate products of biotechnology[15]. In Canada, the *CEPA* is the only legislation that directly deals with biotechnology, from a health and environment perspective. The *CEPA* requires that all products of biotechnology that are new to Canada be subject to an assessment of their potential 'toxicity' before they can be manufactured, imported or sold in Canada.

The Seeds Act,[16]Feeds Act,[17] and Fertilizers Act[18]regulate agricultural biotechnology but contain no clear legislative authority for the evaluation of genetically engineered products from an environmental or human health perspective. The *Seeds Regulations*[19] covers plants including plants with novel traits (PNTs). The Seeds Act

[12]*Ibid* at para 37.
[13]*Ibid* at para 21.
[14]SC 1999, c 33 (*CEPA*).
[15]The Federal Regulatory Framework for Biotechnology, 1993, has defined biotechnology as "the application of science and engineering in the direct or indirect use of living organisms or parts or products of living organisms in their natural or modified forms."See The Regulatory Framework, *supra* note 37.
[16]RSC 1985, c S-8.
[17]RSC 1985, c F-9.
[18]RSC 1985, c F-10.
[19]CRC, c 1400, ss 107, 110, 111.1.

and Seeds Regulations, which are listed in the *CEPA*'s Schedule 4, have provisions addressing the notification and assessment of PNTs.[20] If a PNT is found to pose a significant risk to the environment, it shall not be released in Canada(Canadian Food Inspection Agency [CFIA], 2012c). These acts are administered by the Canadian Food Inspection Agency (CFIA),[21] which has the authority to enact regulations dealing with issues such as seed quality (grades), inspection, and packaging and labelling. The Seed Regulations, Feeds Regulations,[22] and Fertilizers Regulations[23]were enacted in Canada. The CFIA is also responsible for regulating the Plant Protection Act[24] and the Plant Protection Regulations[25] in Canada.

The Canadian Food and Drugs Act[26] and the Food/Drug Reg cover foods and drugs (human and veterinary), cosmetics, and medical devices including those derived through biotechnology. The Food/Drug Reg has created a new division under the Food/Drugs Act, Division 28, regarding Novel Foods. The Pest Control Products Act[27] and the Pest Control Products Regulations[28] require that pesticides, including those derived through biotechnology, be assessed for health and environmental risks and value, and only if both risks and value are acceptable can they be registered for use. The Health of Animals Act[29] and Health of Animals Regulations[30] regulate veterinary biologics. The Fisheries Act[31] and the Fishery (General) Regulations[32] regulate transgenic aquatic organisms.

A PNT is a new variety of a species that has one or more traits that are novel to that species in Canada (Canadian Food Inspection Agency [CFIA], 2012d). All genetically engineered plants contain novel traits. Some traits can be developed through other techniques such as mutagenesis, cell fusion, and traditional breeding. Such PNT's also have the potential to affect the safety of the environment and human health (CFIA, 2012d). The Plant Biosafety Office of the CFIA is responsible for regulating the environmental release of PNTs under the Seeds Regulations (Part V).It

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[20] The provisions, for notification and assessment of plants with novel traits, of the *Seeds Act* and*Seeds Regulations* are comparable to that in the *CEPA* 1999 for organisms that are products of biotechnology.
[21] Established under the *Canadian Food Inspection Agency Act*, SC 1997, c 6.
[22] SOR/83-593.
[23]CRC, c 666.
[24]SC 1990, c 22.
[25] SOR/95-212.
[26]RSC 1985, c F-27 [*Food/Drugs Act*].
[27]SC 2002, c 28.
[28] SOR/2006-124.
[29]SC 1990, c 21.
[30]CRC, c 296.
[31]RSC 1985, c F-14.
[32] SOR/93-53.

administers safety evaluations of all PNTs before they are grown, fed to livestock, or are imported. Such PNTs are subject to confined research field trails under Directive 2009-09: Plants with novel traits regulated under Part V of the Seeds Regulations*:* Guidelines for determining when to notify the CFIA(Canadian Food Inspection Agency [CFIA], 2012b) and Directive 2000-07 (Dir2000-07: Conducting Confined Research Field Trials of Plants with Novel Traits in Canada(Canadian Food Inspection Agency [CFIA], 2012a).Then, a detailed environmental assessment is required for the plant's unconfined release into the environment. Such assessment will be conducted under Dir 94-08(CFIA, 2012c) and Dir 2009-09(CFIA, 2012b). If the PNT is to be used as livestock feed, it must be assessed for safety before it can be used for commercial production. If the PNT is also to be used as human food, it must undergo a separate safety assessment by Health Canada for food safety. After a submission of application by proponent and environmental safety assessment, the PNT may be authorised for environmental release with or without conditions.

(B). GM Foods Safety Assessment

Heath Canada is responsible for conducting safety assessments of novel foods including GM foods. Health Canada's (2006) Guidelines for the Safety Assessment of Novel Foods provides the reasoning of the safety concerns of GM foods. It states, "The application of genetic modification through either traditional breeding or genetic engineering is not considered to increase or decrease the inherent risk associated with consuming the organism as a food. However, the wide variety of manipulations possible through genetic modification, and the potential for the introduction of toxic compounds, unexpected secondary effects and changes in the nutritional and toxic characteristics of the food product may give rise to safety concerns"(Health Canada, 2006, s. 1.1). The safety criteria for the assessment of novel foods are outlined in Health CAN Guidelines (Health Canada, 2006) and Division 28 of Part B of the Food/Drug Reg.

In Canada, safety assessment of GM foods involves the following steps:

I. Pre-submission consultation

II. Pre-market notification

III. Scientific assessment

IV. Requests for additional information

V. Summary report of findings

VI. Preparation of food rulings proposal

VII. Letter of no objection

Health Canada conducts, in line with the pre-market notification requirement, pre-market evaluations to assess the safety of GM foods.[33]Before such pre-market notification, applicants are encouraged to consult with the Novel Foods Section of the Food Directorate and to clarify safety issues.

When manufactures or importers who wish to sell or advertise GM foods have complete knowledge regarding the safety of GM foods, they must submit a pre-market notification to the Novel Foods Section. Based on the criteria described in Health CAN Guidelines, a scientific safety assessment is then conducted by scientific evaluators, who assess the following in regards to GM foods:

- development of the modified organism, including the molecular biological data that characterises the genetic change;
- composition of and nutritional information on the GM food compared to a non-modified counterpart food;
- the potential for production of new toxins in the food;
- the potential for causing allergic reactions;
- microbiological and chemical safety of the food;
- the potential for any unintended or secondary effects;
- key nutrients and toxicants; and,
- major constituents (for example, fats, proteins, carbohydrates) and minor constituents (for example, minerals and vitamins).

Health Canada evaluators, if required, may request further information. Once evaluators complete their assessments, they prepare a report. Then, a Health Canada Food Rulings Proposal is prepared and is reviewed by senior staff in the Food Directorate, who make sure that all issues have been addressed. After, a decision on whether or not to approve the GM food is made. If the decision is to approve, a "Letter of No Objection" is issued to the applicant, and the approved GM foods can be sold in the market.

In the US, there are no specific statutes that deal with biotechnology or GMOs. GM crops or food products are regulated under existing laws that address health, safety, efficacy, and environmental safety. The existing laws applicable to conventional or non-GMO products also apply to GMO products (Stewart & Johanson, 1999). The

[33]*Food/Drug Reg*, *supra* note 2 at s B.28.002.

Co-ordinated Framework for Regulation of Biotechnology Products[34](CFR) is the main US governmental policy, and it specifies that no new and specific biotechnology law is needed to regulate the products of biotechnology in the US. It references the existing Federal Plant Pest Act,[35] the Federal Plant Quarantine Act[36] and the Federal Insecticide, Fungicide and Rodenticide Act[37]as an adequate basis for regulating biotechnology (Nap, Metz, Escaler & Conner, 2003). "This *CFR* decision implies that in USA the regulation focuses primarily on the characteristics of the product, rather than the way in which the product is produced"(Nap, Metz, Escaler & Conner, 2003, p. 9). However, as and when needed, federal agencies have developed a number of regulations[38] and guidelines[39] specific to particular biotechnology products (Pew Initiative on Food and Biotechnology, 2001).

In the US, no single federal agency is responsible for the regulation of biotechnology products (Pew Initiative on Food and Biotechnology, 2001). The CFR has named the Animal and Plant Health Inspection Service (APHIS) of the United States Department of Agriculture (USDA), the Environment Protection Agency (EPA) and the Food and Drug Administration (FDA) as the primary governmental agencies for regulating biotechnology.

> *"The Biotechnology, Biologics and Environmental Protection (BBEP) unit of USDA-APHIS focuses on the environmental impact of GM plants under (revised) regulation 7 [CFR]Part 340"(Nap, Metz, Escaler & Conner, 2003, p. 9). APHIS has the authority to regulate transgenic plants under the Plant Protection Act[40] to control plant pests and to ensure protection of commercial crops and the environment. Accordingly, APHIS may "impose regulatory restrictions on the importation, transportation and planting of transgenic plants"*
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> *(Pew Initiative on Food and Biotechnology, 2001, p. 3).*

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[34] 51 Fed Reg 23302 (1986) [*CFR*].The Coordinated Framework for Regulation of Biotechnology is considered a cornerstone of US biotechnology policy.

[35] 7 USC § 150bb or 150cc (1957) [*Plant Pest Act*], as repealed by *Plant Protection Act*, 7 USC §§ 7701-86 (2000).

[36] 7 USC §§ 151-167 (1994) [*Plant Quarantine Act*], as repealed by *Plant Protection Act*.

[37] 7 USC §§ 136-136y (1994)[*FIFRA*].

[38] Federal agencies issue regulations, which have binding effect, to implement the provisions of statutes.

[39] Guidelines have no binding effect.

[40] This Act (7 USC §§ 7701-86 (2000)) was passed in 2000. It repealed and consolidated the authorities of all or part of nine other pre-existing statutes, including the *Plant Pest Act* of 1957, the *Federal Noxious Weed Act* of 1974, and the *Plant Quarantine Act* of 1912. See Pew Initiative on Food and Biotechnology, 2001.

US has a provision of issuing a "determination of non-regulated status" to new GM plants, i.e., only to non-plant pests. Developers of a new GM plant submit an application to APHIS (Stewart & Johanson, 1999).Then, APHIS conducts an environmental risk assessment and determines the plant's possible effects on human health and the environment (Stewart & Johanson, 1999).Accordingly, APHIS issues a "determination of non-regulated status" to such GM plant if it is not a plant pest. The new GM plant will no longer be subject to APHIS' plant pest rules and it may be released into the environment (Stewart & Johanson, 1999). The Plant Pest Act and the Plant Quarantine Act provide authority to APHIS for regulating GM plant pests (Stewart & Johanson, 1999).

Under FIFRA, the EPA is responsible for regulating "[t] ransgenic plants that have been modified to produce a pesticide"(Pew Initiative on Food and Biotechnology, 2001, p. 8).In accordance with FIFRA, a manufacturer needs to register a pesticide, including plants with pesticidal qualities, with the EPA before it is commercialised in the market. Through the Federal Food, Drug, and Cosmetic Act,[41]the EPA sets out maximum tolerance levels for pesticide residues in foods. Furthermore, a notice must be submitted to the EPA in accordance with the Toxic Substances Control Act[42] before it can be manufactured or imported (Stewart & Johanson, 1999). The National Environmental Policy Act[43] has provision for the environmental assessment process and provision for exclusion from NEPA requirements.

Regarding GMO foods, "[t]he key to the U.S. approach to regulation of GMOs is the principle of minimal oversight of food products that are generally regarded as safe (GRAS). Conventional food products are considered GRAS, and this is the standard by which GM foods are being judged in the United States"(Sheldon, 2004, p. 11).In this respect, the "concept of substantial equivalence" is "the process of evaluating the safety of GM foods." Its objective is to not establish absolute safety but rather to evaluate "whether a GM food …is as safe as its conventional counterpart"(Sheldon, 2004, p. 11).

The US FDA is responsible under the FFDCA to ensure the safety of foods including GM foods. "As a general rule, the FDA regulates GMOs no differently than food products developed through traditional plant breeding techniques"(Stewart & Johanson, 1999, p. 248).The FDA has taken the view "that crop development through genetic modification is simply an extension to the molecular level of traditional plant-breeding methods," and "GM foods do not differ in any substantial way from

[41]21 USC §§ 301-395 (1994).
[42]15 USC § 2603(d) (1976).
[43] 42 USC § 4321 *etseq* (1970) [*NEPA*].

those foods developed through traditional plant-breeding methods"(Sheldon, 2004, p. 11).

Companies that introduce GM foods into the market do not necessarily need to obtain approval from authorities. Such companies may voluntarily consult with the FDA before the GM food product is marketed (Stewart & Johanson, 1999). If it is revealed during the consultation that the food product may have a negative health effect, "the FDA has authority under the *FFDCA* to require a pre-market review" to determine the safety of the product through testing. Section 402(a)(1) of the *FFDCA* obligates the food producer to ensure that the food is safe(Stewart & Johanson, 1999, p. 248).

In Europe, GM foods are strictly regulated and there are specific laws and regulations for GM foods. Regulation 1829/2003 defines GM foods, stating, "genetically modified food" means "food containing, consisting of or produced from GMOs."[44]

The EU regulatory system on GM foods differs from the Canadian system. The Canadian system focuses on all kind of novel foods produced from genetic engineering technology as well as other methods that produce new traits. In contrast, the EU system covers only foods produced from genetic engineered technology. This system regulates products "produced from a GMO" but it does not regulate products "produced with a GMO." For example, products obtained from animals fed with genetically modified feed are not subject to the EU's authorisation or labelling requirements (Scott, 2003).The Canadian system is silent on this issue. The EU system differs from the US in regards to GMOs products and governing regulations. The EU system requires risk assessments and authorisation of all kinds of GM foods before they can be commercialised.

The EU for the first time adopted Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms.[45] It was amended twice and finally repealed and replaced by Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC.[46]The next law adopted was Regulation (EC) No 258/97 of the

[44] *Regulation 1829/2003, supra* note 6 art.2(6).

[45] EC, *Council Directive 90/220/EEC of 23 April 1990 on the deliberate release into the environment of genetically modified organisms*, [1990] OJ, L 117/15 [*Directive 90/220*].

[46] EC, *Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC*, [2001] OJ, L 106/1 [*Directive 2001/18*].

European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients.[47]In July 2003, the European Parliament adopted rules requiring mandatory labelling of food products that contain traces of GM ingredients by amending the EU regulatory system(Sheldon, 2004).

Directive 90/220, Regulation 258/97,Directive 2001/18, Regulation 1829/2003, and Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms[48] are the major EU regulations addressing GMOs. Directive 90/220 and Directive 2001/18 concern the environmental release of GMOs either for market or experiment. Regulation 258/97 deals with novel foods. "Regulation 1829/2003 and Regulation 1830/2003 create a new authorisation regime and new requirements on traceability for GM [f]ood and [f]eed"Male, 2004, p. 443).Directive 2009/41 lays down the minimal standards for the contained use of genetically modified microorganisms. Member states are permitted to take more stringent measures to protect human health and the environment.

In the EU, a scientific risk assessment is carried out by the European Food Safety Authority (EFSA)(European Commission). The EU regulatory system has established a centralised procedure for prior authorisation and labelling of GM food and feed that must be followed before GM products can be released into the market. An application is submitted to the competent member state authority where the GMO would be marketed, along with the required information and documents. The competent member state authority forwards the application to the EFSA, who publishes summaries of the application to inform other member states and the European Commission. The EFSA issues an opinion on the application, then sends this to the Commission, member states and the applicant, along with its risk assessment report and reasons for its opinion. After, the Commission develops a proposal to grant authorisation, which needs to be approved by a majority of the member states. This authorisation is subject to a post-market monitoring plan and is granted for a period of ten years. It can be renewed if it meets all requirements.

EU regulations do not ban GM crops or GM foods. Rather, they give freedom to member states to decide whether to ban a crop or food based on health safety.EU member states may invoke a safeguard provision to ban GM crops or foods

[47] 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*, [1997] OJ, L 43/1 [*Regulation 258/97*].

[48] EC, *Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms*, [2009] OJ, L 125/75 [*Directive 2009/41*].

temporarily. Art. 12 of Regulation 258/97 allows member states to temporarily ban products if there are "detailed grounds for considering that the use of a food or a food ingredient . . . endangers human health or the environment." Accordingly, many member states have invoked the safeguard provision and banned GM foods. For example, Italy invoked the safeguard clause (Art. 12) under Regulation 258/97 on novel foods in August 2000. The next time Italy banned novel foods pursuant to Art. 12 of Regulation 258/97, the ECJ in *Monsanto Agricoltura Italia SpA v Prezidenza del Consigliodei Ministri*[49] interpreted Art. 12 of the Regulation 258/97 and ruled, "it is apparent that, in the light of the [P]recautionary[P]rinciple, the implementation of such measures is necessary in order to ensure that novel foods do not present a danger for the consumer."[50]

France banned the cultivation of the GM maize variety MON810 on 7 February 2008[51] and the ban has been maintained despite pressure from the European Commission to reverse it. On 17 April 2009, the cultivation of MON810 was provisionally banned in Germany[52]by the German Administrative Court. The Court stipulated that indicators of risk to the environment were sufficient for a cultivation ban on genetically modified crops or plants (GMO Safety, 2009). The Court held, "[T]here do not need to be confirmed scientific findings available in order for a temporary cultivation ban to be valid. All that was needed was for there to be new or additional indications that humans or animals might be at risk… In the event of uncertainties regarding the existence or scale of risks, safety precautions could be taken without waiting for the risks to be fully investigated"(GMO Safety, 2009).

The EU has provisions for the co-existence of GM crops and non-GM crops. The EU has adopted Commission Recommendation of 23 July 2003 on guidelines for the development of national strategies and best practices to ensure the co-existence of genetically modified crops with conventional and organic farming[53]and Commission Recommendation of 13 July 2010 on guidelines for the development of national co-existence measures to avoid the unintended presence of GMOs in conventional and

[49] See *Monsanto Agricoltura Italia SpA and Others v Presidenza del ConsigliodeiMinistri and Others*, C-236/01, [2003] ECR I-8105 [*Monsanto Agricoltura*].
[50] *Ibid* at para 114.
[51] Ministerial Decree of 7 February 2008 Suspending the Cropping of Genetically Modified Maize Seed (Zea Mays L Line MON810), JO No 34 of 9 February 2008, NOR: AGRG0803466A, amended 13 February 2008, NOR: AGRG0803888A.
[52] *Agra Europe Weekly* No 2357, 17 April 2009, EP/1. See also *Bablok*,*supra* note 31 at para 29.
[53] EC, *Commission Recommendation of 23 July 2003 on guidelines for the development of national strategies and best practices to ensure the co-existence of genetically modified crops with conventional and organic farming*, [2003] OJ, L 189/36.

organic crops.[54]The latter has aprovision for declaring GM-free zones.[55]Sixteen EU member countries have adopted co-existence guidelines and made co-existence law and policies(Chiarabolli, 2011). Many EU member states have declared GM-free zones. For example, as of 2008, 16 of the 20 Italian regions have declared themselves GM-free. Coexistence requirements are aimed at keeping the presence of GMOs in conventional fields below a 0.9% threshold.

2. GM FOODS AND THE PRECAUTIONARY PRINCIPLE

In addition to provisions for safety assessments, there is also a Precautionary Principle that plays an important role in risk management. The Precautionary Principle has been invoked temporarily by many countries to protect health and the environment. It is an established pillar of public policy and an important basis for public health and environmental legislation all across the world. The Precautionary Principle has been accepted as a risk management strategy in several fields, including GM foods, where there are potential hazards to health or the environment, "and when at the same time the available data preclude a detailed risk evaluation"(Male, 2004, p. 444).The Precautionary Principle originated from the German principle of *Vorsorge* (foresight). "At the core of early conceptions of this principle was the belief that society should seek to avoid environmental damage by careful forward planning, blocking the flow of potentially harmful activities"(Tickner, Raffensperger & Myers, 1999, p. 2). Many international environmental agreements have also adopted the precautionary approach. The 1992 Rio Declaration on Environment and Development states, "Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."[56] The 2000 Cartagena Protocol on Biosafety to the Convention on Biological Diversity states, "Lack of scientific

[54] EC, *Commission Recommendation of 13 July 2010 on guidelines for the development of national co-existence measures to avoid the unintended presence of GMOs in conventional and organic crops*, [2010] OJ, C200/1 [*Commission Recommendation 2010*].

[55]*Ibid*. Number 1 of the Recommendation states, "Member states may take appropriate measures to avoid the unintended presence of genetically modified organisms… in other products… [or] crops, such as conventional or organic." Number 4 of the Recommendation states, "The objective of co-existence measures … is to avoid unintended presence of GMOs in other products, preventing the potential economic loss and impact of the admixture of GM and non-GM crops (including organic crops)." Number 5 of the Recommendation has a provision declaring GM-free zones. "In some cases… it may be necessary to exclude GMO cultivation from large areas… [if] other measures are not sufficient to prevent the unintended presence of GMOs in conventional or organic crops."

[56]*Rio Declaration on Environment and Development*, 14 June 1992, 31 ILM 874 at Principle 15.

certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the living modified organism in question . . . in order to avoid or minimise such potential adverse effects."[57]It has also been claimed that the Precautionary Principle is a "general principle of international environmental" agreements (World Trade Organization b).

The Precautionary Principle has been widely used in Europe, and it is considered one of the four basic pillars of the EU system. In Europe, the Precautionary Principle is guided by the anti-GMOs movements. The basic concern of consumers is "being expected to bear all of the risk with very little benefit"(Sheldon, 2004, p. 6).The Precautionary Principle is enshrined in EU treaties and legal decisions. Art. 174 of the EC Treaty states, "Community policy on the environment … shall be based on the precautionary principle and on the principles that preventive action should be taken"(European Commission, 2000, p. 22).In Europe, the scope of the Precautionary Principle has been "broadened from environmental protection…to encompass human, animal, or plant health"(Lynch & Vogel, 2001).The European Commission stated that the Precautionary Principle is intended to be invoked when "potentially dangerous effects deriving from a phenomenon, product or process have been identified, and … scientific evaluation does not allow the risk to be determined with sufficient certainty"(European Commission, 2000, p. 3)"because of the insufficiency of the data, their inconclusive or imprecise nature"(European Commission, 2000, p. 14).

With respect to GM foods and GM crops, Art. 12 of Regulation 258/97 is known as a safeguard provision. Art. 12 allows member states to temporarily ban products if there are "detailed grounds for considering that the use of a food or a food ingredient . . . endangers human health or the environment."[58]On the issue of GM foods, the ECJ in *Monsanto Agricoltura* has also interpreted Art. 12 of the Regulation 258/97 and ruled that "it is apparent that, in the light of the [P]recautionary [P]rinciple, the implementation of such measures is necessary in order to ensure that novel foods do not present danger for the consumer."[59]

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[57]29 January 2000, 2226 UNTS 208, 39 ILM 1027 (entered into force 11 September 2003) at art 10(6) [*Cartagena Protocol*]. See Lesley K McAllister, "Judging GMOs: Judicial Application of the Precautionary Principle in Brazil" (2005) 32:1 Ecology LQ 149 at n 20.

[58]*Regulation 258/9*, *supra* note 101at art 12(1).

[59]*Monsanto Agricoltura, supra* note 106 atpara 114.

The Precautionary Principle is not accepted by every country. The US policy differs from the EU policy in this respect; the US has not recognised the Precautionary Principle in its law and policies (Kogan, 2004).However, there is a counterargument that the Precautionary Principle has been adopted in US law. "[N]o country has so fully adopted the essence of the precautionary principle in domestic law as the United States"(Cameron, 2000, p. 250).American food safety regulation has adopted the norm of the Precautionary Principle. The Delaney clause to the Food, Drug and Cosmetic Act enshrined the Precautionary Principle by banning the use of any food additive that causes cancer (Lynch & Vogel, 2001). "[E]lements of the [P]recautionary[P]rinciple… [are] firmly entrenched in American environmental law"(Applegate, 2000, p. 438). For example, "the 1970 Clean Air [Act][60] and Clean Water Act[61] required the EPA to apply 'an adequate margin of safety' in setting emission limits for hazardous pollutants… The 1997 Clean Air Act Amendments authorised EPA to 'assess risk rather than wait for proof or actual harm'"(Cameron, 2000, p. 251). "In Reserve Mining [Co v EPA][62] the Supreme Court permitted EPA to regulate an effluent based on only a 'reasonable' or 'potential' showing of danger, rather than on the more demanding 'probable' finding requested by the industrial plaintiff"(Lynch & Vogel, 2001).

Professor Cass Sunstein has criticised this principle heavily: "The most serious problem with the Precautionary Principle is that it offers no guidance – not that it is wrong, but that it forbids all courses of action, including inaction (Sunstein, 2002, p. 33)… Genetic modification of food has become a widespread practice. But the risks involved are not known with precision. Some people fear that genetic modification will result in serious ecological harm and large risks to human health. Other people claim that genetic modification will have significant health benefits"(Sunstein, 2002, p. 33-34).At the Kennedy School of Government: "There is considerable controversy on the meaning, scope, context and application of the [P]recautionary [P]rinciple in international trade and environment management"(Harvard Kennedy School, 2000).This principle has been commented on as "wholly arbitrary" (Adler, 2011) and "literally incoherent,"(Sunstein, 2005) and characterised as an anti-scientific, simplistic and irrational shortcut(Majone, 2002).

Canadian law and policy are silent on the Precautionary Principle. In 2001, Health Canada submitted, "The five departments[63] fully support a precautionary approach

[60] 42 USC § 7401 *etseq* (1970).
[61] 33 USC § 1251 *etseq* (1972).
[62]514 F (2d) 492 (8th Cir 1975).
[63] The names of the five Governmental Departments are: Health Canada, the Canadian Food Inspection Agency, Environment Canada, Agriculture and Agri-Food Canada and the Department of Fisheries and Oceans.

when reviewing products for human and environmental safety. The language of Principle 15 of the 1992 Rio Declaration on Environment and Development, and the approach that it represents are consistent with today's regulatory practices in the field of environmental protection in Canada. This is expressed in a number of documents including a commitment by the Government of Canada in the preamble of the Canadian Environmental Protection Act"(Health Canada, 2001). However, it has not been directly incorporated into law, government authority has not invoked this principle, and courts have not relied on this principle. When there is no evidence of harmfulness by GM foods to health or the environment but there is some reasonable doubt, the Precautionary Principle may be justified as an exception. It is good to have in case the need for it arises. Canadian legislature and policy makers may need to give serious consideration to the Precautionary Principle.

3. LABELLING GM FOODS: A RIGHT TO CHOICE AND A RIGHT TO BE INFORMED

In the US, like in Canada, there is no mandatory regulation requiring GM foods to be labelled. Labelling is only required when the GM food differs significantly from the same type of conventional food in its nutritional content or when it poses a threat to health. In the US, the Genetically Engineered Food Right-to-Know Act[64] was tabled in Congress in 1999, but it was never enacted. A US Federal Appeal Court in *International Dairy Foods Ass'nv Amestoy* held that a mandatory state labelling law for certain GM products might be unconstitutional (Stewart & Johanson, 1999). Regarding GM foods, "the key to the U.S. approach to regulation of GMOs is the principle of minimal oversight of food products that are generally regarded as safe (GRAS). Conventional food products are considered GRAS, and this is the standard by which GM foods are being judged in the United States … the concept of substantial equivalence has been developed as part of the process of evaluating the safety of GM foods. The objective of such an approach is not to establish absolute safety, but to consider whether a GM food (ingredient) is as safe as its conventional counterpart" (Sheldon, 2004, p. 11).

The FDA has established the substantial equivalence principle, which states that existing GM foods do not differ in any substantial way from those developed through conventional methods. However, the FDA requires labelling of a GM-food product "if the GM version of an existing food product is substantially different, if the GM version has very different nutrition properties, and if the GM food contains an allergen that would not normally be present in that food product"Sheldon, 2004, p. 11).

[64] US, Bill S 2080, *Genetically Engineered Food Right-to-Know Act*, 106th Cong, 2000.

In Europe, all GM foods have to be labelled "to allow consumers to make an informed choice in the market place"(Zarrilli, 2005, p. 4).The requirement of mandatory labelling is a central part of the EU regulatory system, which differs completely with the US and Canadian systems. "The system of mandatory labelling is also supplemented by the requirement of traceability"(Sheldon, 2004, p. 10). Food and feed products produced by GMOs, or foods consisting of or containing more than 0.9%percent GMOs, are subject to labelling and traceability. Non-GM foods contaminated by GMOs below 0.9% are not subject to labelling and traceability requirements, provided that such presence of GMO is adventitious or technically unavoidable. There are no labelling and traceability requirements on products such as milk, eggs, or meat obtained "from animals fed with GM feed …[C]heese and beer produced with GM-based enzymes are also exempt from label[l]ing"(Sheldon, 2004, p. 10).The labelling and traceability requirements are governed by Regulation 1829/2003 and Regulation 1830/2003.

In Canada, there is no mandatory labelling of GM foods; GM foods may be labelled on a voluntary basis. However, there is pressure from the public for mandatory labelling of GM foods. The Government of Canada recognises that "[F]or many Canadians, labelling of foods derived from biotechnology is an important issue of consumer preference or choice"(Health Canada, 2005)."[S]everal private members' bills have been introduced into the House of Commons" in favour of the mandatory labelling of GM foods(USDA, 2012, p. 13). For example,C-287, a private member's bill requiring mandatory labelling of GM foods proposed by MP Charles Caccia, was defeated in Parliament on 17 October 2001(CBC News Online, 2004). Again in February 2011, a Bill requiring labelling or disclosure of GM content was defeated in Parliament(Bradshaw, 2011). The Canadian approach on GM food labelling is very much similar to the US approach. At an international level on 5 July 2011, the FAO/WHO Codex Alimentarius Commission (Codex)[65] adopted the Compilation of Codex texts relevant to labelling of food derived from modern biotechnology(Codex Alimentarius, 2011). The Codex recognised "that each country has the right to adopt its own approach to labelling GM food[s]"(Galloway, 2011; Consumers International, 2011).

The Canadian regulatory system has no provision regarding the mandatory labelling of GM foods. The main arguments against mandatory labelling concern the additional costs of implementing the labelling of GM foods and trade

[65] The Codex Alimentarius Commission is a joint commission of the World Health Organization and the Food and Agricultural Organization formed in 1963. It has been tasked with establishing health and safety standards and regulating the international food trade.

implications(Hubbard, 2002). “The adoption of [a] mandatory labelling system by Canada could have a significant impact on its trade relationship with its largest agricultural trading partner, the United States (U. S.), which does not support mandatory labelling of biotechnology-derived foods”(Parliament of Canada, 2002). “[T]he increased costs associated with mandatory labelling would place Canadian farmers, food manufacturers and exporters at a significant disadvantage”(Parliament of Canada, 2002).

“Health Canada has taken the position that GM foods are just as safe as conventional foods. Food must be labelled in Canada if it is pasteurised, irradiated, or contains possible allergens such as peanuts”(CBC News Online, 2004).Health Canada states, “Currently in Canada, labelling is mandatory if there is a health or safety issue with a food, which might be mitigated through labelling. For example, if the nutritional value or composition of the food has been changed, or if there is an allergen present in the food, the food must be labelled as such. In this situation, special labelling is required to alert consumers or susceptible groups in the population. This applies to all foods, including GM foods”(Health Canada, 2005).

In February 2001, the Royal Society of Canada prepared the report “Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada”(Royal Society of Canada, 2001),and in August 2002, the Canadian Biotechnology Advisory Committee prepared the report “Improving the Regulation of Genetically Modified Foods and Other Novel Foods in Canada”(Biotechnology Ministerial Coordinating Committee, 2002). Both reports indicated their support for voluntary food labelling in Canada. Further to this, in 2004, the Standards Council of Canada adopted the National Standard for Voluntary Labelling and Advertising of Foods That Are and Are Not Products of Genetic Engineering(Government of Canada, 2004),which deals with the labelling of GM foods(USDA, 2012).

Under the Food/Drugs Act and Food/Drugs Reg, Health Canada is responsible for food labelling relating to health and safety issues. The CFIA under the *Food/Drugs Act* is responsible for prescribing basic food labelling and advertising standards. It is also responsible for protecting consumers from misrepresentation and fraud relating to food labelling, including packaging and advertisement.

In principle, it is the consumer’s right to know what they are eating and they have right to choose what they want to eat. This is why Canada’s trading partners, such as the EU, Japan, Australia, and New Zealand and other countries have mandatory labelling of GM foods (Zarrilli, 2005). In China, the labelling requirement applies to “soybean, corn seeds, rapeseeds, cotton seeds and tomato seeds, as well as to products thereof (Zarrilli, 2005, p. 6).”Consumers’ preferences to foods with GM labels have been growing in global markets. Hence, arguments in favour of non-

mandatory labelling, such as trading implications and cost of labelling, will weaken with time. Companies like Nestlé and Unilever, which do business in North America and Europe, have already "dropped GM ingredients from their products" in Europe(CBC News Online, 2004).

4. GM FOODS AND CROSS-CUTTING ISSUES

Since GM foods are products of GM crops, plants and animals, issues related to GM crops or plants, such as co-existence, adventitious presence (AP),[66] liability, and transparency, are directly related to GM foods. In Canada and the US, there is no law addressing the co-existence between conventional, organic, and GM crops. The EU, however, has adopted a recommendation on guidelines for coexistence measures to avoid AP in non-GM crops.[67]Sixteen EU member states have already enacted co-existence laws, which address minimising AP of GMOs in non-GM crops and compensation to non-GM farmers for economic loss from AP. In the EU, coexistence measures are aimed at keeping AP of GMOs in conventional fields below a 0.9% threshold.

Because of the lack of co-existence laws to minimise AP levels in Canada and the US, there is the problem of GMO contamination on conventional and organic crops. Consequently, foods produced by conventional and organic crops happen to be GMO-contaminated foods. Regulation is silent on whether such foods are GM foods, whether such foods need to go through safety assessments, who will compensate for economic losses caused by GMO cross-contamination, and whether there are any measures that can minimise GMO contamination. These issues are not regulated in Canada(USDA, 2012).

It has been recognised that a 0% tolerance policy towards AP is not possible to implement, but maintaining a certain Low Level Presence (LLP) of AP is possible. "LLP refers to the incidental presence of tiny amounts of a GM material mixed in with a non-GM product"(USDA, 2012, p. 18).There is no unanimity about the proper level of LLP so far. In Canada, the issue of LLP has become increasingly important in recent years(Dawson, 2011).Since the Triffid flax issue, where non-approved GM flax was exported from Canada and reached 35 countries,[68] the Canadian

[66]Adventitious presence refers to both genes that have entered conventional and organic crops, as well as a mixture of GM product with conventional/organic product, e.g., a crop being mixed in the grain conveyor.

[67]*Commission Recommendation 2010*, *supra* note 54.

[68]*House of Commons Debates*, 40th Parl, 3rd Sess, No 108 (1 December 2010) (Alex Atamanenko).

Government has been proactive in pursuing international standards for AP[69] that can be classified as a LLP[70]. The government has accepted the importance of LLP management and has conducted "consultation in the fall of 2011" to develop suitable LLP management policy (Agriculture and Agri-Food Canada, 2012a).

The Government of Canada developed the Proposed Domestic Policy on the Management of Low-Level Presence of Genetically Modified Crops in Imports and its Associated Implementation Framework to Manage Low-Level Presence in Grain(Agriculture and Agri-Food Canada, 2012b) in September 2012. This proposed policy talks about LLP management of and importation of GM crops in Canada. This issue arise when AP is identified on non-GM crops. If it is already GM crops, there is no requirement of management of LLP. Furthermore, this proposed policy applies to imported GM crops only, notto domestic crops. It does not talk about the domestic problem of AP, which is a serious matter in Canadian agriculture. Also this policy may discriminate between the treatment of national and foreign products.

In Canada, there is no regulation of GM animals as such. The University of Guelph developed a genetically engineered 'Enviropig' for food. It applied for approval on 23 April 2009 and is "waiting for Health Canada to approve 'Enviropig' for human consumption"(Canadian Biotechnology Action Network [CBAN], 2010, p. 5)."No genetically modified animals have been approved for eating anywhere in the world. The only GM animal approved globally is the GloFish pet (not approved in Canada). In addition 'Enviropig' the Canadian company Aquabounty is seeking approval for its GM fish, a fast growing Atlantic salmon. They have requested approval in the US but not yet in Canada"(CBAN, 2010, n. ii)."On the animal side, guidance from the three regulatory agencies in Canada (Health Canada, Environment Canada and the Canadian Food Inspection Agency) is still to be issued on the question of whether the offspring or progeny of clones fall under Canada's Novel Foods provisions of the Food and Drug Regulations. At this point, there is no indication that such decision would be made in the near future"(USDA, 2012, p. 2). The Department of Fisheries and Oceans is currently developing draft regulations on transgenic aquatic organisms (USDA, 2012).

It is important to incorporate public participation into the GM food law-making and decision-making process. Provisions addressing access to information, transparency,

[69] Here in the term Adventitious presence (AP) is used to refers to both genes that have entered conventional and organic crops, as well as mixture of GMO product with conventional/organic product, for example e.g., a crop being mixed in the grain conveyor.

[70] Although the term is being used a lot in the current discussions on 'low levels' of AP, there are differing arguments as to what it means.

public participation in decision-making, and access to justice are fundamental to GMO regulation. Many international conventions[71] have urged participating countries to have public participation provisions in their domestic law.

In the EU, Directive 2001/18 has a provision requiring public consultation by member states when introducing GMOs into the environment.[72]"[N]ational authorities are to take into account the views and concerns of the public"(Bodiguel & Cardwell, 2010, p. 16). In the UK, the public are engaged extensively in the consultation process (Bodiguel& Cardwell, 2010). In New Zealand, a "participatory approach has been adopted" and "[i]n 1999 the Independent Biotechnology Advisory Council was established to inform and consult the public on matters of biotechnology"(Bodiguel & Cardwell, 2010, p. 18). In Africa, the African Model Law on Safety in Biotechnology[73] has a public participation provision.

Public input into the regulation of GM foods is significant. It is the public who eat GMOs and who bear all risks if there are any. In Canada, governmental agencies have claimed that there is public participation. But if there is no specific GM foods law, no labelling provisions, and GM and other foods are treated equally, the question of public participation cannot arise.

CONCLUSION

In many countries, the labelling of GM foods is the central part of policy debates. Australia, Japan, European countries, and other many countries have regulatory provisions that require labelling of GM foods, whereas others such as Canada and the USA do not. There are some fundamental differences between GMOs and non-GM foods. GMOs are patentable, whereas conventional or organic foods are generally not. A patent gives exclusive rights to a GMO patentee, whereas others do not have this right. Non-GM seeds typically can be planted, replanted, saved, or sold by farmers, but farmers do not have these same rights with GM seeds. GM plants or crops have cross-pollination effects and 'contaminate' non-GM plants or crops (foods too),which is not usually an issue with non-GM plants.

Common sense says that it may take some time to learn the negative effects of GM foods if there are any. If you do not label GM foods, you may not be able to know

[71] *Convention on Biological Diversity*, 5 June 1992, 1760 UNTS 79, Can TS 1993 No 24 (entered into force 29 December 1993) art 14(1)(a); *Cartagena Protocol*, *supra* note 119 art 23(2);*Convention on Access to Information, Public Participation in Decision–Making and Access to Justice in Environmental Matters*, 25 June 1998, 2161 UNTS 447, 38 ILM 517 (entered into force 30 October 2001).

[72] *Directive 2001/18*, *supra* note 100art 9.

[73] *African Model Law on Safety in Biotechnology*, (AU), 2007, arts 5(2), 5(4).

their long-term effects on health and the environment. There is no easy choice for India. On the one hand, there are economic concerns, particularly agricultural trade with other nations. On the other there is an issue for food security. Yet again, there are public concerns: the citizens' right to choice and right to information. This balance may change in the future, since the number of consumers favouring the right to know has been growing in global markets, and even in the US market.

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