

**RISKS, RESPONSIBILITY, AND RIGHTS IN TRANSGENIC PLANT  
TECHNOLOGY GOVERNANCE: A TRANSNATIONAL PERSPECTIVE**

A THESIS SUBMITTED IN ACCORDANCE WITH THE CONDITIONS  
GOVERNING CANDIDATURE FOR THE DEGREE OF

DOCTOR OF PHILOSOPHY

THE UNIVERSITY OF CARDIFF

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## **DECLARATION OF STATEMENTS**

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This work has not been previously accepted in substance for any degree and is not being concurrently submitted in candidature for any degree.

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## ABSTRACT

Whilst the adoption of commercial transgenic plant agriculture continues to spread globally, it is not necessarily indicative of universal support, and would appear to belie the inherent existential tensions and conflicting rights between transgenic, organic, and conventional plant agricultural systems. These tensions are typically vented via the inevitable adventitious presence of transgenes in non-transgenic crops, and the competing, and often conflicting scientific and acrimonious claims and counter-claims on the merits and proprieties of transgenic plant agriculture for the environment and public health. Nevertheless, the virtual irreversibility of transgenic plant agriculture, the exigencies of feeding the growing world population amidst continuing global food security scares, and the continuing dependency of livestock farming on transgenic plant feedstuff, especially in Europe, underscore the imperatives for mutual co-existence of all three forms of plant agricultural systems. Drawing on the socio-legal theory that risks and responsibility are correlatives, it is argued in the thesis that our “technological society” is also a “risk society”, and as it is for comparable “technologies of risk” in the post-industrial era, the regulatory framework for the co-existence of transgenic and non-transgenic plant agriculture, must of necessity, invoke corresponding responsibility in law for any consequential economic loss and damage to the environment and public health, in order to balance and moderate the conflicting rights in the coexistence paradigm for transgenic and non-transgenic plant agriculture. Whilst drawing on relevant and analogous case law and legislations from the United Kingdom, the European Union and North America, the thesis defines the boundaries of inherent risks, responsibility and rights in the current coexistence paradigm for transgenic and non-transgenic plant agriculture, and proposes a modality for an effective *sui generis* compensation regime, as an integral part of the broader coexistence policy, on the grounds that such a regime could moderate conflicting rights, increase public acceptance, and build public confidence in transgenic plant technology, rather than hinder its continuing global growth and promise.

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## TABLE OF CASES

- A & Others v. National Blood Authority, [2001] 3 All ER 289.
- Alliance for Bio-Integrity, et al. v. Donna Shalala, 116 F. Supp. 2d 166 (2000).
- B v. DPP, [2000] 2 AC 428.
- Bablok , K. H. and Others v. Freistaat Bayern and Others, Case C-442/09.
- Bai (Run Off) Limited & Others v. Durham & Others, [2012] UKSC 14.
- Bamford v Turnley (1862) 3 B&S 66.
- Barker v. Corus UK Ltd [2006] 2 WLR 1027.
- Bonnington Castings Ltd v Wardlaw [1956] AC 613.
- Brend v. Wood, (1946), 62 T.L.R. 462, at 475.
- Burnie Port Authority v General Jones Pty Ltd (1994).
- Cambridge Water v Eastern Counties Leather, [1994], 2 AC 264.
- Canada-Patent Protection for Pharmaceutical Products, WT/DS114/R (17 March, 2000).
- Caparo Industries plc v. Dickman, [1990] AC 605.
- Customs and Excise Commissioners v. Barclays Bank plc, [2006] 3 WLR 1.
- Dunlop Tyre Company v. Selfridge, [1915] AC at 847.
- East River S.S. Corp. V. Transamerica Delaval Inc., 476 U.S. 858 (1986).
- [Escola v. Coca-Cola Bottling Co.](#), [24 Cal. 2d 453, 462](#) (1944).
- European Commission v. The Republic of Poland, (Case C-165/08) (16 July 2009).
- European Communities: Measures Affecting the Approval and Marketing of Biotech Products, (WT/DS291R); (WT/DS292R); & (WT/DS293R), (29, September 2006).
- Ex Parte Hibberd et al, 227 U.S.P.Q. 443, (Bd, Pat. App.1985).
- Fairchild v Glenhaven Funeral Services Ltd [2003] 1 AC 32.
- Frederick L. Sample, et al., v Monsanto Company et al., 283 F. Supp. 2d 1088 (2003).
- Gamon v. AG for Hong Kong, (1984).
- Green v. General Petroleum Corporation, 205 Cal. 328, 270 Pac. 952, (1928).
- Greenman v. Yuba Power Products, [59 Cal. 2d 57](#) (1963).
- Healy v. Beer Institute, (1989), 491 U.S.
- Hoffman et al, v. Monsanto Canada Inc, and Bayer Crop Science, (SKQB).
- In re StarLink Corn Products Liability Litigation: Marvin Kramer, et al., v. Aventis CropScience USA Holding, Inc., et al., 212F. Supp. 2d 828 (N.D. III 2002).
- In Re StarLink Product Liability Litigation, [Proposed Settlement and Fairness Hearing Document](#), at 3, MDL Docket No. 1403, (N.D. III. Feb. 14, 2003).



J.E.M. Ag Supply v. Pioneer Hi-Bred International Inc, 534, U.S, 124, (2001).

Lamb v Camden LBC (1981) QB 625.

Land Oberosterreich and Austria v Commission of the European Communities, (Joined Cases C-439/05 P and C-454/05 P of 13 September 2007).

Larry Hoffman; L.B. Hoffman Farms Inc., and Dale Beaudoin v. Monsanto Canada Inc, [2005] Saskatchewan Queen's Bench (SKQB).

Larry Hoffman; L.B. Hoffman Farms Inc., v. Monsanto Canada Inc., and Bayer Cropscience Inc., [2007] Saskatchewan Court of Appeal, (SKCA), 47.

Les Affreteurs Reunis v. Leopold Walford, [1919] AC 801.

McGhee v. National Coal Board [1973] 1 WLR 1.

Merck Genéricos Produtos Farmacêuticos v. Merck & Co. Inc. (Case C-431/05).

Monsanto Canada Inc, v. Schmeiser, [2004] 1. S.C.R. 902.

Monsanto Co. v. McFarling, 302 F.3d 1291 (Fed. Cir. 2002) w, Volume 65, Number 4, July 2002).

Monsanto Company & Monsanto Technology L.L.C. v. Maurice Parr, 545, F. Supp. 2d 836 (N.D. Ind. 2008).

[Norwich Pharmacal Co. v Customs and Excise Commissioners](#), [1974] AC 133.

Ohana Pale Ke Ao; Kohanaiki Ohana; GMO-Free Hawai`i, and Sierra Club, Hawai`i Chapter, v. Board of Agriculture, State of Hawaii, Intermediate Court of Appeals of Hawaii, 188P 3d 761(2008).

Overseas Tankship (UK) Ltd v. Morts Dock & Engineering Co Ltd, The Wagon Mound [1961] AC 388.

Panel Report, Canada-Patent Protection for Pharmaceutical Products, WT/DS114/R, (17 March, 2000).

Pharmaceutical Society of Great Britain v Storkwain (1986) 2 ALL ER 635.

R v. Brockley, (1994) 99 Criminal Appeal Report, 385

R v. Secretary of State for the Environment and MAFF, ex parte Watson, [1999], Environmental Law Report, 310.

Re B (A Child) [2008] UKHL 35.

Read v J Lyons & Co [1947] AC 156.

Riboux -v- S.A. Schweppes Belgium, 21.11.96, Civ. Namur, 5e. Ch.

Richardson v. LRC Products, [2000] Lloyd's Rep. Med. 280.

Rickards v Lothian, [1913] AC 263.

Robinson v Kilvert (1888), 41 Chancery Division, 88.

Rothwell v. Chemical & Insulating Co Ltd [2008] 7 AC 281.  
Rylands v Fletcher, (1866) LR 1 Exch, 265.  
Salvin v North Brancepeth Coal Co [1873] LR 9.  
Scruttons Ltd v. Midland Silicones Ltd [1962] AC 446.  
Shanklin Pier v. Detel Products [1951] 2 KB 854.  
Strathcona SS Company v. Dominion Coal Company, [1926] AC 108.  
Sweet v. Parsley, (1970) AC 132.  
The Commission v. The United Kingdom, (Case C-203/99).  
Transco plc v Stockport MBC [2004] 2 AC 1.  
Vernon Hugh Bowman v Monsanto Company, 569 U.S. (2013).  
Whitehouse v. Lemon Gay News, [1979] 2 WLR 281.  
Wilsher v. Essex Area Health Authority [1988] AC 1074.

## TABLE OF STATUTES.

Agreement on the Application of Sanitary and Phytosanitary Measures, Final Act Embodying the Results of the Uruguay Round of Multilateral Trade negotiations. General Agreement on Tariffs and Trade, Annex 1A, (15 April 1994).

Agreement on Trade-Related Aspects of Intellectual Property Rights 1994 (TRIPs Agreement).

APHIS, Introduction of Genetically Modified Organisms, Draft Programmatic Environmental Impact Statement, (July 2007), Docket APHIS-2006-0112.

APHIS, Introduction of Organisms and Products Altered or Produced Through Genetic Engineering, 71 *Federal Register* 39,021, 39,022, (17 July 2007).

APHIS, USDA, Importation, Interstate Movement, and Release into the Environment of Certain Genetically Engineered Organisms, 73, *Federal Register* 60,008, 60,009, (6 October 2008).

APHIS, Policy on Responding to the Low-Level Presence of Regulated Genetically Engineered Plant Materials, 72 *Federal Register*, 14,649 (29 March 2007).

Austrian Gene Technology Act 510, 1994 (as amended).

Austrian Gene Technology Act 2004.

Cartagena Protocol on Biosafety to the Convention on Biological Diversity: Texts and Annexes, (Montreal: 2000).

Commission of the European Communities, proposal for a regulation concerning the traceability and labelling of GMOs and traceability of food and feed produced from GMOs (COM 2001-1821 final)

Commission Recommendation on Guidelines for the Development of National Strategies and Best Practices to Ensure the Co-existence of Genetically Modified (GM) Crops with Conventional and Organic Farming; (Brussels, July 2003).

Commission Regulation (EC) No 889/2008 of 5 September 2008, laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control, *Official Journal of the European Union*, 18.9.2008 L 250/1.

Commission Regulation (EC) No. 1235/2008 of December 2008 laying down detailed rules for implementation of Council Regulation (EC) No. 834/2007 as regards the arrangements for imports of organic products from third countries, *Official Journal of the European Union*, 12.12.2008 L334/25.

Compensation Act, 2006.

Consumer Protection Act 1987.

Constitution of the United States of America.

Contract (Rights of Third Parties) Act 1999.

Council Regulation (EC) No 834/2007 on organic production and labelling of organic products, *Official Journal of the European Union*, 20.7.2007. L/189/1.

Directive (EU) 2015/412 of the European Parliament and of the Council, amending Directive 2001/18/EC, *Official Journal of the European Union*, (13.3.2015).

Environmental Protection Agency, 63 Federal Register 28252 (22 May 1998).

Environmental Protection Agency, Pesticide Registration (PR) Notice 2007-2: Guidance on Small-Scale Field Testing and Low-Level Presence in Food of Plant-Incorporated Protectants, (PIPs) (EPA Doc EPA-HQ-OPP-2007-0654-0001, 2007).  
Environmental Protection Agency, Plant-Incorporated Protectants: Potential Revisions to Current Production Regulations, 72 *Federal Register* 16,312 (4 April 2007).

Environmental Protection Agency, Regulations Under the Federal Insecticide, Fungicide, and Rodenticide Act for Plant-Incorporated Protectants (Formerly Plant-Pesticides), 66 Federal Register 37,772 (19 July 2001).

Environmental Protection Agency, Statement of Priorities, 72 Federal Register 69,922, 69,939 (10 December 2007).

EC Regulation No 1829/2003 of the European Parliament and the Council of 22 September 2003 on Genetically Modified Food and Feed. L268/2, *Official Journal of the European Union*, (18/10/2003).

EC Regulation 178/2002 laying down the requirements of food, establishing the European Food Safety Authority and laying down procedures in matters of food safety (Food Law Regulation), [2002] *Official Journal of the European Union*, L31/1.

European 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, *Official Journal of the European Union*, (2010/C 200/01).

EC Product Liability Directive 85/374/EEC (as amended).

EC Regulation 1830/2003 of the European Parliament and of the Council on the traceability and labelling of genetically modified organisms, *Official Journal of the European Union*, L 268/24 18.10.2003.

European Commission Recommendation 2003/556/EC 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.

European Communities Food and Feed Regulation (EC) 1829/2003.

European Community Deliberate Release 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 (as amended), *Official Journal of the European Union*, L 106 17.4.2001).

EEC Product Liability Directive 85/347/EEC (as amended by 1999/34/EC).

European Patent Convention 2000.

Federal Food, Drug, and Cosmetic Act, 21 U.S.C.

Federal Insecticide, Fungicide, and Rodenticide Act, 21U.S.C.

Food, Conservation and Energy Act of 2008, Pub L 110-246.

Food and Drug Administration (FDA), “Premarket Notice Concerning Bioengineered Foods: Proposed Rule”, *Federal Register*, Volume 66, (2001).

Food and Drug Administration (FDA) *Statement of Policy: Foods Derived from New Plants Varieties*, *Federal Register*, Volume 57, of (29 May 1992), at 22,984.

General Agreement on Tariffs and Trade (GATT 1947).

Indecency with Children Act 1960.

National Organic Program Standards, *Federal Register*, Volume 65, No 246, (Thursday 21 December 2001) / Rules and Regulations.

Norwegian Gene Technology Act, April, 1993.

Organic Foods Production Act 1990, Title 21 of [Food, Agriculture, Conservation, and Trade Act of 1990](#), codified at Title 7, United States Code, Chap. 94.

Patents Act 1977.

Plant Protection Act (2000), 7 U.S.C. 7701.

Plant Variety Protection Act, 1997.

Product Liability Directive 85/347/EEC (as amended by 1999/34/EC).

Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 on the traceability and labelling of genetically modified organisms, *Official Journal of the European Union*, L268 /24 18.10.2003.

Regulation (EC) No 258/97 Concerning Novel Foods and Novel Food Ingredients, *Official Journal of the European Communities*, No L43/1.

Rio Convention on Biological Diversity, (1992).

The Environmental Damage (Prevention and Remediation) (England) Regulations 2015, (2015 No. 810)

The Environmental Liability (Prevention and Remediation) Regulations (Northern Ireland) 2009.

The Environmental Liability (Scotland) Regulations 2009 N. 266.

The Environmental Damage (Prevention and Remediation) (Wales) Regulations 2009 (as amended).

The Organic Products Regulations 2009, No. 842.

The Organic Products (Amendment) Regulations 2010, No. 1902.

United States Department of Health and Services (HHS), Food and Drug Administration (FDA) *Statement of Policy: Foods Derived From New Plant Varieties*, Docket No. 92N-0139, *The Federal Register* volume 57, (1992).

United States Environmental Protection Agency, *The Federal Register*, Volume 63, 28252, (22 May, 1998).

United States Food and Drugs Administration, “Statement of Policy: Foods Derived from New Plant Varieties, *Federal Register*, Volume 57, (29 May 1992).

## **ABBREVIATIONS**

Bt. -Bacillus thuringiensis.

CBD - Convention of Biodiversity.

CJEU - Court of Justice of the European Union.

CPB Cartagena Protocol on Biosafety.

DNA- Recombinant Deoxyribonucleic Acid.

DEFRA - Department of Environment, Food & Rural Affairs.

EC - European Commission.

EPA- Environmental Protection Agency.

EPO- European Patent Office.

EU - European Union.

FDA Food and Drug Administration.

GMOs - Genetically Modified Organisms.

LMO Living Modified Organisms.

UPOV - International Union for the Protection of New Varieties of Plant.

USDA - United States Department of Agriculture.

WTO - World Trade Organisation.

## SUMMARY

Whilst the adoption of commercial transgenic plant agriculture continues to spread globally, it is not necessarily indicative of universal support, and would appear to belie the inherent existential tensions and conflicting rights between transgenic, organic, and conventional plant agricultural systems. These tensions are typically vented via the inevitable adventitious presence of transgenes in non-transgenic crops, and the competing, and often conflicting scientific and acrimonious claims and counter-claims on the merits and proprieties of transgenic plant agriculture for the environment and public health. Nevertheless, the virtual irreversibility of transgenic plant agriculture, the exigencies of feeding the growing world population amidst continuing global food security scares, and the continuing dependency of livestock farming on transgenic plant feedstuff, especially in Europe, underscore the imperatives for mutual co-existence of all three forms of plant agricultural systems. Drawing on the socio-legal theory that risks and responsibility are correlatives, it is argued in the thesis that our “technological society” is also a “risk society”, and as it is for comparable “technologies of risk” in the post-industrial era, the regulatory framework for the co-existence of transgenic and non-transgenic plant agriculture, must of necessity, invoke corresponding responsibility in law for any consequential economic loss and damage to the environment and public health, in order to balance and moderate the conflicting rights in the coexistence paradigm for transgenic and non-transgenic plant agriculture. Whilst drawing on relevant and analogous case law and legislations from the United Kingdom, the European Union and North America, the thesis defines the boundaries of inherent risks, responsibility and rights in the current coexistence paradigm for transgenic and non-transgenic plant agriculture, and proposes a modality for an effective *sui generis* compensation regime, as an integral part of the broader coexistence policy, on the grounds that such a regime could moderate conflicting rights, increase public acceptance, and build public confidence in transgenic plant technology, rather than hinder its continuing global growth and promise.



## Chapter One

### Introduction: Problem Definition and Literature Review

#### 1.1.0. Introduction.

In 2014, commercial transgenic crops were cultivated on 181.5 million hectares in twenty-eight countries across six continents, a dramatic hundred-fold increase since their 1996 commercial debut in North America.<sup>1</sup> However, the ostensible spiralling global growth figures belie the inherent existential tensions between transgenic, organic and conventional plant agricultural systems.<sup>2</sup> The tensions are typically vented via the inevitable adventitious presence of transgenes in non-transgenic crops, and the competing, and often conflicting scientific and acrimonious claims and counter-claims on the merits and proprieties of transgenic plant organisms for the environment and public health.<sup>3</sup>

Even so, whilst the spiralling global transgenic crops growth arguably underscores its virtual irreversibility,<sup>4</sup> the continuing opposition in some quarters, especially in Europe,<sup>5</sup> underlines the imperatives for comprehensive coexistence policy regime comprising effective, pragmatic and workable liability and redress measures, which the thesis argues could simultaneously incentivise compliance with coexistence rules, help rein in or stem possible damage in the

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<sup>1</sup> See Clive James, *Global Status of Commercialized Biotech/GM Crops*. (New York: ISAAA Brief No: 49), at <http://www.isaaa.org/resources/publications/pocketk/16/> (accessed on 14 May 2015).

<sup>2</sup> See Miguel A. Altieri, "Genetically Engineered Crops: Separating the Myths from Reality", *Bulletin of Science, Technology & Society*, Volume 21, No. 2 (April 2001), at 130-140.

<sup>3</sup> See Shantharam, S., Sullia, S. B. & Shivakumara Swamy, G. "Peer Review Contestations in the Era of Transgenic Crops", *Current Science*, Volume 95, Number 2, (25 July 2008), at 168; Emily Waltz, "GM Crops: Battlefield: Papers suggesting that biotech crops might harm the environment attract a hail of abuse from other scientists," *Nature*, Volume 461, Number 7260, (3 September 2009), at 27; Thomas Bernauer, *Genes, Trade, and Regulation: The Seeds of Conflict in Food Biotechnology*, (Princeton and Oxford: Princeton University Press, 2003), at 5-6.

<sup>4</sup> The possibility that transgenic plant organisms may be irreversible following deliberate release into the environment was indeed anticipated by Recital 4, of the preamble to Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on deliberate release into the environment of genetically modified organisms. The said Recital 4 provides that provides inter alia that the effects of releasing transgenic plant organisms into the environment "may be irreversible."

<sup>5</sup> See Robert Lee, "GM Resistant Europe and the WTO Panel Dispute on Biotech Products," in Jennifer Gunning and Soren Holm, (editors), *Ethics, Law and Society: Volume 1*, (Aldershot: Ashgate Publishing, 2005), at 131-140; Stefaan Blancke, et al., "Fatal Attraction: The Intuitive Appeal of GMO Opposition," *Trends in Plant Science*, (April 2015), at 1-5. Doi:10.1016/j.tplants.2015.03.011.

coexistence paradigm, and act as a regulatory instrument for boosting public confidence in transgenic plant technology, rather than a punitive regulatory restraint on its promise. Thus, an effective and coherent compensation regime could be a positive force for mutual coexistence of transgenic and non-transgenic plant organisms. This indeed, is the primary objective of the United Nations-sponsored Cartagena Protocol on Biosafety of 2000.<sup>6</sup>

Therefore, drawing on the socio-legal theory that risk and responsibility are correlatives in law,<sup>7</sup> it is hypothesised in the thesis that the inevitability of adventitious presence of transgenes in non-transgenic plant agricultural products with concomitant economic loss,<sup>8</sup> and the continuing scientific uncertainties, claims and counter-claims on the proprieties of transgenic plant technology for the environment and public health,<sup>9</sup> have in concert, invoked a level of risk for which there should be a corresponding and commensurate legal responsibility, in the same way that the society routinely demands legal responsibility for technologies of comparable risks in the post-industrial “risk society.”<sup>10</sup> Responsibility, in this context, connotes obligation, accountability, or liability in the juridical or legal sense.<sup>11</sup> It is therefore proposed in the thesis that legal responsibility for economic, environmental, and public health risks posed by the advent of transgenic plant technology could only be measured by adequate, practical, enforceable and effective compensation regime, which structures and operational modalities are discussed and analysed in Chapter Seven of the thesis.

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<sup>6</sup> See *Cartagena Protocol on Biosafety to the Convention on Biological Diversity: Texts and Annexes*, (Montreal: 2000), at 1.

<sup>7</sup> See Anthony Giddens, “Risk and Responsibility,” *The Modern Law Review*, Volume 62, No. 1, (January 1999), at 1-10; Ulrich Beck, *Ecological Politics in an Age of Risk*, (Oxford: Blackwell Publishers, 1995), at 58-69; Christopher H. Schroeder, “Corrective Justice: Liability for Risks and Tort Law,” *University of California Law Review*, Volume 38, (1990), at 143-146.

<sup>8</sup> See David Lee and Ellen Natesan, “Evaluating genetic containment strategies for transgenic plants,” *TRENDS in Biotechnology*, Volume 24, Number 3, (March 2006), at 109-114; Miguel A. Altieri, “The Myth of Coexistence: Why Transgenic Crops Are Not Compatible with Agro-ecologically Based Systems of Protection,” *Bulletin of Science, Technology & Society*, Volume 25, Number 4, (August 2005), at 361-371.

<sup>9</sup> See Thomas Bernauer, *Genes, Trade, and Regulation: The Seeds of Conflict in Food Biotechnology*, *supra*, note 3, at 5-6.

<sup>10</sup> See Ulrich Beck, *Risk Society: Towards a New Modernity*, (London: Sage Publications, 1992), at 51-84.

<sup>11</sup> See Anthony Giddens, “Risk and Responsibility,” *Modern Law Review*, *supra*, note 7, at 8.

Moreover, despite scientific uncertainties surrounding the safety science of transgenic plant technology for public health and the environment, the fundamentals of the coexistence paradigm transcend mere safety issues and pose critical questions regarding freedom of choice for farmers, and consumers as well as possible economic loss for non-transgenic plant farmers who could be barred from their primary organic and conventional crops and seeds markets, due to adventitious presence of transgenic organisms in their harvest that is in excess of the 0.9 per cent labelling threshold within the European Union.<sup>12</sup> Therefore, an effective compensation regime could at once help guarantee the choice of farmers and consumers, by incentivising compliance with coexistence rules, keeping transgenic organisms in non-transgenic crops below the 0.9 per cent labelling threshold,<sup>13</sup> and ensuring appropriate damages for consequential economic loss for non-transgenic crops farmers.

However, whilst authorities in Europe and North America are rightly preoccupied with transgenic plants' risk assessment and risk management measures,<sup>14</sup> the parameters of concomitant legal "responsibility" and civil liability for possible economic loss or damage to public health and the environment are not clearly defined or delineated in the current national and transnational coexistence policy arrangements. This regulatory deficit is well exemplified by the disparate and ill-fitting civil liability and redress regimes in domestic laws, such as that of the United Kingdom,<sup>15</sup> and the virtual absence of a coherent, harmonised and pragmatic civil liability and redress regime in the only international treaty on the subject, which was drawn up in 2010 in Nagoya Japan, pursuant to the provisions of United Nations Cartagena Protocol on

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<sup>12</sup> See Articles 12(2) and 24(2) of Regulation (EC) No. 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, *Official Journal of the European Union*, (18.10.2003 L268/1).

<sup>13</sup> *Id.*

<sup>14</sup> For instance, the European Food Safety Authority that is tasked with risk assessment oversight over transgenic plant products routinely publishes scientific opinions on risk assessments. See for example, European Safety Authority, Scientific Opinion on application (EFSA-GMO-DE-2011-95) for placing on the market of genetically modified maize 5307 for food and feed uses, import and processing under Regulation (RC) No 1829/2003 from Syngenta Crop Protection AG, *European Food Safety Authority Journal*, Volume 13, No. 5 (2015), at 1-29.

<sup>15</sup> See Christopher Rodgers, "DEFRA's Coexistence Proposals for GM Crops: A Recipe for Confrontation?" *Environmental Law Review*, Volume 10 (2008), at 1-8.

Biosafety following several years of negotiations.<sup>16</sup> It is hypothesised in the thesis that this national and international policy failure is due in part to the “substantial equivalence” doctrine,<sup>17</sup> which is anathema to the very concept of compensation, because it would be unreasonable to expect economic, environmental or public health damage from adventitious admixture of products of essentially similar or equivalent genetic properties, and because a proactive compensation regime could give the impression that transgenic plant technology is inherently unsafe. This is exemplified by the initial opposition to enforceable compensation regimes by the biotechnology industry, during the six year-long negotiations for appropriate liability and redress measures for damage caused by living modified organisms under the provisions of Cartagena Protocol on Biosafety Protocol.<sup>18</sup>

As a necessary backgrounder to the nature and uncertainties of risks posed by transgenic plant technology in the coexistence paradigm, the literature review chapter highlights the conflicting scientific claims and counter-claims on the propriety of transgenic plant technology in relative detail, the inherent dilemmas posed by the scientific uncertainties dogging economic, environmental and public health ramifications of transgenic plant agriculture and food products,<sup>19</sup> and the concomitant legal implications for consumers, transgenic crops farmers, non-transgenic crops farmers and transgenic seeds firms. The chapter also reviews the

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<sup>16</sup> See Article 12 of the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety, available at [https://bch.cbd.int/protocol/NKL\\_text.shtml](https://bch.cbd.int/protocol/NKL_text.shtml) (accessed on 14 May 2015); Gurdial Singh Nijar, “The Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety: An Analysis and Implementation Challenges”, *International Environmental Agreements: Policy, Law and Economics*, Volume 13, Issue 3, (September 2013), at 271-290.

<sup>17</sup> The FDA substantial equivalence policy operates on the presumption that transgenic plant agricultural products are generally recognized as safe (GRAS), and are no different from conventional agricultural products. See the FDA *Statement of Policy: Foods Derived from New Plants Varieties*, *Federal Register*, Volume 57, of (29 May 1992), at 22,984.

<sup>18</sup> See Gurdial Singh Nijar, “The Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to Cartagena Protocol on Biosafety: An Analysis and Implementation Challenges,” *International Environmental Agreements: Policy, Law and Economic*, Volume 13, Issue 3, (September, 2013), at 279.

<sup>19</sup> See Thomas Bernauer, *Genes, Trade, and Regulation: The Seeds of Conflict in Food Biotechnology*, *supra*, note 3, at 5-6 (noting that the benefits and commercial risks of transgenic agriculture for public health and environment remained open and contested). See also Mathilde Bourier, “Applying Safety Science to Genetically Modified Agriculture,” in Michael Baram and Mathilde Bourier, (editors), *Governing Risk in GM Agriculture*, (Cambridge: Cambridge University Press, 2011), at 236.

literature on the highly contested conceptual and technical meanings of transgenic plant organisms, and the equally contested official characterisations of transgenic plant agricultural products, such as "genetically modified organisms" (GMOs),<sup>20</sup> and the "substantial equivalence" policy of the United States Food and Drug Administration,<sup>21</sup> which is partly supported by the European Commission's coexistence policy.<sup>22</sup>

The analysis of the literature on the contested and disputed scientific claims and contested concepts is meant to highlight absence of unanimity of scientific opinions on the safety science of transgenic plant technology, and provide a justificatory ground for the thesis' central narrative and key hypothesis that the safety science of transgenic plant technology is so mired in scientific uncertainties, claims and counter-claims, and the nature of associated risks are so unsettled as to make transgenic plant technology a contested technology in our post-industrial "risk society".<sup>23</sup> Consequently, transgenic plant technology's risks should be matched by concomitant legal responsibility and commensurate civil liability and redress regimes, which could simultaneously incentivise compliance with coexistence rules, inspire consumers' confidence in the technology, and guarantee the choice of consumers and farmers in the coexistence paradigm.

Significantly, a transnational perspective and review of the literature on the current regulatory framework is imperative because some of the fundamental and defining terms of coexistence policies, are transcendental of national policies and boundaries, and include the 'substantial equivalence' doctrine, which originated in the United States,<sup>24</sup> and the

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<sup>20</sup> See Ronald J. Herring, "Epistemic Brokerage in the Bio-property Narrative: Contributions to Explaining Opposition to Transgenic Technologies in Agriculture," *New Biotechnology*, Volume 27, Number 5, (November 2010), at 614-622.

<sup>21</sup> See the FDA *Statement of Policy: Foods Derived from New Plants Varieties*, *Federal Register*, Volume 57, of (29 May 1992), at 22,984.

<sup>22</sup> See Chapter Two of the thesis a for detailed analysis of comparative interpretation of substantial equivalence doctrine in the United States, the European Union and the United Kingdom..

<sup>23</sup> See Ulrich Beck, *Risk Society: Towards a New Modernity*, *supra*, note 7, at 51-84.

<sup>24</sup> See Les Levidow, Joseph Murphy, and Susan Carr, "Recasting "Substantial Equivalence": Transatlantic Governance of GM Food," *Science, Technology & Human Values*, Volume 32, Number 1, (January 2007), at 35.

“precautionary principle”, which originated in Germany in the 1970s,<sup>25</sup> and was an integral part of the United Nations Cartagena Protocol on Biosafety of 2000.<sup>26</sup> Furthermore, the *European Communities Biotech Products Case*, which overruled and branded as a trade barrier, the European Commission’s moratorium on the importation and approval of new transgenic plant organisms and associated products,<sup>27</sup> underscores the transnational reach of the current regulatory framework for coexistence governance, and the necessity for a comparative review of relevant transnational literature on coexistence, concomitant risks, and associated compensation regimes.

Also, given the propensity for, and the inevitability of adventitious flow of genes from transgenic plant organisms across national and international borders,<sup>28</sup> and the cultivation of transgenic plant crops across six continents,<sup>29</sup> with concomitant prospects for trans-border litigation for possible economic, environmental and public health damage, it would seem justified to conduct a holistic review of relevant literature on transnational regulatory framework on coexistence policy, and the role of effective and pragmatic compensation regime on transgenic plant technology governance in mitigating possible damage, and fostering public acceptance and confidence in transgenic plant technology.

Furthermore, within the context of the broader transnational coexistence policy framework, the introductory chapter reviews the literature on key concepts, and highlights research

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<sup>25</sup> See Jenny Steel, *Risks and Legal Theory*, (Oxford: Hart Publishing, 2004), at 196-197.

<sup>26</sup> See Article 1 Cartagena Protocol on Biosafety to the Convention on Biological Diversity, (Montreal, 2000), available at <http://www.biodiv.org> (accessed on 14 May 2015).

<sup>27</sup> See Doc. WT/DS291/1, *European Communities – Measures Affecting the Approval and Marketing of Biotech Products Request for Consultations by the United States*, 20 May, 2003; Doc. WT/DS292/1, *European Communities – Measures Affecting the Approval and Marketing of Biotech Products Request for Consultations by Canada*, 20 May, 2003; *European Communities – Measures Affecting the Approval and Marketing of Biotech Products Request for Consultations by Argentina*, 20 May, 2003.

<sup>28</sup> See Carol Mallory-Smith and Maria Zapiola, “Gene Flow from Glyphosate-Resistant Crops,” *Pest Management Science*, Volume 64, (2008), at 428-440; Miguel A. Altieri, “The Myth of Coexistence: Why Transgenic Crops Are Not Compatible With Agro-ecologically Based Systems of Production,” *Bulletin of Science, Technology & Society*, Volume 25, Number 4, (August 2005), at 363-365; Elena Angulo and Ben Gilna, “When Biotech Crosses Borders,” *Nature Biotechnology*, Volume 26, Number 3, (March 2008), at 277-282.

<sup>29</sup> See Clive James, *Global Status of Commercialized Biotech/GM Crops*. *Supra*, note 1.

problems, research hypotheses, research objectives, research methodology, and research background, and sets out the general outline and synopsis for the thesis' chapters.

### **1.1.1. Relevance of Definitional Overview of Transgenic Organisms to the Thesis.**

The following section on the definitional and conceptual nature of transgenic plant organisms is necessary in order to highlight the key differences between transgenic plant agriculture and crops and conventional and organic plant agriculture and crops. This distinction is particularly important as a crucial rebuttal to the 'substantial equivalence' policy narrative, which posits that transgenic plant foods are substantially equivalent to conventional and organic plant foods.<sup>30</sup> As previously noted in the introductory section 1.1.0 above, one of the thesis' two hypotheses is predicated on the effects of the substantial equivalence doctrine on current compensation regime, and this is fully analysed in section 1.1.9 of the thesis. Therefore, the following analysis on the conceptual and contested nature of transgenic plant organisms is relevant both as a preliminary rebuttal to the substantial equivalence policy narrative, and as an exemplar of the contestations, claims and counter-claims on the safety science and proprieties of transgenic plant technology for the environment and public health, which the thesis offers as evidence of risks, and as a basis for the thesis' second hypothesis in section 1.1.9 of the thesis, to the effect that risks and responsibility are correlatives in law, and that transgenic plant risks must, of necessity, be matched by commensurate and enforceable legal responsibility.

### **1.1.2. Definitional and Conceptual Overview of Transgenic Plant Organisms.**

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<sup>30</sup> See the FDA Statement of Policy: Foods Derived from New Plants Varieties, *Federal Register*, *supra*, note 18, at 22,984; Bruce M. Chassy, "Food Safety Risks and Consumer Health," *New Biotechnology*, Volume 27 Number 5, (November 2010), at 541.

A genetically modified organism is defined by Article 2(2) of the European Community Deliberate Release Directive 2001/18/EC as: “an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.”<sup>31</sup> Technically, genetic engineering technique for intra and trans-species genes transfer is broadly defined as “a technique of altering an organism’s genotype by inserting genes from another organism into its DNA.”<sup>32</sup> The resultant product is known technically as transgenic organism,<sup>33</sup> or in general parlance, as genetically modified organisms or (GMOs).<sup>34</sup>

Perhaps, the most ground-breaking twentieth century scientific innovation in the field of biology, with the most profound implications for medical and agricultural technologies, is the ability of scientists to selectively move genes from one species or organism into another species or organism, and across natural boundaries or structural barriers that separate, define, and distinguish species or organisms.<sup>35</sup> The procedure or technique of moving, recombining, or shuffling of genes from one organism into another organism, is typically undertaken to confer a desirable trait from one organism into another organism, with the recipient organism being able to manifest the desirable traits via the chemical produced by the transferred novel genes.<sup>36</sup>

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<sup>31</sup> See Article 2(2) of the European Community Deliberate Release 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 (as amended), *Official Journal of the European Union*, L 106 17.4.2001).

<sup>32</sup> See Chris Prescott, *Oxford Science Study Dictionary*, (Oxford: Oxford University Press, 1999), at 101.

<sup>33</sup> See Ronald J. Herring, “Epistemic Brokerage in the Bio-property Narrative: Contributions to Explaining Opposition to Transgenic Technologies in Agriculture,” *New Biotechnology*, *supra*, note 19, at 614-622.

<sup>34</sup> See Article 2(2) of the European Community Deliberate Release Directive 2001/18/EC, *supra*, note 30.

<sup>35</sup> See Mark L. Winston, *Travels in the Genetically Modified Zone*, (Cambridge, Massachusetts: Harvard University Press, 2002), at 1; Jack Ralph Kloppenburg JR, *First The Seed: The Political Economy of Plant Biotechnology*, Second Edition, (Madison, Wisconsin: University of Wisconsin Press, 2004), at 2-4.

<sup>36</sup> *Id.*, at 2.



In the context of transgenic plant agriculture, desirable traits range from delayed fruit ripening,<sup>37</sup> drought tolerance,<sup>38</sup> pest resistance,<sup>39</sup> yield enhancement,<sup>40</sup> to crop nutrition enhancement properties.<sup>41</sup> The resultant products is exemplified by the StarLink transgenic corn produced by Aventis CropScience Corporation, which was a progeny of the marriage of genes between *Bacillus thuringiensis* bacterium (a micro-organism), and corn (a plant organism).<sup>42</sup> *Bacillus thuringiensis* is naturally imbued with insecticide properties, and is routinely used to eliminate unwanted insects in plant agriculture, forests, and urban areas.<sup>43</sup>

Scientists at Aventis CropScience Corporation had inserted Cry9C pesticidal proteins from *Bacillus thuringiensis* bacteria into the corn genome. The resultant StarLink corn product was imbued with natural immunity and defences against its traditional insect foes, such as the European corn borer and corn earthworm, thus obviating the use of chemical pesticide.<sup>44</sup> The StarLink corn was also encoded with insulin precursor (*Trypsin*), a pharmaceutical property designed to combat diarrhoea in piglets.<sup>45</sup> Thus, the StarLink corn was effectively fortified with

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<sup>37</sup> See Sheldon Krimsky and Nora K. Murphy, "Biotechnology at the Dinner Table: FDA's Oversight of Transgenic Food," *The Annals of the American Academy of Political and Social Sciences*, Volume 584, Issue 1, (November 2002), at 81

<sup>38</sup> See Jeff Tollefson, "Drought-tolerant maize gets US debut: Seed Companies Race to Tap Multibillion Dollar Market," *Nature* (11 January 2011), doi:10.1038/469144a; Eleonora Cominelli and Chiara Tonelli, "Transgenic Crops Coping with Water Scarcity," *New Biotechnology*, Volume 27, Number 5, (November 2010), at 473-477.

<sup>39</sup> See Jikun Huang, Ruifa Hu, Scott Rozelle and Carl Pray, "Insect-Resistant GM Rice in Farmers' Fields: Assessing Productivity and Health Effects in China," *Science*, Volume 308, (29 April 2005), at 688-690; Robert Paarlberg, *Starved for Science: How Biotechnology is Being Kept Out of Africa*, (Harvard: Harvard University Press, 2009), at 149-177; Taiwo A Oriola, "Consumer Dilemmas: The Right to Know, Safety, Ethics, and Policy of Genetically Modified Food," *Singapore Journal of Legal Studies*, (December 2002), at 516.

<sup>40</sup> See Guanming Shi, Jean Paul Chavas and Joseph Lauer, "Commercialized Transgenic Traits: Maize Productivity and Yield Risk," *Nature Biotechnology*, Volume 31 Number 2, (February 2013), 111-114.

<sup>41</sup> Martin Quaim, "Benefits of Genetically Modified Crops for the Poor: Household Income, Nutrition, and Health," *New Biotechnology*, Volume 27, Number 5, (November 2010), at 552-557.

<sup>42</sup> The Aventis CropScience StarLink corn was approved by the United States Environmental Protection Agency on 22 May, 1998. See *The Federal Register*, Volume 63, 28252, (22 May, 1998). See also Michael R. Taylor and Jody S. Tick, *The StarLink Case: Issues for the Future*, A report commissioned by the Pew Initiative on Food and Biotechnology, (October 2001), available at [www.pweagbiotech.org](http://www.pweagbiotech.org) at 1.

<sup>43</sup> See Carrie Swadener, "Bacillus Thuringiensis (BT)," *Journal of Pesticide Reform*, Volume 14, No. 3 (Fall 1994), at 13-20.

<sup>44</sup> See Madhuri Kota, Henry Daniel, Sam Varma, Stephen F. Garczynski, Fred Gould, and William J. Major, "Over expression of the *Bacillus thuringiensis* (Bt) Cry2Aa2 protein in Chloroplasts confers resistance to plants against susceptible and Bt-resistant insects," *Proceedings of National Academy of Science*, Volume 96, (March 1999), at 1840-1845.

<sup>45</sup> See Bill Hord, "The Road Back: Prodigene and Other Biotech Companies Are Moving Ahead in an Environment of Increasing Fear of Crop Contamination," *Omaha World Herald*, (19 January 2003), at 1.

bacteria and pharmaceutical properties by the mixing-up of genes between totally unrelated plant and microorganisms' species, a feat characterised by Jack Kloppenburg as "breaching the wall of speciation",<sup>46</sup> which is patently impossible for conventional plant breeders to accomplish, as the following section of the thesis will demonstrate.

### **1.1.3. A History of Transgenic Plant Agriculture and Modern Biotechnology.**

Genetic engineering technique is a subset of modern biotechnology, which is defined by the Cartagena Protocol on Biosafety as the application of "(a) In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or (b) Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection."<sup>47</sup> Similarly, a 1984 definition by the United States Congressional Office of Technology Assessment defines modern biotechnology as: 'any technique that uses living organisms (or part of organisms) to make or modify products, to improve plants or animals, or to develop micro-organisms for specific uses'.<sup>48</sup>

Historically, modern biotechnology, as opposed to traditional biotechnology,<sup>49</sup> dates from the mid-1970s, and involves the use of cutting-edge genetic engineering techniques<sup>50</sup> in

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<sup>46</sup> See Jack Ralph Kloppenburg, JR, *First The Seed: The Political Economy of Plant Biotechnology*, *supra*, note 34, at 2-4.

<sup>47</sup> See Article 3(i) of the 2000 Cartagena Protocol on Biosafety, made pursuant to Article 19, paragraphs 3 and 4, and Articles 8(g) and 17 of the 1992 Rio Convention on Biological Diversity, available at <http://www.biodiv.org/convention/articles.asp> (accessed on 14 May 2015).

<sup>48</sup> See OTA, *Commercial Biotechnology: An International Analysis*, (Washington, D. C.: U.S. Congress, Office of Technology Assessment, OTA-BA-218, January 1984), at 503.

<sup>49</sup> Traditional biotechnology comprises centuries' old practices of plant and animal domestication, selection, breeding, and the use of microorganisms in the production of beer, wine, bread, yogurt, and cheese. See Michael J. Reiss and Roger Straughan, *Improving Nature? The Science and Ethics of Genetic Engineering*, *supra*, note 27, at 2-5. Jack R. Kloppenburg, *First The Seed: The Political Economy of Plant Biotechnology* *supra* note 32, at 46; Cary Fowler, *Unnatural Selection: Technology, Politics, and Plant Evolution* (Amsterdam: Gordon and Breach, 1994), at 3.

<sup>50</sup> See Michael J Reiss and Roger Straughan, *Improving Nature? The Science and Ethics of Genetic Engineering*, *supra*, note 3, at 1-2.

shuffling or transferring of genes between plant and animal species, with the aim of passing on certain desirable hereditary traits to the host plants or animals.<sup>51</sup>

The technique of genetic engineering or modern biotechnology was first successfully pioneered in 1973, when Stanley Cohen of Stanford University and Herbert Boyer of the University of California, San Francisco, successfully used restriction enzymes,<sup>52</sup> to transfer a DNA sequence from one organism into bacteria plasmid DNA, and then used the properties of the plasmid to insert the gene into an *Escherichia coli* bacterium, where the transferred gene was successfully expressed.<sup>53</sup> The feat earned the duo a United States patent in 1980, and precipitated a genetic engineering revolution and gold rush, as industry and university laboratories around the world became embroiled in the highly competitive and lucrative commercial race to discover and shuffle useful and desirable heritable genetic information between higher and lower organisms into microbes and vice versa.<sup>54</sup>

The genetic engineering technique pioneered by Cohen and Boyer was first used commercially in the field of medicine in 1982, when the United States Food and Drug Administration gave approval for the use of human insulin, which was produced using a genetically modified bacterium.<sup>55</sup> This was swiftly followed by genetically engineered animals

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<sup>51</sup> See Stephen Nottingham; *Eat Your Genes, How Genetically Modified Food Is Entering Our Diet*, 2<sup>nd</sup> updated edition, (London, Zed Books Ltd., 2003) at 10-26.

<sup>52</sup> Restriction enzymes are culled from bacteria, and are used by bacteria as natural defence mechanism against invading viruses. Scientists employ restriction enzymes as “molecular scissors” to cut out DNA strands with accuracy and precision. See George Wei, *An Introduction to Genetic Engineering, Life Sciences and the Law*, (Singapore: Singapore University Press, 2002), at 28.

<sup>53</sup> See Jack R. Kloppenburg, *First The Seed: The Political Economy of Plant Biotechnology supra*, note 34, at 193-194.

<sup>54</sup> *Id.*

<sup>55</sup> See Robert Paarlberg, *Starved for Science: How Biotechnology is Being Kept Out of Africa, supra*, note 38, at 10-11.

such as Dolly the sheep,<sup>56</sup> and genetically engineered agricultural crops, such as Bt. maize, soybean, and canola.<sup>57</sup>

Whilst it is clear from the foregoing that transgenic plant agriculture as a product of modern biotechnology is a relatively recent phenomenon and very distinct from conventional or traditional plant agricultural system that has evolved for centuries, the question on whether the products of the two distinctive form of plant agricultural systems are substantially equivalent is a recurring theme of the thesis and central to the debate on the nature of regulation, if any, for transgenic plant technology since its commercial debut in the United States in 1996.<sup>58</sup> The central argument of the thesis as canvassed in section 1.1.9 below and in chapter two, is that products of transgenic plant technology are sufficiently genetically distinct from that of conventional plant agriculture, to merit appropriate liability and redress regime that reflect current uncertainties on its safety science and the nature of its inherent risks.

#### **1.1.4. Conventional and Genetic Engineering Plant Breeding Techniques.**

Notably, unlike genetic engineering techniques, conventional plant breeding techniques are known as ‘cross-breeding’, and are typically accomplished by the transfer of pollens of one plant to the female organ of another plant. Approximately 40 per cent of the genetic material in the resulting hybrid plant or crop is typically reorganised. However, conventional plant breeding is a ‘hit-and-miss’, unpredictable and a relatively inefficient technique that could only be accomplished between related species.<sup>59</sup>

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<sup>56</sup> Dolly the sheep was a domestic sheep, and the first mammal to be cloned from an adult somatic cell, using the genetic engineering technique of nuclear transfer. See Wilmut I, Schnieke AE, McWhir J, Kind AJ, Campbell KH "Viable offspring derived from fetal and adult mammalian cells", *Nature*, Volume 385, Issue 6619, (1997) at 810–813.

<sup>57</sup> See Robert Paarlberg, *Starved for Science: How Biotechnology is Being Kept Out of Africa*, *supra*, note 31, at 11. See also Jack Ralph Kloppenburg Jr., *First the Seed: The Political Economy of Plant Biotechnology*, *supra*, note 34, at 296.

<sup>58</sup> See generally section 1.1.9 in chapter one, and chapter two of the thesis for the analysis of the substantial equivalence doctrine and its impacts on the regulatory and policy framework for transgenic plant technology.

<sup>59</sup> See Norman E. Borlaug, “Contributions of Conventional Plant Breeding to Food Production.” *Science*, Volume 219, Number 4585 (11 February 1983), at 689-693; Muhammad Ashraf and Nudrat Aisha Akram, “Improving

According to Jack Kloppenburg, the use of recombinant DNA technology for plant breeding is superior to conventional plant breeding techniques, and is tantamount to “outdoing evolution.”<sup>60</sup> This superiority is two-dimensional. First, genetic engineering operates at the cellular and molecular levels.<sup>61</sup> Second, unlike conventional plant breeding technique, which relies on sexual templates for genetic materials transfer, genetic engineering technique dispenses with sexual reproduction and allows for the transfer of genes between totally unrelated organisms.<sup>62</sup>

Therefore, to the extent that genetic engineering techniques allows for the incorporation of genes from totally unrelated species such as bacteria and other micro-organisms into the plant genome, (as exemplified by the StarLink corn), transgenic plants and conventionally bred plants are genetically distinct with different genetic blueprints, and their resulting food products cannot be regarded as substantially equivalent as such, a point that is well canvassed in chapter two of the thesis as a rebuttal to the substantial equivalence policy narrative, and the imperatives for effective and coherent liability and redress regimes that duly reflect the nature of risks posed by transgenic plant technology.

#### **1.1.5. Genetically Modified Organisms (GMOs) or Transgenic Plant Organisms?**

It is not only the safety science of transgenic plant technology that is contested.<sup>63</sup> Scientists and scholars do routinely quibble over “genetically modified organisms” or “GMOs” semantics, which is the official name for products of plant biotechnology under the European Community

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Salinity Tolerance of Plants through Conventional Breeding and Genetic Engineering: An Analytical Comparison,” *Biotechnological Advances*, Volume 27, (2009), at 744-752.

<sup>60</sup> See Jack Ralph Kloppenburg, JR, *First The Seed: The Political Economy of Plant Biotechnology*, *supra*, note 34, at 2-4.

<sup>61</sup> *Id.*, at 3.

<sup>62</sup> *Id.*

<sup>63</sup> See section 1.1.7 of the thesis below.

laws,<sup>64</sup> and similar international official documents such as the Food and Agriculture Organization of the United Nations.<sup>65</sup>

However, the term “genetically modified organisms” or “GMOs” has been criticised as a political construct, and a variant of the strategic, systematic, subjective, and hostile framing of transgenic plant agriculture by oppositional “epistemic brokers” or “intermediaries of knowledge”, who are bent on undermining the adoption of transgenic plant agriculture, and stifling its concomitant promise and potential contributions to human development.<sup>66</sup> For instance, while affirming preference for the term: “transgenic organisms” due to its supposedly neutral and apolitical connotations,<sup>67</sup> Ronald J. Herring criticised what he described as negative, inflammatory or discriminatory political connotations and undertones inherent in the use of the term: “genetically modified organisms” or “GMOs” for transgenic plant agriculture and products:

The ‘GMO’ is political shorthand for any agricultural product involving recombinant DNA (rDNA) techniques; its success as a cognitive frame is such that even proponents of genetic engineering in agriculture accept this political terminology. The frame does not apply to rDNA techniques in pharmaceuticals, medicine or industry where transgenics have been globally accepted.<sup>68</sup>

Ronald J. Herring further argued that the framing of agricultural products of recombinant DNA technology as GMOs lacked “biological coherence”, and that it was necessary to deconstruct the framing in order to confront the misconceptions that continued to constrain the use of transgenic plant technology for addressing pressing global food security challenges.<sup>69</sup> Herring’s argument is valid to the extent that pharmaceutical and medicinal products that are by-products

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<sup>64</sup> See Article 2(2) of the European Community Deliberate Release 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, *supra*, note 28.

<sup>65</sup> See Food and Agriculture Organization, “Weighing the GMO Arguments,” FAONEWSROOM, at <http://www.fao.org/english/newsroom/focus/2003/gmo8.htm> (accessed on 14 May 2015).

<sup>66</sup> See Ronald J. Herring, “Epistemic Brokerage in the Bio-property Narrative: Contributions to Explaining Opposition to Transgenic Technologies in Agriculture,” *New Biotechnology*, *supra*, note 19, at 614-615.

<sup>67</sup> *Id.*, at 614-615.

<sup>68</sup> *Id.*, at 614-615.

<sup>69</sup> See Ronald J. Herring, “Opposition to Transgenic Technologies: Ideology, Interests and Collective Action Frames,” *Nature*, Volume 9, (June 2008), at 458-462.

of recombinant DNA techniques are neither branded as GMOs as such, nor is their safety science subject to the same level of unrelenting scrutiny as transgenic plant agricultural products.

However, unlike transgenic plant technological products, pharmaceutical and medicinal products are subject to comparatively more rigorous clinical trials on animals and human subjects, both at the pre and post market debut phases that averages 12 to 15 years.<sup>70</sup> Moreover, whilst pharmaceutical and medicinal products are subject to control and are often administered by prescriptions with strict dosage rules for specific ailments afflicting a small percentage of the population at any point in time,<sup>71</sup> transgenic plant foods are freely available on the market for the entire population without any restrictions on consumption whatsoever. Furthermore, most pharmaceutical and medicinal products are known for their possible side-effects, and there are official protocols for products withdrawal, should they pose any imminent risks to public health.<sup>72</sup> On the other hand, if a particular transgenic plant food were to have any side effects or pose any imminent danger, the percentage of the population that could potentially be affected would greatly outnumber that of comparable pharmaceutical or medicinal products.

Thus, whilst recombinant DNA technology is used in the manufacture of transgenic plant crops and pharmaceutical products, the latter is subject to relatively more stringent regulatory control, it is often by prescription and not freely available for everyone, it is not expected to be consumed at the same rate and frequency as the former, and the percentage of the population that could potentially be adversely affected are relatively lower than those who could consume any transgenic plant food that is freely available on the market. This distinction might perhaps

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<sup>70</sup> See Taiwo A. Oriola, " "Strong Medicine: Patents, Market, and Policy Challenges for Managing Neglected Diseases and Affordable Prescription Drug," *Canadian Journal of Law and Technology*, Volume 7, Number 1, (April 2009), at 86-92.

<sup>71</sup> *Id.*

<sup>72</sup> *Id.*, at 88.

explain the discrepancy in public attitudes to the two products of recombinant DNA technology, and why some people are very wary of the products of transgenic plant technology.

Nevertheless, in order to maintain a tone of neutrality that transcends the fray on "GMOs" semantics and the alleged political and negative connotations in the use of "GMOs", the term "transgenic" plant organisms or "transgenic" plant agriculture, or "transgenic" plant crops, is adopted and used throughout the thesis, except where quotations that use the term "GMOs or "genetically modified organisms" are directly cited or referenced.

Moreover, for the same reasons, the use of the term "contamination" is deliberately avoided in the description and analysis of adventitious presence of transgenes in non-transgenic plant crops and products. Although the use of the word "contamination" is perfectly normal in material science to describe the presence of foreign or unwanted contaminants in a material or physical or natural environment, its use in the context of transgenic and non-transgenic plant organisms is arguably liable to inflame the coexistence discourse, and give the impression that transgenes are inherently unsafe for public health and the environment. Such a representation could undermine the scientific basis for mandatory risks assessments on which approval for new transgenic plant organisms are routinely predicated in Europe and North America.<sup>73</sup> For it is logical and reasonable to conclude that transgenic plant organisms that have passed risks assessments, safety tests and the approval process for release into the environment, could not and should not be deemed as contaminants.

Therefore, the use of neutral terms in the thesis is designed in part to avoid the increasingly deeply partisan nature of the debates and discourses that have come to characterise recent scholarship on the legal, ethical, and scientific proprieties of the use of recombinant rDNA

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<sup>73</sup> See Article 4(1) of the EC Deliberate Release Directive 2001/18/EC *supra*, note 30, enjoins Member States to "ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment which might arise from the deliberate release or placing on the market of GMOs." See also Paragraph 20 of the Preamble to the Deliberate Release Directive, which enjoins Member States to "establish a common methodology to carry out the environmental risk assessment based on independent scientific evidence."



technology in plant agriculture.<sup>74</sup> Indeed, as Ronald J. Herring rightly noted, genetic engineering technique is widely used and accepted in medicine, pharmaceuticals, and numerous industrial applications without question,<sup>75</sup> and there is absolutely no reason why its use in plant agriculture should not be equally welcome, unless there is proven scientific evidence supporting harm to public health and the environment.

However, the main problems and challenges are that the evidence of harm in scientific literature allegedly caused by transgenic plant technology to the environment and potentially to public health, is highly contested, whilst there is no unanimity of views amongst scientists and scholars on the safety science and nomenclature for transgenic plant technology.<sup>76</sup> It is argued in the thesis that these contestations, claims and counter-claims in scientific literature have inevitably heightened and reinforced the perception of risks for which there should be concomitant legal responsibility.<sup>77</sup>

#### **1.1.6. Global Adoption and Growth of Transgenic Plant Technology.**

Commercial transgenic crops currently include food and industrial crops such as maize, canola, soybean, cotton, carnation, tomato, papaya, sweet pepper, poplar, and petunia.<sup>78</sup> As previously observed in the introduction to the thesis, approximately 181.5 millions of hectares of arable farmlands were cultivated with transgenic plant crops in twenty-eight countries across six continents in 2014, an unprecedented one hundred-fold increase from the global 1.7 million hectares cultivated with commercial transgenic crops in 1996.<sup>79</sup> Moreover, the 2014 global market value for transgenic crops was estimated at US\$15.7 billion, which represented

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<sup>74</sup> See Ronald J. Herring, “Epistemic Brokerage in the Bio-property Narrative: Contributions to Explaining Opposition to Transgenic Technologies in Agriculture, *New Biotechnology*, *supra*, note 19, at 614-615.

<sup>75</sup> *Id.*, at 614-615.

<sup>76</sup> See section 1.1.7 of the thesis below.

<sup>77</sup> See sections 1.1.7 and 1.1.8 of the thesis below.

<sup>78</sup> See Clive James, ISAAA, *Global Status of Commercialized Biotech/GM Crops: 2014*, ISAAA Brief No. 49 ISAAA: Ithaca, New York, at <http://www.isaaa.org/> (accessed on 14 May 2015).

<sup>79</sup> *Id.*

approximately 35 percent of the global US\$45 billion commercial seed market, and 22 percent of the US\$72.3 billion global crop protection market.<sup>80</sup> All evidence indicates that the global transgenic crops growth is now stuck in a relentless spiral climb, as developing countries such as China, India, South Africa, and Brazil flock to embrace the technology.<sup>81</sup>

However, in contrast to North America and other parts of the world, most European Union Member States are generally opposed to transgenic technology, reflecting the fierce and popular dislike for the technology by European citizenry.<sup>82</sup> The reasons adduced for European rejection of transgenic plant agriculture range from distaste for ‘Frankenstein’ food,<sup>83</sup> lack of trust in regulatory institutions,<sup>84</sup> objection to presumed corporate control and monopoly over transgenic seeds and crops,<sup>85</sup> preservation of traditional organic and conventional farming, or preservation of competitive and economic edge conferred by traditional and organic farming in rural communities,<sup>86</sup> environmental protection,<sup>87</sup> to religious, cognitive and “teleological intuitions and disgust.”<sup>88</sup>

Furthermore, studies have found that most Europeans are prepared to pay less for transgenic plant technological products than they would pay for organic and conventionally bred plant food products.<sup>89</sup> Even so, farmers from five European Union Countries of Spain, Portugal,

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<sup>80</sup> Id.

<sup>81</sup> Id.

<sup>82</sup> See Robert Lee, “GM Resistant Europe and the WTO Panel Dispute on Biotech Products,” in Jennifer Gunning and Soren Holm, (editors), *Ethics, Law and Society: Volume 1*, *supra*, note 5, at 131-140.

<sup>83</sup> See Michael G. Palmgren, et al, “Are we ready for back-to-nature crop breeding?” *Trends in Plant Science*, Volume 20, Number 3, (March 2015) at 160; Ronald J. Herring, "Opposition to Transgenic Technologies: Ideology, Interests and Collective Action Frames," *Nature*, Volume 9 (June 2008), at 458-463.

<sup>84</sup> Id, at 160.

<sup>85</sup> See Gabriela Pechlaner, *Corporate Crops: Biotechnology, Agriculture, and the Struggle for Control*, (Austin: University of Texas, 2012), at 172-205; Ronald J. Herring, "Epistemic Brokerage in the Bio-property Narrative: Contributions to Explaining Opposition to Transgenic Technologies in Agriculture," *New Biotechnology*, *supra*, note 19, at 615-620.

<sup>86</sup> See *Land Oberosterreich and Austria v Commission of the European Communities*, (Joined Cases C-439/05 P and C-454/05 P of 13 September 2007).

<sup>87</sup> See Elsa Tsioumani, "Genetically Modified Organisms in the EU: Public Attitudes and Regulatory Developments," *RECIEL*, Volume 13, Number 3, (2004), at 279-288.

<sup>88</sup> See Stefaan Blancke, et al., “Fatal Attraction: The Intuitive Appeal of GMO Opposition,” *Trends in Plant Science*, *supra*, note 5, at 5; *European Commission v. The Republic of Poland*. (Case C-165/08).

<sup>89</sup> See Michael G. Palmgren, et al, “Are we ready for back-to-nature crop breeding?” *Trends in Plant Science*, *supra*, note 82, at 160.

Slovakia, The Czech Republic and Romania, reportedly cultivated a record 129,071 hectares of transgenic Bt. maize in 2012, a substantial increase of 13 percent over the 2011 figures.<sup>90</sup>

The European Commission had initially reacted to public opposition to transgenic plant technology, by imposing a de facto moratorium in 1998. This culminated in a complaint filed at the World Trade Organization in 2003,<sup>91</sup> by a coalition of commercial transgenic crops growers comprising Argentina, Canada, and the United States,<sup>92</sup> in pursuance of Article 4.4 of the WTO Dispute Settlement Understanding (DSU).<sup>93</sup> The complainants argued that the de facto moratorium had no scientific justifications, and that it was no more than a trade barrier.<sup>94</sup> However, characterising the moratorium and the general European skepticism of transgenic crops as a trade barrier ostensibly rang true, even if it was not the primary objective of the moratorium. This is evidenced by the dramatic fall in American transgenic soybeans exports to Europe from 11 million tones in 1998 to 6 million tones in 1999, when the moratorium became effective.<sup>95</sup>

The European Commission had rationalised the moratorium on the need to build trust and confidence of citizens in transgenic plant agriculture and products,<sup>96</sup> in the face of fierce opposition to the technology by the overwhelming majority of European citizens.<sup>97</sup> However, critics have observed that the World Trade Organization *European Communities Biotech*

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<sup>90</sup> See Clive James, *Global Status of Commercialized Biotech/GM Crops: ISAAA Brief No. 49 ISAAA, supra*, note 1.

<sup>91</sup> See Robert Lee, “GM Resistant Europe and the WTO Panel Dispute on Biotech Products,” *supra*, note 5, at 131-140.

<sup>92</sup> See Doc. WT/DS291/1, *European Communities – Measures Affecting the Approval and Marketing of Biotech Products Request for Consultations by the United States*, 20 May, 2003; Doc. WT/DS292/1, *European Communities – Measures Affecting the Approval and Marketing of Biotech Products Request for Consultations by Canada*, 20 May, 2003; *European Communities – Measures Affecting the Approval and Marketing of Biotech Products Request for Consultations by Argentina*, 20 May, 2003.

<sup>93</sup> See Doc. WT/DS291/1, *European Communities – Measures Affecting the Approval and Marketing of Biotech Products Request for Consultations by the United States, supra*, note 27.

<sup>94</sup> See Robert Lee, “GM Resistant Europe and the WTO Panel Dispute on Biotech Products,” *supra*, note 5, at 131-140.

<sup>95</sup> See Miguel A. Altieri, “Genetically Engineered Crops: Separating the Myths from the Reality,” *Bulletin of Science, Technology & Society*, Vol. 21, No. 2, (April 2001), 130-140, at 135.

<sup>96</sup> See Robert Lee, “GM Resistant Europe and the WTO Panel Dispute on Biotech Products,” *supra*, note 5, at 132.

<sup>97</sup> *Id.*, at 132.

*Products Case* that forced the European Commission to revoke its moratorium was undemocratic, and a triumph of international trade rules over cultural values that underpinned the opposition to transgenic plant agriculture in the European Union.<sup>98</sup> Arguably, using trade rules to impose transgenic crops on unwilling consumers underscores the primacy of international trade laws on regional and domestic laws, which ostensibly gloss over the genuine “social, cultural, and ethical” concerns of most Europeans to the technology.<sup>99</sup>

Even so, over the years, the European Commission has approved for importation, more than 40 transgenic plant products, which included cotton, soybean and maize, whilst more than 70 percent of the European Union’s protein-based animal feed is based on transgenic plant crops.<sup>100</sup> The approval and authorisation process continued apace with the authorisation in April 2015, of 10 new transgenic plant varieties for food and animal feeds uses, comprising maize, soybean and cotton; and the renewal of 7 new applications for transgenic maize, oil seed rape, and cotton.<sup>101</sup>

It would thus appear that transgenic crops are indispensable for the textile, food and feed industries in the European Union, and that the importation of transgenic plant crops for food and feed are dictated by economic necessity and market imperatives, notwithstanding the continuing opposition by some Member States. Therefore, the continuing reliance of European textile and food and feed industries on transgenic plant crops on the one hand, and the continuing anti-transgenic crops rhetoric by some European Union Member States and citizens on the other hand, underscores the disconnect between the reality of the growing dependency of European agricultural economy and market on transgenic plant technology, and the

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<sup>98</sup> See Oren Perez, “Anomalies at the Precautionary Kingdom: Reflections on the GMO Panel’s Decision,” *International Law Forum, The Hebrew University of Jerusalem, Research Paper No. 13-06*, (October 2006), at 1-19.

<sup>99</sup> Robert Lee, “GM Resistant Europe and the WTO Panel Dispute on Biotech Products,” *supra*, note 5, at 138.

<sup>100</sup> See House of Commons Science and Technology Committee, *Advance Genetic Techniques for Crop Improvement: Regulation, Risk and Precaution*, (Fifth Report of Session 2014-15), at 9.

<sup>101</sup> See European Commission Press Release, “Commissions authorises 17 GMOs for food/feed uses and 2 GM carnations,” (Brussels, 24 April 2015), at [http://europa.eu/rapid/press-release\\_IP-15-4843\\_en.htm](http://europa.eu/rapid/press-release_IP-15-4843_en.htm). (accessed on 14 May 2015).

continuing strong opposition to the technology by some Member States and citizens. And most importantly, the continuing reliance of the European textile, food and feed market, on transgenic plant technology, arguably underscores the primacy of market imperatives over cultural, and social economic objections to the technology in the European Union, and explains the paradox of the continuing global growth of transgenic plant technology in the face of stiff opposition and resistance in some European countries and around the world.

However, whilst the continuing authorisations and renewals for new and old transgenic plant crops respectively would appear to signal a favourable policy dispensation for transgenic plant crops and agriculture in Europe, in March 2015, the European Parliament and the Council passed Directive 2015/412 that allowed Member States to opt-out of fully approved and authorised transgenic plant crops on non-scientific grounds.<sup>102</sup> This was a significant policy shift from previous regime under which Member States were compelled to adopt transgenic crops that had passed through the centrally managed approval and authorisation procedures, and the new Directive 2015/415 would appear to be an acknowledgement of the continuing resistance and opposition to transgenic plant agriculture by some Member States.<sup>103</sup>

Arguably, the new opt-in-opt-out provision of Directive 2015/415 is vulnerable to similar legal challenge mounted against the 1998 European Commission moratorium on transgenic crops import at the World Trade Organization in the European *Communities Biotech Products Case* by aggrieved transgenic plant crops growing countries,<sup>104</sup> and could have legal

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<sup>102</sup> See Directive (EU) 2015/412 of the European Parliament and of the Council, amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory.

<sup>103</sup> See *European Commission v. The Republic of Poland*. (Case C-165/08), *supra*, note 87; *Land Oberösterreich and Austria v Commission of the European Communities*, (Joined Cases C-439/05 P and C-454/05 P of 13), September 2007, *supra*, note 85; Robert G. Lee, “Humming a different tune? Commercial cultivation of GM crops in Europe,” (2015), (paper is on file with author).

<sup>104</sup> See Doc. WT/DS291/1, European Communities – Measures Affecting the Approval and Marketing of Biotech Products Request for Consultations by the United States, 20 May, 2003; Doc. WT/DS292/1, European Communities – Measures Affecting the Approval and Marketing of Biotech Products Request for Consultations by Canada, 20 May, 2003; European Communities – Measures Affecting the Approval and Marketing of Biotech Products Request for Consultations by Argentina, 20 May, 2003, *supra*, note 27.

ramifications for the single market policy, because Member States that opted-in might not be able to export transgenic plant crops and products to Member States that opted-out of transgenic plant technology.<sup>105</sup>

Moreover, in the context of the currently decentralised liability and redress regime in the European Union, the propensity for cross-border flow of transgenes from the territory of a Member State that embraces transgenic plant organisms, into the territory of a Member State that prohibits transgenic plant organisms could create unprecedented legal conflicts for which there are no clear solutions in the current disparate and decentralised liability and redress regime, thus reinforcing the imperatives for a comprehensive, practical, enforceable and coherent liability and redress regime in the coexistence policy paradigm.

Unlike the European Union, the United States has an official proactive transgenic plant technology policy, which is designed around the promotion of biotechnological products via the substantial equivalence doctrine.<sup>106</sup> However, there are pockets of opposition and resistance to transgenic plant technology, and a growing demand for labelling rules that could facilitate consumer choice between transgenic and non-transgenic plant foods. For example, 93 per cent of Americans polled in a 2003 survey expressed preference for labeling of transgenic plant food products.<sup>107</sup> Furthermore, in *Alliance for Biointegrity v. Donna Shalala*, a United States Federal Court dismissed a legal challenge to the official non-labelling policy for transgenic plant foods filed by a coalition of religious and environmental groups.<sup>108</sup> Even so, opposition

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<sup>105</sup> See Robert G. Lee, “Humming a different tune? Commercial cultivation of GM crops in Europe,” *supra*, note 102, (paper is on file with author).

<sup>106</sup> See Les Levidow, Joseph Murphy, and Susan Carr, “Recasting “Substantial Equivalence” Transatlantic Governance of GM Food”, *Science, Technology & Human Values*, Volume 32, Number 1, (January 2007), at 34-36.

<sup>107</sup> See Robert Paarlberg, *Starved for Science: How Biotechnology is Being Kept out of Africa*, *supra*, note 38, at 17-23.

<sup>108</sup> See *Alliance for Bio-integrity and Donna Shalala*, 116 F. Supp. 2d (2000), at 166-181.

to transgenic plant technology in the United States is disparate, weak and not as prominent and proactive as it is in the European Union.<sup>109</sup>

In the United States, the first ever transgenic plant food was approved by the Food and Drug Administration in 1994.<sup>110</sup> It was a transgenic tomato with the trade name of “Flavr Savr”.<sup>111</sup> The DNA sequence of the key gene in the tomato: polygalacturonase enzyme, which was responsible for “the degradation of pectin and the initiation of ripening” in the tomato had been reversed via a process known as “antisense technology” in order to slow down the rate of ripening.<sup>112</sup> Since 1996, the United States farmers have grown commercial transgenic crops for export and domestic markets.<sup>113</sup>

From the foregoing analysis of the literature, it is clear that the continuing global growth of transgenic plant technology is set in a perpetual spiral climb, despite opposition in some parts of the United States, in Europe and other parts of the world. It is also clear that the growth is largely underpinned by market forces as exemplified by the continuing dependency of the European textile and agricultural industries on transgenic crops for raw materials and animal feeds. Thus, given the market-driven demands for transgenic plant technology, it is safe to assume that its continuing global growth and adoption is assured, and that transgenic plant technology is now virtually irreversible. However, the current coexistence laws for transgenic and non-transgenic plant agriculture have yet to match transgenic plant technology's inexorable growth and associated risks induced by the inherent uncertainties on its safety science, as evident by the absence of a commensurate, coherent, practical and effective compensation regime that could address possible economic, environmental, or public damage from

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<sup>109</sup> See Robert Paarlberg, *Starved for Science: How Biotechnology is Being Kept out of Africa*, *supra*, note 38, at 17-23.

<sup>110</sup> See Sheldon Krinsky and Nora K. Murphy, “Biotechnology at the Dinner Table: FDA’s Oversight of Transgenic Food,” *The Annals of the American Academy of Political and Social Sciences*, *supra*, note 36, at 81.

<sup>111</sup> *Id.*

<sup>112</sup> *Id.*

<sup>113</sup> See Robert Paarlberg, *Starved for Science: How Biotechnology is Being Kept out of Africa*, *supra*, note 38, at 17.

adventitious presence of transgenes in non-transgenic plant products and the environment. The nature of the scientific uncertainties on the safety science of transgenic plant technology and its relevance to associated risks and the need for adequate liability and redress regime, is further analysed in section 1.1.7 of the thesis below.

### **1.1.7. Transgenic Plant Agriculture: Contested Science, Contested Technology.**

The propriety of transgenic plant technology for existing forms of plant agriculture, the environment and public health is highly contested. Underlying the disputes and contestations surrounding transgenic plant agriculture in Europe, North America, and elsewhere, is the uncertainties surrounding the safety science of transgenic plant agriculture, which perhaps makes transgenic plant technology one of the most hotly contested of contemporary technologies. These uncertainties are further exacerbated by disagreements amongst scientists, which are rife, typically polemical, and often acrimonious, with opposing sides firmly entrenched in their respective views on the merits and propriety of transgenic plant agriculture for non-transgenic plant agriculture, the environment and public health. According to Ronald J. Herring, some scientists are deeply troubled and divided by transgenic plant agriculture, due to "specifiable 'known unknowns': horizontal gene flow, allergenicity from novel proteins, and almost certainly unknown unknowns' as well."<sup>114</sup>

Indeed, a cursory look at the annals of cognate literature reveals a dramatic and eclectic mix of titles that are symptomatic of the emotionally charged and highly polemical claims and counter-claims on the proprieties of transgenic plant agriculture for the environment and public health: *Seeds of Destruction: The Hidden Agenda of Genetic Manipulation*;<sup>115</sup> *Genetic*

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<sup>114</sup> See Ronald J. Herring, "The Genomics Revolution and Development Studies: Science, Poverty and Politics," in Ronald J. Herring, (editor), *Transgenics and the Poor: Biotechnology in Development Studies*, (Abingdon, Oxon & New York: Routledge Publishing, 2007), at 2.

<sup>115</sup> See F. William Engdahl, *Seeds of Destruction: The Hidden Agenda of Genetic Manipulation*, (Montreal: Global Research, 2007), pp. 341.



*Roulette: The Documented Health Risks of Genetically Engineered Foods*;<sup>116</sup> *Seeds of Contention: World Hunger and the Global Controversy over GM Crops*;<sup>117</sup> *Seeds of Deception: Exposing Corporate and Government Lies about the Safety of Genetically Engineered Food*;<sup>118</sup> *Genetically Modified Food: A Short Guide for the Confused*;<sup>119</sup> *GMO Free: Exposing the Hazards of Biotechnology to Ensure the Integrity of Our Food Supply*;<sup>120</sup> and *Genes, Trade, and Regulation: The Seeds of Conflict in Food Biotechnology*.<sup>121</sup>

Notably, the palpable polemics, contestations, tensions and dissents inherent in the aforementioned literature, are but symptomatic of the general discontents and contestations on the merits or otherwise of transgenic plant agriculture in the wider society. Even academic researchers and scientists, who are routinely caught up in transgenic plant agriculture discourse, are neither entirely above the fray nor immune from the typically polemical, partisan and often stifling environment in which unfavourable research outputs perceived as “bad science” could effectively truncate a burgeoning or promising academic career. For example, Dr Arpad Pusztai controversially lost his job due to alleged premature release of “flawed research data on the toxicity of GM potatoes,” whilst Ignacio Chapela of the University of California, Berkeley, allegedly forfeited his tenure for publishing “a faulty paper on Bt maize”.<sup>122</sup>

Moreover, scientific publications have been swiftly and dramatically retracted by editors or publishers,<sup>123</sup> or have been vigorously panned and rebutted by opponents. Examples include a

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<sup>116</sup> See Jeffrey M. Smith, *Genetic Roulette: The Documented Health Risks of Genetically Engineered Foods*, (Fairfield, IA: Yes! Books, 2007), pp. 319.

<sup>117</sup> See Per Pinstrup-Andersen and Ebbe Schiøler, *Seeds of Contention: World Hunger and the Global Controversy over GM Crops*, (Baltimore & London: John Hopkins University Press, 2001), pp. 164.

<sup>118</sup> See Jeffrey M. Smith, *Seeds of Deception: Exposing Corporate and Government Lies about the Safety of Genetically Engineered Food*, (Foxhole, Dartington, UK, 2004), pp. 254.

<sup>119</sup> See Andy Rees, *Genetically Modified Food: A Short Guide for the Confused*, (London & Ann Arbor, Michigan: Pluto Press, 2006), pp. 248.

<sup>120</sup> See Mae-Wan Ho and Lim Li Ching, *GMO Free: Exposing the Hazards of Biotechnology to Ensure the Integrity of Our Food Supply*, (Ridgefield, CT & London: Institute for Science in Society, 2004), pp.133.

<sup>121</sup> See Thomas Bernauer, *Genes, Trade, and Regulation: The Seeds of Conflict in Food Biotechnology*, *supra*, note 3, pp. 229.

<sup>122</sup> See Shantharam, S., Sullia, S. B. & Shivakumara Swamy, G. “Peer Review Contestations in the Era of Transgenic Crops”, *Current Science*, *supra*, note 3, at 168.

<sup>123</sup> *Id.*, at 168.

1999 research, which demonstrated that nearly half of the monarch butterfly caterpillars that ate leaves dusted with transgenic Bt Maize pollen died within 4 days.<sup>124</sup> The highly controversial research prompted further research funded by industry and governments, and by 2001, six research papers had been published, which effectively neutered the 1999 research by concluding that most common types of Bt. maize pollen were not toxic to monarch larvae in concentrations that the insects would encounter in the wild, and that Losey and colleagues had used higher concentrations of Bt. maize pollen for their laboratory research.<sup>125</sup>

Furthermore, there are abiding suspicions that research results are routinely skewed in favour of funding industry or agency. For example, the strong pro-transgenic crops stance of The Royal Society, (the UK national academy of science and the world's oldest scientific organisation, which was founded in 1660), has been attributed to the alleged millions of pounds in funding from major agricultural biotechnology companies.<sup>126</sup> Also, there are concerns that industry scientists, who conduct safety assessments of new transgenic crops for government on a voluntary basis, are usually unwilling to submit their research for wider scientific review.<sup>127</sup>

Most significantly, opposition to transgenic plant research and agriculture sometimes borders on threats of actual harm to person and property. Indeed, several research institutes have had their experimental transgenic plant fields picketed, threatened and physically trashed. For instance, in 2012, anti-transgenic plant agriculture activists rallied against, and threatened to thrash an open transgenic wheat trial fields at Hertfordshire in England, where scientists were experimenting with genetically engineered wheat plant that could resist aphid pests.<sup>128</sup>

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<sup>124</sup> See John E. Losey, Linda S. Rayor, and Maureen E. Carter, "Transgenic pollen harms monarch larvae," *Nature*, Volume 399, (20 May 1999), at 214.

<sup>125</sup> See J. Mark Scriber, "Bt or not Bt: Is that the question?" *Proceedings of the National Academy of Sciences of the United States of America*, Volume 98, Number 22, (23 October, 2001), at 12328-12330.

<sup>126</sup> See Andy Rees, *Genetically Modified Food: A short Guide for the Confused*, *supra*, note 118, at 43-44.

<sup>127</sup> See Paul R. Billings and Peter Shorett, "Coping with Uncertainty: The Human Health Implications of GE Foods," in Iain E. P. Taylor, (editor), *Genetically Engineered Crops: Interim Policies, Uncertain Legislation*, (New York: Haworth Food & Agricultural Products Press, (2007), at 75- 86.

<sup>128</sup> See Clive Cookson, "Food Battle Looms on Hertfordshire Fields," *Financial Times*, (25 May, 2012), available at <http://www.ft.com/cms/s/0/e69684d2-9cf1-11e1-9327-00144feabdc0.html>. (Accessed on 14 May 2015).

Moreover, transgenic crops scientists are known to have succumbed to sustained intimidations and pressures to terminate open field trials of promising transgenic crops. For example in 2008, two German universities were forced to discontinue open field trials of transgenic maize crops, due to aggressive picketing and threats from anti-transgenic agriculture activists, who had allegedly the full support of the local population.<sup>129</sup>

Also, whilst constructive criticisms of scientific research are an integral and validating feature of the peer-review system, the rejoinders and scathing criticisms routinely levelled by scientists against research perceived as unfavourable, often bordered on the personal, and are sometimes ad hominem, questioning researchers' credibility, integrity, and ability.<sup>130</sup> For example, David Schubert, a cell biologist at the Salk Institute in La Jolla, California, was pilloried for his 2002 commentary in *Nature Biotechnology Journal*, which opined that sufficient attention was not being paid to the potential unintended molecular effects and implications of inserting novel genes into plant cell.<sup>131</sup> David Schubert later reflected on the perils of transgenic plant research by noting that "people who look into safety issues and pollination and contamination issues get seriously harassed."<sup>132</sup>

In a related development, an attempt was made to suppress the publication of Bruce Tabashnik's 2008 paper, on how the evolution of insect resistance threatened the success of transgenic crops producing *Bacillus thuringiensis* (Bt.) toxins designed to combat traditional pests such as the European corn borer.<sup>133</sup> Prior to the publication of the paper, Bruce Tabashnik had received an email from William Moar, an entomologist at Auburn University, warning that

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<sup>129</sup> See Quirin Schiermeiser, "German Universities Bow to Public Pressure Over GM Crops," *Nature*, Volume 453, (14 May 2008), at 263.

<sup>130</sup> See Emily Waltz, "GM Crops: Battlefield: Papers suggesting that biotech crops might harm the environment attract a hail of abuse from other scientists," *Nature*, *supra*, note 3, at 27.

<sup>131</sup> See David Schubert, "A different Perspective on GM Food", *Nature Biotechnology*, Volume 20, (2002), at 969.

<sup>132</sup> Cited in Emily Waltz, "GM Crops: Battlefield: Papers suggesting that biotech crops might harm the environment attract a hail of abuse from other scientists," *Nature*, *supra*, note 3, at 27.

<sup>133</sup> See Bruce E. Tabashnik, Aaron G. Gasmann, David W. Crowder, and Yves Carriere, "Insect Resistance to Bt Crops: Evidence Versus Theory," *Nature Biotechnology*, Volume 26, (7 February, 2008), at 199-202).

the paper would give anti-transgenic crops brigade the ammunition to attack the technology.<sup>134</sup> However, following the publication of the paper in *Nature Biotechnology Journal* in February 2008, William Moar, (who had since swapped academia for the laboratory of Monsanto, a transgenic Bt crops manufacturer based in St Louis, Missouri, USA), criticised the paper at conferences,<sup>135</sup> and in a swift rejoinder to *Nature Biotechnology Journal*,<sup>136</sup> challenged the methodology, validity, accuracy, and reliability of Bruce Tabashnik's paper, on grounds inter alia, that the conclusions were scientifically unsound because they were based on laboratory measurements, rather than on field studies, where proof of insect resistance could be best measured and assessed.<sup>137</sup>

Similarly, Rosi-Marshall's paper on the negative effects of transgenic Bt. maize on caddisfly larvae and the ecosystems was greeted by hostile and ad hominem rebuttals.<sup>138</sup> The Rosi-Marshall paper was critically panned by fellow scientists who branded her two-year research as "bad science",<sup>139</sup> with accompanying, albeit unfounded insinuations of scientific misconduct.<sup>140</sup> Rosi-Marshall, who was then a stream ecologist at Loyola University Chicago, Illinois, and her colleagues, had spent two years studying twelve streams in northern Indiana, where transgenic Bt. maize designed to express insecticidal toxins from *Bacillus Thuringiensis*, was extensively cultivated.<sup>141</sup> Rosi-Marshall and colleagues then discovered that the twelve streams under study were strewn with leaves, pollen, stalks, and cobs from transgenic Bt.

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<sup>134</sup> See Emily Waltz, "GM Battlefield: Papers suggesting that biotech crops might harm the environment attract a hail of abuse from other scientists," *Nature*, *supra*, note 3, at 31.

<sup>135</sup> *Id.*, at 32.

<sup>136</sup> See William Moar, Rick Roush, Anthony Sheldon, Juan Ferre, Susan MacIntosh, B Rogers Leonard, and Craig Abel, "Field-evolved Resistance to Bt Toxins," *Nature Biotechnology*, Volume 26, (2008), at 1072-1074.

<sup>137</sup> *Id.*

<sup>138</sup> See E.J. Rosi-Marshall, J.L. Tank, T.V. Royer, M.R. Whiles, M. Evans-White, C. Chambers, N.A. Griffiths, J. Pokelsek, and M.L. Stephen, "Toxins in Transgenic Crop By-products May Affect Headwater Stream Ecosystems," *Proceedings of the National Academy of Sciences of the United States of America*, Volume 104, Number 41, (October 9, 2007), at 16204-16208.

<sup>139</sup> See Emily Waltz, "GM Battlefield: Papers suggesting that biotech crops might harm the environment attract a hail of abuse from other scientists," *Nature*, *supra*, note 3, at 27-30.

<sup>140</sup> *Id.*, at 28-29.

<sup>141</sup> *Id.*, at 27.

maize.<sup>142</sup> In subsequent laboratory studies, the researchers found that caddis-fly larvae (herbivorous stream insects) that “fed only on Bt. maize debris, grew half as fast as those that ate debris from conventional maize”.<sup>143</sup> Furthermore, caddis-flies that were “fed with high concentrations of Bt maize pollen died at more than twice the rate of caddis-flies that were fed with non-Bt pollen”.<sup>144</sup> Rosi-Marshall and colleagues then summed-up their research by concluding that transgenic Bt. maize “may have negative effects on the biota of streams in agricultural areas,” and that “widespread planting of Bt. crops has unexpected ecosystem-scale consequences.”<sup>145</sup>

Significantly, the Rosi-Marshall paper was not the first to study the possible deleterious effects of transgenic Bt. crops on the environment and the ecosystems. There had been numerous previous studies on the possible negative effects of transgenic crops on the environment, which included a 1999 German publication that was based on the first ever field study, and which provided prima facie evidence that transgenic DNA had transferred from genetically modified sugar-beet plant debris into soil bacteria.<sup>146</sup>

Even so, the ensuing negative rejoinders and hostile rebuttals to the Rosi-Marshall paper in half-a-dozen letters sent to the editor of the *Proceedings of the National Academy of Sciences of the United States of America*, by a dedicated alliance of pro-transgenic plant scientist and researchers, was at once predictable, lacerating, and ad hominem.<sup>147</sup> Amongst numerous pejoratives deployed in the negative rebuttals, the Rosi-Marshall paper was branded as a “sloppy experimental design” that was “so bad that an undergrad would have done a better

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<sup>142</sup> Id.

<sup>143</sup> Id.

<sup>144</sup> Id; E.J. Rosi-Marshall, et al., “Toxins in Transgenic Crop By-products May Affect Headwater Stream Ecosystems,” *Proceedings of the National Academy of Sciences of the United States of America*, *supra*, note 137, at 16204-16208.

<sup>145</sup> Id, at 16208.

<sup>146</sup> See Frank Geghard, And Kornelia Smalla, “Monitoring Field Releases of Genetically Modified Sugar Beets for persistence of Transgenic Plant DNA and Horizontal Gene Transfer,” *FEMS Microbiology Ecology*, Volume 28, Issue 3, (1999), at 261-272.

<sup>147</sup> See Emily Waltz, “GM Battlefield: Papers suggesting that biotech crops might harm the environment attract a hail of abuse from other scientists,” *Nature*, *supra*, note 3, at 27.

job.”<sup>148</sup> Also, the paper was branded as “an idiotic experiment”,<sup>149</sup> whilst its conclusions were described as “dubious” and “arguably amounts to investigator misconduct.”<sup>150</sup> In a related attack in the journal of *Current Science*, the Rosi-Marshall paper was described as “offending” and liable to be used by anti-transgenic plant agriculture activists to “hamper the progress of science.”<sup>151</sup>

But then, the hostile response to the Rosi-Marshall paper was typically predictable and characteristic of the increasingly negative tactics by scientists and researchers, who often “forcefully present themselves as the ultimate arbiters of truth.”<sup>152</sup> The *modus operandi* of the characteristically hostile and negative nature of the rebuttals against research perceived as unfavourable to transgenic plant agriculture was aptly summed up by Emily Waltz thus:

No one gets into research on genetically modified (GM) crops looking for a quiet life. Those who, like Rosi-Marshall and her colleagues, suggest that biotech crops might have harmful environmental effects are learning to expect attacks of a different kind. These strikes are launched from within the scientific community and can sometimes be emotional and personal; heated rhetoric that dismisses papers and can even, as in Rosi-Marshall’s case, accuse scientists of misconduct.<sup>153</sup>

However, it has been noted that pre-emptive attacks against unfavourable transgenic plant research outputs with perceived flaws are ostensibly designed to counter any possible influence on policy makers.<sup>154</sup> This strategy was however justified by Brian Federici, an insect pathologist at the University of California, Riverside, on grounds that “bad science deserves more criticism than your typical peer-reviewed paper”.<sup>155</sup>

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<sup>148</sup> Id, at 28.

<sup>149</sup> Id, at 32.

<sup>150</sup> Id, at 28-29.

<sup>151</sup> See Shantharam, S., Sullia, S. B. & Shivakumara Swamy, G. “Peer Review Contestations in the Era of Transgenic Crops”, *Current Science*, *supra*, note 3, at 168.

<sup>152</sup> See Emily Waltz, “GM Battlefield: Papers suggesting that biotech crops might harm the environment attract a hail of abuse from other scientists,” *Nature*, *supra*, note 3, at 31, (citing an editor for the Entomological Society of America).

<sup>153</sup> Id, at 27.

<sup>154</sup> Id, at 28.

<sup>155</sup> Id, at 27.

But it would seem that pre-emptive attacks on disputed scientific research are needless, because flawed scientific research papers would surely become apparent over time, whether or not the research favoured transgenic plant agriculture. After all, numerous published biomedical and life-science research papers have been retracted over the past decades on grounds that range from error, plagiarism, to fraud. For example, between 1975 and 2012, a total of 2,047 biomedical and life-science research articles were allegedly retracted on grounds that ranged from error, fraud, to misconduct.<sup>156</sup> Therefore, the characteristically partisan and hostile rebuttals of research perceived unfavourable is hardly warranted, and would only serve to aggravate the deepening divide and acrimony between scientists and stifle credible and beneficial scholarship on transgenic plant agriculture.

Most importantly, the ongoing squabbles amongst scientists on the safety science of transgenic plant technology could further reinforce the uncertainties on its propriety, heighten the perception of its risks for the environment and public health, and foster discordant coexistence policy and governance systems amongst countries. For example, despite the strenuous and concerted efforts made by other scholars to discredit the Rosi-Marshall paper in the eyes of regulatory authorities, the research nevertheless gained some traction and has some influence on policy makers in Europe, particularly in France, where the paper was referenced and relied upon by the French authority, as evidence of possible deleterious effects of Bt. crops on wildlife, and as a justification for banning the cultivation of Monsanto's Bt. maize (MON810) in France in January 2008,<sup>157</sup> even though the crop had been approved by the European Commission following rigorous risk assessment procedures.

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<sup>156</sup> See Ferric C. Fang, R. Grant Steen, and Arturo Casadevall, "Misconduct accounts for the majority of retracted scientific publications," *The Proceedings of the National Academy of Sciences*, ((1 October, 2012), at 1-6.

<sup>157</sup> See Emily Waltz, "GM Crops: Battlefield: Papers suggesting that biotech crops might harm the environment attract a hail of abuse from other scientists," *Nature*, *supra*, note 3, at 32.

Similarly, Germany discontinued commercial transgenic maize cultivation in 2009, and the total area of European transgenic maize hectares decreased from 100,000 to 95,000,<sup>158</sup> although it was unclear whether the German decision was influenced by the Rosi-Marshall paper. Apart from the French authorities, no other European government was known to have expressly relied on the Rosi-Marshall paper, whilst Spain continued to be the largest transgenic maize grower with 80 percent of the total transgenic Bt. maize area in Europe.<sup>159</sup> However, the Rosi-Marshall paper would appear to have been largely ignored by the Canadian and U.S regulatory authorities.

Thus, within the context of the relevance and significance of "science" for the coexistence policy, the French government's overt reliance on the Rosi-Marshall paper, arguably underscores the visceral hold of "science" over policy and regulatory framework for transgenic crops, and the dramatic transformation of "science" into an unwitting policy battleground for transgenic crops policy and governance stratagems. Most importantly, the disputed and contested safety science arguably heightens the perception of associated risks, and provides a compelling evidence for a coexistence policy that duly reflects the nature of risks posed by transgenic plant technology to non-transgenic plant agriculture, the environment, and public health: an adequate and effective liability and redress regime for possible economic, environmental and public health damage induced by the coexistence of transgenic and non-transgenic plant organisms. The structure and operational modalities for such a regime is the subject matter of Chapter Seven of the thesis.

#### **1.1.8. Research Problems and Rationale for Research.**

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<sup>158</sup> See Marta Czarnak-Klos and Emilio Rodriguez-Cerezo, "European Coexistence Bureau: Best Practice Documents for Coexistence of Genetically Modified Crops with Conventional and Organic Crop Farming," *European Commission /JTC Scientific and Technical Reports*, (2010), at 7.

<sup>159</sup> *Id.*



Given the widespread global adoption of transgenic plant agriculture by farmers;<sup>160</sup> the social, cultural, political, legal, economic and environmental imperatives for the parallel existence of organic and conventional systems of agriculture,<sup>161</sup> and the continuing dependency of the European animal feedstuff industry on transgenic crops as evidenced by the current sourcing of more than 70 percent of the European Union's protein-based animal feed from transgenic crops,<sup>162</sup> it is inevitable that transgenic plant agriculture must coexist with organic and conventional forms of agriculture. Therefore, ensuring the mutual coexistence of all forms of plant agriculture is as much about economic pragmatism, as about the socio-cultural and political imperatives for safeguarding global food security,<sup>163</sup> maximising the potentials and benefits of transgenic plant technology,<sup>164</sup> and guaranteeing consumers' choice.<sup>165</sup>

Even so, whilst reflecting on the necessity for the mutual coexistence of all forms of plant agricultural systems,<sup>166</sup> the coexistence policy framework in the European Union is not oblivious to the inherent frictions and tensions in the current coexistence paradigm, as evidenced by the Commission Recommendation of 13 July 2010, which summed-up the necessity, challenges and paradox of the current coexistence arrangements:

The cultivation of GMOs in the EU has implications for the organisation of agricultural production. On the one hand, the possibility of the unintended presence of genetically modified (GM) crops in non-GM crops (conventional and organic), raises the question as to how producer choice for the different production types can be ensured. In principle, farmers should be able to cultivate the types of agricultural crops they choose: be it GM crops, conventional or organic crops. This possibility should be combined with the wish of some farmers and operators to ensure that their crops have

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<sup>160</sup> See Clive James, *Global Status of Commercialized Biotech/GM Crops*, *supra*, note 1.

<sup>161</sup> See Per Pinstrup-Andersen and Ebbe Schiøler, *Seeds of Contention: World Hunger and the Global Controversy over GM Crops*, *supra*, note 116, at 32-56.

<sup>162</sup> See House of Commons Science and Technology Committee, *Advance Genetic Techniques for Crop Improvement: Regulation, Risk and Precaution*, *supra*, note 99 at 9.

<sup>163</sup> See Drew L. Kershen, "Trade and Commerce in Improved Crops and Food: An Essay on Food Security," *New Biotechnology*, Volume 27, Number 5, (5 November 2010), at 623-627; M.S. Swaminathan, "Achieving Food Security in Times of Crisis," *New Biotechnology*, Volume 27, Number 5, (5 November 2010), at 453-460.

<sup>164</sup> See Thomas Bernauer, *Genes, Trade, and Regulation: The Seeds of Conflicts in Food Biotechnology*, *supra*, note 3, at 28-30.

<sup>165</sup> See paragraph 1.1 of the Preamble to Commission Recommendation of 13 July 2010 on guidelines for the development of national co-existence measures to avoid the unintended presence of GMO in conventional and organic crops, *Official Journal of the European Union*, (22.7.2010. C 200/1).

<sup>166</sup> *Id.*

the lowest possible presence of GMOs.<sup>167</sup>

Thus, whilst tacitly acknowledging the inevitability of adventitious presence of transgenic organisms in non-transgenic crops, the 2010 Commission Recommendation reiterated the right of farmers to keep the percentage of transgenes in organic and conventional crops to the lowest minimum possible, and then proceeded to define “coexistence” in terms of the ability of farmers to make a practical choice between conventional, organic and transgenic crop production.<sup>168</sup> In effect, there could be no expectations by farmers that organic and conventional crops would be completely free from transgenic organisms, because the coexistence arrangements never guarantee a right to transgenic-free harvests for organic and conventional crops farmers as such. This, without a doubt, is tantamount to a radical re-conceptualisation of what organic and conventional crops are, and would also appear to contradict Article 4 (a) (iii) of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products, which defines organic production principles as excluding "the use of GMOs and products produced from or by GMOs with the exception of veterinary medicinal products."<sup>169</sup> Moreover, Article 9(1) of Council Regulation (EC) No 834/2007 expressly prohibits the use 'GMOs' in organic plant agriculture:

GMOs and products produced from or by GMOs shall not be used as food, feed, processing aids, plant protection products, fertilisers, soil conditioners, seeds, vegetative propagating material micro-organisms and animals in organic production.<sup>170</sup>

Furthermore, Article 2(c) of Council Regulation (EC) No 834/2007 defines "organic" as "coming from or related to organic",<sup>171</sup> whilst Article 2(a) of Council Regulation No 834/2007 defines "organic production" as "the use of production method compliant with the rules

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<sup>167</sup> Id.

<sup>168</sup> Id.

<sup>169</sup> See Council Regulation (EC) No 834/2007 on organic production and labelling of organic products, *Official Journal of the European Union*, 20.7.2007. L/189/1.

<sup>170</sup> Id.

<sup>171</sup> Id.

established in this Regulation, at all stages of production, preparation and distribution."<sup>172</sup> Moreover, Article 12(1) (i) of Council Regulation (EC) No 834/2007, which deals with organic plant production rules, requires that only "organically produced seed and propagating material shall be used" for organic plant cultivation.<sup>173</sup> These production rules are reiterated and elaborated upon in greater detail in Commission Regulation (EC) No 889/2008 on organic production and labelling of organic products with regards to organic production, labelling and control.<sup>174</sup> Thus, there is a difference between statutory definition of organic and organic plant agricultural production processes and the reality of coexistence. Arguably, this could be the price of "coexistence" exacted from organic and conventional farmers to accommodate transgenic crops, and foist on all farmers, an inclusive "coexistence" paradigm for all forms of plant agricultural systems. The enforced coexistence paradigm is exemplified in the UK by *R v. Secretary of State for the Environment and MAFF, ex parte Watson*, in which Guy Watson, a leading producer of organic vegetables and fruits, unsuccessfully objected to the trial of transgenic maize on a neighbouring farm by the National Institute of Agricultural Botany, on grounds of evidence of real risk for cross-pollination between the transgenic maize and his organic sweet corn. The Court of Appeal dismissed his concerns as premature, affirmed the high court's decision, and held inter alia that if damage did occur to his organic sweet corn due to cross-pollination, then Guy Watson could have a cause of action in private nuisance.<sup>175</sup>

Most significantly, the International Federation of Organic Agriculture Movements in the European Union (IFOAM), would appear to tacitly accept the dichotomy between statutory definition of organic plant production, and the reality of organic plant production on the fields,

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<sup>172</sup> Id.

<sup>173</sup> Id.

<sup>174</sup> See Article 36 of the Commission Regulation (EC) No 889/2008 of 5 September 2008, laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control, *Official Journal of the European Union*, 18.9.2008 L 250/1.

<sup>175</sup> See *R v. Secretary of State for the Environment and MAFF, ex parte Watson*, [1999], Environmental Law Report, at 310 -321.

when they made clear in a 2003 position paper on the coexistence paradigm, that transgenic organisms were not allowed in organic plant agriculture, and that there should be no traces of transgenes in organic crops, except in cases of adventitious presence.<sup>176</sup> Thus, the IFOAM tacitly acknowledged that whilst there could be no deliberate use of transgenic organisms in organic plant agriculture, their adventitious presence could not be completely ruled out.

In the United Kingdom, Council Regulation (EC) No 834/2007, and Commission Regulation (EC) No 889/2008, were implemented by The Organic Products Regulations 2009;<sup>177</sup> and The Organic Products (Amendment) Regulations 2010;<sup>178</sup> whilst the organic standards stipulated under Council Regulation 834/2007 were implemented by organised control bodies approved by the Department for Environment, Food and Rural Affairs (DEFRA) of Agriculture, comprising Ascisco, The Biodynamic Agriculture Association, Organic Farmers & Growers Ltd, The Organic Food Federation, Quality Welsh Food Certification, The Scottish Organic Producers Association, and The Soil Association Certification Limited.<sup>179</sup> In Northern Ireland, two organic control bodies comprising Irish Organic Farmers and Growers Association, and The Organic Trust were approved by Irish authorities.<sup>180</sup> These control bodies comprising organic certification associations have statutory roles of maintaining organic plant production standards stipulated in Articles 9, 10, 11 and 12 of Council Regulation (EC) No 834/2007,<sup>181</sup> as reiterated in greater detail in Commission Regulation (EC) No 889/2008,<sup>182</sup>

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<sup>176</sup> See International Federation of Organic Agriculture Movements - EU Regional Group, "Co-existence between GM and Non-GM Crops: Necessary Anti-contamination and Liability Measures," (Position Paper, October 2003), available at [http://www.ifoam.org/pospap/ge\\_position\\_0205.html](http://www.ifoam.org/pospap/ge_position_0205.html). (accessed on 14 May 2015).

<sup>177</sup> See The Organic Products Regulations 2009, No. 842.

<sup>178</sup> See The Organic Products (Amendment) Regulations 2010, No. 1902.

<sup>179</sup> See Guidance Document on European Union Organic Standards, (January 2010), available at <https://www.gov.uk/government/organisations/department-for-environment-food-rural-affairs> (accessed on 14 May 2015).

<sup>180</sup> *Id.*

<sup>181</sup> See Council Regulation (EC) No 834/2007 on organic production and labelling of organic products, *supra*, note 168.

<sup>182</sup> See Commission Regulation (EC) No 889/2008 of 5 September 2008, laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control, *supra*, note 173.

and implemented in the UK by The Organic Products Regulations 2009,<sup>183</sup> and The Organic Products (Amendment) Regulations 2010.<sup>184</sup> Therefore, the control bodies are fully aware that the statutory production standards for organic crops in the EU and the UK exclude the use of transgenic organisms, except in cases of adventitious commingling.

In the United States, the Department of Agriculture (USDA) is in charge of setting coexistence policy for transgenic and non-transgenic plant agriculture.<sup>185</sup> The USDA defines coexistence as "the concurrent cultivation of conventional, identity preserved, and genetically engineered crops consistent with underlying consumer preferences and farmer choices."<sup>186</sup> Thus, like the European Commission coexistence policy,<sup>187</sup> the USDA coexistence policy is about facilitating the choice of consumers and farmers. Also, the USDA regards all forms of plant agriculture as crucial to meeting domestic and global food needs, and therefore considers coexistence as critical to the success of U.S. plant agriculture.<sup>188</sup> The USDA also recognises the challenges of coexistence posed by the potential clashes of the right and ability of all farmers to cultivate their favoured crops, and the need to keep transgenes out of non-transgenic crops in the coexistence paradigm.<sup>189</sup> The USDA reiterates its policy drive to continue to increase awareness amongst farmers of the need for coexistence, as well as offer supports for coexistence of all forms of plant agriculture.<sup>190</sup>

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<sup>183</sup> See The Organic Products Regulations 2009, *supra*, note 176.

<sup>184</sup> See The Organic Products (Amendment) Regulations 2010, *supra*, note 177.

<sup>185</sup> See United States Department of Agriculture, "Agricultural Coexistence," available at <http://www.usda.gov/wps/portal/usda/usdahome?navid=coexistence> (accessed on 14 May 2015).

<sup>186</sup> See United States Department of Agriculture, "USDA Coexistence Facts Sheets: Conventional Farming," (February 2015), at <http://www.usda.gov/documents/coexistence-conventional-farming-factsheet.pdf> (accessed on 14 May 2015).

<sup>187</sup> See paragraph 1.1 of the Preamble to Commission Recommendation of 13 July 2010 on guidelines for the development of national co-existence measures to avoid the unintended presence of GMO in conventional and organic crops, *supra*, note 164.

<sup>188</sup> *Id.*; United States Department of Agriculture, "USDA Coexistence Facts Sheets: Crop Production Methods," (February 2015), at <http://www.usda.gov/documents/coexistence-crop-production-methods-factsheet.pdf> (accessed on 14 May 2015).

<sup>189</sup> *Id.*

<sup>190</sup> *Id.*

To this ends, there are clear definitions of organic crops and organic plant production processes, and clear policy on segregation methods for transgenic and non-transgenic plant agriculture under the Organic Foods Production Act 1990,<sup>191</sup> and National Organic Program Standards 2001.<sup>192</sup> The Organic Foods Production Act requires the USDA to develop national standards for organic products,<sup>193</sup> and establish an organic certification programme for producers and handlers of agricultural products that have been produced using organic methods.<sup>194</sup> Organic production is defined as "a production system that is managed in accordance with the Act and regulations...to respond to site-specific conditions by integrating cultural, biological, and mechanical practices that foster cycling of resources, promote ecological balance, and conserve biodiversity."<sup>195</sup>

Furthermore, the USDA National Organic Program establishes a national list of allowed and prohibited substances in the production of organic plant agriculture.<sup>196</sup> In order for a product to be labelled and sold as organically produced, it must have been produced without the use of synthetic chemicals, except as otherwise stated, and must not be produced on land to which any prohibited substances, including synthetic chemicals, have been applied during the 3 years immediately preceding the harvest of the agricultural products.<sup>197</sup> Significantly, section 2107(b)(1)(A)(C) of Organic Foods Production Act requires an organic farm or field area to be certified with a distinct, defined boundaries and buffer zones separating the farmland from neighbouring non-organic farmland. Also, appropriate physical facilities, machinery, and management practices must be established to prevent the possibility of a mixing of organic and non-organic products, or a penetration of prohibited chemicals or substances on the certified

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<sup>191</sup> See Organic Foods Production Act 1990, Title 21 of [Food, Agriculture, Conservation, and Trade Act of 1990](#), codified at Title 7, United States Code, Chap. 94, section 6504.

<sup>192</sup> See National Organic Program Standards, *Federal Register*, Volume 65, No 246, (Thursday 21 December 2001) / Rules and Regulations. Title 7 Code of Federal Regulations. 205.

<sup>193</sup> See section 2102(1), Organic Foods Production Act 1990, *supra*, note 187.

<sup>194</sup> See section 2104 (a), Organic Foods Production Act, *supra*, note 187.

<sup>195</sup> See section 205.2 National Organic Program, *supra*, note 188.

<sup>196</sup> See section 2105 (1) and (2), Organic Production Act 1990, *supra*, note 187.

<sup>197</sup> *Id.*

area.<sup>198</sup> Furthermore, the use of transgenic organisms in organic plant agriculture is expressly prohibited.<sup>199</sup>

Similarly, the USDA defines conventional farming as "the use of seeds that have been genetically altered using a variety of traditional breeding methods, excluding biotechnology, and are not certified organic."<sup>200</sup> However, the USDA also acknowledges commingling risks in the coexistence paradigm, and urges conventional farmers to manage the risks very well, by abiding by recommended best practices, if they intend to sell their crops at markets with specific requirements for conventionally grown crops.<sup>201</sup> The USDA recommended coexistence best practices for organic and conventional crop farmers, include: verifying seeds from suppliers to ensure they are not transgenic; establishment of good communication with neighbouring farmers; ascertaining which neighbours are cultivating transgenic crops; signposting fields as conventional or organic; setting up of physical barriers by isolation, wind breaks, and distance between transgenic crop fields and conventional or organic crop fields; coordinating planting dates with transgenic crop farmers to offset pollen drift; keeping harvesting and hauling vehicles clean or segregated to minimise commingling risks; keeping equipments, storage facilities and transportation unit clean or segregated; keeping good records; saving samples of seed, harvest crop and delivered crop; knowing biotech tolerances, if allowed, outlined in a contract.<sup>202</sup>

The USDA official and recommended best practices for transgenic crop farmers in the coexistence paradigm include: strict observance of buffer and refuge zones between transgenic and non-transgenic crops; establishment of good communication by neighbouring farmers to ascertain where transgenic; organic and conventional crops are cultivated; coordination of

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<sup>198</sup> See Section 2107(b) (1) (A) (C), Organic Foods Production Act, *supra*, note 187.

<sup>199</sup> *Id.*

<sup>200</sup> See United States Department of Agriculture, "USDA Coexistence Facts Sheets: Conventional Farming," (February 2015), *supra*, note 184.

<sup>201</sup> *Id.*

<sup>202</sup> *Id.*

planting dates with neighbouring farmers to minimise pollen drifts; spraying pesticides in correct weather conditions to avoid pesticide drift; cleaning equipments regularly, particularly if they could be used in multiple fields because dusts and grains could contaminate organic and conventional plant fields; keeping good records to ensure correct best management practices were taken, to help limit liability in case of adventitious commingling.<sup>203</sup>

Whilst the above recommended best practices for transgenic and non-transgenic plant farmers are not legally binding,<sup>204</sup> they could significantly impact any subsequent compensation claims in torts, if there was evidence of non-compliance with recommended best practices.<sup>205</sup> Also, it is clear that complying with the above recommended best practices could come at a cost to transgenic, conventional and organic crop farmers. However, whilst transgenic crop farmers might see the added costs of compliance with the recommended coexistence best practices as necessary externalities to the overall costs of transgenic plant agriculture, organic and conventional crop farmers might rightly see the added costs of compliance as unnecessary but inevitable burdens imposed by coexistence. Invariably, all farmers could pass on the costs of coexistence compliance to the consumers. It is also clear from the foregoing that the USDA, like the European Commission, regards adventitious commingling as an ever present threat in the coexistence paradigm.

However, whether all systems of plant agriculture could flourish equally in the current coexistence paradigm is highly debatable, given the predictable market scepticism of the policy re-conceptualisation or redefinition of organic and conventional crops in the European Union.<sup>206</sup> It is however arguable that the price of "coexistence" paid by organic and

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<sup>203</sup> See United States Department of Agriculture, "USDA Coexistence Facts Sheets: Best Practices," (February 2015), at <http://www.usda.gov/documents/coexistence-best-practices-factsheet.pdf> (accessed on 14 May 2015).

<sup>204</sup> *Id.*

<sup>205</sup> This point is analysed extensively in chapter five of the thesis.

<sup>206</sup> See paragraph 1.1 of the Preamble to Commission Recommendation of 13 July 2010 on guidelines for the development of national co-existence measures to avoid the unintended presence of GMO in conventional and organic crops, *supra*, note 164



conventional farmers, and ultimately by the consumers, could be for the greater good, in light of the continuing dependency of the European and US agricultural economy on transgenic plant technology.<sup>207</sup>

Even so, it would appear that the European Commission does not recognise the USDA recommended best practices for coexistence of transgenic and organic crops, because the United States was not amongst the list of third countries, whose organic crop production methods were deemed equivalent or comparable to that of the European Union standards.<sup>208</sup> Interestingly, the list of recognised bodies and control authorities from third countries, for the purposes of compliance with Article 32(2) of Regulation (EC) No. 834/2007,<sup>209</sup> include commercial transgenic crops growing countries such as Australia, Argentina, India, and New Zealand.<sup>210</sup>

Arguably, the exclusion of the United States from the list of third countries with comparable standards that could export organic crops to the European Union, could have serious economic implications for organic crops farmers in the United States, who, despite having presumably complied with the USDA recommended best practices for coexistence, might still not be able to access European markets. Although it is not made clear why the United States, whose organic market value for 2013 totalled more than US\$35 billion,<sup>211</sup> was excluded from the list, but it could be due to the preponderance of transgenic plant agriculture in the United States, and the inevitability of adventitious transgenes in organic production, possibly in excess of the

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<sup>207</sup> See House of Commons Science and Technology Committee, *Advance Genetic Techniques for Crop Improvement: Regulation, Risk and Precaution*, *supra*, note 99 at 9; United States Department of Agriculture, "USDA Coexistence Facts Sheets: Crop Production Methods," *supra*, note 186.

<sup>208</sup> See Commission Regulation (EC) No. 1235/2008 of December 2008 laying down detailed rules for implementation of Council Regulation (EC) No. 834/2007 as regards the arrangements for imports of organic products from third countries, *Official Journal of the European Union*, 12.12.2008 L334/25.

<sup>209</sup> See Council Regulation (EC) No 834/2007 on organic production and labelling of organic products, *supra*, note 168.

<sup>210</sup> See Annex III, Commission Regulation (EC) No. 1235/2008 of December 2008 laying down detailed rules for implementation of Council Regulation (EC) No. 834/2007 as regards the arrangements for imports of organic products from third countries, *supra*, note 206.

<sup>211</sup> See United States Department of Agriculture, "USDA Coexistence Fact Sheets: Organic Farming," (February 2015), at <http://www.usda.gov/documents/coexistence-organic-farming-factsheet.pdf> (accessed on 14 May 2015).

statutory 0.9 labelling threshold in the European Union.<sup>212</sup> For example, in 2013, 93 percent of the 95 million acres cultivated with transgenic maize in the United States were transgenic,<sup>213</sup> whilst the 2008 Organic Production Survey showed that 1.6 million acres were reserved for organic crops in the United States.<sup>214</sup>

It is thus clear from the foregoing analysis of literature that the coexistence paradigm is far from a frictionless level-playing field utopia, where the advent of transgenic plant crops had no adverse economic effects on existing conventional and organic crops. Rather the reviewed literature shows how inherently disruptive transgenic plant technology is for existing plant agricultural systems, and the inherent costs of its advent for organic and conventional crops farmers. However, this is very typical of the disruptive nature of most technological advancements of the post-industrial risk society, and is not in any way peculiar to transgenic plant technology.<sup>215</sup> For whilst organic and conventional farmers theoretically had the "choice" to cultivate their crops in the coexistence paradigm, and the right to "wish" "to ensure that their crops have the lowest possible presence of GMOs",<sup>216</sup> these legitimate rights and aspirations are inherently constrained by the inevitability of adventitious presence of transgenes in non-transgenic crops, with concomitant economic, environmental, and public health implications.<sup>217</sup>

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<sup>212</sup> See Articles 12(2) and 24(2) of Regulation (EC) No. 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, *supra*, note 12.

<sup>213</sup> See United States Department of Agriculture, "USDA Coexistence Facts Sheets: Corn," (February 2015), at <http://www.usda.gov/documents/coexistence-corn-factsheet.pdf> (accessed on 14 May 2015).

<sup>214</sup> See United States Department of Agriculture, "USDA Coexistence Fact Sheets: Organic Farming," (February 2015), *supra*, note 209.

<sup>215</sup> See Ulrich Beck, *Risk Society: Towards a New Modernity*, *supra*, note 7, at 51-84; Anthony Giddens, "Risks and Responsibility," *Modern Law Review*, *supra*, note 7, at 1-10; Taiwo A. Oriola, "The Limits of Regulatory Science in Transnational Governance of Transgenic Plant Agriculture and Food Systems," *North Carolina Journal of International Law and Commercial Regulation*, Volume 39, Number 3, (Spring 2014), at 758-779.

<sup>216</sup> See paragraph 1.1 of the Preamble to Commission Recommendation of 13 July 2010 on guidelines for the development of national co-existence measures to avoid the unintended presence of GMO in conventional and organic crops, *supra*, note 164.

<sup>217</sup> See David Lee and Ellen Natesan, "Evaluating genetic containment strategies for transgenic plants," *TRENDS in Biotechnology*, *supra*, note 8, at 109-114.

However, in the European Union, the mere presence of transgenes in organic or conventional crops would not automatically exclude organic and conventional farmers from non-transgenic crops market, provided the percentage of adventitious transgenic organisms in their crops was below the 0.9 percent statutory minimum labelling threshold.<sup>218</sup> Even so, meeting the minimum statutory labelling threshold might not automatically guarantee access to the non-European transgenic crops markets with different coexistence rules and criteria for what should constitute organic or conventional crops, as exemplified by the denial of US organic crops farmers, of automatic market entry into the European Union.<sup>219</sup> Thus, organic and conventional crops farmers could still incur economic loss if they were barred from international non-transgenic crops markets, even if the EU statutory 0.9 percent minimum labelling threshold was met. In the European Union, this scenario is indeed envisaged by the July 2010 Commission Recommendation on Coexistence, which acknowledged that: "... the presence of traces of GMOs in particular food crops - even at a level below 0.9% - may cause economic damages to operators who would wish to market them as non-containing GMOs."<sup>220</sup> Thus, the inevitability of economic loss for conventional and organic farmers, irrespective of whether their harvests exceed the minimum 0.9 percent transgenes contents, highlights the perennial nature of the tensions and conflicting rights in the coexistence paradigm, and the imperatives for adequate and effective compensation regimes that duly reflect the underlying tensions and conflicts of coexistence.

It was perhaps the inevitability of adventitious transgenes in non-transgenic crops, the concomitant economic loss, and the complexity of the coexistence rules that prompted the

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<sup>218</sup> See Articles 12(2) and 24(2) of Regulation (EC) No. 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, *supra*, note 12.

<sup>219</sup> See Annex III, Commission Regulation (EC) No. 1235/2008 of December 2008 laying down detailed rules for implementation of Council Regulation (EC) No. 834/2007 as regards the arrangements for imports of organic products from third countries, *supra*, note 206.

<sup>220</sup> See paragraph 1.1 of the Preamble to Commission Recommendation of 13 July 2010 on guidelines for the development of national co-existence measures to avoid the unintended presence of GMO in conventional and organic crops, *supra*, note 164.

European Commission to devolve coexistence authority to Member States? The July 2010 Commission Recommendation on Coexistence granted Member States the flexibility to take into account, their regional and national conditions in the formulation of coexistence rules and measures that could pre-empt adventitious presence of transgenic organisms in conventional and organic crops.<sup>221</sup>

Farm structures and farming systems, and the economic and natural conditions under which farmers in the European Union operate, are extremely diverse. The diversity of farming systems and natural and economic conditions in the EU needs to be taken into consideration when designing measures to avoid the unintended presence of GM crops in other crops.<sup>222</sup>

However, whilst the devolution of coexistence authority no doubt empowers national governments to take into consideration the peculiarities of their economic, environmental and farming systems in the crafting of coexistence rules, it inadvertently ensures the possibility that national coexistence rules in one Member State could invariably defer from the national coexistence rules in another Member State. Whilst this is not necessarily a bad thing, it could potentially strengthen existing disparate national liability and redress regimes, with concomitant economic and legal ramifications for the European single market system that has been the primary driver for harmonisation of EU laws since the establishment of the European Union. It is the central argument of the thesis that the absence of a harmonised liability and redress regime across the EU Member States, and amongst nations trading in transgenic plant technological products, undermines the effectiveness of the current national and transnational coexistence rules on compensation regimes for inherent damage in the coexistence paradigm.

Furthermore, coexistence rules are much more than regulation and policy, and include technical specifications that range from the type of crops, desirable segregation distances, climatic conditions, presence or absence of transgenic crops' wild relatives, etc. For example,

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<sup>221</sup> See paragraph 2, *id.*

<sup>222</sup> *Id.*

technical specifications for coexistence rules for transgenic maize, which is predominantly cultivated in the European Union,<sup>223</sup> do defer from the technical specifications for the coexistence rules for transgenic soybean.<sup>224</sup>

With regards to transgenic maize for example, statistical analysis of different field trials revealed that segregation or isolation distance of between 30 metres between non-transgenic field, resulted in cross-fertilisation value below the 0.9 percent statutory labelling threshold under the EU laws.<sup>225</sup> Also, cultivating transgenic and non-transgenic maize on different "planting dates" of up to 10 days apart, could reduce cross-fertilisation incidents by up to 65 percent.<sup>226</sup> Moreover, field studies have shown that cross-fertilisation greatly depend on wind conditions, and that wind direction and speed have strong influence on cross-fertilisation rates at certain distances.<sup>227</sup> However, with regards to soybean, a French case study showed that keeping adventitious presence of transgenes below the 0.9 minimum statutory labelling threshold, required a segregation distance of 10 metres between transgenic and non-transgenic soybean fields.<sup>228</sup> However, in Canada, the approved segregation distance of 3 metres between transgenic and non-transgenic soybean fields, was adjudged sufficient market requirements for keeping adventitious transgenes in non-transgenic soybean to between 0.5 and 0.1 percent.<sup>229</sup> It is thus clear that technical specifications for coexistence rules would defer from one crop to another, and even from one country to another.

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<sup>223</sup> See Petra Kozjak, Jelka Sustar-Volzlic and Vladimir Meglic, "Adventitious Presence of GMOs in Maize in the View of Coexistence," *Acta Agriculturae Slovenica*, Volume 97, (3 September 2011), at 275-284.

<sup>224</sup> See European Coexistence Bureau, "Best Practice Document: Coexistence of Genetically Modified Soybean Crops with Conventional and Organic Farming," Plenary Meeting of the Advisory Group on Food Chain, Animal and Plant Health, Brussels, (12 December 2014), at [www.jrc.ec.europa.eu](http://www.jrc.ec.europa.eu). (accessed on 14 May 2015).

<sup>225</sup> See Petra Kozjak, Jelka Sustar-Volzlic and Vladimir Meglic, "Adventitious Presence of GMOs in Maize in the View of Coexistence," *supra*, note 221, at 278.

<sup>226</sup> *Id.*

<sup>227</sup> *Id.*

<sup>228</sup> See European Coexistence Bureau, "Best Practice Document: Coexistence of Genetically Modified Soybean Crops with Conventional and Organic Farming," *supra*, note 222.

<sup>229</sup> *Id.*

In the European Union, although coexistence authority is devolved to Member States, the European Coexistence Bureau seeks to harmonise technical specifications for coexistence rules, by facilitating the exchange and dissemination of technical and scientific information on best agricultural management practices for coexistence to Member States, whilst simultaneously ensuring that crop-specific guidelines allow for sufficient flexibility that would allow Member States to take into account, their regional and local factors, such as share of different crops in cultivation, crop rotation, field sizes, etc.<sup>230</sup> The technical and scientific information includes segregation measures and other measures that could minimise potential cross-border problems in the coexistence paradigm.<sup>231</sup>

In the United States, the US Department of Agriculture (USDA), through the office of Biotechnology Regulatory Services (BRS) of the Animal and Plant Health Inspection Service (APHIS), is responsible for transgenic plant agriculture policy oversight.<sup>232</sup> Therefore the USDA sets and oversees the ground rules for the release of transgenic crops into the environment,<sup>233</sup> which include technical information on segregation rules for transgenic and non-transgenic crops.<sup>234</sup> For example, the recommended separation distance between transgenic maize and regulated plants that are allowed to pollinate openly is 660 feet or 201.17 metres.<sup>235</sup> This defers dramatically from the 30 metres separation distance requirement for maize in the European Union.<sup>236</sup> With regards to transgenic soybean, the recommended

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<sup>230</sup> See European Commission, Joint Research Centre, Institute for Prospective Technological Studies, at <http://ecob.jrc.ec.europa.eu/about.html> (accessed on 14 May 2014).

<sup>231</sup> *Id.*

<sup>232</sup> See Alan McHughen and Stuart J. Smyth, "Regulation of Genetically Modified Crops in USA and Canada: American Overview," in Chris A. Wozniak and Alan McHughen, (editors), *Regulation of Agricultural Biotechnology: The United States and Canada*, (Heidelberg, New York & London: Springer, 2013), at 4146.

<sup>233</sup> See section 340 (a) & (b), *Federal Register*, Volume 52, 22908, (June 1987).

<sup>234</sup> See USDA and Biotechnology Services, "Minimum Separation Distances to Be Used for Confined Field Tests of Certain Genetically Engineered Plants," available at [http://www.aphis.usda.gov/biotechnology/downloads/sep\\_dist\\_table\\_0813.pdf](http://www.aphis.usda.gov/biotechnology/downloads/sep_dist_table_0813.pdf). (August 2013), (accessed on 14 May 2015).

<sup>235</sup> *Id.*

<sup>236</sup> See Petra Kozjak, Jelka Sustar-Volzlic and Vladimir Meglic, "Adventitious Presence of GMOs in Maize in the View of Coexistence," *supra*, note 221, at 278.

separation distance is 10 feet or 3.05 metres, in order to prevent mechanical mixing during agricultural operations.<sup>237</sup> Again, this defers greatly from the recommended 10 metre separation distance for the French soybean field trial,<sup>238</sup> but closer to the 3 metres segregation distance for soybean field trial in Canada.<sup>239</sup> Thus, a comparison of the recommended separation distances between transgenic and non-transgenic crops in North America and the European Union shows considerable differences, and the latter would appear to be more stringent than the former. However, the differences could also be explained by the fact that technical information on segregation distances and coexistence measures must, of necessity, account for the peculiarities of national environmental dispositions, climatic conditions, wind direction, wind speed, type or nature of neighbouring crops, etc.<sup>240</sup>

Even so, compliance with technical segregation distance measures does not guarantee absence of adventitious transgenes in non-transgenic crops, and this could impinge on the adequacy of the fault-based liability regime in torts law, and make strict liability regime a more attractive compensation regime in the circumstances.<sup>241</sup> Indeed, the International Federation of Organic Agriculture Movements in Europe, had urged the European regulatory authorities in their 2003 position paper to recognise the inevitability of adventitious presence of transgenes in organic crops, the concomitant economic loss, and the imposition of a strict liability regime to compensate any consequential economic loss.<sup>242</sup>

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<sup>237</sup> See USDA and Biotechnology Services, "Minimum Separation Distances to Be Used for Confined Field Tests of Certain Genetically Engineered Plants," *supra*, note 188.

<sup>238</sup> See European Coexistence Bureau, "Best Practice Document: Coexistence of Genetically Modified Soybean Crops with Conventional and Organic Farming," *supra*, note 226.

<sup>239</sup> *Id.*

<sup>240</sup> See Petra Kozjak, Jelka Sustar-Volzlic and Vladimir Meglic, "Adventitious Presence of GMOs in Maize in the View of Coexistence," *Acta Agriculturae Slovenica*, *supra*, note 221, at 275-284.

<sup>241</sup> See Charles O. Gregory, "Trespass to Negligence to Absolute Liability," in David Campbell and Robert Lee, *Environmental Law and Economics Volume II*, (Aldershot, England & Burlington, USA: Ashgate, 2007), at 1-39. See generally the analysis and discussion in chapter five of the thesis on the viability of the law of torts as a compensation regime for damage induced in the coexistence paradigm.

<sup>242</sup> See International Federation of Organic Agriculture Movements - EU Regional Group, "Co-existence between GM and Non-GM Crops: Necessary Anti-contamination and Liability Measures," *supra*, note 174, at 3.

Moreover, even with all the technical segregation measures and rules in the coexistence paradigm, empirical evidence and recent case law from Europe and North America would suggest that the current coexistence arrangements for transgenic and non-transgenic plant agriculture and products is fraught with existential conflicts, with concomitant legal battles that stemmed primarily from adventitious presence of transgenes in conventional and organic crops and the environment. For example, proteins from transgenic pharmaceutical corn primarily designed to rid piglets of diarrhoea were discovered in transgenic soybean designed for human consumption in the United States in 2002.<sup>243</sup> Similarly, in 1998, StarLink corn, which was primarily approved for animal feed, and which was unsuitable for human consumption, was subsequently found in transgenic corn destined for the food chain in the United States and as far afield as Europe, South America and Japan.<sup>244</sup> There were consequential fears of possible adverse public health impacts in the United States, but subsequent blood tests proved inconclusive.<sup>245</sup> Also, there is a high propensity for adventitious cross-border genes flow between transgenic and non-transgenic crops, and between transgenic crops approved for livestock feeds, and transgenic crops approved for human consumption.<sup>246</sup> This is exemplified by the 2005 discovery in Europe and the United Kingdom, of unapproved Bt10 corn variety, which was mistakenly sold and exported from the United States, as the approved Bt11 corn variety.<sup>247</sup>

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<sup>243</sup> See Stephanie Simon, "Fearing a Field of Genes: The Food Industry loves engineered crops, but not when plants altered to 'grow' drugs and chemicals can slip into its products", *Los Angeles Times*, (23 December 2001), at 1.

<sup>244</sup> See Andy Rees, *Genetically Modified Food: A Short Guide for the Confused*, *supra*, note 118, at 69; Michael R. Taylor and Jody S. Tick, *The Starlink Case: Issues for the Future, A Report Commissioned by the Pew Initiative on Food Biotechnology*, (October 2001), at 1. [www.pweagbiotech.org](http://www.pweagbiotech.org) (accessed on 14 May 2015).

<sup>245</sup> See Jeffrey M. Smith, *Genetic Roulette: The Documented Health Risks of Genetically Engineered Foods*, *supra*, note 115, at 229 - 230.

<sup>246</sup> See Elena Angulo and Ben Gilna, "When Biotech Crosses Borders," *Nature Biotechnology*, *supra*, note 27, at 277-282; Carol Mallory-Smith and Maria Zapiola, "Gene Flow from Glyphosate-Resistant Crops," *Pest Management Science*, *supra*, note 27, at 428-440.

<sup>247</sup> See Jeffrey M. Smith, *Genetic Roulette: The Documented Health Risks of Genetically Engineered Foods*, *supra*, note 115, at 136.



Moreover, the scenario of adventitious gene flow in the coexistence paradigm and the consequential economic loss, was exemplified by *Karl Heinz Bablok and Others v. Freistaat Bayern and Others*, in which the Court of Justice of the European Union held that adventitious presence of proteins from Monsanto's transgenic maize pollens in the beehives of a Bavarian amateur commercial beekeeper, exceeded the statutory 0.9 percent labelling threshold, and had consequently transformed the honey harvested from the beehives into a transgenic variety. Consequently, prior authorisation was needed before the honey could be sold on to the general public.<sup>248</sup>

Therefore, to the extent that there are parallel and thriving organic and conventional crops markets in Europe and North America; and to the extent that organic and conventional crops have been essentially redefined to accommodate the inevitable adventitious presence of transgenes by 0.9 percent maximum threshold in the European Union; economic loss induced in circumstances analogous to *Karl Heinz Bablok Case* would continue to dog the coexistence paradigm, and nothing short of appropriate compensation regime could balance the rights of transgenic and non-transgenic crops farmers, assuage disgruntled farmers, and fulfil the European Commission and USDA's coexistence policy objective of facilitating and empowering consumers and farmers' choice in the coexistence paradigm.<sup>249</sup>

Furthermore, coexistence of transgenic and non-transgenic plant agriculture could precipitate patents infringement in proprietary transgenic seeds that strayed into a neighbouring farmland, if the neighbouring farmer cultivated the said transgenic seeds. This scenario would be tantamount to a use of patented technology without prior consent or authorisation of the patent proprietor, and is well exemplified by *Monsanto v. Schmeiser*, in which the Supreme

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<sup>248</sup> See *Karl Heinz Bablok and Others v. Freistaat Bayern and Others*, Case C-442/09 (6 September 2011).

<sup>249</sup> See paragraph 1.1 of the Preamble to Commission Recommendation of 13 July 2010 on guidelines for the development of national co-existence measures to avoid the unintended presence of GMO in conventional and organic crops, *supra*, note 164; United States Department of Agriculture, "USDA Coexistence Facts Sheets: Crop Production Methods," (February 2015), *supra*, note 186.

Court of Canada held inter alia that a non-transgenic soybean farmer was liable for patent infringement for cultivating adventitious transgenic soy seeds that he found growing on his farmland.<sup>250</sup>

The *Schmeiser Case* scenario is particularly worrisome because it potentially leaves neighbouring farmers vulnerable to expensive patents litigations. It is even more worrisome because of the strict liability nature of the patent system, and the absence of any legal defence mechanism or redress regime for non-transgenic plant farmers in the current coexistence policy paradigm.<sup>251</sup> Albeit a Canadian Supreme Court Judgment, and despite the presumed territoriality of national patent laws,<sup>252</sup> the decision in *Schmeiser Case* could potentially be replicated in the UK and EU Courts because of the harmonising effects of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights,<sup>253</sup> which sets a legally binding minimum level of patents protection for all trading partners,<sup>254</sup> and the provisions of which the Grand Chamber of the Court of Justice of the European Union held were compatible with European Community laws, and over which the Court held that it had jurisdiction in *Merck Genéricos Produtos Farmacêuticos v. Merck & Co. Inc.*<sup>255</sup> In effect, the provisions of the TRIPs Agreement is legally binding on Member States of the European Union,<sup>256</sup> and its globalising objective and transnational reach may have neutered the presumed territoriality of

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<sup>250</sup> See *Monsanto Canada Inc. v. Schmeiser*, [2004] 1. S.C.R. 902, and *Hoffman v. Monsanto Canada Inc. & Bayer CropScience Inc.*, [2005] (SKQB), at 225.

<sup>251</sup> See Maria Lee, and Robert Burrell, "Liability for the Escape of GM Seeds: Pursuing the 'Victim'?" *The Modern Law Review*, Volume 65, Issue 2, (2002), at 520.

<sup>252</sup> See James Ernstmeier, "Does Strict Territoriality Toll the End of Software Patents?" *Boston University Law Review*, Volume 89, (2009), at 1267-1303.

<sup>253</sup> See Articles 1 and 27-34 of the Agreement on Trade-Related Aspects of Intellectual Property Rights, 1994, at [https://www.wto.org/english/tratop\\_e/trips\\_e/t\\_agm3c\\_e.htm#5](https://www.wto.org/english/tratop_e/trips_e/t_agm3c_e.htm#5), (accessed on 14 May 2015).

<sup>254</sup> See *Canada Pharmaceutical Patents Case*, (WT/DS114/R, 17/03/2000); Taiwo A. Oriola, "Against the Plague: Exemption of Pharmaceutical Patent Rights as a Biosecurity Strategy," *University of Illinois Journal of Law, Technology & Policy*, Volume 2007, Issue 2, (Fall 2007), at 317-337.

<sup>255</sup> See *Merck Genéricos Produtos Farmacêuticos v. Merck & Co. Inc.* (Case C-431/05).

<sup>256</sup> See Sujitha Subramanian, "EU Obligation to the TRIPs Agreement: EU Microsoft Decision," *The European Journal of International Law*, Volume 21 Number 4, (2011), at 997-1023.

national patents laws.<sup>257</sup> Besides, Monsanto and other multinational transgenic seeds firms routinely register their patents in multiple jurisdictions, including the European Union in order to defeat possible patent territoriality defence to patent infringements.<sup>258</sup>

With regards to the impacts of transgenic plant agriculture on the environment, recent scientific papers, albeit disputed, have indicated that proteins from *Bacillus Thuringiensis*, which was an integral component of all commercial transgenic Bt. crops currently on the market, could be deleterious to other microorganisms in the ecosystem and the environment.<sup>259</sup> Furthermore, scientists and experts have expressed concerns that transgenic plant technology, which currently comprises a handful of purposed-made *Bacillus thuringiensis* transgenic seeds, could foster a mono-cultural plant agricultural system, impinge on crop variety diversity, and precipitate genetic erosion, with concomitant negative implications for plant biodiversity and global food security.<sup>260</sup> For example, Mauricio Bellon et al argued that the introduction of transgenic maize with multiple transgenes into Mexico, which has been a centre of maize domestication and diversity for centuries, could threaten the diversity of local maize populations, unless a procedure was in place to ensure reversibility.<sup>261</sup> However, Vijesh Krishna et al hypothesised that transgenic plant technology could preserve crops varietal

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<sup>257</sup> See Alexander Peukert, "Territoriality and Extraterritoriality in Intellectual Property Law," in Gunther Handl & Joachim Zekoll, (editors), *Beyond Territoriality: Transnational Legal Authority in An Age of Globalization*, (Leiden/Boston: Brill Academic Publishing, 2012), at 189-227.

<sup>258</sup> For example in 2011, Monsanto was granted a patent by the European Patent Office in Munich for melon plants that were resistant to a virus. The patent covered the modified plant, part of the plant and seeds, but not the breeding process. See European Patent Specification, "Closterovirus-Resistant Melon Plants", at <https://data.epo.org/publication-server/pdf-document?pn=1962578&ki=B1&cc=EP> (accessed on 14 May 2015).

<sup>259</sup> See E.J. Rosi-Marshall, J.L. Tank, T.V. Royer, M.R. Whiles, M. Evans-White, C. Chambers, N.A. Griffiths, J. Pokelsek, and M.L. Stephen, "Toxins in Transgenic Crop By-products May Affect Headwater Stream Ecosystems," *Proceedings of the National Academy of Sciences of the United States of America*, *supra*, note 137, at 16204-16208.

<sup>260</sup> See Eric Holt-Giménez & Miguel A. Altieri, "Agroecology, Food Sovereignty, and the New Green Revolution," *Agroecology and Sustainable Food Systems*, Volume 37, Issue 1, (2013), at 90-102; Mauricio R. Bellon and Julien Berthaud, "Transgenic Maize and the Evolution of Landrace Diversity in Mexico: The Importance of Farmers' Behavior," *Plant Physiology*, Volume 134, (2004), at 883-888.

<sup>261</sup> See Mauricio R. Bellon and Julien Berthaud, "Transgenic Maize and the Evolution of Landrace Diversity in Mexico: The Importance of Farmers' Behavior," *Plant Physiology*, *id*, at 885.

diversity if farmers had access to and cultivated more transgenic crops varieties, but noted that this was unlikely in places where there were restrictions on transgenic plant agriculture.<sup>262</sup>

Moreover, there is no scientific consensus on possible risks of transgenic plant technology for human health, which range from toxicity, allergenicity, antibiotic immunity, to chemical reactions to human cell.<sup>263</sup> And as noted in section 1.1.7 of the thesis, the blood test results of people who allegedly fell ill following the consumption of foods containing StarLink corn meant to cure diarrhoea in piglets, proved inconclusive for any known links to the alleged illness, amidst allegations of critical data suppression by Aventis Corporation.<sup>264</sup> Thus, the prevailing scientific uncertainties and acrimonious claims and counter-claims by scientists on the proprieties of transgenic plant technology for the environment and public health, have arguably exacerbated the perception of risk, and justified the imperatives for pragmatic and effective liability and redress regime.

Yet, the current national and transnational liability and redress regimes have failed to adequately address some of the existential conflicts highlighted in the preceding sections of the thesis. In the European Union, the decentralisation of the legal framework for liability and redress regimes in the EU coexistence policy framework,<sup>265</sup> could potentially increase the likelihood of disparate liability and redress regime within the EU single market, and the prospects for forum shopping by potential litigants. For example, whilst Austria has a statutory strict liability and redress regime under the Gene Technology Act,<sup>266</sup> England and Wales, Scotland and Northern Ireland have no special statutory liability regime for transgenic plant

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<sup>262</sup> See Vijesh Krishna, Martin Quam and David Zilberman, "Transgenic Crops, Production Risk and Agrobiodiversity," *European Review of Agricultural Economics*, (4 June 2015), at 1-28.

<sup>263</sup> See Reece Walters, *Eco Crime and Genetically Modified Food*, (Abingdon, Oxon, Routledge: 2011), at 30-31.

<sup>264</sup> See Jeffrey M. Smith, *Genetic Roulette: The Documented Health Risks of Genetically Engineered Foods*, *supra*, note 115, at 229 - 230.

<sup>265</sup> See Christopher Rodgers, "DEFRA's Coexistence Proposals for GM Crops: A Recipe for Confrontation?" *Environmental Law Review*, *supra*, note 15, at 1-8.

<sup>266</sup> See Manuela Weissenbacher, 'Damage Caused by GMOs under Austrian Law', in Bernhard A. Koch (ed.) *Damage Caused by Genetically Modified Organisms: Comparative Survey of Redress Options for Harm to Persons, Property or the Environment*, (Berlin/New York, Walter de Gruyter GmbH: 2010), at 2-10.

technology as such.<sup>267</sup> In England and Wales, the Department of Environment and Rural Affairs (DEFRA) would prefer that existing liability and redress regimes should address any consequential damage in the coexistence paradigm,<sup>268</sup> whilst Scotland and Northern Ireland currently have no liability and redress regime policy specifically for transgenic plant technology. The scenario of disparate compensation regimes is further complicated by Directive 2015/412 of March 2015, which allowed EU Member States to opt-out of transgenic plant organisms on grounds other than scientific evidence,<sup>269</sup> thus making it highly likely that Member States that opted-out could have more stringent liability and redress regime, than those that opted-in and embraced transgenic plant organisms and agriculture.

On the international level, the United Nations-sponsored liability and redress regime for transgenic organisms, which was agreed to in Japan and published in 2010 following six years of negotiations, failed to specify the character, nature and modalities for civil liability and redress regimes for possible damage from transgenic organisms.<sup>270</sup>

Most significantly, the insurance industry is reluctant to insure risks associated with transgenic plant agriculture. In fact, a survey carried out in the United Kingdom in 2003 found that insurers were equating risks associated with transgenic plant agriculture with risks posed by asbestos, thalidomide and acts of terrorism.<sup>271</sup>

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<sup>267</sup> In the UK, whilst existing civil and statutory liability regimes could theoretically afford remedies, there is as yet no statutory liability and redress regime specifically designed to address possible damage in the coexistence of transgenic and non-transgenic plant agriculture.

<sup>268</sup> See Christopher Rodgers, "Defra's Coexistence Proposals for GM Crops: A Recipe for Confrontation?" *supra*, note 15, at 1-8.

<sup>269</sup> See Directive (EU) 2015/412 of the European Parliament and of the Council, as regards the possibility of Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory, *supra*, note 101; Robert G. Lee, "Humming a Different Tune? Commercial Cultivation of GM Crops in Europe," *supra*, note 102.

<sup>270</sup> See Gurdial Singh Nijar, "The Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety: An Analysis and Implementation Challenges", *International Environmental Agreements: Policy, Law and Economics*, *supra*, note 15, at 271-290.

<sup>271</sup> See Paul Brown, "Insurers refuse to cover GM farmers: Leading companies liken risk to thalidomide and terrorism." *The Guardian*, (8 October, 2003) at 6.

Therefore, since commingling risks of transgenic and non-transgenic crops are currently perceived as uninsurable by the insurance industry, scholars have floated possible causes of action and remedies that ranged from contract, negligence, trespass, private nuisance, public nuisance, product liability to strict liability.<sup>272</sup> The thesis will critically evaluate the adequacy and viability of these remedies in the context of the laws of the United Kingdom, the European Union and the United States and Canada for comparative effects, and then recommend a framework for coherent and effective liability and redress regime for possible economic, proprietary, environmental and public health damage induced by adventitious admixture of transgenic and non-transgenic crops, and adventitious presence of unapproved transgenic organisms in approved transgenic plant organisms. This exercise would necessitate exploring the nature of liability emanating from adventitious presence of transgenes in the environment and the food chain, and the legal instruments for apportioning liability and remedying consequential economic and non-economic damage. The thesis will then propose a sui generis compensation regime that would complement existing liability regimes, with a view to balancing the conflicting rights in the coexistence paradigm.

#### **1.1.9. Research Hypotheses.**

The research is framed by two hypotheses. The first hypothesis is hinged on the proposition that the current lackadaisical national and transnational coexistence policies on compensation regime for inherent economic, environmental and public health damage in the coexistence paradigm, is partly underpinned by the “substantial equivalence” doctrine, which posits that foods derived from transgenic crops are equivalent to and no different from those from conventional and organic crops, and that no special legislation is needed to regulate transgenic

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<sup>272</sup> See Maria Lee and Robert Burrell, “Liability for the Escape of GM Seeds: Pursuing the ‘Victim’?” *The Modern Law Review*, *supra*, note 249, at 517-537.

crops.<sup>273</sup> Thus, by extrapolation, transgenic plant agriculture would also be substantially equivalent to conventional and organic plant agriculture, and therefore, no system of plant agriculture can cause harm or impede the other from flourishing, and it would therefore be unnecessary to formulate any compensation policy for the coexistence paradigm. This indeed is the cornerstone of the official U.S plant biotechnology policy, which is geared primarily at promoting and maximising the benefits of transgenic plant technology.<sup>274</sup>

Furthermore, as a major producer and promoter of transgenic plant technology, the US was able to spread its substantial equivalence policy internationally, and this arguably partly explained the reluctance of some national regulators like the UK Department for Environment, Food and Rural Affairs (DEFRA), in formulating coherent and effective compensation regime for inherent damage in the coexistence paradigm.<sup>275</sup> Thus, the substantial equivalence policy arguably removes the urgency and exigency for proactive and effective compensation regime that is especially tailored to deal with the unique challenges posed by the coexistence of transgenic and non-transgenic plant agriculture.<sup>276</sup> For why would a proactive compensation regime be necessary for possible admixture of products of essentially similar genetic properties? Indeed, the biotechnology industry was opposed to a compensation regime precisely for similar reasons, and the possibility that it could give the impression that transgenic plant technology was inherently unsafe.<sup>277</sup> Furthermore, it is argued that the influence of the substantial equivalence doctrine is palpable in the lack of effective civil liability regime in the United Nations-sponsored transnational liability regime, drawn up in 2010 in Nagoya, Japan,

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<sup>273</sup> See The United States Department of Health and Services (HHS), Food and Drug Administration (FDA) *Statement of Policy: Foods Derived From New Plant Varieties*, Docket No. 92N-0139, *The Federal Register* volume 57, (1992), *supra*, note 17, at 22984.

<sup>274</sup> *Id.*

<sup>275</sup> See Christopher Rodgers, “Defra’s Coexistence Proposals for GM Crops: A Recipe for Confrontation?” *Supra*, note 15, at 1-8.

<sup>276</sup> See section 1.1.5 above.

<sup>277</sup> See Gurdial Singh Nijar, “The Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety: An Analysis and Implementation Challenges”, *International Environmental Agreements: Policy, Law and Economics*, *supra*, note 18, at 279.

pursuant to the provisions of the United Nations Cartagena Protocol on Biosafety, following several years of negotiations.<sup>278</sup> The hypothesis on the full impacts of the substantial equivalence doctrine, is tested, discussed and analysed in Chapter Two of the thesis.

The second hypothesis of the thesis is theoretical, and draws largely on the socio-legal theory espoused by Ulrich Beck and Anthony Giddens on the imperatives for concomitant responsibility, obligations, accountability and liability for "technologies of risks" in our post-industrial, technological and "risk society".<sup>279</sup> In his seminal book, *Risk Society: Towards a New Modernity*, Beck argued that the modern society had entered a "reflexive" stage in which there was a growing realisation that the industrial and technological society had birthed new and unintended risks, which were hard to control, monitor, and contained, despite the proliferation of "risk techniques." Ulrich Beck characterised the new technological risks as unnatural man-made hazards and argued that the "risk society" was preoccupied with safety and distribution of risks.<sup>280</sup>

However, unlike Ulrich Beck, Anthony Giddens did not equate "risk" with "hazard", noting that "a risk society is not, as such, the same as hazard or danger", nor is it "intrinsically more dangerous or hazardous than pre-existing forms of social order."<sup>281</sup> However, Anthony Giddens similarly attributed the "risk society" to the advent of "science and technology", which effectively put an end to "nature" and "tradition" as we knew it.<sup>282</sup> However, he observed that "the end of nature" did not mean that "the natural environment" had disappeared, but that there were now few of the physical worlds "untouched by human intervention."<sup>283</sup> However, Anthony Giddens noted that a distinction must be made between two kinds of risk: the first

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<sup>278</sup> Id, at 271-290.

<sup>279</sup> See Ulrich Beck, *Risk Society: Towards a New Modernity*, *supra*, note 10, at 51-84; Anthony Giddens, "Risk and Responsibility", *Modern Law Review*, *supra*, note 7, at 1-10.

<sup>280</sup> See Ulrich Beck, *Risk Society: Towards a New Modernity*, *id*, at 51-62.

<sup>281</sup> See Anthony Giddens, "Risk and Responsibility", *Modern Law Review*, *supra*, note 7, at 3.

<sup>282</sup> Id, at 3.

<sup>283</sup> Id, at 3.



was the “external risk”, which characterised the first two-hundred years of the industrial society; whilst the second was “manufactured risk”, which was ushered in by the advent of science and technology.<sup>284</sup> He noted that whilst “external risk” of the industrial society, such as “sickness, disablement and unemployment” were easily calculable by actuarial tables and treated as “accidents of fate” for which insurance was collectively provided; “manufactured risk” referred to new unprecedented “risk environments” for which history provided us with very little previous experience.<sup>285</sup> Anthony Giddens then reflected on “the interesting consequences” of the risk society, which included the BSE debate in Britain and continental Europe and the Chernobyl nuclear accident, with concomitant long-term effects that were difficult to chart.<sup>286</sup>

Anthony Giddens further observed that no risk could be described without reference to human value, which could be the preservation of human life.<sup>287</sup> He was pessimistic and sceptical about the reliability of science in resolving the unique problems posed by the risk society, not least because scientific opinions are often characterised by disagreements and uncertainties:

We cannot simply ‘accept’ the findings which scientists produce, if only because scientists so frequently disagree with one another, particularly in situations of manufactured risk. And everyone now recognizes the essentially sceptical character of science. Whenever someone decides what to eat, what to have for breakfast, whether to drink decaffeinated or ordinary coffee, that person takes a decision in the context of conflicting, changeable scientific and technological information.<sup>288</sup>

Most significantly, Giddens observed that risk was always about “security and safety”, and “responsibility” and that as we moved towards a world dominated by manufactured risk, there would be a renewed discussion about the nature of concomitant responsibility. He defined ‘responsibility’ as “an interestingly ambiguous or multi-layered term”:

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<sup>284</sup> Id, at 4.

<sup>285</sup> Id, at 4.

<sup>286</sup> Id at 4-5.

<sup>287</sup> Id, at 5.

<sup>288</sup> Id, at 4.

In one sense, someone who is responsible for an event can be said to be the author of that event. This is the original sense of ‘responsible’, which links it with causality or agency. Another meaning of responsibility is where we speak of someone being responsible if he or she acts in an ethical or accountable manner. Responsibility also however means obligation, or liability, and this is the most interesting sense to counterpose with risk.<sup>289</sup>

Whilst drawing on the socio-legal theory espoused by Ulrich Beck and Anthony Giddens, it is hypothesised in the thesis that transgenic plant technology is not an “external risk” of the industrial age that characterised much of the 19<sup>th</sup> and early 20<sup>th</sup> centuries, but a “manufactured risk” that is very much part of the 21<sup>st</sup> century contemporary technological landscape, given that the technology debuted commercially in 1996.<sup>290</sup> Moreover, like most high-risk technology of the post-industrial risk society, the underlying science for transgenic plant technology is rife with uncertainties and counter-claims on its proprieties for the environment and public health, as amply demonstrated in previous analyses in section 1.1.7 of the thesis.

Also, whether as a “manufactured risk” a la Giddens, or as “an unnatural man-made hazards” a la Beck, the governance systems for the technology of the post-industrial “risk society”, which range from nuclear, nanotechnology, to transgenic plant technology, is preoccupied with safety issues and how best the attendant and inherent risks could be fairly distributed. This invariably raises the important question of “responsibility”, which in this context, connotes legal or juridical “obligation” or “liability” as ably adumbrated by Anthony Giddens.<sup>291</sup>

However, because the risk posed by transgenic plant technology is not easily calculable and its causation is not easily determined, it is not an “external risk” that could be easily dealt with by actuarial tables and therefore cannot be categorised as “accidents of fate” in the same way as the risks associated with the old industrial society order.<sup>292</sup> It is therefore not surprising that

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<sup>289</sup> Id, at 7-8.

<sup>290</sup> See Robert Paarlberg, *Starved for Science: How Biotechnology is Being Kept Out of Africa*, *supra*, note 38, at 149.

<sup>291</sup> See Anthony Giddens, “Risk and Responsibility”, *Modern Law Review*, *supra*, note 7, at 8.

<sup>292</sup> Id, at 4.

the insurance industry refused to insure transgenic plant technological risks, which they equated with asbestos, thalidomide, and acts of terrorisms.<sup>293</sup> According to Ina Ebert and Christian Lahstein, transgenic plant technology risks and losses are usually explicitly excluded from insurance coverage due to “the incalculability of associated risks”, especially in countries with strict liability laws, such as Germany where losses associated with transgenic plant technology are deemed uninsurable and excluded from coverage due to the strict liability nature of its legal environment.”<sup>294</sup>

Thus, to the extent that the risks posed by transgenic plant technology are “manufactured risks” in the post-industrial and high technology “risk society”, as espoused by Ulrich Beck;<sup>295</sup> and to the extent that risks should, of necessity, beget responsibility, accountability, obligation and liability, as espoused by Anthony Giddens;<sup>296</sup> it is proposed in the thesis that the risks posed by transgenic plant technology in the coexistence paradigm must necessarily be accounted for in law, in the same way that “the risk society” routinely demands responsibility and accountability of all technologies of risks that range from nuclear technology to nanotechnology. This argument is further reinforced by the scientific uncertainties, claims and counter-claims that underpin the safety science of transgenic plant technology, which uncertainties, the thesis argues, have arguably heightened public perception of transgenic plant technology risks .

### **1.2.0. Research Questions.**

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<sup>293</sup> See Paul Brown, “Insurers refuse to cover GM farmers: Leading companies liken risk to thalidomide and terrorism.” *The Guardian*, *supra*, note 269, at 6.

<sup>294</sup> See Ina Ebert and Christian Lahstein, “GMO Liability: Options For Insurers”, in Bernhard A. Koch, (editor), *Economic Loss Caused by Genetically Modified Organisms: Liability and Redress for the Adventitious Presence of GMOs in Non-GM Crops*, (Wien & New York: Springer, 2008), at 577-578. .

<sup>295</sup> See Ulrich Beck, *Risk Society: Towards a New Modernity*, *supra*, note 7, at 51-62.

<sup>296</sup> See Anthony Giddens, “Risk and Responsibility”, *Modern Law Review*, *supra*, note 7, at 8.

The thesis is framed by four research questions: The first question asks about the extent to which the substantial equivalence doctrine informs or hampers current national and transnational liability and redress regimes within the broader coexistence policy paradigm? This question is very pertinent because it is the basis of one of the thesis' two hypotheses, which implicates substantial equivalent doctrine for the current lackadaisical compensation regime in national and international laws. The research question and the hypothesis are tested in Chapter Two of the thesis, which analyses the origin, history and impacts of the substantial equivalence doctrine on the current coexistence laws of the United States, the European Union, and the United Kingdom.

The second research question asks about the propriety and adequacy of the current national and transnational civil compensation regimes? This question underpins the essence of the research, which is a critique of the current disparate and largely incoherent and uncertain liability and redress regime for damage induced by transgenic plant technology. Moreover, the question is an integral part of the central argument of the thesis, and underpins the basis for the proposed sui generis legal framework in Chapter Seven of the thesis.

The third question asks whether a sui generis liability and redress regime would be best suited to addressing the gaps in the current disparate and largely ineffective national and international compensation regimes? Chapters Five and Six of the thesis seek to highlight the inherent flaws in the current compensation regimes, and thereby justify the imperatives for a sui generis compensation regime as a complementary, harmonising, and moderating force for the current disparate compensation regimes. If the answer to the third question is yes, then the next question is what form and modality should such the sui generis compensation regime take? The answer to this secondary question is provided in the analyses contained in Chapter Seven of the thesis.

The fourth question stems from the third, and asks about possible limitations of the proposed sui generis regime, and how they could be overcome? Again, answers to this question are provided in the discussions and analyses in Chapter Seven of the thesis.

### **1.2.1. Scope of Research**

In order to effectively answer the research questions listed in section 1.2.0 of the thesis, the scope of the research would, of necessity, be transnational. Therefore the thesis will conduct a comparative analysis of relevant case laws, and statutes from the United Kingdom, the European Union, the United States, and Canada; and review the propriety of possible causes of action that range from strict liability, product liability, tortious liability to contractual liability, for remedying inherent damage in the coexistence of transgenic and non-transgenic plant agriculture. The analysis will draw heavily on analogous case law from North America and Europe to explicate various liability scenarios of harm or damage to property, person and health due to adventitious presence of transgenes in the environment and in non-transgenic plant agricultural products.

A transnational rather than national or regional scope is preferable for the following reasons. First, commercial transgenic plant agriculture originates in North America, where the preponderance of emerging case law also originate. Also, Canada and the United States, which are common law countries, provide invaluable templates and insights into how Courts in the United Kingdom might rule in circumstances analogous to emerging legal issues on liability and redress regimes for damage induced by adventitious transgenes. Second, the internationalisation of trade in transgenic seeds, crops and food products, and the prohibition of national barriers to transnational trades in transgenic plant agricultural products by the institutions of the World Trade Organization, as exemplified by the *European Communities*

*Biotech Products Case*,<sup>297</sup> have ensured the inexorable spread of transgenic plant agriculture and food products around the world, inevitably rendering a national treatment of the associated legal problems narrow and incomplete. For example, as noted earlier in section 1.1.0 of the thesis, transgenic crops are now cultivated commercially across six continents, and in 2014, 181.5 million hectares were cultivated in twenty-eight countries.<sup>298</sup> Third, some of the fundamental and defining terms of coexistence policies, are transcendental of national policies and boundaries, and include the ‘substantial equivalence’ doctrine, which originated in the United States,<sup>299</sup> and the “precautionary principle”, which originated in Germany in the 1970s,<sup>300</sup> and was an integral part of the United Nations Cartagena Protocol on Biosafety of 2000.<sup>301</sup>

However, there is an inherent limitation to the coverage of such wide-ranging causes of actions across disparate subjects areas and jurisdictions in Europe and North America with different national legislations and policies on coexistence policy for transgenic plant technology. For example, in Chapters Five and Six of the thesis, possible causes of action discussed are in subject areas of torts, contract, product liability, strict liability, environmental liability, intellectual property, and procedural Norwich Pharmacal actions, amongst others. The subjects are each distinctive in their own rights and typically cover wider scope of issues than those discussed in the thesis. Therefore, it is necessary to be selective and apply only the aspects of the subject areas that are of immediate relevance to the disputes in the current coexistence paradigm. For example, whilst intellectual property law covers a wide-range of topics from copyright, confidential information, trademarks, patents, plant breeders' rights, industrial

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<sup>297</sup> See *European Communities Biotech Products Case*, *supra*, note 27.

<sup>298</sup> See Clive James, *Global Status of Commercialized Biotech/GM Crops*, *supra*, note 1.

<sup>299</sup> See Les Levidow, Joseph Murphy, and Susan Carr, "Recasting Substantial Equivalence": Transatlantic Governance of GM Food," *Science, Technology & Human Values*, *supra*, note 23, at 35.

<sup>300</sup> See Jenny Steel, *Risks and Legal Theory*, *supra*, note 24, at 196-197.

<sup>301</sup> See Gurdial Singh Nijar, "The Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety: An Analysis and Implementation Challenges", *International Environmental Agreements: Policy, Law and Economics*, *supra*, note 16, at 271-290.

designs, to character merchandising, etc.,<sup>302</sup> only the aspects of intellectual property subject area that are most pertinent to the common disputes in the coexistence paradigm will be discussed in the thesis.

### **1.2.2. Research Methodology.**

The research uses qualitative, conceptual, applied, and analytical research methods for the evaluation, analysis and discussion of research problems, research objectives, research scope, research hypotheses, and proposed solutions to research problems.

Qualitative methodology is used in the thesis to explore comparative literature on the coexistence of transgenic and non-transgenic plant agriculture, with the aim of ascertaining why it is currently difficult to achieve coherent and effective compensation regimes for damage induced by adventitious admixture in the coexistence paradigm, and the best regulatory model to achieve this objective. The scope of literature covers primary and secondary materials from the European Union, the United Kingdom, the United States, and Canada for comparative effective. Whilst the scope of research primarily relates to the coexistence laws of the United States and the European Union, as implemented in the United Kingdom and other selected European Union countries, such as Germany and Austria, there are occasional references to Canadian literature for the following reasons: First, alongside the United States, Canada is a major grower and exporter of transgenic plant agricultural products to the European Union. Second, Canada was one of the complainants against the European Commission's 1998 moratorium in the *European Communities Biotech Products Case*.<sup>303</sup> Third, just like the United States, Canadian commercial transgenic plant agriculture has generated a body of case law and materials, which are relevant to issues highlighted in the research problems description. Fourth, Canada is a common law country, and whilst Canadian courts' judgments are not binding on

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<sup>302</sup> See William Cornish, David Llewelyn, and Tanya Aplin, *Intellectual Property: Patents, Copyrights, Trademarks and Allied rights*, 8th edition, (London: Sweet & Maxwell, 2013).

<sup>303</sup> See *European Communities Biotech Products Case*, *supra*, note 27.

UK Courts, they could provide useful academic templates for comparative analyses of analogous problems and help shape the burgeoning coexistence policy in the UK.

Conceptual methodology is used in the thesis to integrate the two research hypotheses highlighted in section 1.1.9 into the central argument of the thesis on the exigency and imperatives for effective compensation regimes in the coexistence paradigm. For example, the hypothesis that the substantial equivalent doctrine partly underpins the current lackadaisical and disparate compensation regime for transgenic plant technology is integrated into the central arguments in Chapters Two and Three of the thesis. Also, the hypothesis that draws on the socio-legal theory on the link between the "risk society", technological advancements, and the imperatives for legal responsibility, is integrated into the analyses of the arguments and issues raised in Chapter Three of the thesis, which discusses the underlying regulatory science in the current coexistence regimes, and the solutions proffered in Chapter Seven of the thesis, which sets out the framework and modality for coherent, effective and enforceable transnational compensation regimes.

Applied research methodology is used in the thesis for the discussion and application of relevant case law, legislations, literature, and documented accounts, which demonstrate the unique existential challenges posed by the coexistence of transgenic and non-transgenic plant organisms and agricultural systems. The said literature is then applied and used as the basis for the analysis of research problems, research questions and objectives, scope of research, research hypotheses, and proposed solutions to research problems. For example, the thesis' hypotheses are used to press the central arguments on the need for effective and coherent liability and redress regime for damage induced by transgenic plant technology in the coexistence paradigm. Also, the propriety of possible causes of action at common law and under statutes are applied to liability and redress scenarios involving for damage induced by transgenic plant technology in Chapters Five and Six of the thesis.



Analytical research methodology is used for critical evaluation and discussion of relevant literature with regards to the nature of research problems, research objectives, the scope of research, and research questions. For example, Chapter Two of the thesis analyses and evaluates the propriety of the substantial equivalence doctrine; Chapter Three of the thesis analyses and evaluates the impacts of the underlying science of transgenic plant technology on the current regulatory framework and policy on coexistence; whilst Chapter Four of the thesis evaluates the underlying existential conflicts in the coexistence paradigm. Furthermore, Chapters Five and Six of the thesis critically analyse and evaluate the adequacy of the current compensation regimes, whilst Chapter Seven of the thesis analyses and justifies the modalities and structures of the prescribed sui generis compensation regime as a complementary and parallel coexistence governance system.

### **1.2.3. Research Background.**

Prior to enrolling for doctoral study at Cardiff University in September 2006, I was involved in a comparative research focusing on the labelling rules for transgenic plant technological products in the European Union and the United States. Drawing on ethical, safety, and rights arguments, the research supported the EU labelling regulations, and questioned the reluctance of the US regulatory authorities in establishing a labelling regime, despite a survey that showed that more than 93 percent of US residents preferred labelling of transgenic plant technological products. The research paper was subsequently published in *Singapore Journal of Legal Studies* in December 2002.<sup>304</sup> In September 2006, I enrolled on the doctoral programme at Cardiff Law School, whilst working as a graduate teaching assistant at the Law School. Although I was open to conducting a doctoral study on any socio-legal topics, my interest in transgenic plant agriculture governance and the problems of coexistence was rekindled by

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<sup>304</sup> See Taiwo A. Oriola, "Consumer Dilemmas: The Right to Know, Safety, Ethics, and Policy of Genetically Modified Food," *Singapore Journal Legal Studies*, *supra*, note 39, pp. 514-573.

Professor Robert Lee, who was a Professor of Law at Cardiff Law School and a Co-director at the Centre for Business Relationships, Accountability, Sustainability and Society (BRASS), Cardiff University. I was fortunate to be able to draw on the expertise of Professor Robert Lee on the subject, as well as the supports and encouragement of staff and colleagues at Cardiff Law School and BRASS. I have since benefitted immensely from my association with Cardiff Law School and the Staff whose invaluable supports helped me in the completion of the doctoral research.

#### **1.2.4. Chapters Outline.**

The thesis is broadly divided into four parts. Part I comprises Chapter One; Part II comprises Chapters Two and Three; Part III comprises Chapters Four, Five and Six; and Part IV comprises the concluding Chapter Seven. Chapter One reviews relevant literature, discusses and analyses key terms and concepts, key research problems, rationale for the research, scope of research, research hypotheses, research methodology, and background to the research.

Chapter Two of the thesis tests the validity of one of the thesis' hypotheses, which posits that the "substantial equivalence doctrine" partly underpins the current disparate and non-effectual compensation regimes in national and transnational legal frameworks on the coexistence of transgenic and non-transgenic plant organisms. The chapter highlights the impacts of the substantial equivalence doctrine on the current regulatory framework in the United States, the European Union, and the United Kingdom, and how the doctrine undermines the imperatives for adequate and coherent compensation regime in the coexistence paradigm.

Chapter Three of the thesis analyses the current regulatory framework for transgenic plant agriculture governance in the European Union, the United Kingdom, and the United States. The chapter provides an insight into the approval systems and coexistence arrangements for transgenic plant organisms, and the inherent limitations of regulatory science for transgenic

plant technology governance. The chapter explores the symbiotic relationship between science and transgenic plant technology policy, and the undue policy deference to science, which is uncertain and highly contested. The chapter seeks to link the primacy of science to the incoherent, ineffective, and disparate compensation regimes in the coexistence paradigm.

Chapter Four discusses the reality of the coexistence paradigm, through a mixture of descriptive and analytical narrative of real events culled from primary and secondary literature. The nature of the materials which range from anecdotal accounts, newspapers interviews, to primary literature, dictate the descriptive nature of the analysis and review of scenarios of existential conflicts inherent in the advent of transgenic plant organisms and agriculture, and the impacts of the conflicts on stakeholders, who range from the consumers, farmers to transgenic seeds firms. The chapter seeks to demonstrate the imperatives for concomitant liability and redress regimes that could facilitate mutual coexistence of transgenic and non-transgenic plant organisms and agriculture.

Chapter Five examines and discusses the scenarios for tortious liability for damage caused by adventitious transgenes in the coexistence paradigm. Possible causes of action range from negligence, private nuisance, trespass, to the rule in *Rylands v Fletcher*. The chapter explores the propriety and effectiveness of these causes of action to inherent damage in the coexistence paradigm.

Chapter Six examines the relevance and costs of traceability and possible causes of action for inherent damage in the supply chain. The supply chain liability is used as a generic platform to introduce other possible causes of action outside of torts law, but which could crop up in the supply chain for transgenic plant technological products. These range from torts, contract, product liability, environmental liability strict liability, to procedural Norwich Pharmacal actions. The importance of traceability to supply chain liability is analysed and discussed in the context of conceivable scenarios of strict liability, product liability, environmental liability

and contractual liability. The chapter highlights and discusses the proprieties of these causes of action in conceivable supply chain liability scenarios.

Chapter Seven, which concludes the thesis, proposes an outline and modalities for a sui generis compensation regime that would supplement, harmonise, and moderate existing disparate national and international compensation regimes for inherent damage in the coexistence paradigm. The sui generis liability regime draws on the templates for Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress Regime, and proposes structural and enforcement mechanisms. The chapter also highlights the challenges of enforcement, and weaknesses of the proposed transnational compensation regime, and proposes workable mechanisms for overcoming these weaknesses, whilst drawing on comparable international treaties such as the WTO 1994 Trade Related Intellectual Property Agreements.

## **Chapter Two Substantial Equivalence and the Coexistence Paradigm.**

### **2.1.0. Introduction.**

Chapter Two sets out to test one of the two hypotheses of the thesis, which posits that substantial equivalence doctrine undermines the need for effective liability and redress regime. The chapter discusses the origin of the substantial equivalence doctrine, and analyses its putative role as a quasi-regulatory and scientific tool in the coexistence policy and governance structures for transgenic and non-transgenic plant agriculture in the United States and the European Union. The chapter tests the validity of the hypothesis by questioning the underlying motives, propriety and legitimacy of the substantial equivalence doctrine. The chapter also highlights the influences of the substantial equivalence doctrine on national and international coexistence policies and international institutions, and the extent to which it undermines the imperatives for effective liability and redress regime for possible damage in the coexistence arrangements for transgenic and non-transgenic plant agriculture.

### **2.1.1. The Concept of the Substantial Equivalence Doctrine.**

The substantial equivalence doctrine is the official policy of the United States government, which is rooted in the Food and Drug Administration Policy that posits that transgenic plant foods are similar in their chemical composition to organic and conventional foods, and are therefore “generally recognised as safe”, as they “do not introduce unique health risks to consumers.”<sup>305</sup> Thus, there is a tacit assumption in the substantial equivalence doctrine that genetic materials used in transgenic plant crops “will likely be the same or substantially similar to substances commonly found in foods, such as proteins, fats, and oils, and carbohydrates.”<sup>306</sup> The substantial equivalence doctrine also posits that similarity between a transgenic plant food and its conventional counterpart could be demonstrated by testing their chemical

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<sup>305</sup> See Paul R. Billings and Peter Shorett, “Coping with Uncertainty: The Human Health Implications of GE Foods,” in Iain E.P. Taylor, (editor), *Genetically Engineered Crops: Interim Policies, Uncertain Legislation*, *supra*, note 126, at 78-79.

<sup>306</sup> See the United States Department of Health and Services (HHS), Food and Drug Administration (FDA) *Statement of Policy: Foods Derived From New Plant Varieties*, *supra*, note 17, at 57.

composition,<sup>307</sup> and if comparative study of chemical composition could not resolve safety concerns, then “feeding studies or other toxicological tests may be warranted.”<sup>308</sup> Even so, the Food and Drug Administration have acknowledged the limitations of “feeding studies” and “toxicological tests”, by noting that “feeding studies on whole foods have limited sensitivity” since it would be relatively difficult “to administer exaggerated doses.”<sup>309</sup> Thus, despite its apparent limitations as a safety assessment and regulatory tool for transgenic plant foods and products, substantial equivalence doctrine has been used primarily by the United States regulatory authorities as an unqualified scientific and quasi-regulatory tool for transgenic plant foods and products, as exemplified by the United States Food and Drug Administration’s presumptive policy that transgenic plant foods and products are “generally recognised as safe.”<sup>310</sup>

### **2.1.2. The Origin of Substantial Equivalence Doctrine**

In 1984, the Administration of President Ronald Regan established an interagency group that was tasked with examining the adequacy of existing regulatory framework for products of biotechnology.<sup>311</sup> The remit of the interagency group was “to achieve a balance between regulation that was adequate to ensure health and environmental safety, while maintaining sufficient regulatory flexibility to avoid impeding the growth of an infant industry.”<sup>312</sup> In December 1984, the interagency group published its proposal for a coordinated framework, and subsequently announced its regulatory policy proposal in June 1986. In the policy proposal,

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<sup>307</sup> Id, at 24.

<sup>308</sup> Id.

<sup>309</sup> Id. See also Les Levidow, Joseph Murphy, and Susan Carr, “Recasting “Substantial Equivalence”: Transatlantic Governance of GM Food,” *Science, Technology & Human Values*, *supra*, note 23, at 35.

<sup>310</sup> See Paul R. Billings and Peter Shorett, “Coping with Uncertainty: The Human Health Implications of GE Foods,” in Iain E.P. Taylor, (editor), *Genetically Engineered Crops: Interim Policies, Uncertain Legislation*, *supra*, note 126 at 78-79.

<sup>311</sup> See D.L. Uchtmann, “STARLINK: A Case Study of Agricultural Biotechnology Regulation”, *Drake Journal of Agricultural Law*, Volume 7, (2002), at 169.

<sup>312</sup> See Office of Science and Technology Policy (OSTP), Coordinated Framework for Regulation of Biotechnology, *Federal Register*, Vol. 51, (26 June, 1986), at 23,303.

the interagency group recommended that no new policy or legislation was necessary for the governance of products of biotechnology, and that existing laws as administered by existing federal agencies, would be adequate.<sup>313</sup> The interagency group justified its recommendations on grounds that there was no alternative comprehensive regulatory framework for biotechnological products; and that existing laws managed by existing agencies had several advantages, which included the provision of immediate legal protection for consumers, whilst simultaneously obviating the need for the biotechnology industry to learn and deal with new laws.<sup>314</sup>

The policy recommendation against the enactment of new laws for the governance of biotechnological products was not at all surprising, given the group's official remit to strike a balance between public health and environmental protection on the one hand and the guarantee of regulatory flexibility conducive to the growth of the nascent biotechnology industry on the other hand.<sup>315</sup> Most significantly, the policy recommendation was in conformity with the United States government's official promotional policy for agricultural biotechnology, which was regarded as an integral part of national economic development strategies.<sup>316</sup> The official position of nil to minimal regulatory regime for biotechnology products, was given a fillip five years later by the joint Report of the Biotechnology Working Group and the President's Council on Competitiveness, which urged the government to maintain "risk-based regulation" and "avoid excessive restrictions that curtail the benefits of biotechnology to society."<sup>317</sup> According to Michael Braham, the group's recommendation of favourable and auspicious regulatory environment for biotechnology products was symptomatic of President Ronald

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<sup>313</sup> Id.

<sup>314</sup> See Office of Science and Technology Policy (OSTP), Coordinated Framework for Regulation of Biotechnology, *Federal Register*, *supra*, note 305, at 23,303.

<sup>315</sup> Id, at 23,303.

<sup>316</sup> See Les Levidow, Joseph Murphy, and Susan Carr, "Recasting "Substantial Equivalence": Transatlantic Governance of GM Food," *Science, Technology & Human Values*, *supra*, note 23, at 35.

<sup>317</sup> Id, at 35.

Regan Administration's policy of minimal or light federal regulation of new businesses.<sup>318</sup> However, the biotechnology industry is unlike most conventional businesses, because it essentially involves genetic modifications of organisms for subsequent uses in fields as diverse as medicine and agriculture, with concomitant implications for public health and the environment.<sup>319</sup> Therefore, the group's recommendation that no new legislation was needed for biotechnology products would appear to have glossed over the unique and existential challenges and risks posed by transgenic plant technology, and negated the essence of the socio-legal theory espoused by Ulrich Beck and Anthony Giddens on the imperatives for concomitant responsibility, obligations, and liability for risks technologies in the post-industrial technological "risk society".<sup>320</sup>

In 1992, the United States Food and Drug Administration, which was the agency responsible for food safety and for coordinating approval process for transgenic plant foods and products,<sup>321</sup> published policy guidelines that implemented the 1986 Office of Science and Technology Policy recommendations that no new legislation was required for biotechnology products.<sup>322</sup> According to the 1992 policy guidance, the United States Food and Drug Administration expected that the chemical compositions of transgenic plant foods would be "substantially similar" to those commonly found in conventional plant foods that were generally recognised as safe (GRAS).<sup>323</sup> The policy guideline effectively adopted substantial equivalence doctrine as a scientific and regulatory tool for the governance of transgenic plant foods.

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<sup>318</sup> See Michael Baram, "Governance of GM Crop and Food Safety in the United States," in Michael Baram and Mathilde Bourier, (editors), *Governing Risk in GM Agriculture*, *supra*, note 18, at 26-44.

<sup>319</sup> See Michael J. Reiss and Roger Straughan, *Improving Nature? The Science and Ethics of Genetic Engineering*, *supra*, note 48, at 1-2.

<sup>320</sup> See generally section 1.1.9 for the thesis' central hypotheses.

<sup>321</sup> See United States Food and Drugs Administration, "Statement of Policy: Foods Derived from New Plant Varieties," *Federal Register*, *supra*, note 17, at Part V, Paragraph A.

<sup>322</sup> See Les Levidow, Joseph Murphy, and Susan Carr, "Recasting "Substantial Equivalence": Transatlantic Governance of GM Food," *Science, Technology & Human Values*, *supra*, note 38, at 35.

<sup>323</sup> *Id.*



However, the validity and legality of the substantial equivalence doctrine was challenged before the United States District Court of Columbia in *Alliance for Bio-integrity et al., v. Donna Shalala, et al.*<sup>324</sup> The plaintiffs were a coalition of groups, individuals, scientists, and religious leaders, who contended inter alia that transgenic plant foods should be labelled, and that the Food and Drug Administration's substantial equivalence policy presumption that transgenic plant foods as a class was "generally recognized as safe", and therefore not subject to regulation as food additives, should be discountenanced by the court, because it violated the GRAS requirements of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321(s), and therefore arbitrary and capricious.

According to the provisions of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321(s), a producer of food additive must submit food additive petition to the Food and Drug Administration for approval, unless the Food and Drug Administration determines that the additive "is generally recognized [by qualified experts] ... as having been adequately shown through scientific procedures ... to be safe under the conditions of its intended use."<sup>325</sup>

The plaintiffs' claim did raise a pertinent question before the Federal District Court of Columbia: why did the Food and Drug Administration not characterise nucleic acid proteins used in the genetic modifications of transgenic plant food as "food additive", in order to allow for automatic submission of transgenic plant food to the FDA approval process prior to market

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<sup>324</sup> See *Alliance for Bio-Integrity, et al. v. Shalala, supra*, note 107, at 166-181.

<sup>325</sup> See the Federal Food, Drug, and Cosmetic Act, 21, Chapter 9, U.S.C. § 321(s), which defines "food additive" as "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; except that such term does not include: (1) a pesticide chemical residue in or on a raw agricultural commodity or processed food; or (2) a pesticide chemical; or (3) a color additive; or (4) any substance used in accordance with a sanction or approval granted prior to the enactment of this paragraph 4 pursuant to this Act... (5) a new animal drug; or (6) an ingredient described in paragraph (ff) in, or intended for use in, a dietary supplement."

debut? The Federal District Court of Columbia reasoned that it was because “nucleic acid proteins”, were not only generally recognised as safe, but also deemed crucial for the survival of plant and animal organisms:

Nucleic acids are present in the cells of every living organism, including every plant and animal used for food by humans or animals, and do not raise a safety concern as a component of food. Therefore the FDA concluded that rDNA engineered foods should be presumed to be GRAS unless evidence arises to the contrary.<sup>326</sup>

The plaintiffs had contended that although nucleic acid proteins might be safe in their natural environment as such, there was no unanimity of scientific views on the safety implications of using nucleic acid proteins to genetically alter or modify a plant’s genome.<sup>327</sup>

Nevertheless, the Federal District Court of Columbia dismissed the plaintiffs’ claims, and held that the “FDA’s decision to accord genetically modified foods a presumption of GRAS status” was not “arbitrary and capricious” as claimed by the plaintiffs. The Federal District Court arrived at this conclusion even though the Court accepted that there were differing scientific opinions as to whether or not nucleic acid proteins were generally recognized as safe, when used to alter organisms genetically. The Federal District Court rationalised the premise for deferring to the Food and Drug Administration’s judgment in awarding GRAS status to transgenic plants foods thus:

The rationale for deference is particularly strong when the [agency] is evaluating scientific data within its technical expertise ... In an area characterized by scientific and technological uncertainty ... this court must proceed with particular caution, avoiding all temptation to direct the agency in a choice between rational alternatives.<sup>328</sup>

The Federal District Court's reluctance to pick and choose between conflicting scientific opinions or “rational alternatives”, on whether or not nucleic acid proteins are generally recognised as safe, when used in the alteration of the genome of transgenic plant foods, is

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<sup>326</sup> Id, at 176-177.

<sup>327</sup> Id, at 177.

<sup>328</sup> Id, at 182.

understandable, given the Federal District Court's lack of relevant scientific expertise on a subject “characterized by scientific and technological uncertainty.”<sup>329</sup>

However, perhaps the Federal District Court could have ruled in favour of the plaintiffs, had the Federal District Court taken judicial notice of the acknowledgement by the Food and Drug Administration that transgenic plant foods “are likely in some cases to present more complex safety and regulatory issues than seen to date”? And that “feeding studies” and “toxicological tests”, which could be used to establish the differences between transgenic and conventional foods, and validate the substantial equivalence doctrine, were impossible because “feeding studies on whole foods have limited sensitivity” and it would be relatively difficult “to administer exaggerated doses.”<sup>330</sup>

It is argued that the Federal District Court of Columbia was wrong to have discountenanced and excluded “consumer interest” or “consumer demand” from its interpretation of what constitutes “material facts” for the purposes of determining whether or not “foods misbranding” had occurred to warrant labelling of transgenic plant foods under The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321(n). This is especially so since Congress did not expressly make any distinction between “safety concerns” and “consumer interest” in the determination of what constitutes “material facts” for the purposes of establishing whether “foods misbranding” had occurred to justify labelling of transgenic plant foods under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321(n).

But then, by narrowly conceptualising “material facts” solely in safety terms for the purposes of labelling of transgenic plant food, the Federal District Court was able to focus entirely on scientific considerations, which were easily explained by the doctrine of substantial equivalence that posits that transgenic plant food were substantially equivalent to conventional

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<sup>329</sup> Id, at 182.

<sup>330</sup> See the United States Department of Health and Services (HHS), Food and Drug Administration (FDA) *Statement of Policy: Foods Derived From New Plant Varieties*, *supra*, note 17, at 24.

plant food. However, whilst this interpretation of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321(n) rendered the labelling debates moot and nugatory, it completely glossed over genuine consumer interest in being able to make a free choice between transgenic and non-transgenic plant food, as exemplified by the 94 per cent support for labelling of transgenic plant food in a 2003 survey in the United States.<sup>331</sup>

It is argued that the ruling was a classic policy judgment in which the judge deferred to the judgement of the Food and Drug Administration tasked with implementing the official government biotechnology promotional policy. The judge was fully aware of “the rational alternatives” predicated on scientific data “in an area characterized by scientific and technological uncertainty,”<sup>332</sup> but nevertheless, chose to defer to the judgement of the FDA, and preferred the FDA’s “alternative” interpretation and narrative of the scientific data, without adducing any reason other than to avoid “all temptation to direct the agency in a choice between rational alternatives.”<sup>333</sup> Arguably, a contrary judgment could deal a blow to the essence of substantial equivalence doctrine, and open a floodgate of litigations on other grounds that bothered on the safety of transgenic plant foods in the United States.

### **2.1.3. International Institutions and the Substantial Equivalence Doctrine.**

Most significantly, the substantial equivalence doctrine was given a fillip by its tacit international recognition and cautious endorsement in a 1991 joint statement by the Food and Agriculture Organization and the World Health Organization, which posited that “safety assessment should be based on sound scientific principles and data”, and that transgenic plant food could be compared with conventional food as part of safety assessment measures.<sup>334</sup>

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<sup>331</sup> See Robert Paarlberg, *Starved for Science: How Biotechnology is Being Kept Out of Africa*, *supra*, note 38, at 150.

<sup>332</sup> See *Alliance for Bio-Integrity, et al. v. Shalala*, *supra*, note 107, at 182.

<sup>333</sup> *Id.*

<sup>334</sup> See Food and Agriculture Organization/World Health Organization (FAO/WHO), Report of a Joint FAO/WHO Expert Consultation, *Strategies for Assessing the Safety of Foods Produced by Biotechnology*, (Rome:

However, a subsequent joint statement five years later explicitly endorsed the substantial equivalence doctrine, and ostensibly drew on the doctrine to allay any concerns on possible negative effects of transgenic plant foods on public health:

Food safety considerations regarding organisms produced by techniques that change the heritable traits of an organism, such as rDNA technology, are basically of the same nature as those that might arise from other ways of altering the genome of an organism, such as conventional breeding... Substantial equivalence embodies the concept that if a new food or food component can be found to be substantially equivalent to an existing food or food component, it can be concluded to be as safe as conventional food or food component.<sup>335</sup>

The joint report further noted that substantial equivalence was not a safety assessment in itself, but a “dynamic analytical exercise in the assessment of the safety of a new food relative to existing food.”<sup>336</sup> Again, in a subsequent joint report published in September 2001, the Food and Agriculture Organization and the World Health Organization reiterated the essence of substantial equivalence doctrine as an analytic tool for the comparison of the components of transgenic and conventional plant foods, and as “the starting point for safety regulation.”<sup>337</sup>

Similarly in 1993, the Organisation for Economic Cooperation and Development (OECD) noted in their Report that transgenic plant food “does not necessitate a fundamental change in established principles, nor does it require a different standard of safety.” The 1993 OECD report explicitly endorsed the substantial equivalence doctrine thus:

If a new food or food component is found to be substantially equivalent to an existing food or food component, it can be treated in the same manner with respect to safety. No additional safety concerns would be expected. Where the substantial equivalence is more difficult to establish because the food or food component is either less well-known or totally new, then the identified differences, or the new characteristics, should be the focus of further safety considerations.<sup>338</sup>

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FAO/WHO, 1991), at 23-24. The report noted *inter alia* that “comparative data on the closest conventional counterpart are critically important in the evaluation of a new food, including data on chemical composition and nutritional value.” The report also noted that such data were not widely available at the time of consultation and writing. *Id.*

<sup>335</sup> See WHO/FAO (World Health Organization/Food and Agriculture), *Biotechnology and Food Safety: Report of a Joint FAO/WHO Consultation*, (Rome: Italy, September 30- October 4, 1996), at [www.fao.org](http://www.fao.org).

<sup>336</sup> *Id.*

<sup>337</sup> See FAO/WHO, *Report of a Joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology*, (Geneva: September 2001), at 7-8.

<sup>338</sup> See Organization for Economic Cooperation and Development, *Safety Evaluation of Foods Derived from Biotechnology: Concepts and Principles*, (Paris: OECD, 1993), at 10.

Thus, the endorsement of substantial equivalence doctrine by cognate and reputable international organisations undoubtedly facilitated international harmonisation of mutually accepted “safety judgements” for transgenic plant and foods, and paved the way for the liberalisation of international trade in transgenic plant products and food.<sup>339</sup> For example, the substantial equivalence doctrine was adopted by Canadian authorities as a safety assessment tool for transgenic plant foods and food ingredients.<sup>340</sup> Therefore, the official international consensus amongst policy makers on the viability of the substantial equivalence doctrine, for the regulation of transgenic plant foods, is indicative of the transnational reach of the doctrine as a putative scientific and quasi-regulatory tool for safety assessment of transgenic plant foods and food ingredients.

#### **2.1.4. Substantial Equivalence in the Laws of the EU and UK.**

Following international endorsements of the substantial equivalence doctrine, it was implemented in the European Union in 1997, via Novel Food Regulation 258/97, which gave substantial equivalence a statutory role,<sup>341</sup> and adopted a simplified procedure for assessing the safety of transgenic plant foods and food ingredients.<sup>342</sup> The second preamble to the Regulation provides thus: “...in the case of novel foods and novel food ingredients which are substantially equivalent to existing foods or food ingredients a simplified procedure should be provided for.”<sup>343</sup> Article 3(2) of the Regulation also extended simplified procedure for novel foods and food ingredients that were “substantially equivalent to existing foods or food ingredients as

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<sup>339</sup> See Les Levidow, Joseph Murphy, and Susan Carr, “Recasting ‘Substantial Equivalence’: Transatlantic Governance of GM Food,” *Science, Technology, & Society*, *supra*, note 23, at 36.

<sup>340</sup> See Paul R. Billings and Peter Shorett, “Coping with Uncertainty: The Human Health Implications of GE Foods,” in Iain E. P. Taylor, (editor), *Genetically Engineered Crops: Interim Policies, Uncertain Legislation*, *supra*, note 62, at 79.

<sup>341</sup> See Les Levidow, Joseph Murphy, and Susan Carr, “Recasting ‘Substantial Equivalence’: Transatlantic Governance of GM Food,” *Science, Technology, & Society*, *supra*, note 23, at 36.

<sup>342</sup> See Regulation (EC) No 258/97 Concerning Novel Foods and Novel Food Ingredients, *Official Journal of the European Communities*, No L43/1.

<sup>343</sup> *Id.*

regards their composition, nutritional value, metabolism, intended use and the level of undesirable substances contained therein.”<sup>344</sup> Although the Regulation did not expatiate further on the above provisions, it has been suggested that the provisions effectively endorsed the substantial equivalence doctrine to the effect that if a transgenic plant food product was substantially equivalent to a conventional plant food, then no risk assessment would be required; and that several transgenic plant foods and food ingredients were approved under the simplified procedure in the late 1990s.<sup>345</sup>

According to Les Levidow et al, the simplified procedure of the substantial equivalence doctrine helped achieved international transgenic plant foods trade liberalisation, by harmonising transgenic plant foods products approval procedure across the Atlantic, in line with the OECD liberal conception of substantial equivalence doctrine.<sup>346</sup> However, the main weakness of the simplified procedure of the substantial equivalence doctrine was that it could allow companies to avoid rigorous risk assessment if they could show that a transgenic food or food ingredient was substantially equivalent to an existing safe food.<sup>347</sup> This is a fatal gap in the simplified safety assessment procedure made possible by the absence of coherent regulatory regime that explicitly defined the limits of the substantial equivalence doctrine. This arguably demonstrates the visceral grip of the substantial equivalence doctrine over substantive regulation, and the extent to which the substantial equivalence doctrine indirectly undermined the necessity for effective and coherent liability and redress regime for transgenic plant technology.

In 1997, the United Kingdom government implemented EU Novel Food Regulation 258/97, and adopted the simplified procedure of the substantial equivalence doctrine, which was

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<sup>344</sup> Id.

<sup>345</sup> See Les Levidow, Joseph Murphy, and Susan Carr, “Recasting ‘Substantial Equivalence’: Transatlantic Governance of GM Food,” *Science, Technology, & Society*, *supra*, note 23, at 36.

<sup>346</sup> Id, at 36.

<sup>347</sup> Id, at 36.

subsequently endorsed by the Royal Society in their Report published in 2002.<sup>348</sup> In the late 1990s, several companies applied for approval for their transgenic plant food products under the simplified procedure to the UK Advisory Committee on Novel Foods (ACNFP), who prior to April 2004, were responsible for the approval of transgenic plant foods in the United Kingdom.<sup>349</sup> In the late 1990s, applications submitted by companies to ACNFP for approval included insect-resistant transgenic cottonseed submitted by Monsanto Europe; herbicide tolerant cottonseed submitted by Monsanto Europe; and transgenic tomato that was genetically modified using *agrobacterium tumefaciens*.<sup>350</sup>

#### **2.1.5. A Stricter Variant of Substantial Equivalence Doctrine in the UK and EU.**

Amidst a public outcry on the adequacy of the simplified procedure of the substantial equivalence doctrine, the UK ACNFP began to question the propriety and adequacy of the substantial equivalence doctrine in the late 1990s, and concluded that the simplified procedure was suitable only for fully processed foods that no longer contained intact DNA or protein.<sup>351</sup> In an interview, a member of the ACNFP provided an insight into the reasons for tightening the substantial equivalence criterion for the approval of transgenic plant foods thus:

If we must use that criterion alone, then we will tighten its definition... a food cannot be regarded as substantially equivalent if it contains any intact GM DNA, so the product must be highly refined to ensure that all DNA has been denatured. Moreover, we will specify what tests are required; the company must monitor generations of the crop over two years at six sites..<sup>352</sup>

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<sup>348</sup> See The Royal Society, *Genetically Modified Plants for Food Use and Human Health*, (2002), at 5, available at <http://www.royalsoc.ac.uk>.

<sup>349</sup> See Advisory Committee for Novel Foods and Processes (ACNFP), <http://acnfp.food.gov.uk/> (Since 2004, transgenic plant foods has been centralised and managed by the European Food Safety Authority, which conducts a centralised risks assessment procedure, pursuant to the provisions of Regulation (EC) No 1829/2003 on Genetically Modified Food and Feed, *Official Journal of the European Union*, 18.10.03 L.268/1.

<sup>350</sup> See Ministry of Agriculture, *Fisheries and Food, Advisory Committee on Novel Foods and Processes, Annual Report*, (1998), at 1-6.

<sup>351</sup> See Advisory Committee on Novel Foods and Processes (ACNFP) 1998 Annual Report, cited in Les Levidow, Joseph Murphy, and Susan Carr, "Recasting "Substantial Equivalence": Transatlantic Governance of GM Food," *Science, Technology & Human Values*, *supra*, note 66, at 39.

<sup>352</sup> Cited in Les Levidow, et al. Id, at 38-39.



In 2003, the European Union subsequently repealed some of the provisions of Novel Food Regulation 258/97 to the extent that they applied to the simplified approval process of the substantial equivalence doctrine for transgenic plant foods and food ingredients via Article 38 to Regulation (EC) No. 829/2003 on Genetically Modified Food and Feed.<sup>353</sup> In paragraph 6 of the preamble to Regulation (EC) No. 1829/2003 on Genetically Modified Food and Feed, the European Union apparently jettisoned the simplified approval procedure of Novel Food Regulation 258/97 for transgenic plant foods by noting that: “whist substantial equivalence is a key step in the procedure for assessment of the safety of genetically modified foods, it is not a safety assessment in itself”.<sup>354</sup> In effect, the European Union effectively adopted United Kingdom’s relatively more stringent variant interpretation of the substantial equivalence doctrine.<sup>355</sup>

Even so, the relatively stricter interpretation of the substantial equivalence doctrine subsequently adopted by the United Kingdom and the European Union would arguably have no impacts on imported transgenic plant crops and food and feed from North America and elsewhere in the world, unless the stringent interpretation could be supported by scientific evidence. This proposition is premised on the World Trade Organization Dispute Settlement Board’s Panel decision in the *European Communities Biotech Products Case*,<sup>356</sup> in which certain pre-emptive safeguard measures taken by the European Union were held in breach of the risk assessment criteria of the Sanitary and Phytosanitary Measures of the Uruguay Round

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<sup>353</sup> See Article 38(2) of Regulation (EC) No. 1829/2003 on Genetically Modified Food and Feed, which repealed Articles 1(2)(a) and (b); 3(2), second subparagraph, and (3), 8(1)(d) and 9 of Regulation (EC) No. 258/97 on Novel Food.

<sup>354</sup> See Paragraph 6 of the Preamble to Regulation (EC) No 1829/2003 of the European Parliament and the Council of 22 September 2003 on Genetically Modified Food and Feed. L268/2, *Official Journal of the European Union*, (18/10/2003), at 1.

<sup>355</sup> See Les Levidow, Joseph Murphy, and Susan Carr, “Recasting “Substantial Equivalence”: Transatlantic Governance of GM Food,” *Science, Technology & Human Values*, *supra*, note 66, at 39.

<sup>356</sup> See *European Communities: Measures Affecting the Approval and Marketing of Biotech Products*, (WT/DS291R); (WT/DS292R); & (WT/DS293R), (29, September 2006), available at [http://www.worldtradelaw.net/reports/wtopanels/ec-biotech\(panel\).pdf](http://www.worldtradelaw.net/reports/wtopanels/ec-biotech(panel).pdf)

(SPS Agreement).<sup>357</sup> Notably, the European Union was held to have breached, amongst others, the provisions of Articles 5(1) and 5(2) of the SPS Agreement, which provide *inter alia* that all food safety measures must be based on a risk assessment and scientific evidence.<sup>358</sup> Thus, unless the United Kingdom and the European Union could establish the scientific merit of the stringent interpretation or variant of the substantial equivalence doctrine, it could hardly be used to legally bar the importation of transgenic plant foods and products from the United States, Canada, Argentina, and other countries with similar or comparable lax interpretation of the substantial equivalence doctrine.

Furthermore, whilst preferable to its simplified variant for the fulfilment of public health protection objectives of Regulation (EC) No. 1829/2003, the stringent interpretation of substantial equivalence doctrine via Regulation (EC) No. 1829/2003, would appear to have come too late in time because several transgenic plant foods, which are still on the market, had been approved under the simplified process regime of the Novel Food Regulation No. 258/97 in the European Union and the United Kingdom. And most importantly, the simplified variant of the substantial equivalent doctrine had by this time, arguably fostered a lackadaisical regulatory mind-set that was oblivious to the uniqueness of the existential conflicts posed by the coexistence of transgenic and non-transgenic plant organisms, and the imperatives for concomitant liability and redress regime.

#### **2.1.6. Criticisms of the Substantial Equivalence Doctrine.**

Although the “substantial equivalence” doctrine enjoys an ostensible transnational reach and supports, critics have challenged the validity and propriety of its underlying science, and described the doctrine as questionable, dubious and ideological.<sup>359</sup> For example, critics have

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<sup>357</sup> See *id.*

<sup>358</sup> See *id.*

<sup>359</sup> See Michael Baram, “Governance of GM Crop and Food Safety in the United States,” in Michael Baram and Mathilde Bourier, (editors), *Governing Risk in GM Agriculture*, *supra*, note 1, at 26-44.

characterised the doctrine as unscientific and ideologically driven policy contrivance of the government of the United States, which was primarily aimed at promoting and expediting the adoption of plant agricultural biotechnology products by “minimizing federal constraints on the advance of commercially advantageous technology and preventing growth of the federal bureaucracy.”<sup>360</sup>

It is even more remarkable that the Organization for Economic Cooperation and Development (OECD),<sup>361</sup> the Food and Agriculture Organization (FAO), and the World Health Organization (WHO),<sup>362</sup> would endorse the substantial equivalence doctrine with few reservations at it were, despite the acknowledgement by the United States Food and Drug Administration that “feeding studies” and “toxicological tests”, which were the key validating tests for substantial equivalence doctrine, were extremely limited, because “feeding studies on whole foods have limited sensitivity” and that it would be relatively difficult “to administer exaggerated doses.”<sup>363</sup>

It is therefore unsurprising that critics like Paul R. Billings et al., have characterised the substantial equivalence doctrine as a ruse designed “to justify introducing GE foods into the market without long-term nutritional and toxicological testing on animals.”<sup>364</sup> According to Paul R. Billings et al., without long term nutritional and toxicological testing of transgenic plant products on animals, “we have few ways of assessing the full effects of foreign gene insertion”<sup>365</sup> into the plant genome. Similarly, David Schubert expressed concerns on the lack

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<sup>360</sup> Id, at 27.

<sup>361</sup> See Organization for Economic Cooperation and Development, *Safety, Evaluation of Foods Derived by Modern Biotechnology: Concepts and Principles*, supra, note 71, at 10-13.

<sup>362</sup> See Food and Agriculture Organization/World Health Organization (FAO/WHO), Report of a Joint FAO/WHO Expert Consultation, *Strategies for Assessing the Safety of Foods Produced by Biotechnology*, supra, note 70, at 23-24.

<sup>363</sup> See also Les Levidow, Joseph Murphy, and Susan Carr, “Recasting “Substantial Equivalence”: Transatlantic Governance of GM Food,” *Science, Technology & Human Values*, supra, note 23, at 35.

<sup>364</sup> See Paul R. Billings and Peter Shorett, “Coping with Uncertainty: The Human Health Implications of GE Foods,” in Iain E. P. Taylor, (editor), *Genetically Engineered Crops: Interim Policies, Uncertain Legislation*, (New York: The Haworth Press), supra, note 62, at 79.

<sup>365</sup> Id, at 79.

of sufficient study on the potential unintended molecular effects and implications of inserting novel genes into plant cell,<sup>366</sup> thus underscoring the limits of the substantial equivalence doctrine as a scientific and quasi-regulatory tool for transgenic plant foods safety.

This view was shared by Esther J. Kok and Harry A. Kuiper, who opined that the substantial equivalence doctrine was no more than “a tool to identify potential differences” between conventional and transgenic plant crops, and should not displace or override toxicological and nutritional studies, which were key to assessing the safety and nutritional impacts of transgenic plant foods on humans and animals.<sup>367</sup> The authors then suggested rephrasing of the substantial equivalence doctrine as “Comparative Safety Assessment” approach, which “better outlines the comparative nature of the assessment, while avoiding the idea that it is a safety assessment itself.”<sup>368</sup>

Even Consumers International, an independent and authoritative global voice for consumers, did express their reservations and concerns on the validity and propriety of the substantial equivalence doctrine for transgenic plant foods safety and quality assurance:

Consumer experts are concerned that this concept has only limited value. First of all, it is very difficult to assess substantial equivalence doctrine... Too much importance is attached to digestibility tests for assessing safety. Finally, there is a lack of available scientific data on safety of traditional foodstuffs used for comparison with GEFs [genetically engineered foods... In a field of science in which many of mechanisms are still a mystery, great caution is needed.<sup>369</sup>

Moreover, further doubts were cast on the propriety of the substantial equivalence doctrine, by the United States Food and Drug Administration’s acknowledgement that transgenic plant

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<sup>366</sup> See David Schubert, “A different Perspective on GM Food”, *Nature Biotechnology*, Volume 20, (2002), at 969.

<sup>367</sup> See Esther J. Kok and Harry A. Kuiper, “Comparative Safety Assessment for Biotech Crops,” *Trends in Biotechnology*, Volume 21, Number 10, (October 2003), at 440.

<sup>368</sup> *Id.*, at 443.

<sup>369</sup> See Consumers International (CI), *Genetic Engineering and Food Safety: The Consumer Interests*, (London: Consumers International Global Policy Campaign Unit, 1996), at 1&3. Available at [www.consumersinternational.org](http://www.consumersinternational.org), cited in Les Levidow, Joseph Murphy, and Susan Carr, “Recasting “Substantial Equivalence”: Transatlantic Governance of GM Food,” *Science, Technology & Human Values*, *supra*, note 23, at 35.

foods “are likely in some cases to present more complex safety and regulatory issues than seen to date.”<sup>370</sup>

### **2.1.7. Impacts of Substantial Equivalence Doctrine on Liability and Redress Regimes.**

One of the thesis’ hypotheses is that the substantial equivalence doctrine is liable for the general weakness of national and transnational regulatory oversight for transgenic plant agriculture and food, especially with regards to the regulatory framework for liability and redress regime for damage induced by adventitious presence of transgenes in the coexistence of transgenic and non-transgenic plant organisms. In the following sections, this hypothesis will be tested by analysing key elements of the regulatory framework for coexistence of transgenic plant technology and non-transgenic plant agriculture in the United States, the European Union, and the United Kingdom.

### **2.1.8. Weak Regulatory Oversight for Transgenic Plant Organisms in the U.S.**

In the United States, the first noticeable effect of the substantial equivalence doctrine is that the 1986 coordinated framework that recommended nil to minimal regulation for biotechnology products, and that vested oversight in existing agencies such as the FDA,<sup>371</sup> arguably facilitated the circumvention of Congressional regulatory oversight for transgenic plant organisms, thus denying transgenic plant technological products similar or comparable regulatory oversight to that of pharmaceutical products, which equally rely on cutting-edge genetic engineering techniques for product development.<sup>372</sup>

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<sup>370</sup> See United States Food and Drug Administration, Premarket Notice Concerning Bio-engineered Foods: Proposed rules, *Federal Register*, Volume 66, (2001), 4706-4738, cited in Sheldon Krinsky and Nora K. Murphy, “Biotechnology at the Dinner Table: FDA’s Oversight of Transgenic Food,” *The Annals of the American Academy of Political and Social Science*, *supra*, note 28, at 80-96.

<sup>371</sup> See Office of Science and Technology Policy (OSTP), Coordinated Framework for Regulation of Biotechnology, *Federal Register*, *supra*, note 204, at 23,303.

<sup>372</sup> See Ronald J. Herring, “Epistemic Brokerage in the Bio-property Narrative: Contributions to Explaining Opposition to Transgenic Technologies in Agriculture, *New Biotechnology*, *supra*, note 13, at 614-615, (discussing how recombinant DNA technique is used in pharmaceutical and other industries).

The comparison between pharmaceutical products and transgenic plant technological products is germane for two main reasons: First, the comparison highlights the palpable disparity in regulatory rigour for transgenic plant technological products and new pharmaceuticals. Thus whilst the latter is subject to mandatory rigorous pre and post-market clinical trials on animals and humans, which could take up to twelve years to conclude,<sup>373</sup> the former literally piggybacks on the substantial equivalence doctrine to the marketplace. The contrast in regulatory processes for the two products, is further underscored by the drug companies' routine use of recombinant DNA in new pharmaceuticals production, which has been estimated to constitute 25 percent of all newly approved pharmaceutical products, as exemplified by transgenic human insulin, which was the first commercial transgenic product produced in 1982, using genetically modified bacterium.<sup>374</sup>

Second, the comparison between pharmaceuticals and transgenic plant food products is particularly legitimate and germane because pro-transgenic plant agriculture scientists and scholars like Ronald J. Herring and Robert Paarlberg do routinely bemoan the inherent irony in the unquestioning acceptance by the general public, of the use of recombinant DNA technology in medicine and pharmaceuticals,<sup>375</sup> and the relative paradoxical disdain and scepticism of the general public for the use of recombinant DNA in plant agriculture and products, especially in Europe.<sup>376</sup>

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<sup>373</sup> See Taiwo A. Oriola, "Strong Medicine: Patents, Market, and Policy Challenges for Managing Neglected Diseases and Affordable Prescription Drug," *Canadian Journal of Law and Technology*, Volume 7, Number 1, (April 2009), at 86-89, (discussing the expensive and extensive pre and post market mandatory clinical trials of new pharmaceuticals, which could take several years to ensure safety).

<sup>374</sup> See Robert Paarlberg, *Starved for Science: How Biotechnology is Being Kept Out of Africa*, *supra*, note 38, at 11.

<sup>375</sup> This is exemplified by transgenic human insulin. See Robert Paarlberg, *Starved for Science: How Biotechnology is Being Kept Out of Africa*, *supra*, note 38, at 11. See also Pandey Shivanand and Suba Noopur, "Recombinant DNA Technology: Applications in the Field of Biotechnology and Crime Sciences," *International Journal of Pharmaceutical Sciences Review and Research*, Volume 1, Issue 1, (March-April 2010), at 43-49 (noting how transgenic human insulin, albeit from animal protein, is structurally identical to naturally produced insulin in humans).

<sup>376</sup> See Ronald J. Herring, "Epistemic Brokerage in the Bio-property Narrative: Contributions to Expanding Opposition to Transgenic Technologies in Agriculture," *New Biotechnology*, *supra*, note 13 at 614-615, (noting how rDNA techniques were widely accepted in pharmaceuticals, medicine, and industry). See also Robert Paarlberg, *Starved for Science: How Biotechnology is Being Kept Out of Africa*, *supra*, note 38, at 18, (discussing

Perhaps, the general public's ready embrace and acceptance of transgenic medicine and pharmaceuticals, in contradistinction to their relative scepticism and disdain for transgenic plant technological products, could be partly explained by the perceived weakness or inadequacy of the regulatory framework largely facilitated by the substantial equivalence doctrine, in addressing unresolved and outstanding safety and liability issues, relative to the stringent regulatory standards required of comparable pharmaceutical products? This is arguably exemplified by the relative lack of public confidence in the Federal regulatory oversight regime for transgenic plant agriculture and food in the United States, especially in the wake of national food scares precipitated by the StarLink corn fiasco,<sup>377</sup> the continuing vulnerability of non-transgenic plant farmers to intellectual property lawsuits,<sup>378</sup> and possible economic damage from in situ gene flow, and adventitious commingling of transgenic and non-transgenic plant materials,<sup>379</sup> and lack of labelling for transgenic food products.<sup>380</sup> The effects of the substantial equivalence doctrine on U.S regulatory regime is aptly summed-up by Michael Baram thus:

Among developed nations, the United States is the leading proponent and most permissive regulator of GM crops and foods. The executive branch, led by the President's Office, has promoted the commercialization and export of GM seeds, crops, and food, and discouraged regulations that would treat these products differently from their conventional, non-GM counterparts. The regulatory agencies, which are subject to presidential direction, have acted accordingly by lessening test requirements, creating regulatory exemptions and approving commercialization despite scientific uncertainties about risks to public health and the environment. They have steadfastly resisted

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the ready acceptance of genetic engineering techniques in medicine by rich countries and the relative opposition to the use of genetic engineering techniques in agriculture).

<sup>377</sup> See David Winickoff, Sheila Jasanoff, Lawrence Busch, Robin Grove-White, and Brian Wynne, "Adjudicating the GM Food Wars: Science, Risk, and Democracy in World Trade Law", *The Yale Journal of International Law*, vol. 30, (2005), 81, at 103. See also Bill Hord, "The Road Back: Prodigene and Other Biotech Companies Are Moving Ahead in an Environment of Increasing Fear of Crop Contamination", *Omaha World Herald*, (19 January 2003), at 1.

<sup>378</sup> See *Monsanto Co. v. McFarling*, 302 F.3d 1291 (Fed. Cir. 2002) (holding that farmer McFarling's saving of transgenic seeds was tantamount to intellectual property infringement). *w*, Volume 65, Number 4, July 2002), at 517-537.

<sup>379</sup> See *In re LL601 Rice Litigation*, (2007); *Sample v. Monsanto*, 283 F. Supp. 2d 1088 (E.D. Mo. 2003).

<sup>380</sup> See Robert Paarlberg, *Starved for Science: How Biotechnology is Being Kept Out of Africa*, *supra*, note 38, at 17-23. See also Taiwo A. Oriola, "Consumer Dilemmas: The Right to Know, Safety, Ethics, and Policy of Genetically Modified Food," *Singapore Journal of Legal Studies*, *supra*, note 30, at 530, (discussing the state of Oregon's aborted transgenic foods labelling rule, and the preference of most Americans for labelling of transgenic food products).

petitions for more stringent safety reviews and precautionary policies, and rejected proposals for labeling GM products that would enable informed choice by consumers.<sup>381</sup>

Viewed from the foregoing discourse, the ultimate effect of the substantial equivalence doctrine is that there is no specific Federal statute on liability and redress regime in the United States.<sup>382</sup> Invariably, aggrieved parties seeking damages for injury resulting from the release of transgenic organisms into the environment, which range from allergic reaction to cross-pollination of conventional or organic crops, must rely on the common law's difficult burden of proof.<sup>383</sup>

### **2.1.9. Decentralised Liability and Redress Regimes in the European Union.**

Within the European Union, it is argued that the substantial equivalence doctrine is implicated in the decentralised, disparate, and incoherent liability and redress regime for possible damage in the coexistence of transgenic and non-transgenic plant agriculture.<sup>384</sup> For example, Article 26(a) of the Deliberate Release Directive 2001/18 enjoins Member States to “take appropriate measures to avoid the unintended presence of GMOs in other products.”<sup>385</sup>

Moreover, the Commission Recommendation of 13 July 2010 on guidelines for the development of national coexistence measures to avoid the unintended presence of GMOs in conventional and organic crops provides that “matters concerning financial compensation or liability for economic damage are the exclusive competence of Member States.”<sup>386</sup>

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<sup>381</sup> See Michael Baram, “Governance of GM Crop and Food Safety in the United States,” in Michael Baram and Mathilde Bourier, (editors), *Governing Risk in GM Agriculture*, *supra*, note 1, at 16.

<sup>382</sup> See A. Bryan Enders, “GMO”: Genetically Modified Organism or Gigantic Monetary Obligation? The Liability Schemes for GMO Damage in the United States and the European Union”, *Loyola of Los Angeles International and Comparative Law Review*, Volume 22 (2000), at 459.

<sup>383</sup> *Id.*, at 459.

<sup>384</sup> See Commission Recommendation 2003/556/EC 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.

<sup>385</sup> See Article 26(a) of Deliberate Release Directive 2001/18.

<sup>386</sup> See 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, *Official Journal of the European Union*, (2010/C 200/01), paragraph 2.5.



Arguably, the decentralised liability and redress regime system within the European Union with a single market system, constitutes a major weakness, which allows for disparate and largely ineffective causes of action that range from statutory strict liability regimes in Denmark, Germany, and Austria,<sup>387</sup> to possible product, contractual, and tortious liability regimes in the United Kingdom.<sup>388</sup>

There is certainly a real prospect for cross-border conflict of laws amongst Member States, especially for damage caused by trans-border border gene flow between Member States with disparate liability regimes.<sup>389</sup> Crucially, such disparate liability regimes could also frustrate the European Commission's current agenda to embrace transgenic plant agriculture, as disgruntled Member States could use stringent national liability regimes to indirectly discourage or block prospective transgenic crops farmers.

It is argued that notwithstanding the precautionary principle and the labelling and traceability laws, the substantial equivalence doctrine offers a false sense of safety and security for transgenic plant agriculture and food products, lures regulators into a state of lethargy, and removes the urgency and imperatives for a harmonised and coherent liability regime across the European Union.

### **2.2.0. Absence of Coherent Liability and Redress Regime in the United Kingdom.**

Even within the United Kingdom, liability regimes could potentially differ considerably amongst the constituent nations, with Wales tilting towards a strict liability regime,<sup>390</sup> whilst

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<sup>387</sup> See Manuela Weissenbacher, "Damage Caused by GMOs under Austrian Law," in Bernhard A. Koch, (editor), *Damage Caused by Genetically Modified Organisms: Comparative Survey of Redress Options for Harm to Persons, Property or the Environment*, (Berlin & New York: Walter de Gruyter Publishing, 2010), at 2. See generally the analyses in chapters five and six of thesis, *infra*.

<sup>388</sup> See Christopher Rodgers, "Defra's Coexistence Proposals for GM Crops: A Recipe for Confrontation?" *Supra*, note 61, at 1-8.

<sup>389</sup> See Stuart J. Smyth and Drew L. Kershen, "Agricultural Biotechnology: Legal Liability Regimes from Comparative and International Perspectives," *Global Jurist Advances*, Vol. 6, Issue 2, (2006), at 1-78.

<sup>390</sup> See Technical Services Division 2, *Summary of Responses to the Welsh Assembly Government Consultation on Proposals for Managing the Coexistence of GM, Conventional and Organic Crops in Wales*, (December 2009). (In response to question 26 on the distribution of the burden of a redress system, majority of respondents favoured placing the burden of redress on transgenic seed firms).

the Department of Agriculture and Rural Affairs (DEFRA), would prefer existing remedies at common law, and product liability to apply in England.<sup>391</sup> Following the 2006 national consultation with stakeholders, DEFRA had noted on its website that “existing product liability laws will apply to GM products as they do now to non-GM products.”<sup>392</sup>

It is argued that DEFRA’s preference for existing liability regimes would appear to overlook the unique challenges and problems posed by the advent of transgenic plant technology, which, arguably could only be dealt with by specialised liability and redress regime. For it is doubtful that common law’s difficult burden of proof system or product liability’s remedies would provide adequate redress for potential litigants. Moreover, the potentially differing liability regimes amongst the constituent nations of the United Kingdom, could precipitate complex causes of action in circumstances of trans-border genes-flow, and encourage forum shopping by potential litigants.

It is argued that substantial equivalence doctrine is partly responsible for the current disarray in the coexistence regulatory regime in the United Kingdom, especially with regards to the absence of a coherent liability regime, because it lured authorities into a sense of false security on the safety science of transgenic plant technology, and obviated the need for specialised liability and redress measures.

### **2.2.1. Conclusions.**

Chapter two sets out to test one of the thesis’ hypotheses that substantial equivalence doctrine undermines the imperatives for effective and coherent liability and redress regime. The hypothesis is premised on the logic that if products of transgenic plant agriculture were

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<sup>391</sup> See Christopher Rodgers, “Defra’s Coexistence Proposals for GM Crops: A Recipe for Confrontation?” *Supra*, note 15, at 1-8.

<sup>392</sup> See DEFRA's website at <http://Defra.co.uk> (accessed on 14 May 2015).

substantially equivalent to that of non-transgenic plant agriculture, then, by extrapolation, the commingling of transgenic plant organisms with non-transgenic plant organisms could not give rise to damage. Arguably, the need for a specialised liability and redress regime is rendered moot and academic in the circumstances, despite the unique problems and challenges thrown up by the advent of transgenic plant technology.

The hypothesis is further supported by the US origin of the substantial equivalence doctrine, which was a 1986 coordinated policy framework especially designed to fulfil the US government's promotional policy for biotechnology products via a regime of nil to minimal regulatory regime. Thus, substantial equivalence doctrine, which tacitly eschews non-regulation, fits neatly into the non-regulatory regime narrative of the policy, as exemplified in the FDA approval process for transgenic plant foods, which was for several years on a voluntary basis. Even when this was subsequently made mandatory following public outcry, the FDA continued to rely exclusively on industry-generated data for its approval process for transgenic plant foods.

Following the subsequent endorsement of the substantial equivalent doctrine in Reports authored by the World Health Organization, the Food and Agriculture Organization, and the OECD, it was subsequently incorporated into the EU and UK laws. While the UK and EU variant was subsequently modified and made more stringent, it is argued that its implementation could be hamstrung by international trade rules on transgenic plant agricultural products, unless the stringent variant is backed by proven science. The chapter then reviews the current liability and redress regimes systems in the EU and the UK, and attributes its incoherence and disparate nature to the influence of the substantial equivalence doctrine.

## **Chapter Three**

### **Comparative Regulatory Science and Coexistence Policy**

#### **3.1.0. Introduction.**

Chapter Three builds on the analysis in Chapter Two, by exploring the broader scientific underpinnings of the regulatory and policy framework for the coexistence of transgenic and non-transgenic plant agriculture and products in the European Union and the United States.

The chapter provides an insight into the approval systems and the coexistence arrangements for transgenic and non-transgenic plant agriculture, and the inherent limitations of regulatory science for transgenic plant technology governance. Whilst Chapter Two disputes the scientific legitimacy of the substantial equivalence doctrine, and questions its undue influence on the coexistence arrangements, Chapter Three focuses exclusively on the dynamic and symbiotic relationship between “science” (in the broadest sense) and policy, and the influence and limits of scientific opinions on the regulatory and policy framework for the coexistence of transgenic and non-transgenic plant agriculture.

The aim of the chapter is to provide a deeper perspective and insight into the extent to which the current coexistence arrangement for transgenic and non-transgenic agricultural products are science-dependent, and how this dependency could impact effective liability and redress regimes. The chapter characterises science-based policy for transgenic plant technology as “regulatory science”, and explores its proprieties, legitimacy, and effectiveness, amidst ongoing scientific uncertainties, claims and counter-claims on the safety science of transgenic plant technology for public health and the environment. The chapter again draws on Anthony Giddens’ pessimism on the reliability of science for the governance of “manufactured risks” in the post-industrial “risk society”, and serves as a backgrounder for chapter four, which explores the reality of the science-dependent coexistence arrangements for transgenic and non-transgenic plant agriculture, and tests the effectiveness of the current coexistence laws in the European Union, the United Kingdom and the United States.

### **3.1.1. Science and Coexistence Policy: A Symbiotic Relationship.**

To the extent that the approval processes for transgenic crops, the cultivation of transgenic crops, the *in situ* coexistence of transgenic and non-transgenic plant agriculture, and the post-

harvest movements of transgenic crops are rooted in science-based risks assessments methods, the resultant policy framework or rules would qualify as regulatory science.

Thus, in technical parlance, science-dependent policy and regulations are known as regulatory science.<sup>393</sup> This is exemplified by the underlying scientific risks assessments for the approval of new transgenic plant organisms. For example, the European Food and Safety Authority's guidance document on the environmental risk assessment of genetically modified plants, inter alia, enjoins the conduct of risk assessment:

in a scientifically sound manner based on available scientific and technical data and on common methodology for identification, gathering and interpretation of the relevant data...Sufficient scientific data must be available in order to arrive at qualitative/quantitative risk estimates.<sup>394</sup>

Similarly, scientific risk assessment and scientific evidence form an integral part of the Agreement on the Application of Sanitary and Phytosanitary Measures, (SPS Agreement), an international treaty of the World Trade Organization, which is aimed at the protection of human, animal or plant health from risks.<sup>395</sup> Articles 5(1) and 5(2) of the SPS Agreement require that all food safety measures must be based on risk assessment and scientific evidence.<sup>396</sup> The primary aim of the treaty is to prevent “scientifically unfounded” barriers to trade disguised as health and safety regulations.<sup>397</sup>

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<sup>393</sup> See Yeonwoo Lebovitz, Rebecca English, and Anne Claiborne, *Building a National Framework for the Establishment of Regulatory Science for Drug Development: Workshop Summary*, *supra*, note 6, at 6.

<sup>394</sup> See EFSA Panel on Genetically Modified Organisms, European Food Safety Authority: *Scientific Opinion: Guidance on the Environmental Risk Assessment of Genetically Modified Plants*, *EFSA Journal*, 2010; 8 (11): 1879, at 3.

<sup>395</sup> See the *Agreement on the Application of Sanitary and Phytosanitary Measures*, Final Act Embodying the Results of the Uruguay Round of Multilateral Trade negotiations, General Agreement on Tariffs and Trade, Annex 1A, (15 April 1994), at <http://www.worldtradelaw.net/uragreements/spsagreement.pdf>; Peter Van den Bossche and Werner Zdouc, *The Law and Policy of the World Trade Organization: Text, Cases and Materials*, (Cambridge: Cambridge University Press, 2013), at 834.

<sup>396</sup> See the *Agreement on the Application of Sanitary and Phytosanitary Measures*, Final Act Embodying the Results of the Uruguay Round of Multilateral Trade negotiations, General Agreement on Tariffs and Trade, Annex 1A, (15 April 1994), at <http://www.worldtradelaw.net/uragreements/spsagreement.pdf>

<sup>397</sup> See Robert Cunningham, ‘The ABC of GMOs, SPS & The WTO: An analysis of the Application of the Agreement on Sanitary and Phytosanitary Measures within the context of biotechnology and International Trade,’ *Australian Southern Cross University Law Review*, Volume 9, (2005), 19-37, at 24; .

In the same vein, juridical interpretations of transgenic plant laws and policy on national and international levels are ostensibly guided by the science that underpins the laws. For example, in the *European Communities Biotech Products Case*, a 1998 de facto moratorium imposed on the approval of new transgenic crops and seeds and on importation of transgenic crops and associated products by the European Commission, was held in contravention of Articles 5(1) and 5(2) of the SPS Agreement, as a disguised barrier to international trade in transgenic plant agricultural products, on grounds that the said moratorium was not supported by proven scientific evidence.<sup>398</sup> The European Commission had relied on the economic and socio-cultural objections of Member States and their citizens for imposing the moratorium.<sup>399</sup>

Similarly, in *Alliance for Bio-Integrity v. Dona Shalala*, the Federal District Court of Columbia had deferred to the scientific opinions of the Food and Drug Administration, which was premised on the substantial equivalence doctrine, and held inter alia that transgenic plant food was not “food addictive”, and therefore labelling was not required. The Court had rejected plaintiffs’ alternative interpretation of the underlying science, and their religious and cultural objections to transgenic plant foods.<sup>400</sup> Thus, both rulings invariably affirm the primacy of science over non-scientific considerations and policy for transgenic plant technological products governance.

However, whilst the ostensible science-centric policy disposition of legislative and juridical regulatory science might invoke a vista of a tyrannical or deterministic science, regulatory science is by no means peculiar to the governance of transgenic plant agricultural technology,<sup>401</sup> being a putative and interpretive policy tool for defining, delimiting, and

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<sup>398</sup> See Panel Report, *European Communities – Measures Affecting the Approval and Marketing of Biotech Products*, WTO Doc WT/DS291, WT/DS292/R, WT/DS293/R (2006).

<sup>399</sup> Id. See also Robert Lee, “GM Resistant Europe and the WTO Panel Dispute on Biotech Products,” in Jennifer Gunning and Soren Holm, (editors), *Ethics, Law and Society: Volume 1*, *supra*, note 5, at 131-140.

<sup>400</sup> See *Alliance for Bio-Integrity v. Donna Shalala*, *supra*, note 218, at 177-182.

<sup>401</sup> Regulatory science is routinely employed in the governance of pharmaceuticals and new drug development. See Yeonwoo Lebovitz, Rebecca English, and Anne Claiborne, *Building a National Framework for the Establishment of Regulatory Science for Drug Development: Workshop Summary*, *supra*, note 6, at 5-11.

deconstructing the relationship between virtually all forms of technology and nature, a point aptly adumbrated by Robert G. Lee thus: “while nature is inevitably interpreted and technically constructed through science, it is now also shaped by its deliberative intrusion.”<sup>402</sup>

However, despite the presumed primacy and pervasiveness of science on transgenic plant technology regulatory framework, transgenic plant technology continues to be a subject of relentless public anxiety, intense public scrutiny, and relentless opposition, amidst continuing, often acrimonious, conflicting scientific data on the degree of its susceptibility to mutations, new toxins and allergens, as well as its full ramifications for public health and the environment.<sup>403</sup> Even so, the current regulatory system for the coexistence policy is largely predicated on scientific risk assessment on issues that range from transgenic plant food allergens and toxins, the coexistence of transgenic and non-transgenic plant, to the safety of transgenic plant agriculture and food respectively for the environment and public health.<sup>404</sup>

### **3.1.2. The General Nature and Scope of Regulatory Science.**

In general terms, “regulatory science”<sup>405</sup> connotes science-based regulation, policy, or decision-making processes,<sup>406</sup> and “a unique application of science, at all levels, to the societal

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<sup>402</sup> See Robert G. Lee, “Look at Mother Nature on the Run in the 21st Century: Responsibility, Research and Innovation,” *Transnational Environmental Law*, vol. 1, Issue 1, (April 2012), 105-117, at 107.

<sup>403</sup> See Per Pinstrup-Andersen and Ebbe Schiøler, *Seeds of Contention: World Hunger and the Global Controversy over GM Crops*, (Baltimore & London: John Hopkins University Press, 2001), at 47-48.

<sup>404</sup> See Mae-Wan Ho, *GMO Free: Exposing the Hazards of Biotechnology to Ensure the Integrity of our Food Supply*, (Ridgefield, CT & London: Institute for Science in Society, 2004) at 21-25, (describing the “substantial equivalence” doctrine on which the safety of transgenic crops was premised as “unscientific”, and noting how the contrarian findings of Professor Puszi on the dangers posed by transgenic crops to public health and the environment, were attacked within the scientific establishment).

<sup>405</sup> For discussion on the concept of regulatory science and various definitions, see Yeonwoo Lebovitz, Rebecca English, and Anne Claiborne, *Building a National Framework for the Establishment of Regulatory Science for Drug Development: Workshop Summary* (Washington D.C: The National Academies Press, 2011), at 5-11.

<sup>406</sup> See Alan Irwin, Henry Rothstein, Steven Yearley and Elaine McCarthy, “Regulatory Science: Towards a Sociological Framework,” *Futures: The Journal of Policy, Planning and Futures Studies*, Volume 29, Number 1, (1997), at 17-31.



decision process”,<sup>407</sup> or as “the development and use of new tools, standards and approaches to more efficiently develop products and to more effectively evaluate product safety, efficacy and quality.”<sup>408</sup> Thus to the extent that the underlying coexistence policy is underpinned by "science", the said policy could be described as regulatory science. The discussion of regulatory science is germane to the discourse on the effectiveness or otherwise of the coexistence policy for transgenic plant technology. This is especially so when the underlying science of coexistence policy is uncertain, contested and disputed, as exemplified by Anthony Giddens' scepticism of science-dependent policy, which is amply demonstrated in the analyses in section 1.1.7, and Chapter Two of the thesis.<sup>409</sup> Thus, this section is meant to highlight the dynamics of regulatory science for transgenic plant technology governance in the United States and the European union, the susceptibility of science-dependent policy to the inherent uncertainty of science, and the how the coexistence policy could be improved by a proactive compensation regime.

Significantly, a distinction is often made between “regulatory science” and “research science”, with the latter being regarded as qualitatively superior to the former.<sup>410</sup> According to Sheila Jasanoff:

Whereas, research science places greatest value on published papers, certified by peers as true, original, and significant, science conducted for policy is rarely innovative and may never be submitted to the discipline of peer review and publication.<sup>411</sup>

Whilst it is beyond the remit of this chapter to join the fray on the contested theoretical and empirical distinctions between “regulatory” and “research” science,<sup>412</sup> it would suffice to argue

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<sup>407</sup> See Yeonwoo Lebovitz, Rebecca English, and Anne Claiborne, *Building a National Framework for the Establishment of Regulatory Science for Drug Development: Workshop Summary*, *supra*, note 6, at 6, (citing Alan Moghissi).

<sup>408</sup> *Id.*, (citing NIH-FDA definition).

<sup>409</sup> See Anthony Giddens, "Risks and Responsibility," *Modern Law Review*, *supra*, note 7, at 4.

<sup>410</sup> See Sheila Jasanoff, *The Fifth Branch: Science Advisers as Policymakers*, (Cambridge Massachusetts: Harvard University Press, 1994), at 76-83.

<sup>411</sup> *Id.*, at 77.

<sup>412</sup> See Alan Irwin, Henry Rothstein, Steven Yearley and Elaine McCarthy, “Regulatory Science: Towards a Sociological Framework,” *Futures: The Journal of Policy, Planning and Futures Studies*, *supra*, note 7, at 17-31. See also Yeonwoo Lebovitz, Rebecca English, and Anne Claiborne, *Building a National Framework for the*

that there is no evidence to suggest that “research science” is either infallible,<sup>413</sup> or sacrosanct as such,<sup>414</sup> or that the current crop of regulatory and policy framework for national and transnational governance of transgenic plant agricultural technology is premised entirely on inferior or un-refereed science.<sup>415</sup> Rather, an audit of scientific literature on transgenic plant technology, which was commissioned by the United Kingdom Department of Environment and Rural Affairs (DEFRA), and published by GM Science Review Panel in 2004, showed that most of the literature by academic and industry researchers was in peer-reviewed and refereed journals.<sup>416</sup>

Furthermore, in October 2001, the Research Directorate of the European Union released an eighty-one page review of scientific studies published on transgenic crops over a fifteen year period, and concluded that “research on GM plants and derived products so far developed and marketed, following usual risk assessment procedures, has not shown any new risks to human health or the environment”.<sup>417</sup> It is instructive to note that the report released by the European

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*Establishment of Regulatory Science for Drug Development: Workshop Summary, supra*, note 6, at 1-78, which *inter alia*, discusses the role of regulatory science in the context of drug development, as inclusive of assessment of laboratory data, review and assessment of animal and human clinical data, methods of drug development, development of technical and scientific standards for preclinical assessment, product development, post market surveillance manufacturing, food safety standards, and food processing technologies, all of which would mostly require peer review work.

<sup>413</sup> For example, between 1975 and 2012, a total of 2,047 research articles in life-sciences and biomedical research indexed by PubMed were retracted. A detailed review of the reasons underlying retractions showed that 21.3 per cent were attributable to errors, while a whopping 67.4 per cent were attributable to misconduct including fraud or suspected fraud. See Ferric C. Fang, R. Grant Steen, and Arturo Casadevall, “Misconduct accounts for the majority of retracted scientific publications,” *The Proceedings of the National Academy of Sciences*, (1 October, 2012), at 1-6.

<sup>414</sup> See Bernard d'Espagnat, “Is Science Cumulative? A Physicist Viewpoint,” *Boston Studies in the Philosophy of History of Science*, Volume 255, Number 5, (2008), 145-151. Moreover, many “research science” results that are borne out of rigorous peer-review systems, are known to lack replicability and tend to generate conflicting results. For discussion, see Jonah Lehrer, “The Truth Wears Off: Is there Something Wrong with the Scientific Method?” *The New Yorker*, (13 December, 2010), at <http://www.newyorker.com>

<sup>415</sup> See The GM Science Review Panel, *GM Science Review (Second Report): An Open Review of the Science Relevant to GM Crops and Food based on Interests and concerns of the Public*, (January 2004), at <http://www.bis.gov.uk/files/file14992.pdf>

<sup>416</sup> See *id.*

<sup>417</sup> See European Union Research Directorate, *GMOs: Are There Any Risks?* (Brussels: EU Commission Press Briefing, 9 October, 2001), at [http://ec.europa.eu/research/biosociety/pdf/gmo\\_press\\_release.pdf](http://ec.europa.eu/research/biosociety/pdf/gmo_press_release.pdf) A summary of the report noted at page 1 that it was meant “to raise the voice of science in the GMO debate by establishing an ongoing discussion forum on the research results relating to benefits and risks of GMOs.”

Union Research Directorate had no reason to qualify the quality of the scientific publications and research audited, which was a mixture of academic and industry research.<sup>418</sup>

Thus, Jasanoff's proposition that regulatory science is inferior to research science ostensibly smacks of an arbitrary distinction and categorisation, because invariably, regulatory science is premised on an amalgam of scientific knowledge from industry and academia, irrespective of publication medium, or the quality of publication outlet, and is as differing from country to country, as it is from one type of technology to another, with concomitant variations in its fundamental constituents, a point that is well adumbrated by Alan Irwin et al., thus:

[T]he literature on science and policy-making suggests that the institutional culture of regulatory science changes from country to country so that cross-national comparison suggests significant variation. Thus, it can be implied from the work of several authors that in Europe, regulatory science shows greater similarities to academic science than is the case in the USA.<sup>419</sup>

Thus, by extrapolation, and in the context of transgenic plant agricultural technology policy for example, cross-country variations in regulatory and policy science framework is exemplified by the European Union precautionary principle,<sup>420</sup> which arguably informed legislations such as transgenic food products labelling rules, to which the United States did not subscribe,<sup>421</sup> despite evidence suggesting that ninety-four percent of Americans polled in a survey published in 2003 showed preference for the labelling of transgenic plant food products.<sup>422</sup> Therefore, in

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<sup>418</sup> See id.

<sup>419</sup> The term "academic science" as used in this context, connotes "research science". See Alan Irwin, Henry Rothstein, Steven Yearley and Elaine McCarthy, "Regulatory Science: Towards a Sociological Framework," *Futures: The Journal of Policy, Planning and Futures Studies*, supra, note 7, at 20.

<sup>420</sup> The precautionary principle involves applying provisional risk management measures, where there is a high probability of harm to public health, in the face of scientific uncertainties. The precautionary principle is premised on a range of scientific research highlighting the uncertainties surrounding transgenic plant agriculture and food respectively for the environment and public health. See Commission of the European Communities, (Brussels: 02 February 2000), *Communication From The Commission on the Precautionary Principle*, paragraph 5.1.2, at 14, at [http://ec.europa.eu/dgs/health\\_consumer/library/pub/pub07\\_en.pdf](http://ec.europa.eu/dgs/health_consumer/library/pub/pub07_en.pdf)

<sup>421</sup> For example, while the European Union has a law mandating the labelling of transgenic agricultural food products, the United States has no national labelling policy, and attempts by States such as Oregon to enact labelling legislations were scuppered in mid 2000s. See Margaret Rosso Grossman, "European Community Legislation for Traceability and Labeling of Genetically Modified Food," in Paul Weirich, (editor), *Labeling Genetically Modified Food: The Philosophical and Legal Debate*, (Oxford: Oxford University Press, 2007), at 32-62.

<sup>422</sup> See Robert Paarlberg, *Starved for Science: How Biotechnology is Being Kept Out of Africa*, supra, note 23, at 17-23.

this chapter, the term “regulatory science” will, *ipso facto* be employed in a generic, comprehensive, and utilitarian sense to denote all science-based regulation and policy regimes for transgenic plant agricultural technology governance, (whether peer-reviewed or otherwise), and irrespective of the nature, quality, or characteristics of the publication medium.<sup>423</sup>

However, barring any unsavoury or blatant instrumental uses of regulatory science for political ends, there is nothing intrinsically wrong with regulatory science and policy as such, primarily because it is ostensibly predicated on “science”, which has been defined as “the systematic study of the structure and behaviour of the physical and natural world through observation and experiment,”<sup>424</sup> or as “an organised body of knowledge on any subject”.<sup>425</sup> For according to Francis Bacon, experimental observation of materials and the concomitant inductions or deductions thereof are the hallmarks of science.<sup>426</sup> Therefore, observable, verifiable, and replicable scientific knowledge should arguably be preferable to ethical, religious, conscientious, cultural, whimsical, subjective, or idiosyncratic rationales for regulating technological inventions,<sup>427</sup> precisely because of science's perceived neutrality, objectivity, rationality, agnosticism and relative certitude.<sup>428</sup> This point is aptly summed up by

David Papineau thus:

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<sup>423</sup> However, while no distinction is made between research and regulatory science, the quality of the science on which regulatory science is premised will be subject to scrutiny in parts III and IV of this essay, in order to ascertain the limits and propriety of regulatory science vis-a-vis ethical, cultural, and religious framework in the governance of transgenic plant agricultural technology.

<sup>424</sup> See *Oxford Paperback Dictionary*, at 802.

<sup>425</sup> See *id.*

<sup>426</sup> See Claude Bernard, *An Introduction to the Study of Experimental Medicine*, (Dover Publications, 1st June, 1957), at 6. Sir Francis Bacon, who lived between 1561 and 1626, was widely regarded as the original philosopher of science, who “proposed a scientific method that suspended most traditional belief in favour of a project of establishing a comprehensive new understanding of the world.” See also David Papineau, (General Editor), *Philosophy*, (London: Duncan Bird Publishers, 2009), at 96.

<sup>427</sup> For example, in the *Commission of the European Communities v Republic of Poland*, (Case C-165/08), Judgment of the Court (Second Chamber) of 16 July 2009. Polish anti-transgenic seeds legislation, which prohibited the marketing of seeds derived from genetically modified varieties and the registration of such varieties in the national catalogue of seed varieties, on ethical and religious grounds, was challenged by the European Commission. The Polish law was held violative of the provisions of Articles 22 and 23 of the Deliberate Release Directive 2001/18/EC..

<sup>428</sup> See Hans Radder, “Science and Technology: Positivism and Critique,” in Jan Kyrre Berg Olsen, Stig Andur Pedersen, and Vincent F. Hendricks, (editors), *A Companion to the Philosophy of Technology*, (Chichester, England: Blackwell Publishing, 2009), at 61-65, (discussing how “science and technology are seen as yielding universally valid knowledge and objectively working tools that are normatively neutral and acquire value only

The uniqueness of scientific knowledge seems to derive from two factors. First, scientific theories are not wild speculations. Unlike theological or metaphysical claims, they are grounded in careful observation and controlled experiment. Second, scientific theories are very abstract. They use concepts that are not found in common sense and explain familiar events in terms of things we cannot see. This combination of the observable and the theoretical is unprecedented in human thought.<sup>429</sup>

But then the pertinent question, which is at the core of this chapter is the extent to which “science” that underpins the risks assessment for transgenic plant agriculture, is ultimately reliable, objective, agnostic, or neutral in its pivotal role as the fulcrum anchoring the regulatory and governance systems of transgenic plant agricultural technology?<sup>430</sup> After all, if the general public were to rely on “science” to the exclusion of alternative governance systems such as ethics, religious beliefs, or cultural imperatives for regulating technologies both old and new,<sup>431</sup> then the general public should certainly have legitimate expectations of “science” to deliver a relative degree of reliability, neutrality and certitude in the governance of transgenic plant agriculture and foods?<sup>432</sup> Otherwise, what would be the justifications for excluding or denying those with legitimate claims to alternative or parallel technological governance systems in ethics, religion, or culture, which arguably are notoriously heterogeneous and ostensibly lacking in neutrality, objectivity, and predictability?<sup>433</sup> This question is particularly relevant to any general academic inquiry into the limits and propriety of regulatory science in the

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when applied for specific social purposes.” However, the author also noted recent studies, which questions science neutrality and universal validity). See id, at 61-62.

<sup>429</sup> See David Papineau, (General Editor), *Philosophy*, *supra*, note 420, at 98. See also Roger A. Pielke, Jr., *The Honest Broker: Making Sense of Science in Policy and Politics*, (Cambridge: Cambridge University Press, 2007), at 43-44, (discussing how society tend to ascribe high value to scientific information and regard it as authoritative, while non-scientific information is perceived negatively).

<sup>430</sup> Even the uncertainties, which scientists acknowledge signify more than one outcome, and which routinely dog science and scientific claims, could be framed or measured objectively and subjectively. According to Roger A. Pielke, “so long as there exist...different, valid scientific perspectives, some degree of uncertainty will always exist.” See Roger A. Pielke, Jr., *The Honest Broker: Making Sense of Science in Policy and Politics*, *supra*, note 29, at 59-61.

<sup>431</sup> For example, the ethical, religious, and cultural oppositional grounds to transgenic plant agriculture and foods were discountenanced by court in the U.S. case of *Alliance for Bio-integrity v. Donna Shalala*, *supra*, note 107, at 116. See also the *Commission of the European Communities v Republic of Poland*, (2009/C220/16).

<sup>432</sup> Indeed, it has been proven that many scientific ideas generate conflicting results, and that not all scientific studies are replicable. For discussion, see Jonah Lehrer, “The Truth Wears Off: Is There Something Wrong with the Scientific Method?” *The New Yorker*, *supra*, note 14. See also John P.A. Ioannidis, “Why Most Published Research Findings Are False,” *PLoS Medicine*, Volume 2, Issue 8, (August 2005), at 0696-0701.

<sup>433</sup> See David Papineau, (General Editor), *Philosophy*, *supra*, note 420, at 98.

governance of transgenic plant agricultural technology, in light of the hotly contested and highly contentious safety science of transgenic plant agriculture,<sup>434</sup> and recent assertion by approximately two hundred and fifty members of the United States National Academy of Sciences, in a letter published in the *Science Journal*, that there was always some uncertainty associated with scientific conclusions, and that “science never absolutely proves anything.”<sup>435</sup>

Anthony Giddens shared similar pessimism regarding the primacy of “science” and its presumed prerogative to manage “manufactured risks” in the “risk society”, citing science’s inconsistencies on BSE, global warming, drinking red wine, eating beef, environmental toxins and declining sperm counts, asbestos, and tobacco smoking. He noted the “unstable and complex framework of scientific claims and counterclaims”, and concluded that “science does not produce proof and can never do more than approximate to truth.”<sup>436</sup>

But then, perhaps, the hypothesis that “science never absolutely proves anything” is explainable or justifiable by the axiom that most published research findings especially in the field of genetics, are irreproducible or false.<sup>437</sup> Yet, replicability of scientific results is crucial to the validation or affirmation of their reliability, as aptly expressed by Jonah Lehrer thus:

The test of replicability, as it is known, is the foundation of modern research. Replicability is how the community enforces itself. It is a safeguard for the creep of subjectivity. Most of the time, scientists know what results they want, and that can

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<sup>434</sup> There is a plethora of literature on the dangers and promise of transgenic plant agricultural technology. For a quintessential view on the danger of the technology, see F. William Engdahl, *Seeds of Destruction: The Hidden Agenda of Genetic Manipulation*, (Montreal: Global Research, 2007). For a contrarian account on the promise of the technology, see Robert Paarlberg, *Starved for Science: How Biotechnology is Being Kept Out of Africa*, *supra*, note 23, at 1-80.

<sup>435</sup> See Peter, H. Gleick et al., “Climate Change and the Integrity of Science,” *Letters, Science*, Volume 328, (7 May 2010), at 689-690; William Kerr and Jill Hobbs, “Consumers, Cows and Carousels: Why the Dispute over Beef Hormones is Far More Important than its Commercial Value’ in Nicholas Perdakis and Robert Read (eds), *The WTO and the regulation of international trade : recent trade disputes between the European Union and the United States*, (Edward Elgar Publishing Limited, 2005), at 193 (noting that scientific evidence can never be conclusive, and that it was not possible to test for all health risks that could arise from importation of certain products).

<sup>436</sup> See Anthony Giddens, “Risk and Responsibility”, *Modern Law Review*, *supra*, note 7, at 1-4.

<sup>437</sup> See Jonah Lehrer, “The Truth Wears Off: Is There Something Wrong with the Scientific Method?” *The New Yorker*, *supra*, note 14; John P.A. Ioannidis, “Why Most Published Research Findings Are False,” *PLoS Medicine*, *supra*, note 32, at 0696-0701; Ramal Moonasinghe, Muin J. Khoury, and A.Cecile J.W. Janssens, “Most Published Research Findings Are False: But a Little Replication Goes a Long Way,” *PLoS Medicine*, Volume 4, Issue 2, (February 2007), at 0218-0221 (noting how a lack of replication in research findings especially in the field of genetics, was due mostly to publication and selection bias).

influence the results they get. The premise of replicability is that scientific community can correct for these flaws.<sup>438</sup>

However, aside from replicability problems, the claim that “science never absolutely proves anything”<sup>439</sup> could also be partly justified by the theory that science, which typically underpins regulatory policy for technologies, could either be “proven” science or “evolving” science.<sup>440</sup> For example, whilst the science that underpins aerodynamics technology,<sup>441</sup> and the constitution of human genetic material,<sup>442</sup> would appear relatively settled, the underlying science on the safety, toxicity and allergenicity of transgenic plant food products is arguably neither precise nor exact, and is at best evolutionary, in light of pervasive scientific uncertainties, conflicting scientific research results, contested and unresolved scientific questions, and as yet unknown ramifications of the advent of transgenic plant agriculture and food respectively for the environment and public health.<sup>443</sup>

Moreover, the theory that the current underlying safety science of transgenic plant agriculture and food products is evolutionary, is not entirely unfounded, as scientific knowledge is arguably, generally organic, and tends to be incremental and cumulative overtime, despite contrarian claims.<sup>444</sup> Indeed current scientific knowledge is invariably built on past or cumulative scientific studies, as aptly exemplified by the famous statement of “the

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<sup>438</sup> See Jonah Lehrer, “The Truth Wears Off: Is There Something Wrong with the Scientific Method?” *The New Yorker*, *supra*, note 14.

<sup>439</sup> See Peter, H. Gleick et al., “Climate Change and the Integrity of Science,” Letters, *Science*, *supra*, note 35 at 689-690.

<sup>440</sup> Science is generally classified into two categories: proven and evolving science. For discussion, see Alan Moghisi, *Institute for Regulatory Science*, “Best Available Science: Metrics for Evaluation of Scientific Claims,” at <http://www.nars.org/bas.html>

<sup>441</sup> Aerodynamics deals with the study of the interaction of air with solid objects, and the knowledge is crucial for designing and calculating the speed of aircrafts relative to their weights and sizes. See John D. Anderson, *Fundamentals of Aerodynamics*, 5<sup>th</sup> edition, (McGraw-Hill Higher Education, 1 June, 2011), pp. 1128.

<sup>442</sup> It is well established that human genetic material comprises DNA, which includes two complementary strands and undergoes transcription and translation. For discussion, see George Wei, *An Introduction to Genetic Engineering, Life Sciences and the Law*, (Singapore: Singapore University Press, 2001), at 1-53.

<sup>443</sup> For example, with regards to allergenicity of transgenic plant foods, it is difficult to ascertain with absolute certainty, whether a transgene protein is a potential allergen. For discussion, see Robert B. Buchanan, “Genetic Engineering and the Allergy Issue,” *Plant Physiology*, Volume 126, Number 1, (May 2001), at 5-7.

<sup>444</sup> See [Bernard d’Espagnat](#), “Is Science Cumulative? A Physicist Viewpoint,” *Boston Studies in the Philosophy and History of Science*, *supra*, note 14, at 145-151, (dismissing Kuhn’s theory or its interpretation thereof to the effect that science is not cumulative).

greatest and most influential scientist who ever lived”,<sup>445</sup> Isaac Newton, who while at University of Cambridge, wrote a letter to Robert Hooke on 5 February 1676 stating amongst other things that: “If I have seen further, it is by standing on the shoulders of the giants.”<sup>446</sup>

Moreover, the cumulative nature of scientific knowledge is mirrored by the broad categorisation of scientific information or knowledge into two classes: “proven science” and “evolving science”.<sup>447</sup>

Furthermore, the generally progressive and cumulative nature of the science underlying most technological advancements is transcendental of technology types, and not in any way peculiar to transgenic plant technology. Also, and most crucially, the central argument in this chapter that the science that underpins risks assessment for transgenic plant agricultural technology is cumulative, evolving, or evolutionary, especially on its safety implications for public health and the environment, is arguably buttressed and exemplified by a publication in 2012, on the impact of transgenic *Bacillus thuringiensis* (Bt.) maize on non-target soil organisms.<sup>448</sup> The research revealed that transgenic Bt. maize, which was designed to curb traditional maize foes such as the European corn borer, could be deleterious to the populations of non-target soil organisms such as *arbuscular mycorrhizal* fungi.<sup>449</sup> Notably, the revelatory findings were the first ever demonstration of a probable link between the possible reduction in *arbuscular mycorrhizal* fungi populations and the cultivation of transgenic Bt. maize, and

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<sup>445</sup> See Daniel S. Burt, *The Biography Book: A Reader's Guide to Non-fiction, Fictional and Film Biographies of More than 500 of the Most Fascinating Individuals of All Time*, (Westport, CT & Oxford: Greenwood Publishing Group Inc, 2001), at 315.

<sup>446</sup> See Jean-Pierre Maury, Newton: *Understanding the Cosmos*, New Horizon Series, (London: Thames & Hudson, 1992), at 117.

<sup>447</sup> For discussion, see Alan Moghissi, *Institute for Regulatory Science*, “Best Available Science: Metrics for Evaluation of Scientific Claims,” *supra*, note 39.

<sup>448</sup> See Tanya E. Cheeke, Todd N. Rosentiel, and Mitchell B. Cruzan, “Evidence of reduced arbuscular mycorrhizal fungal colonization in multiple lines of Bt maize,” *American Journal of Botany*, Volume 99, Number 4, (April 2012), at 700-707.

<sup>449</sup> See *id.*, at 700-707.



contributed to the growing and evolutionary body of knowledge on the “unanticipated effects of Bt. crop cultivation on non-target soil organisms”.<sup>450</sup>

Therefore, within the context of the evolutionary or evolving nature of the safety science underpinning the risk assessment for transgenic plant agricultural technology, and the current scientific uncertainties pervading its full ramifications for public health and the environment, the pertinent questions, which are central to the theme of this chapter are as follows: First, could future scientific breakthroughs reveal as yet unknown adverse effects of transgenic plant agriculture and food respectively on the environment and public health, which could be as dramatic as the recent findings on the probable debilitating impacts of transgenic Bt crops on *arbuscular mycorrhizal* fungi populations? Second, how does the current science-dependent coexistence policy in the United States and the European Union deal with the uncertain underlying science? Third, how should coexistence policy on transgenic and non-transgenic plant agriculture reflect or address the pervasive uncertainties dogging the long-term safety science of transgenic plant agriculture and food respectively for the environment and public health? Answering these questions would entail a comparative analysis of how the current science-dependent regulatory framework governing risk assessment for transgenic plant agriculture has fared in the United States, the European Union, and the United Kingdom.

### **3.1.3. Regulatory Science Framing of Coexistence Policy in the United States.**

It is apt to begin with the coexistence policy in the United States because it was where commercial transgenic plant agriculture first began in the 1990s, and it was the country that coined the doctrine of substantial equivalence in a 1986 national policy statement designed primarily to promote new businesses in biotechnology.<sup>451</sup> Thus, whilst the science of

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<sup>450</sup> See *id.*, at 707.

<sup>451</sup> See Office of Science and Technology Policy (OSTP), *Coordinated Framework for Regulation of Biotechnology*, *Federal Register*, Volume 51, (1986), at 23302-93. See also Margret Rosso Grossman, “Genetically Modified Crops and Food in the United States: The Federal Regulatory Framework, State Measures,

substantial equivalence seeks to guarantee the safety of transgenic plant foods and feeds for humans and livestock respectively, other science-based policies include on-farm separation distances designed to pre-empt adventitious presence of transgenes in non-transgenic crops. For example, the United States Department of Agriculture's policy guidelines on on-farm separation distances between transgenic and non-transgenic crops fields, is ostensibly premised on scientific knowledge of plants' sexual reproduction systems and the behaviour of the natural pollinating agencies such as butterflies, birds, winds, etc. This is exemplified by the amended USDA guidelines on experimental field testing of transgenic pharmaceutical corn crop, which inter alia requires that the size of the perimeter fallow zone around a trial field must be 50 feet and that no corn should be grown within 1 mile (5,280 feet) of the trial field throughout the duration of any field test, which involves open-pollinated corn.<sup>452</sup>

### **3.1.4. Regulatory Framework for Transgenic Plant Agriculture in the United States.**

The following three Federal Agencies are responsible for the governance of transgenic plant agriculture and products in the United States: The first is the United States Department of Agriculture, whose responsibility is to ensure that transgenic plant seeds and crops are safe for cultivation; the second is the United States Environmental Protection Agency, whose responsibility is to ensure that transgenic plant agriculture is safe for the environment; whilst the third is the United States Food and Drug Administration, whose responsibility is to ensure that transgenic plant food is safe for human consumption and for public health.<sup>453</sup> The three agencies are primarily guided by the policy articulated in the 1986 Office of Science and

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and Liability in Tort,” in Luc Bodiguel and Michael Cardwell, (editors), *The Regulation of Genetically Modified Organisms: Comparative Approaches*, (Oxford: Oxford University Press, 2010), at 300.

<sup>452</sup> See The U.S Department of Agriculture, “Field testing of Plants engineered to produce pharmaceutical and industrial compounds, *Federal Register*, Volume 68, Number 46, (Monday, 10 March, 2003/Proposed Rule), at 11337-11340.

<sup>453</sup> See Margret Rosso Grossman, “Genetically Modified Crops and Food in the United States: The Federal Regulatory Framework, State Measures, and Liability in Tort,” in Luc Bodiguel and Michael Cardwell, (editors), *The Regulation of Genetically Modified Organisms: Comparative Approaches*, *supra*, note 50, at 300.

Technology Coordinated Framework, on which the substantial equivalence doctrine is predicated.<sup>454</sup> The following paragraphs will discuss how the three agencies regulate and manage transgenic plant agriculture and its coexistence with non-transgenic plant agriculture, their overlapping duties, the inevitable turf wars between the agencies, and how the structural governance system has impacted liability and redress regime for transgenic plant technology.

### **3.1.5. The United States Food and Drug Administration.**

Under the Federal Food, Drug and Cosmetic Act, the United States Food and Drug Administration (FDA) generally regulate the safety of food and feed, including non-pesticidal transgenic plant foods from new varieties.<sup>455</sup> Key provisions of the Food, Drug, and Cosmetic Act deal with the prevention of food adulteration and the regulation of food additives.<sup>456</sup> Additionally, the FDA also relies on the 1992 Policy Statement on the substantial equivalence doctrine, which posits that transgenic plant food is substantially equivalent to organic and conventional plant food.<sup>457</sup> Therefore, pursuant to the provisions of 1992 FDA Policy Statement on foods derived from transgenic plant varieties, which presumed that transgenic plant food had been developed safely and therefore safe for human consumption, the Food and Drug Administration did not conduct mandatory pre-market safety reviews of transgenic plant food.<sup>458</sup> Rather, the Food and Drug Administration would only require voluntary consultations on food safety with transgenic plant foods producers, prior to marketing of transgenic or rDNA-produced foods.<sup>459</sup> In other words, transgenic plant food manufacturers were not obliged to consult the Food and Drug Administration prior to product market debut, because their products were deemed substantially equivalent to organic and conventional plant food. The

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<sup>454</sup> Id.

<sup>455</sup> See the Federal Food, Drug, and Cosmetic Act (FDCA), 21 USC, sections 301-309.

<sup>456</sup> Id.

<sup>457</sup> See Department of Health and Services (HHS), Food and Drug Administration (FDA) *Statement of Policy: Foods Derived From New Plant Varieties*, Docket No. 92N-0139, 57 *Federal Register*, 22984, at 22,990 (29, May 1992).

<sup>458</sup> See Margret Rosso Grossman, “Genetically Modified Crops and Food in the United States: The Federal Regulatory Framework, State Measures, and Liability in Tort,” in Luc Bodiguel and Michael Cardwell, (editors), *The Regulation of Genetically Modified Organisms: Comparative Approaches*, *supra*, note 50, at 310.

<sup>459</sup> Id.

rationale for voluntary pre-market food safety review process is contained in the FDA 1992

Policy Statement as follows:

The regulatory status of a food, irrespective of the method by which it is developed, is dependent upon objective characteristics of the food and the intended use of the food (or its components)... The key factors in reviewing safety concerns should be the characteristics of the food product, rather than the fact that new methods are used.<sup>460</sup>

However, the voluntary consultation process for the implementation of the substantial equivalence doctrine by the Food and Drug Administration would appear to give a short shrift to the safety and risks inherent in transgenic plant organisms.<sup>461</sup> According to Sheldon Krimksy et al., rather than new regulations, the Food and Drug Agency introduced a discretionary and voluntary consultation process for companies planning to introduce transgenic foods into the market.<sup>462</sup> Under the voluntary consultation regime, transgenic seeds developers “are provided a flow chart indicating when consultation with the agency is desirable.”<sup>463</sup> According to the 1996 Food and Drug Administration guidance document for industry on the procedures for consultation:

A developer who intends to commercialize a bioengineered food meets with the agency to identify and discuss relevant safety, nutritional, and other regulatory issues regarding the bioengineered food prior to marketing it... A developer may initiate such a consultation early or late in the development of the food.<sup>464</sup>

However, a lack of mandatory legal obligations for pre-market safety review for transgenic plant food, makes the entire consultation process largely voluntary or discretionary,<sup>465</sup> and it

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<sup>460</sup> See Department of Health and Services (HHS), Food and Drug Administration (FDA) *Statement of Policy: Foods Derived From New Plant Varieties*, Docket No. 92N-0139, 57 *Federal Register*, *supra*, note 62, at 22,984-5.

<sup>461</sup> See Sheldon Krimsky and Nora K. Murphy, “Biotechnology at the Dinner Table: FDA’s Oversight of Transgenic Food,” *The Annals of the American Academy of Political and Social Sciences*, Volume 584, Issue 1, (November 2002), at 80-96.

<sup>462</sup> *Id.*, at 82.

<sup>463</sup> *Id.*, at 82.

<sup>464</sup> See Food and Drug Administration (FDA), Centre for Food Safety and Applied Nutrition, “Guidance on Consultation Procedures: Foods Derived from New Plant Varieties, (1997), at <http://www.cfsan.fda.gov/lrd/consulpr.html>

<sup>465</sup> This conclusion could be inferred from the wording of the FDA guidance document, which is apparently couched in non-obligatory terms, and gives the developer a leeway not to initiate any consultation process: “A developer *may* initiate a consultation early or late in the development of the food.” See *id.* (Italic is mine).

would be logical to infer that most transgenic plant food producers would happily bypass the voluntary pre-market safety review in order to save costs and expedite product market debut. This is in stark contrast to the production process for new pharmaceuticals, for which the United States Congress mandated rigorous statutory clinical trials on animals and humans prior to product market debut.<sup>466</sup>

Even when consultation might be deemed desirable by the Food and Drug Administration, Sheldon Krimsky et al. noted that the Food and Drug Administration might not “usually conduct a comprehensive scientific review of the data produced by the developer for products that are classified as generally regarded as safe.”<sup>467</sup> Rather, the agency would only review the information provided by the developer and then decide “whether any unresolved issues exist regarding the food derived from the new plant variety that could necessitate legal action by the agency if the product were introduced into commerce.”<sup>468</sup> While there is no specific time-frame for the completion of consultation procedures, the estimated median and average time for completion of consultation review by the Food and Drug Administration was 155 days and 175 days respectively.<sup>469</sup> Again, this is in stark contrast to the Food and Drug Administration's approval process for new pharmaceuticals, which could take up to 12 years prior to products commercial debut and marketing.<sup>470</sup> The obvious discrepancies in the approval processes for transgenic plant food and pharmaceutical products, clearly underscore the relative public distrust for the safety science of transgenic plant food. Unsurprisingly, the Food and Drug

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<sup>466</sup> See Taiwo A. Oriola, “Strong Medicine: Patents, Market, and Policy Challenges for Managing Neglected Diseases and Affordable Prescription Drug,” *Canadian Journal of Law and Technology*, Volume 7, Number 1, (April 2009), at 86-89, (discussing the expensive and extensive pre and post market mandatory clinical trials of new pharmaceuticals, which could take several years to ensure safety).

<sup>467</sup> See Sheldon Krimsky and Nora K. Murphy, “Biotechnology at the Dinner Table: FDA’s Oversight of Transgenic Food,” *The Annals of the American Academy of Political and Social Science*, *supra*, note 66, at 82.

<sup>468</sup> See Food and Drug Administration (FDA), Centre for Food Safety and Applied Nutrition, “Guidance on Consultation Procedures: Foods Derived from New Plant Varieties, (1997), *supra*, note 69.

<sup>469</sup> See Sheldon Krimsky and Nora K. Murphy, “Biotechnology at the Dinner Table: FDA’s Oversight of Transgenic Food,” *The Annals of the American Academy of Political and Social Science*, *supra*, note 66, at 83.

<sup>470</sup> See Taiwo A. Oriola, “Strong Medicine: Patents, Market, and Policy Challenges for Managing Neglected Diseases and Affordable Prescription Drug,” *Canadian Journal of Law and Technology*, *supra*, note 71, at 86-89.

Administration's voluntary and discretionary consultation procedures for new transgenic plant foods approval was criticised by stakeholders for its apparent inadequate safeguards for public health protection.<sup>471</sup>

### **3.1.6. The New Guidance Documents on Mandatory Premarket Approval.**

The criticisms of the voluntary consultation process, led to the November 1994 recommendations by a Food and Drug Administration Advisory Committee, which made it mandatory for transgenic plant food producers to submit safety and nutritional assessments to the agency, prior to product market debut.<sup>472</sup> In direct response to the recommendations, the Food and Drug Administration published a proposal on 18 January 2001, which mandated premarket notifications of new transgenic plant foods by developers.<sup>473</sup> Amongst other things, the proposed rule required transgenic plant foods manufacturers to submit a scientific and regulatory assessment of transgenic foods to the Food and Drug Administration 120 days prior to transgenic plant foods market debut.<sup>474</sup> Furthermore, the mandatory scientific data submitted prior to transgenic plant foods market debut, must compare the composition and characteristics of the transgenic plant food in question to that of comparable conventional food.<sup>475</sup> According to Sheldon Krimsky et al., the mandatory scientific data required must also include the following five categories of information: First, “characterization of the parent plant, mode of reproduction, and history of development.”<sup>476</sup> Second, the method of development of the transgenic plant in question, detailing “the construction of the vector used in the transformation

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<sup>471</sup> See Sheldon Krimsky and Nora K. Murphy, “Biotechnology at the Dinner Table: FDA’s Oversight of Transgenic Food,” *The Annals of the American Academy of Political and Social Science*, *supra*, note 66, at 83.

<sup>472</sup> See Food and Drug Administration (FDA), Joint CSAN/CVM Advisory Committee Meeting, “Procedures for industry-FDA interaction prior to commercial distribution of foods derived from new plant varieties developed using recombinant DNA techniques,” (1994), at <http://vm.cfsan.fda.gov/-lrd/bioprop.html>

<sup>473</sup> See Food and Drug Administration (FDA), “Premarket Notice Concerning Bioengineered Foods: Proposed Rule”, *Federal Register*, Volume 66, (2001), at 4706-38.

<sup>474</sup> *Id.*

<sup>475</sup> *Id.* See also Sheldon Krimsky and Nora K. Murphy, “Biotechnology at the Dinner Table: FDA’s Oversight of Transgenic Food,” *The Annals of the American Academy of Political and Social Science*, *supra*, note 66, at 84.

<sup>476</sup> *Id.*, at 84.

of the parent plant and a thorough characterization of the introduced genetic material,” etc.<sup>477</sup> Third, analysis of newly inserted genes with antibiotic properties.<sup>478</sup> Fourth, “substances introduced into or modified (present at an increased level relative to comparative food)”.<sup>479</sup> And fifth, a comparison of the composition and characteristics of the transgenic food in question to comparable conventional foods, as well as an analysis of how the transgenic food is as safe as comparable non-transgenic food.<sup>480</sup> Sheldon Krimsky et al succinctly summarised the new consultation procedure thus:

The FDA’s written consultation reports are approximately four to five pages in length. They discuss the data provided by the developer and summarize the developer’s argument regarding the safety of the expressed proteins and any changes in the compositional analysis of the foods. The consultation reports contain a final sentence indicating whether the FDA considers it consultation complete. By reporting that the consultation is complete, the agency is implicitly stating that it has no questions or reservations about the science, that it is satisfied with the company’s comparative risk statement and that voluntary compliance has been met.<sup>481</sup>

However, whilst the requirement of the submission of mandatory scientific data on the nature and safety of transgenic plant foods to the Food and Drug Administration prior to market debut, is a welcome improvement on the hitherto voluntary consultation process, the research for the said mandatory scientific data is entirely industry-led and generated, and it is doubtful whether the Food and Drug Administration, who suffers from increasingly dwindling personnel, funding, and “deficient scientific base”, would have the necessary wherewithal to vet or verify the accuracy or validity of every self-generated scientific data submitted by applicants.<sup>482</sup> Yet, verifying the accuracy of industry-generated scientific data by regulatory agencies is crucial to an effective science-based regulatory regime, because industry is

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<sup>477</sup> Id, at 84.

<sup>478</sup> Id, at 84.

<sup>479</sup> Id.

<sup>480</sup> Id.

<sup>481</sup> Id, at 86.

<sup>482</sup> Even with regards to new pharmaceutical, which is renowned for its regulatory rigour, the Food and Drug Administration have acknowledged their limitations in form of personnel, “deficient scientific base”, and funding constraints in regulatory oversight of new pharmaceuticals. See Yeonwoo Lebovit, Rebecca English, and Anne Claiborne, *Building a National Framework for the Establishment of Regulatory Science for Drug Development: Workshop Summary*, (Washington D.C. The National Academy Press, 2011), *supra* note 6, at 23-29.

historically notorious for suppressing unfavourable scientific data. For example, some American corporations had allegedly sought to further corporate interests by deliberately suppressing and manipulating data that included information on dangerous industrial toxins that were a threat to public health.<sup>483</sup> Also, it has been alleged that companies do routinely ignore FDA's request for additional information, and that FDA would often review summaries of industry-generated data, rather than the full contents of the studies on which the data were predicated.<sup>484</sup>

Even in the unlikely event that an unfavourable scientific data was submitted by a transgenic plant developer to the Food and Drug Administration, the transgenic plant food in question might still pass the FDA's regulatory muster, if risk analysis of potential danger to public health was deemed reasonable, minimal, or too costly to manage.<sup>485</sup> According to Michael Baram, designated Federal agencies were required "to employ risk analysis to determine if there is a sufficient factual basis for regulatory action, and apply cost-benefit analysis to determine on economic grounds the extent to which a risk is "unreasonable" and worthy of regulation."<sup>486</sup> In the circumstances, a risk would only be worthy of regulation "when the value of the reduction in risk obtained by additional oversight is greater than the cost thereby imposed."<sup>487</sup> *A fortiori*, a potential food risk might still pass the Food and Drug Administration's regulatory muster on the premise that the associated risk is minimal or reasonable relative to the costs of regulation. Furthermore, according to Michael Baram, regulators "are directed to minimize regulatory burdens on product developers, accommodate rapid advances in product development and

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<sup>483</sup> See Gerald Markowitz and David Rosner, "Corporate Responsibility for Toxins," *The Annals of the American Academy of Political and Social Science*, Volume 284, Issue 1, (2002) at 159-174.

<sup>484</sup> See Friends of the Earth, Press Release, "GM Crop Safety Tests Flawed," (16 November 2004), cited in Michael Baram, "Governance of GM Crop and Food Safety in the United States," in Michael Baram and Mathilde Bourier, (editors), *Governing Risk in GM Agriculture*, (Cambridge: Cambridge University Press, 2011), at 39.

<sup>485</sup> *Id.*, at 27.

<sup>486</sup> *Id.*

<sup>487</sup> *Id.*



commercialization, and use flexible performance-based standards rather than rigid prescriptive or design standards to deal with end products risks.”<sup>488</sup>

Thus, it is theoretically possible for the Food and Drug Administration to countenance an unfavourable scientific data on an outstanding or unresolved risk, if the said risk is adjudged “reasonable” or “minimal”, and if regulating the risk would be economically inefficient. However, the framing of transgenic plant foods risks governance purely in terms of economic efficiency, rather than zero tolerance approach to eliminating every conceivable risk that new toxins and allergens might pose to the consuming public, underscores the limits of science-based risk assessment, and could arguably smack of regulatory recklessness.

Moreover, since risk is relative, it is unclear what might constitute “reasonable” or “minimal” risk in transgenic plant food context, and whether the general public who would ultimately consume transgenic plant food, would have the same level of tolerance to the permissible “reasonable” or “minimal” risk that some “cost-benefit” analysts have deemed too costly to regulate. Furthermore, unlike new pharmaceuticals,<sup>489</sup> the Food and Drug Administration has no post-market oversight over transgenic plant foods, and therefore cannot check industry records for evidence of harm or recall unsafe transgenic plant food. According to Michael Baram, the Food and Drug Administration has never carried out any systematic post-market oversight of transgenic plant foods, and would typically expect the United States Department of Agriculture's Animal and Plant Health Inspection Service (APHIS) to handle post-market contamination issues.<sup>490</sup>

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<sup>488</sup> Id.

<sup>489</sup> For example, the United States Food and Drug Administration (FDA) withdrew 10 pharmaceutical drug products between 2000 and 2006 following their market debut, on safety concerns. See Sally Robinson, Robert Pool, and Robert Giffin, *Emerging Safety Measures: Workshop Summary, Forum on Drug Discovery, Development, and Translation*, (Washington DC: National Academy of Sciences, 2008), at 1.

<sup>490</sup> See Michael Baram, “Governance of GM Crop and Food Safety in the United States,” in Michael Baram and Mathilde Bourier, (editors), *Governing Risk in GM Agriculture*, *supra*, note 89, at 42.

Thus, even though the Food and Drug Administration now requires mandatory premarket safety reviews for transgenic plant food, it is still not as rigorous as it should be, and definitely not as rigorous as comparable pharmaceutical products. It is argued that the main reason for the lackadaisical regulatory oversight is that the FDA never sees any differences between transgenic and non-transgenic plant food, due to the substantial equivalence doctrine, a scientific and quasi-regulatory tool used by the FDA for transgenic plant food governance.

It is therefore unsurprising that critics like Paul R. Billings et al., have characterised the substantial equivalence doctrine as no more than a ruse “to justify introducing GE foods into the market without long-term nutritional and toxicological testing on animals.”<sup>491</sup> For according to Paul R. Billings et al., without long term nutritional and toxicological testing of transgenic plant products on animals, “we have few ways of assessing the full effects of foreign gene insertion.”<sup>492</sup>

As previously observed in chapters two, even the Food and Drug Administration have acknowledged the limitations of “feeding studies” and “toxicological tests”, by noting that “feeding studies on whole foods have limited sensitivity” since it would be relatively difficult “to administer exaggerated doses,”<sup>493</sup> and that transgenic plant foods “are likely in some cases to present more complex safety and regulatory issues than seen to date.”<sup>494</sup> In the same vein, David Schubert expressed concerns on the lack of sufficient study on the potential unintended

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<sup>491</sup> See Paul R. Billings and Peter Shorett, “Coping with Uncertainty: The Human Health Implications of GE Foods,” in Iain E. P. Taylor, (editor), *Genetically Engineered Crops: Interim Policies, Uncertain Legislation*, (New York: The Haworth Press), *supra*, note 54, at 79.

<sup>492</sup> *Id.*, at 79.

<sup>493</sup> See Department of Health and Services (HHS), Food and Drug Administration (FDA) *Statement of Policy: Foods Derived from New Plant Varieties*, *The Federal Register*, *supra*, note 52.

<sup>494</sup> See United States Food and Drug Administration, Premarket Notice Concerning Bio-engineered Foods: Proposed rules, *Federal Register*, Volume 66, (2001), 4706-4738, cited in Sheldon Krimsky and Nora K. Murphy, “Biotechnology at the Dinner Table: FDA’s Oversight of Transgenic Food,” *The Annals of the American Academy of Political and Social Science*, *supra*, note 66, at 80-96.

molecular effects and implications of inserting novel genes into plant cell,<sup>495</sup> thus underscoring the limits of the science as a regulatory tool for transgenic plant foods.

### **3.1.7. The USDA and the Regulation of Transgenic Plant Agriculture.**

The United States Department of Agriculture (USDA) is generally responsible for the regulation of the cultivation of transgenic plant and crops.<sup>496</sup> This role is particularly relevant because it allows the USDA to set the ground rules for the cultivation of transgenic crops and on-field physical coexistence of transgenic and non-transgenic crops, such as separation distances etc. Ultimately, the farm represents the first theatre of conflicts between transgenic and non-transgenic crops, and the reliability of the science of on-farm coexistence arrangement would be crucial to combatting adventitious genes flow, which is a bane of the coexistence paradigm.<sup>497</sup>

The USDA's regulatory remit includes granting approval for field trials or confined release of new transgenic plant varieties; granting approval for the importation of transgenic plant varieties; granting approval for interstate movement of transgenic plant varieties; and granting approval for the commercial release of transgenic plant varieties through the Animal and Plant Health Inspection Service, (APHIS) and its Biotechnology Regulatory Services. (BRS)<sup>498</sup>

Most importantly, the Animal and Plant Health Inspection Service uses “a science-based regulatory framework that allows for the safe development and use of genetically engineered (GE) plants.”<sup>499</sup> Additionally, the USDA also regulates transgenic plant varieties under the

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<sup>495</sup> See David Schubert, “A different Perspective on GM Food”, *Nature Biotechnology*, Volume 20 Number 10, (October 2002), at 969.

<sup>496</sup> See Margret Rosso Grossman, “Genetically Modified Crops and Food in the United States: The Federal Regulatory Framework, State Measures, and Liability in Tort,” in Luc Bodiguel and Michael Cardwell, (editors), *The Regulation of Genetically Modified Organisms: Comparative Approaches*, *supra*, note 50, at 301.

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<sup>498</sup> See BRS, AHIS, USDA, *User's Guide: Notification*, (5 February 2008), available at [http://www.aphis.usda.gov/brs/pdf/Notification\\_Guidance.pdf](http://www.aphis.usda.gov/brs/pdf/Notification_Guidance.pdf) (cited in Margret Rosso Grossman, “Genetically Modified Crops and Food in the United States: The Federal Regulatory Framework, State Measures, and Liability in Tort,” *supra*, note 50, at 302).

<sup>499</sup> See APHIS, USDA, APHIS Policy on Responding to the Low-Level Presence of Regulated Genetically Engineered Plant Materials, 72 Federal Register, 14,649 (29 March 2007), cited in Margret Rosso Grossman, “Genetically Modified Crops and Food in the United States: The Federal Regulatory Framework, State Measures,

Plant Protection Act,<sup>500</sup> which allows the United States Department of Agriculture to control plant pests.<sup>501</sup>

Field trials for new transgenic plant could be conducted either by notification to the USDA or by obtaining the permit of the USDA via the Animal and Plant Health Protection Service.<sup>502</sup> For example, between 1987 and 2007, approximately 19,000 notifications were authorized, whilst 4,000 permits were issued by the Animal and Plant Health Protection Service for new transgenic plant field trials.<sup>503</sup> The majority of field trials followed the notification process, which was introduced in 1993 for plants that do not pose novel or new risks.<sup>504</sup> The notification process requires information that range from the location and size of the trial fields to technical data about the transgenic plant in question.<sup>505</sup> Also, multiple environmental releases can be combined in a single notification to the Animal and Plant Health Service.<sup>506</sup> Upon receipt of notification for environmental release of transgenic plant, the Animal and Plant Health Service must inform state regulatory officials and acknowledge within 30 days that environmental release is appropriate under the notification procedure, and the acknowledgement shall apply to field trial of the transgenic plant in question for a period of one year.<sup>507</sup> Significantly, the

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and Liability in Tort,” in Luc Bodiguel and Michael Cardwell, (editors), *The Regulation of Genetically Modified Organisms: Comparative Approaches*, *supra*, note 50, at 301.

<sup>500</sup> See Plant Protection Act (2000), 7 U.S.C. 7701 *et seq.*

<sup>501</sup> The Plant Protection Act, 7 U.S.C. sections 7701-72; and section 7711 authorise the regulation of plant pests by the USDA. For discussion, see Margret Rosso Grossman, “Genetically Modified Crops and Food in the United States: The Federal Regulatory Framework, State Measures, and Liability in Tort,” in Luc Bodiguel and Michael Cardwell, (editors), *The Regulation of Genetically Modified Organisms: Comparative Approaches*, *supra*, note 50, at 302.

<sup>502</sup> *Id.*

<sup>503</sup> See Government Accountability Office, (GAO) *Genetically Engineered Crops: Agencies Are Proposing Changes to Improve Oversight, but Could Take Additional Steps to Enhance Coordination and Monitoring*, (GAO-09-60 November 2008), at 11, (cited in Margret Rosso Grossman, “Genetically Modified Crops and Food in the United States: The Federal Regulatory Framework, State Measures, and Liability in Tort,” in Luc Bodiguel and Michael Cardwell, (editors), *The Regulation of Genetically Modified Organisms: Comparative Approaches*, *supra*, note 50, at 302.)

<sup>504</sup> See BRS, AHIS, USDA, *User’s Guide: Notification*, (5 February 2008), *supra*, note 127.

<sup>505</sup> See 7 CFR 340.3(b) (1)-(6); and 340.3(d)(2) (cited in Margret Rosso Grossman, “Genetically Modified Crops and Food in the United States: The Federal Regulatory Framework, State Measures, and Liability in Tort,” in Luc Bodiguel and Michael Cardwell, (editors), *The Regulation of Genetically Modified Organisms: Comparative Approaches*, *supra*, note 50, at 302).

<sup>506</sup> See BRS, APHIS, USDA, *User’s Guide: Notification*, (5 February 2008), *supra*, note 127.

<sup>507</sup> See 7 CFR 340.3(e)(4), *supra*, note 134.

notification procedure includes strict conditions that would ensure that field trials would not cause environmental or economic harm.<sup>508</sup> These range from proper shipment and storage of transgenic plant in order to prevent adventitious admixture with non-transgenic plant, to the prevention of the resurgence of volunteer transgenic plant following field trials.<sup>509</sup>

The permit procedure would apply to all environmental releases or field trials that exceed a period of one year.<sup>510</sup> The permit procedure would also apply to experimental releases of transgenic plant that may carry higher risks, such as pharmaceutical plants.<sup>511</sup> Furthermore, applicants whose notifications were denied by the Animal and Plant Health Service could also apply for a permit.<sup>512</sup> The permit procedure requires detailed technical information that range from experimental design, geographic locations, containment, to disposal plans.<sup>513</sup> The completed application for a permit and the review conducted by the Animal and Plant Health Service would then be sent by APHIS to the Department of Agriculture of the state in which the transgenic plant field trial would be conducted. APHIS must also conduct an environmental assessment, and if required, an environmental impact statement.<sup>514</sup> Following the review of the application for permit, APHIS could either grant the permit, or deny the application for permit with reasons, which denial is subject to appeal. If permit is granted, conditions could range from maintenance, disposal, to containment of the transgenic plant in question. The permit holder is obliged to report results of field trials, and promptly notify APHIS in the event of accidental or unauthorised release of the experimental transgenic plant, or unusual occurrences

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<sup>508</sup> See CFR 340.3(c), (d)(5) and (6).

<sup>509</sup> *Id.*

<sup>510</sup> See Animal and Plant Health Service, *Policy Statement Regarding Releases of Perennials Under Notification*, (cited in Margret Rosso Grossman, “Genetically Modified Crops and Food in the United States: The Federal Regulatory Framework, State Measures, and Liability in Tort,” in Luc Bodiguel and Michael Cardwell, (editors), *The Regulation of Genetically Modified Organisms: Comparative Approaches*, *supra*, note 50, at 302).

<sup>511</sup> See CFR 340.3(b)(4)(iii).

<sup>512</sup> See 340.3(e)(5).

<sup>513</sup> See 7 CFR 340.4(b) and (f).

<sup>514</sup> See 42 USC sections 4321-70f, (Margret Rosso Grossman, “Genetically Modified Crops and Food in the United States: The Federal Regulatory Framework, State Measures, and Liability in Tort,” in Luc Bodiguel and Michael Cardwell, (editors), *The Regulation of Genetically Modified Organisms: Comparative Approaches*, *supra*, note 50, at 303).

or unexpected consequences of the environmental release of the experimental transgenic plant in question.<sup>515</sup>

With regards to pharmaceutical and industrial transgenic plants, more stringent conditions would apply to the permit procedure.<sup>516</sup> The relative stringency of the conditions for a permit for pharmaceutical and other industrial crops was in ostensible response to a series of mishaps, which included the presence of adventitious transgenes from transgenic pharmaceutical corn in soybeans cultivated for food in a Nebraska field in the summer of 2001.<sup>517</sup> The permit had been issued to ProdiGene Corporation by the Animal and Plant Health Service, who had in turn, commissioned a Nebraska farmer to cultivate the swine pharmaceutical vaccine corn.<sup>518</sup> However, following the disposal and the clearance of the field on which the pharmaceutical vaccine corn was cultivated, it resurged as a volunteer crop amidst soybeans that was subsequently cultivated on the field, and got mixed-up with other soybeans harvest at a storage elevator in Aurora, Nebraska.<sup>519</sup> This led to the destruction of approximately 500,000 bushels of soybeans estimated at \$3 million, which ProdiGene Corporation was made to pay for, on top of an unprecedented \$250,000 fine.<sup>520</sup>

However, if anything, the adventitious transgenes underscores how irrepressible volunteer crops are, and the inevitability of adventitious transgenes in non-transgenic crops and in the environment via natural biological processes such as cross-pollination or the resurgence of

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<sup>515</sup> See 7 CFR 340.4(b) and (f). See also Margret Rosso Grossman, “Genetically Modified Crops and Food in the United States: The Federal Regulatory Framework, State Measures, and Liability in Tort,” in Luc Bodiguel and Michael Cardwell, (editors), *The Regulation of Genetically Modified Organisms: Comparative Approaches*, *supra*, note 50, at 303.

<sup>516</sup> See 340.3(b)(4)(iii).

<sup>517</sup> See Stephanie Simon, “Fearing a Field of Genes: The Food Industry loves engineered crops, but not when plants altered to ‘grow’ drugs and chemicals can slip into its products,” *Los Angeles Times*, (23 December 2002), at 1. See also Andrew Pollack, “U.S. Imposes Stricter Rules for Genetically Modified Crops,” *New York Times*, (7 March 2003), at A22; and Phillip Brasher, “U.S. Tightens rules for growing Parma crops,” *Des Moines Register*, (7 March, 2002), at D1.

<sup>518</sup> *Id.* See generally the discussion in chapters one and two of thesis on the practical problems posed the coexistence of transgenic and non-transgenic plant agriculture.

<sup>519</sup> *Id.*

<sup>520</sup> *Id.*

volunteer transgenic crops amidst non-transgenic crops. The event also demonstrates the limits of the underlying science that underpin the practicality of the coexistence of transgenic and non-transgenic plant agriculture, and by extrapolation, the limits of the regulations and policy predicated on the science of coexistence of transgenic and non-transgenic plant agriculture.

The best that the USDA could do in the circumstances was to tighten the coexistence rule, which they did, following a 2007 public consultation proceedings.<sup>521</sup> The proposed improved coexistence rule, which was mandated by the United States Congress, and published by APHIS in 2008, included ensuring the quality and completeness of records, the availability of representative samples, and requirement that permit holders must “maintain a positive chain of custody” and keep records.<sup>522</sup> The proposed regulation would also eliminate the notification procedure; establish four permit categories, based on risk of persistence and potential harm to the environment, whilst the permit category for transgenic plant with the lowest risk would impose regulatory oversight that is similar to current notifications.<sup>523</sup> Crucially, the proposed regulation would also extend APHIS regulatory oversight under the Plant Protection Act, to cover noxious weeds and biological control organisms.<sup>524</sup>

In 2006, a U.S District judge, Michael Seabright sitting in Hawaii, criticised the USDA biopharmaceutical crops approval process, which ignored both the Endangered Species Act and the National Environmental Policy Act. The USDA had allowed ProdiGene, Monsanto, Hawaii Agriculture Research Center, and Garst Seed, to cultivate transgenic pharmaceutical

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<sup>521</sup> See APHIS, *Introduction of Organisms and Products Altered or Produced Through Genetic Engineering*, 71 *Federal Register* 39,021, 39,022, (17 July 2007). For a list detailing lessons and experiences of APHIS, see APHIS, *Introduction of Genetically Modified Organisms, Draft Programmatic Environmental Impact Statement*, (July 2007), Docket APHIS-2006-0112.

<sup>522</sup> See Food, Conservation and Energy Act of 2008, Pub L 110-246, section 10204.

<sup>523</sup> See APHIS, USDA, *Importation, Interstate Movement, and Release into the Environment of Certain Genetically Engineered Organisms*, 73, *Federal Register* 60,008, 60,009, (6 October 2008), (cited in Margret Rosso Grossman, “Genetically Modified Crops and Food in the United States: The Federal Regulatory Framework, State Measures, and Liability in Tort,” in Luc Bodiguel and Michael Cardwell, (editors), *The Regulation of Genetically Modified Organisms: Comparative Approaches*, *supra*, note 1, at 306).

<sup>524</sup> For the definition of biological control and organisms and noxious weed, see Plant Protection Act, 7 U.S.C. sections 7702(2) and (10).

corn and sugarcane on Kauai, Maui, Molokai and Oahu between 2001 and 2003, without environmental impact assessment and reviews on the Hawaiian Islands, which were the habitat of more than 300 threatened or endangered species.<sup>525</sup> The District Court judgment demonstrates the possibility that certain arable land could be designated as free-zones for transgenic plant agriculture due to the sensitivity, or fragility of the environment, biodiversity, or eco-systems. Most importantly, the judgment also highlights the possibility that regulatory authorities could be selective in what risk assessment they choose to conduct, and why judicial review is crucial for transgenic field trials authorisations in the United States.

Although the USDA reviewed and tightened the on-farm coexistence rule in 2007 to avoid resurgence of volunteer crops and stem on-farm adventitious comingling of transgenic and non-transgenic crops on the one hand, and that of unapproved transgenic crops and approved transgenic crops on the other hand, it is argued that genes flow is a natural phenomenon that cannot be completely eliminated by science-backed separation rules. This will be amply demonstrated in chapter four of thesis, which analyses the reality and practicality of the coexistence of transgenic and non-transgenic plant agricultural products.

### **3.1.8. The US Environmental Protection Agency and Transgenic Plant Agriculture.**

The Environmental Protection Agency (EPA) is one of the three federal agencies with regulatory oversight over transgenic plant agriculture, focusing on transgenic plants that express pesticidal properties.<sup>526</sup> The FDA and the EPA regard transgenic plant that express pesticidal properties such as the *Bacillus thuringiensis* maize, cotton, canola, and soybean varieties as pesticides.<sup>527</sup> The Regulatory remit of the EPA is conferred by the Federal

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<sup>525</sup> See “USDA Criticized for Field Test Approval Process,” *Biotechnology Law Report*, Volume 25, Number 5, (October 2006), at 553.

<sup>526</sup> See Margret Rosso Grossman, “Genetically Modified Crops and Food in the United States: The Federal Regulatory Framework, State Measures, and Liability in Tort,” in Luc Bodiguel and Michael Cardwell, (editors), *The Regulation of Genetically Modified Organisms: Comparative Approaches*, *supra*, note 50, at 307.

<sup>527</sup> *Id.*



Insecticide, Fungicide, and Rodenticide Act (FIFRA),<sup>528</sup> and the Foods, Drug, and Cosmetic Act.<sup>529</sup> In a Policy Statement issued by the FDA in 1992, both the FDA and the EPA agreed to share regulatory oversight over food safety.<sup>530</sup> According to the agreement, the EPA would have oversight over food safety issues associated with the use of pesticides, whilst the FDA would have oversight over food safety issues associated with compositional changes in food such as food additives, as well as over substances intended to enhance plant resistance to chemical herbicides, such as Monsanto's glyphosate.<sup>531</sup> However, there could be considerable overlap in the regulatory oversights of the agencies with regards to food safety, especially where a food safety incident requires the expertise of both agencies.<sup>532</sup>

The EPA regulates pesticides that have been transferred into plants from other organisms such as *Bacillus thuringiensis* bacteria, under the Federal Insecticide, Fungicide, and Rodenticide Act.<sup>533</sup> In 2001, the Environmental Protection Agency characterised pesticides that have been transferred into plant from other organisms as “plant-incorporated protectants” (PIPs), in a policy statement that sets out the regulatory procedures for such transgenic plants.<sup>534</sup> Plant-incorporated protectants such as the crop varieties encoded with pesticidal *Bacillus thuringiensis* proteins, are characterised as pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act because of their ability to prevent, destroy, repel, or mitigate

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<sup>528</sup> See Federal Insecticide, Fungicide, and Rodenticide Act, 21 U.S.C. section 346(a).

<sup>529</sup> See the Foods, Drug, and Cosmetic Act, 21 U.S.C sections 346(a).

<sup>530</sup> See Food and Drug Administration, Statement of Policy: Foods Derived From New Plant Varieties, 57 *Federal Register*, 22,984, 23,005 (29 May 1992).

<sup>531</sup> *Id.*

<sup>532</sup> See Margret Rosso Grossman, “Genetically Modified Crops and Food in the United States: The Federal Regulatory Framework, State Measures, and Liability in Tort,” in Luc Bodiguel and Michael Cardwell, (editors), *The Regulation of Genetically Modified Organisms: Comparative Approaches*, *supra*, note 50, at 307.

<sup>533</sup> For the 1994 Policy Statement and Proposed Rules of the Environmental Protection Agency, which set out the registration procedure for pesticidal plants, see EPA, Plant Pesticides Subject to the Federal Insecticide, Fungicide and Rodenticide Act and the Federal Food, Drug, and Cosmetic Act; Proposed Rule, 59 *Federal Register* 60,496 (23 November 1994).

<sup>534</sup> See Environmental Protection Agency, Regulations Under the Federal Insecticide, Fungicide, and Rodenticide Act for Plant-Incorporated Protectants (Formerly Plant-Pesticides), 66 *Federal Register* 37,772 (19 July 2001).

any pest.<sup>535</sup> All pesticides must be registered in the United States prior to marketing and use.<sup>536</sup> Registration of pesticides requires the production of data vouching for safety and efficacy, and demonstrating that the pesticides would not “cause unreasonable adverse effects on the environment.”<sup>537</sup> Critical data on pesticide safety and efficacy are routinely gathered from experimental tests field trials of unregistered plant-incorporated protectants.<sup>538</sup> However, the EPA must ensure that experimental field trials of pesticides or plant-incorporated protectants would not result in “unreasonable adverse effects” on human health or the environment.<sup>539</sup> Furthermore, if it is expected that a food residue would reasonably result from the experimental field trials of plant-incorporated protectants, the EPA would be obliged to establish a legal limit on the allowable maximum pesticidal substance in food, prior to issuing a permit for experimental field trials.<sup>540</sup>

However, a permit would not be required for experimental field trials of unregistered pesticides or plant-incorporated protectants, provided the trials “are presumed not to involve unreasonable adverse effects.”<sup>541</sup> Exactly how this presumption would be made is clearly stipulated in the Act, but it should invariably be predicated on science-based risk assessment. Also, permits would not be required for pesticides tested in a laboratory or greenhouse, or pesticides tested on a small-scale involving no more than 10 acres of land per pest, provided any resultant food or feed crops are destroyed or eaten by experimental animals, unless the EPA had established a tolerance level or legal limits of pesticides for food or feed residues in the circumstances.<sup>542</sup>

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<sup>535</sup> See the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C section 136(u) and Environmental Protection Agency, Pesticide Registration (PR) Notice 2007-2: *Guidance on Small-Scale Field Testing and Low-Level Presence in Food of Plant-Incorporated Protectants*, (PIPs) (EPA Doc EPA-HQ-OPP-2007-0654-0001, 2007).

<sup>536</sup> See the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C section 136(a).

<sup>537</sup> See the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C section 136(a).

<sup>538</sup> See the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C section 136(c).

<sup>539</sup> See the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C section 136(c) (d).

<sup>540</sup> See the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C section 136(c).

<sup>541</sup> See 40 CFR 172.3(a).

<sup>542</sup> See 40 CFR 172.3(a).

It is important to note that under the Federal Insecticide, Fungicide, and Rodenticide Act, there is no distinction in the regulation of chemical pesticides and plant-incorporated protectants such as Bt. maize, Bt. soybean, Bt. cotton, and Bt. canola.<sup>543</sup> However, plant-incorporated protectants are a living plant, and do differ fundamentally from chemical pesticides, therefore the current regulatory framework for plant-incorporated protectants have been deemed inappropriate, because plant-incorporated protectants pose unique regulatory challenges.<sup>544</sup> The Environmental Protection Agency has recognised this anomaly, and proposed regulatory changes that would require a new set data for the registration of plant-incorporated protectants.<sup>545</sup> The proposed regulatory changes, which were published in 2007, would reflect current scientific advances and “improve the agency’s ability to make regulatory decisions about human health and the environmental effects of PIP pesticides to better protect wildlife, the environment and people.”<sup>546</sup>

Most significantly, the realisation by the Environmental Protection Agency in 2007, that the current regulatory framework under the Federal Insecticide, Fungicide, and Rodenticide Act, was unsuitable for plant-incorporated protectants, which have been used to regulate transgenic food and feed since the mid-1990s, again underscores the evolutionary nature of the science that underpins the regulatory framework for transgenic plant agriculture, and its coexistence with other forms of agriculture. Although the proposal for improved regulatory framework for

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<sup>543</sup> See Margret Rosso Grossman, “Genetically Modified Crops and Food in the United States: The Federal Regulatory Framework, State Measures, and Liability in Tort,” in Luc Bodiguel and Michael Cardwell, (editors), *The Regulation of Genetically Modified Organisms: Comparative Approaches*, *supra*, note 50, at 309.

<sup>544</sup> *Id.*

<sup>545</sup> See Environmental Protection Agency, Plant-Incorporated Protectants: Potential Revisions to Current Production Regulations, 72 Federal Register 16,312 (4 April 2007). See also Margret Rosso Grossman, “Genetically Modified Crops and Food in the United States: The Federal Regulatory Framework, State Measures, and Liability in Tort,” in Luc Bodiguel and Michael Cardwell, (editors), *The Regulation of Genetically Modified Organisms: Comparative Approaches*, *supra*, note 50, at 309

<sup>546</sup> See Environmental Protection Agency, Statement of Priorities, 72 Federal Register 69,922, 69,939 (10 December 2007), cited in Margret Rosso Grossman, “Genetically Modified Crops and Food in the United States: The Federal Regulatory Framework, State Measures, and Liability in Tort,” in Luc Bodiguel and Michael Cardwell, (editors), *The Regulation of Genetically Modified Organisms: Comparative Approaches*, *supra*, note 50, at 309.

transgenic Bt. plant varieties was muted in 2007, no changes have yet been made as at 2015, when this Chapter was written.

However, a review of the current regulatory framework for plant-incorporated protectants is urgently required, in light of a scientific study published in 2012, which linked the depletion of non-target soil micro-organisms such as *arbuscular mycorrhizal* fungi populations that are critical to soil fertility, to Bt. maize variety (a plant-incorporated protectant).<sup>547</sup> The implications of the study is that plant-incorporated protectants such as Bt. maize, Bt soybean, Bt. canola, Bt. cotton, and other Bt. varieties that were cultivated on approximately 181.5 million hectares of arable land across 28 countries in 2014,<sup>548</sup> could be destroying and depleting soil micro-organisms that are critical for plant populations and the preservation of biodiversity.<sup>549</sup> More worryingly, recent controversial studies have revealed that plant-incorporated protectants crops in food and feed could actually survive human and animal guts, with as yet unknown public health implications.<sup>550</sup> Yet, the transgenic crops in question passed the safety tests conducted by the Environmental Protection Agency. This again underscores the uncertainty and the limits of the science that underpins the regulatory framework for transgenic plant agriculture, and by extrapolation, the coexistence of transgenic and non-transgenic plant agriculture.

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<sup>547</sup> See Tanya E. Cheeke, Todd N. Rosentiel, and Mitchell B. Cruzan, "Evidence of reduced arbuscular mycorrhizal fungal conolization in multiple lines of Bt maize," *American Journal of Botany*, *supra*, note 47, at 700-707. See generally the discussions in chapter two of thesis on the environmental impacts of transgenic plant crops.

<sup>548</sup> See Clive James, *ISAAA, Global Status of Commercialized Biotech/GM Crops: supra*, note 1.

<sup>549</sup> There are other controversial studies detailing the negative impacts of plant-incorporated protectants such as Bt maize on the environment. See for example the Rossi-Marshall paper, which demonstrated that caddis-fly larvae (herbivorous stream insects) which fed on strewn leaves, pollens, and stalks of Bt maize in a Northern Indiana streams, died at more than twice the rate of caddis-fly larvae that were fed with non-Bt pollen. See E.J. Rosi-Marshall, et al., "Toxins in Transgenic Crop By-products May Affect Headwater Stream Ecosystems," *Proceedings of National Academy of Sciences*, Volume 104, Number 41, (9 October, 2007), at 16204-16208.

<sup>550</sup> See Aziz Aris and Samuel Leblanc, "Maternal and foetal exposure to pesticides associated to genetically modified foods in Eastern Townships of Quebec," *Reproductive Toxicology*, Volume 31, Issue 4, (May 2011), at 534-539.

Apart from the Federal Insecticide, Fungicide, and Rodenticide Act, the Environmental Protection Agency also exercises its jurisdictional oversight over pesticides and food safety under the Food, Drug, and Cosmetic Act.<sup>551</sup> The Environmental Protection Agency sets pesticides tolerance levels in foods, which are enforced by the Food and Drug Administration.<sup>552</sup> Therefore, raw or processed food or feed that contain pesticide chemical residues, or plant-incorporated protectants, and cannot be sold or moved interstate, unless the residue meets the tolerance level set by the Environmental Protection Agency.<sup>553</sup>

### **3.1.9. Summary of Analysis.**

The foregoing paragraphs show how three federal agencies: the Food and Drug Administration, the Department of Agriculture, and the Environmental Protection Agency regulate transgenic plant agriculture, sometimes with overlapping oversight or jurisdictional remits. The discourse also shows that the entire regulatory framework is largely based on the science of substantial equivalence doctrine. Even so, the safety science that underpins the impacts of transgenic plant agriculture on public health and the environment is at best evolutionary, uncertain, and sometimes, disputed and contested as amply shown in sections 1.1.7 and 3.1.1 of the thesis. For example, as noted in section 3.1.5 of the thesis, the FDA had initially conducted voluntary premarket approval for transgenic plant foods, on the scientific grounds of substantial equivalence, until 2001, when public criticisms forced the agency to require mandatory premarket approval, as discussed in section 3.1.6 above. Even so, the FDA still relies unduly

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<sup>551</sup> See Margret Rosso Grossman, “Genetically Modified Crops and Food in the United States: The Federal Regulatory Framework, State Measures, and Liability in Tort,” in Luc Bodiguel and Michael Cardwell, (editors), *The Regulation of Genetically Modified Organisms: Comparative Approaches*, *supra*, note 50, at 309.

<sup>552</sup> See the Food, Drug, and Cosmetic Act, 21 U.S.C 346(a)(b)(2)(A).

<sup>553</sup> See the Food, Drug, and Cosmetic Act, 21 U.S.C 346(a)(1).

on industry-generated reports for premarket approval process, despite the apparent potential conflicts of interests. It is argued that this lackadaisical approach to policy implementation is rooted in the US official biotechnology policy of nil to minimal regulation, and the use of substantial equivalence doctrine as the ultimate scientific barometer for the assessment of the safety science of transgenic plant foods.

Similarly, despite the strict science-based guidelines for the cultivation of transgenic plant crops, such as on-farm separation distances, the USDA could not prevent adventitious presence of pharmaceutical corn in soybeans cultivated for human consumption on Nebraska farms in the summer of 2001. It is observed in section 3.1.7 above that the incident underscores the irrepressibility of ‘volunteer crops’, the inevitability of genes flow and adventitious commingling of transgenes and non-transgenes in the coexistence paradigm.

Moreover, the fact that the Environmental Protection Agency equated chemical pesticides with transgenic pesticides of Bt. varieties, which comprise all of the commercial transgenic crops currently on the market, is at once symptomatic of the uncertainty of the underlying science for transgenic plant technology policy, and the inherent limitations of science as the sole arbiter for coexistence policy. Even following the realisation of the error, there is no indication that the EPA has changed its policy, an inaction that is arguably consistent with the official US biotechnology promotional policy of nil to minimal regulation, as amply demonstrated in chapter two.

Moreover, the multi-agency regulatory system may not be ideal for a complex and controversial technology like transgenic plant agriculture, due to the real likelihood of turf wars and self-preservation tactics. This is exemplified by the controversial and conflicting scientific test results conducted on the blood sample of people who claimed to have suffered allergies following meals suspected to have contained StarLink corn. Whilst the blood test conducted under the auspices of the Food and Drug Administration exonerated StarLink corn, the result

of the blood test conducted under the auspices of the Environmental Protection Agency found that StarLink corn could not be completely eliminated as the source of allergies suffered by the people whose blood sample were tested.<sup>554</sup> Most significantly, the discrepancy in test results underscores the unreliability of the science that underpins the governance of transgenic plant agriculture and foods.

Nevertheless, countries that import transgenic plant food and feed from the United States and those that are legally obliged to do so due to international trade rules, would have to accept the faulty premise of the safety science that underpins U.S. regulatory framework for transgenic plant agriculture, unless of course such countries have countervailing scientific evidence to impugn the safety science underlying the regulatory framework of transgenic plant agriculture in the United States. Even countries that are in a position to conduct rigorous biosafety tests on transgenic plant agricultural imports from the United States may not be able to ban the importation of transgenic plant agricultural products from the United States, Canada, or Argentina, in the absence of concrete scientific evidence impugning the underlying safety science of transgenic plant agriculture and food respectively for the environment and public health. This scenario is amply demonstrated by the *European Biotech Products Case*.<sup>555</sup> Amongst other things, the ruling arguably demonstrates the insidious spread of the U.S. variant of the substantial equivalence doctrine, which is primarily designed to promote biotechnology products via international trade rules, into the regulatory and policy regimes of countries around the world.

### **3.2.0. Regulatory Science Framing of Coexistence in the European Union.**

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<sup>554</sup> See Environmental Protection agency, *White Paper on the Possible Presence of Cry9C Protein in Processed Foods Fractions produced through the Wet Milling Corn*, (Environmental Protection agency and Office of Pesticide Programs, 2001), at <http://www.epa.gov/pesticides/biopesticides/otherdocs/wetmill18.pdf>; Federal Insecticide, Fungicide, and Rodenticide Act/ Scientific Advisory Panel Meeting Report No. 201-09 (July 2001), at <http://www.epa.gov/scipoly/sap/meetings/2001/july/julyfinal.pdf>. See also paragraph 2.1.7 See also chapter two of thesis for discussion on the implications of the conflicting tests results.

<sup>555</sup> See European Communities - Measures Affecting the Approval and Marketing of Biotech Products - Reports of the Panel, [WT/DS291/R](#) ; [WT/DS292/R](#) ; [WT/DS293/R](#), *supra*, note26.

The regulation of transgenic plant agriculture in the European Union is conducted under a multi-level governance system, in which regulatory powers are shared between the European Commission and Member States.<sup>556</sup> There are a patchwork of European Commission Directives and Regulations on transgenic plant agriculture governance, which range from Directive (EC) 2001/18 of the European Parliament and the Council on deliberate release into the environment of genetically modified organisms (Deliberate Release Directive),<sup>557</sup> Regulation (EC) 1829/2003 of the European Parliament and of the Council on genetically modified food and feed (Food and Feed Regulation),<sup>558</sup> to Regulation (EC) 1830/2003 of the European Parliament and of the Council on the traceability and labelling of genetically modified organisms, (Traceability and Labelling Regulation).<sup>559</sup>

Under the provisions of the Deliberate Release Directive, authorisation must be sought prior to deliberate release and market debut of transgenic plant organisms.<sup>560</sup> Similarly, under the Food and Feed Regulation, transgenic plant developers must seek authorisation for transgenic plant organisms destined for use in food and feed.<sup>561</sup> Thus, whilst the Deliberate Release Directive is primarily for industrial transgenic crops such as cotton or flowers, the Food and Feed Regulation is for transgenic plant food and feed such as soybean and maize. However,

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<sup>556</sup> See Jo Hunt, "Ploughing Their Own Furrow: Subnational Regions and the Regulation of GM Crop Cultivation," in Catherine Barnard and Okeoghene Odudu, (editors), *Cambridge Year Book of European Legal Studies*, Volume 13, (2010-2011), at 135-159. See also Maria Lee, "Multi-level Governance of Genetically Modified Organisms in the European Union: Ambiguity and Hierarchy," in Luc Bodiguel and Michael Cardwell, (editors), *The Regulation of Genetically Modified Organisms: Comparative Approaches*, *supra*, note 50, at 101.

<sup>557</sup> See **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, *Official Journal of the European Union*, L 106, 17/04/2001 P. 0001 – 0039.**

<sup>558</sup> See Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, ***Official Journal of the European Union*, L 268, 18.10.2003, p. 1–23**

<sup>559</sup> See Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 on the traceability and labelling of genetically modified organisms, *Official Journal of the European Union*, L268 /24 18.10.2003.

<sup>560</sup> See **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, *supra*, note 551.**

<sup>561</sup> See Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, *supra*, note 552.



the two legislative instruments could overlap, where a transgenic plant organism doubles up as a transgenic plant food.<sup>562</sup>

An applicant seeking authorisation for market release of transgenic plant food and feed must file a notification to the national competent authority of the Member State where the transgenic plant organism is to be placed on the market for the first time.<sup>563</sup> An applicant's notification for authorisation must be accompanied by environmental risk assessment and detailed plan for post-market release monitoring mechanisms.<sup>564</sup> The notification for authorisation would then be forwarded by the competent authority of the Member State to whom it was made, to the European Commission, who would in turn, forward the notification to the competent authority of other Member States, as well as make a summary of the notification available to the public.<sup>565</sup>

The national competent authority to whom the notification for authorisation was made, would examine the notification to determine whether or not it comply with the provisions of the deliberate Release Directive, and then prepare an assessment report for the European Commission, whose responsibility it is to forward the assessment to other Member States.<sup>566</sup> The assessment report would stipulate whether or not the release of transgenic plant organism into the environment should be authorised.<sup>567</sup> If application for market authorisation is rejected, the competent authority must give reasons for the rejection,<sup>568</sup> whilst the applicant is free to file a new notification with another competent authority for the placement of the transgenic plant organisms on the market. However, if the authorisation is granted, and there is no objection from a Member State or the European Commission, the authorisation granted by the

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<sup>562</sup> See Maria Lee, "Multi-level Governance of Genetically Modified Organisms in the European Union: Ambiguity and Hierarchy," in Luc Bodiguel and Michael Cardwell, (editors), *The Regulation of Genetically Modified Organisms: Comparative Approaches*, *supra*, note 50, at 103-104.

<sup>563</sup> See Article 13(1) of the Deliberate Release Directive, *supra*, note 551.

<sup>564</sup> See Article 13(1) of the Deliberate Release Directive, *id.*

<sup>565</sup> See Article 24(1) of the Deliberate Release Directive, *id.*

<sup>566</sup> See Article 14(1) of the Deliberate Release Directive, *supra*, note 551.

<sup>567</sup> See Article 14(1) of the Deliberate Release Directive, *id.*

<sup>568</sup> See Article 14(3) of the Deliberate Release Directive, *id.*

competent authority for market placement of the transgenic plant organism in question, would be valid throughout the European Union.<sup>569</sup>

However, under the Food and Feed Regulation, the national competent authority has no power to approve the notification for authorisation for the release of transgenic plant organism meant for use in food and feed. Rather, the national competent authority is obliged to pass on the application to the European Food Safety Authority, who would pass on the application to the European Commission, who would in turn pass on the application to Member States.

The European Food Safety Authority was established under Regulation (EC) 178/2002, as an “independent scientific point of reference in risk assessment.”<sup>570</sup> Thus, the primary task and responsibility of the European Food Safety Authority is risk assessment.<sup>571</sup> However, the European Food Safety Authority may commission a national competent authority to conduct a risk assessment on its behalf, whilst preparing to draw-up a technical opinion under the Food and Feed Regulation.<sup>572</sup> Where a transgenic plant organism meant for use in food and feed can also be used for non-food and feed purposes under the Deliberate Release Directive, an environmental risk assessment is mandatory for the application, and the European Food Safety Authority would be obliged to consult all national competent authorities.<sup>573</sup> However, if the application for authorisation is for “seeds or other propagating material”, the European Food Safety Authority is obliged to ask a national competent authority to carry out the environmental risk assessment.<sup>574</sup>

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<sup>569</sup> See Article 15(1) of the Deliberate Release Directive, *id.*

<sup>570</sup> See paragraph 34 of the Preamble to Regulation (EC) 178/2002 laying down the requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (Food Law Regulation), [2002] *Official Journal of the European Union*, L31/1.

<sup>571</sup> See “Multi-level Governance of Genetically Modified Organisms in the European Union: Ambiguity and Hierarchy,” in Luc Bodiguel and Michael Cardwell, (editors), *The Regulation of Genetically Modified Organisms: Comparative Approaches*, *supra*, note 50, at 107.

<sup>572</sup> See Article 6(3)(b)(c) of the Food and Feed Regulation (EC) 1829/2003, *supra*, note 189.

<sup>573</sup> See Article 6(4) of the Food and Feed Regulation, *id.*

<sup>574</sup> See Article 6(3)(c) of the Food and Feed Regulation, *id.*

The European Commission routinely adopts the technical opinions of the European Food Safety Authority on transgenic plant organisms.<sup>575</sup> Opinions of the European Food Safety Authority are published and open to public comments.<sup>576</sup> Whilst opening-up of technical opinions for public comments gives appearance of public participation in the approval process, it belies the reality that any public comments would be ineffectual because the entire approval process is predicated on scientific opinions, underscoring the primacy of science in the shaping of coexistence policies in the European Union. Thus, it is highly unlikely that unfavourable public comments would dissuade the European Commission from adopting or relying on the technical opinions proffered by the European Food Safety Authority.

Even if the European Commission were to allow negative feedback from the public to override technical opinions predicated on science, the decision could invariably be challenged under international trade laws by transgenic crops exporting countries, as exemplified by the *European Communities Biotech Products Case*.<sup>577</sup> Thus, the opportunity for public feedback on scientific opinions *ex post facto*, is no more than a ruse to project an appearance of public participation in the decision making process, because opinions based on scientific risk assessments would surely trump any non-scientific objections, as amply demonstrated by *Land Oberosterreich and Austria v Commission of the European Communities*, where the European Court of Justice upheld the findings of the European Commission that there was no scientific evidence in support of the proposed GM-free zones in Upper Austria for the protection of biodiversity and organic system of agriculture.<sup>578</sup>

### **3.2.1. Science, Regulation and Coexistence Policy in the European Union.**

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<sup>575</sup> See “Multi-level Governance of Genetically Modified Organisms in the European Union: Ambiguity and Hierarchy,” in Luc Bodiguel and Michael Cardwell, (editors), *The Regulation of Genetically Modified Organisms: Comparative Approaches*, *supra*, note 50, at 109.

<sup>576</sup> See Article 6(7) of the Food and Feed Regulation, *supra*, note 552.

<sup>577</sup> See *European Communities - Measures Affecting the Approval and Marketing of Biotech Products - Reports of the Panel*, [WT/DS291/R](#) ; [WT/DS292/R](#) ; [WT/DS293/R](#), *supra*, note 26.

<sup>578</sup> The European Commission had relied on the technical opinion of the European Food Safety Authority. See *Land Oberosterreich and Austria v Commission of the European Communities*, (Joined Cases C-439/05 P and C-454/05 P of 13 September 2007), *supra*, note 85.

As noted in section 3.2.0, the regulatory and policy framework for transgenic plant agricultural technology governance in the European Union is largely underpinned by risk assessment that is rooted in scientific evidence.<sup>579</sup> For example, Article 2(8) of the Deliberate Release Directive defines environmental risk assessment as “the evaluation of risks to human health and the environment, whether direct or indirect, immediate or delayed, which the deliberate release or placing on the market of GMOs may pose.”<sup>580</sup> Furthermore, paragraphs 19 and 20 of the Preamble to the Deliberate Release Directive, which premises the release of transgenic plant organisms on independent scientific evidence, require that:

A case by-by-case environmental risk assessment should always be carried out prior to a release. It should also take due account of potential cumulative long-term effects associated with the interaction with other GMOs and the environment... It is necessary to establish a common methodology to carry out the environmental risk assessment based on independent scientific advice. It is also necessary to establish common objectives for the monitoring of GMOs after their deliberate release or placing on the market as or in products. Monitoring of potential cumulative long-term effects should be considered as a compulsory part of the monitoring plan.<sup>581</sup>

Similarly, paragraph 37 of the preamble to the Food and Feed Regulation, emphasises the scientific basis of the risk assessment for transgenic plant agriculture, by providing that “Technological progress and scientific developments should be taken into account when implementing this Regulation.”<sup>582</sup> Moreover, regulatory framework for transgenic plant agriculture is based on precautionary principle, as exemplified by paragraph 8 of the Deliberate Release Directive, which provides that “The precautionary principle has been taken into account in the drafting of this Directive and must be taken into account when implementing

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<sup>579</sup> According to Sheldon Krimsky et al, the United States regulatory agencies in the 1990s, “adopted the concept of science-based policy to emphasize that, science alone, not politics or values, would be the basis of their decisions...to ensure that there are not unacceptable human health and environmental risks.” See Sheldon Krimsky and Nora K. Murphy, “Biotechnology at the Dinner Table: FDA’s Oversight of Transgenic Food,” *The Annals of the American Academy of Political and Social Sciences*, *supra*, note 66, at 82.

<sup>580</sup> See **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, *supra*, note 188.**

<sup>581</sup> See paragraphs 19 and 20 of the Preamble to the Deliberate Release Directive 2001/18/EC, *supra*, note 188.

<sup>582</sup> See paragraph 37 of the Food and Feed Regulation 1829/2003, *supra*, note 189.

it.”<sup>583</sup> The precautionary principle is necessitated by the environmental and public health implications of the deliberate release of transgenic plant organisms, which the Deliberate Release Directive acknowledged in paragraphs 4 and 5 of its preamble.<sup>584</sup> Consequently, Article 4(1) of the Deliberate Release Directive enjoins that:

Member States shall, in accordance with the precautionary principle, ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment which might arise from the deliberate release or the placing on the market of GMOs. GMOs may only be deliberately released or placed on the market in conformity with part B or part C respectively.<sup>585</sup>

The Deliberate Release Directive further cements the integral role of scientific risk assessment and scientific evidence in transgenic plant governance, by its “safeguard clause”, which allows Member States to derogate from compliance with the obligations to allow for free circulation in their territories, of transgenic plant organisms that are duly released in accordance with the provisions of the Directive.<sup>586</sup> Article 23(1) of the safeguard clause provides thus:

Where a Member State, as a result of new or additional information made available since the date of the consent and affecting the environmental risk assessment or reassessment of existing information on the basis of new or additional scientific knowledge, has detailed grounds for considering that a GMO as or in a product which has been properly notified and has received written consent under this Directive constitutes a risk to human health or the environment, that Member State may provisionally restrict or prohibit the use and/or sale of that GMO as or in a product on its territory...The Member State shall ensure that in the event of a severe risk, emergency measures, such as suspension or termination of the placing on the market, shall be applied, including information to the public...The Member State shall immediately inform the Commission and the other Member States of actions taken under this Article and give reasons for its decision, supplying its review of the environmental risk assessment, indicating whether and how the conditions of the consent should be amended or the consent should be terminated, and, where appropriate, the new or additional information on which its decision is based.<sup>587</sup>

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<sup>583</sup> See paragraph 8 of the Deliberate Release Directive 2001/18/EC, *supra*, note 188.

<sup>584</sup> See paragraphs 4 and 5 of the Preamble to the Deliberate Release Directive 2001/18/EC, *supra*, note 188.

<sup>585</sup> See Article 4(1) of the Deliberate Release Directive 2001/18/EC, *supra*, note 188.

<sup>586</sup> Article 22 of the Deliberate Release Directive 2001/18/EC forbids Member States from prohibiting, restricting or impeding the placing on the market of GMOs and products, which release complied with the provisions of the Deliberate Release Directive, *supra*, note 188.

<sup>587</sup> See Article 23(1) of the Deliberate Release Directive 2001/18/EC, *supra*, note 188.

However, as amply demonstrated in section 3.1.2 of the thesis, the main problem with the science that underpins regulatory risk assessment for transgenic plant agriculture is that it is still evolving, and is beset by uncertainties with regards to its full ramifications for public health and the environment. It is perhaps the realisation that transgenic plant regulatory governance systems should transcend the science that underpins its risk assessment, and embrace alternative governance systems, that the Deliberate Release Directive 2001/18/EC, and the Food and Feed Regulation EC/1829/2003, respectively seek to factor in public participation,<sup>588</sup> socio-economic impacts of transgenic plant agriculture,<sup>589</sup> and the views of ethical committees,<sup>590</sup> into transgenic plant agriculture governance systems. According to Maria Lee, the afore-mentioned provisions constitute “an explicit recognition that ‘scientific risk assessment alone’ may not provide all the necessary information, and that a decision can be based on ‘other legitimate factors’.”<sup>591</sup> Perhaps the aforementioned provisions were a response to the constant clamour by Austria, Italy, Ireland, France, Poland, and other European Member States for “GM-free zones” on cultural, biodiversity and environmental grounds?<sup>592</sup> But the legality of “GM-free zones” “is debatable”, largely because the European Commission Recommendation on the coexistence of transgenic and non-transgenic plant agriculture negates the very essence of “GM-free zones”.<sup>593</sup>

This is aptly demonstrated by the 2002 proposed law by Upper Austria, to ban transgenic plant agriculture and declare their agricultural land as a “GM free-zone” on grounds that Upper Austria had an unusually high proportion of organic or biologically farmed areas.

Genetically modified-free areas represented the only approach, which could ensure

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<sup>588</sup> See generally Article 24(1) of the Deliberate Release Directive 2001/18/EC, *supra*, note 188.

<sup>589</sup> See Paragraph 62 of the Preamble to the Deliberate Release Directive 2001/18/EC, *supra*, note 188.

<sup>590</sup> See generally Articles 6(7) and 18(7) of the Food and Feed Regulation EC/1829/2003, *supra*, note 189.

<sup>591</sup> See Maria Lee, “Multi-level Governance of Genetically Modified Organisms in the European Union: Ambiguity and Hierarchy,” in Luc Bodiguel and Michael Cardwell, (editors), *The Regulation of Genetically Modified Organisms: Comparative Approaches*, *supra*, note 50, 104, (citing Paragraph 32 of the Preamble and Articles 7(1) and 19(1) of the Food and Feed Regulation EC/1829/2003, *supra*, note 189.

<sup>592</sup> See Maria Lee, *EU Regulation of GMOs: Law and Decision Making for a New Technology*, (Cheltenham, UK & Northampton, MA, USA: Edward Elgar Publishing, 2008), at 113-114.

<sup>593</sup> *Id.*

long-term security in relation to the problems of coexistence within the small structured Austrian agricultural sector. Given that the proportion of organic farmers is particularly high in Upper Austria (around 7 %), hardly any areas would be available for a GMO cultivation if the intention was to safeguard the organic production of agricultural products by establishing protection zones with a 4 km radius from sources of foreign contamination.<sup>594</sup>

The Republic of Austria subsequently notified the European Commission of the decision of the Land of Upper Austria to exclude transgenic plant agriculture pursuant to Article 95(5) of the EC Treaty. However, the European Commission rejected the proposed law of Upper Austria in its decision of 3 September 2003,<sup>595</sup> on grounds inter alia that Upper Austria did not provide scientific evidence to justify its national measures that sought to exclude transgenic plant agriculture, which measures were incompatible with Community harmonization measures.<sup>596</sup> In support of its decision, the Commission cited the opinion of the Scientific Panel of the European Food Standard Authority, which observed that the scientific information submitted by the Republic of Austria “provided no new data that would invalidate the provisions for the environmental risk assessment established under Directive 90/220/EEC or Directive 2001/18/EC.”<sup>597</sup> The Panel report also noted that the scientific information submitted by the Republic of Austria did not provide “new scientific evidence, in terms of risk to human health and the environment, that would justify a general prohibition of cultivation of genetically modified seeds and propagating material, the use of transgenic animals for breeding purposes and the release of transgenic animals, authorised for these purposes under Directive 90/220/EEC or Directive 2001/18/EC in this region of Austria.”<sup>598</sup> On appeal to the Court of Justice of the European Union, in *Land Oberösterreich and Austria v Commission of the European Communities*, the Advocate General Sharpston ruled inter alia that the Republic of

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<sup>594</sup> Cited in paragraph 35 of the Commission Decision of 2 September 2003 relating to national provisions banning the use of genetically modified organisms in the region of Upper Austria notified by the Republic of Austria pursuant to Article 95(5) of the EC Treaty, *Official Journal of the European Union*, L. 230/34 (16.09.2003).

<sup>595</sup> Id.

<sup>596</sup> Id, at paragraph 59.

<sup>597</sup> Id, at paragraph 64.

<sup>598</sup> Id.

Austria had failed to provide scientific evidence for its proposed blanket ban on transgenic plant agriculture in Upper Austria, as required by Article 95(5) EC.<sup>599</sup>

Similarly, In *European Commission v Republic of Poland Case*, the European Commission successfully challenged Polish anti-transgenic seeds legislation, which prohibited the marketing of seeds derived from genetically modified varieties and the registration of such varieties in the national catalogue of seeds varieties, on ethical and religious grounds.<sup>600</sup> However, the Court of Justice of the European Union held inter alia that the Polish law contravened the provisions of Articles 22 and 23 of the Deliberate Release Directive 2001/18/EC.<sup>601</sup> Article 22 of the Deliberate Release Directive enjoins Member States not to prohibit or restrict or impede the placing on the market of transgenic plant organisms, which had complied with the requirements of the Deliberate Release Directive.<sup>602</sup> In the same vein, Article 23(1) of the Deliberate Release Directive on safeguard measures, provides that a Member State may only prohibit or restrict the use or sale of transgenic plant organisms that had been duly approved under the Deliberate Release Directive, if new or additional information reveals that the transgenic plant organism in question, constitutes a risk to human health and the environment.<sup>603</sup>

However, the Polish authority did not have any new or additional information that showed that the transgenic plant seeds in question constituted a risk to public health and the environment, therefore, the CJEU (Second Chamber), held that the Polish law prohibiting the registration of transgenic plant seeds in the national catalogue contravened the provisions of Article 22 and 23(1) of the Deliberate Release Directive.<sup>604</sup>

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<sup>599</sup> See *Land Oberösterreich and Austria v Commission of the European Communities*, *supra*, note 85, at paragraphs 61-68.

<sup>600</sup> See *European Commission v. The Republic of Poland*, *supra*, note 87, at 35-66.

<sup>601</sup> See Directive 2001/18/EC, *supra*, note 188.

<sup>602</sup> *Id.*

<sup>603</sup> *Id.*

<sup>604</sup> *Id.* at 66.



It is instructive to note however that the CJEU did not take into consideration the provision of paragraph 9 of the recitals to the Deliberate Release Directive 2001/18/EC, which provides for an ethical framework for the governance of transgenic plant organisms:

Respect for ethical principles recognised in a Member State is particularly important. Member States may take into consideration ethical aspects when GMOs are deliberately released or placed on the market as or in products.<sup>605</sup>

Therefore, CJEU's failure to take into consideration, paragraph 9 of the recitals to the Deliberate Release Directive on ethical framework for transgenic plant governance, once again demonstrates that in the context of transgenic plant agriculture governance, non-scientific imperatives such as ethics and religious beliefs are easily trumped by scientific imperatives. This proposition is further underscored by the fact that the European Parliament and the Council chose to place the provision of paragraph 9 relating to ethical governance of transgenic plant organisms in the recitals, whilst the provisions of Articles 22 and 23(1) relating to scientific consideration are a part of the substantive text of the Deliberate Release Directive.<sup>606</sup> Recitals are no more than preliminary explanations of the purpose, factual background, and essence of legislative texts, and are not construed as part of the substantive texts of legislative instruments.<sup>607</sup> Thus to the extent that the paragraph 9 provision relating to ethical governance of transgenic plant organisms is placed in the largely enforceable part of the Deliberate Release

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<sup>605</sup> See paragraph 9 of the Recital to the Deliberate Release Directive 2001/18/EC of the European Parliament and of the Council, *supra*, note 188.

<sup>606</sup> Recitals are preliminary part of legislative documents, which explain their purpose and provide other factual information. Thus, whilst recitals often help to explain the reasons for legislations, they are not construed as part of legislative texts as such. For example, according to paragraph 10.5.1 of the *Joint Practical Guide of the European Parliament, the Council, and the Commission*, "recitals should constitute a genuine statement of reasons; they should not set out the legal bases (which must be in the citations) nor should they repeat the passage in the provision already cited as the legal basis which empowers the institution to act. Furthermore, recitals which do no more than state the subject-matter of the act or reproduce or even paraphrase its provisions without stating the reasons for them are superfluous or pointless." See *Joint Practical Guide: Guide of the European Parliament, the Council, and the Commission for persons involved in the drafting of legislation within the Community institutions*, *EU-LEX Access to European Union law*, available at <http://eur-lex.europa.eu/en/techleg/10.htm>.

<sup>607</sup> See *id.*

Directive, it is indicative that it is inferior or secondary to the provisions of Articles 22 and 23 of the Deliberate Release Directive.<sup>608</sup>

However, the alienation of strong societal norms and values that are rooted in morality, ethics, or religion, from transgenic plant agriculture governance systems, risks further aggravating public scepticism and dislike for transgenic plant agriculture, especially when science, which is integral to the regulatory and policy regime for transgenic plant agriculture, is not as agnostic or certain as it could or should possibly be. Moreover, scepticism and dislike for the current science-centric regulatory regime for transgenic plant agriculture are bound to fester for as long as the current governance systems failed to sufficiently address concerning questions on public health and environmental safety, as well as liability and redress regime for inevitable economic or property damage from adventitious admixture of transgenic and non-transgenic plant materials.<sup>609</sup>

Thus, even though the Deliberate Release Directive 2001/18/EC, and the Food and Feed Regulation EC/1829/2003 recognise other considerations such as “socio-economic impacts” of transgenic plant agriculture, the role of ethical committees, and public participation in transgenic plant agriculture governance,<sup>610</sup> arguably, such non-scientific considerations cannot legally displace scientific risk assessment and scientific evidence, a reality that was aptly summed up by Maria Lee thus:

But whilst the reference to ‘other legitimate factors’ is more than mere rhetoric, it is likely to be extremely difficult to make this formula meaningful. The legal and policy context of decision-making is deeply entrenched in a technical risk framework. The legal and political incentives to justify all decisions on a scientific

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<sup>608</sup> See paragraph 9 and articles 22 and 23 of the Deliberate Release Directive 2001/18/EC of the European Parliament and of the Council, *supra*, note 188.

<sup>609</sup> For discussion on possible remedies for property and economic damage caused by adventitious commingling of transgenic and non-transgenic plant materials, see Maria Lee and Robert Burrell, “Liability for the Escaped GM Seeds: Pursuing the ‘Victim’?” *The Modern Law Review*, *supra*, note 249, at 517-537.

<sup>610</sup> See generally Article 24(1) of the Deliberate Release Directive 2001/18/EC, *supra*, note 188; Paragraph 62 of the Preamble to the Deliberate Release Directive 2001/18/EC, *supra*, note 188; and Articles 6(7) and 18(7) of the Food and Feed Regulation EC/1829/2003, *supra*, note 189.

basis are not likely to be overcome by simply adding on ‘other legitimate factors’.<sup>611</sup> Indeed, the European Commission is fully aware of the centrality and supremacy of scientific evidence in transgenic plant agriculture governance, having been at the receiving ends in the *European Communities Biotech Products Case*,<sup>612</sup> and having opposed several Member States on the same premise, as exemplified by the *Land Oberosterreich and Austria v Commission of the European Communities Case*,<sup>613</sup> and the *European Commission v The Republic of Poland Case*.<sup>614</sup>

In the *European Communities Biotech Products case*, the United States, Canada, and Argentina, filed a complaint before the World Trade Organization’s Dispute Settlement Body, challenging the legality of the *de facto* moratorium of the European Commission on the approval, import and sale of new transgenic plant products, on grounds *inter alia* that it violated the provisions of General Agreement on Tariffs and Trade (GATT), and that of the Agreement on the Application of Sanitary and Phytosanitary Measures.<sup>615</sup> The European Commission had justified the moratorium on approval of new transgenic plant materials on grounds of precautionary principle, which authorised safeguard measures in the face of scientific uncertainties.<sup>616</sup> The Communication from the Commission on the Precautionary Principle sums up the essence of precautionary principle of the European Union thus:

The Community has consistently endeavoured to achieve a high level of protection, among others in environment and human, animal or plant health. In most cases, measures making it possible to achieve this high level of protection can be determined on a satisfactory scientific basis. However, when there are reasonable grounds for concern that potential hazards may affect the environment or human, animal or plant health, and when at the same time the available data preclude a detailed risk evaluation, the precautionary principle has been politically accepted as a risk management strategy

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<sup>611</sup> See Maria Lee, “Multi-level Governance of Genetically Modified Organisms in the European Union: Ambiguity and Hierarchy,” in Luc Bodiguel and Michael Cardwell, (editors), *The Regulation of Genetically Modified Organisms: Comparative Approaches*, *supra*, note 50, at 104-105.

<sup>612</sup> See *European Communities Biotech Products Case*, *supra*, note 26, at 4-12.

<sup>613</sup> See *Land Oberosterreich and Austria v Commission of the European Communities Case*, *supra*, note 85, at 13-29.

<sup>614</sup> See *The European Commission v. The Republic of Poland*, (Case C-165/08), *supra*, note 87, at 35.

<sup>615</sup> See *European communities – Measures Affecting the Approval and Marketing of Biotech Products*, *supra*, note 26, at 1-5.

<sup>616</sup> See *id.*

in several fields.<sup>617</sup>

However, the United States, Canada, and Argentina argued that the European Commission lacked scientific evidence to justify its concerns that transgenic plant materials were unsafe for the environment and the public health, and that the moratorium on approval and imports of new transgenic plant materials was no more than trade protectionism, in contravention of Article III (4) of the General Agreement on Tariffs and Trade, (GATT) which requires “national treatment” for “like products”, and prohibits countries from applying discriminatory national taxes and regulations to imports. The WTO Dispute Settlement Panel agreed with the complainants that the European Commission moratorium on the approval of new transgenic plant organisms had no scientific basis or justification as protective measures under Article XX of GATT, which recognizes governments’ sovereign right to adopt restrictive trade measures for public health, public moral and environmental safeguards.<sup>618</sup>

The WTO Dispute Settlement Panel further noted that, with regards to the safeguard measures, the European Commission moratorium on the approval and importation of new transgenic plant organisms contravened Articles 5 (1) and 2 (2) of the Marrakesh Agreement on the Application of Sanitary and Phytosanitary Measures, which require that all food safety measures must be based on a risk assessment and scientific evidence. Whilst the European Commission denied that its moratorium was tantamount to trade protectionism as claimed by the complainants, the objections from some member states of the European Union to transgenic plant agriculture and foods, clearly transcended socio-economic issues and included “religious and ethical considerations” going by the argument in the first written submission of the European Commission to the WTO Dispute Settlement Panel. Again, this argument was dismissed by the Dispute Settlement Panel as unscientific and illegal under the combined

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<sup>617</sup> See the Communication from the Commission on the Precautionary Principle (COM (2001), at 9, available at [http://ec.europa.eu/dgs/health\\_consumer/library/pub/pub07\\_en.pdf](http://ec.europa.eu/dgs/health_consumer/library/pub/pub07_en.pdf).

<sup>618</sup> See *European communities – Measures Affecting the Approval and Marketing of Biotech Products*, *supra*, note 26, at 1-13.

provisions of the General Agreement on Tariffs and Trade and the Agreement on the Application of Sanitary and Phytosanitary Measures. Thus, the decision of the WTO Dispute Settlement Panel in *European Communities Biotech Products* case, like that of the US Federal District Court of Columbia in *Alliance for Bio-integrity v Donna Shalala*,<sup>619</sup> is indicative of the triumph of science over non-scientific oppositional grounds to transgenic plant organisms.

Even so, the question of morality or ethics is not as foreign to the jurisprudence of the World Trade Organization as it might seem, in light of the provision of Article XX (a) of the General Agreement on Tariffs and Trade (GATT), which allows for public morality protection as a basis for derogation from compliance with its non-discriminatory provisions.<sup>620</sup> Moreover, albeit a non-science-related case, the WTO case of *US – Measures affecting the cross-border supply of gambling and betting services*, upheld the measures taken by the United States to prohibit internet gambling via offshore websites based in foreign jurisdictions, as consistent with Article XIV (a) of the General Agreement on Tariffs and Trade (GATT).<sup>621</sup> Interestingly, the WTO Appellate Body Report held that the provisions of Article XIV (a) of the General Agreement on Tariffs and Trade (GATT)<sup>622</sup> were analogous to the provision of Article XX (a) of the General Agreement on Tariffs and Trade (GATT) on public morality preservation derogation from general compliance with the non-discriminatory provisions of the General Agreement on Tariffs and Trade.<sup>623</sup>

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<sup>619</sup> See *Alliance for Bio-integrity v. Donna Shalala*, *supra*, note 107, at 166.

<sup>620</sup> Article XX on “General Exceptions” provides in Article XX (a) that contracting parties may adopt measures that derogate from general compliance with non-discriminatory trade measures if they are “necessary to protect public morals”. See Article XX (a) of the General Agreement on Tariffs and Trade (GATT 1947), available at [https://www.wto.org/english/docs\\_e/legal\\_e/gatt47\\_02\\_e.htm](https://www.wto.org/english/docs_e/legal_e/gatt47_02_e.htm)

<sup>621</sup> For discussion, see *US- Measures affecting the cross-border supply of gambling and betting services*, DS 285.

<sup>622</sup> Article XIV on “General Exceptions”, provides in Article XIV (a) that members may adopt discriminatory measures that are “necessary to protect public morals or maintain public order.” See the General Agreement on Tariffs and Trade (GATT 1947), *id.*

<sup>623</sup> The Appellate Body Report concurred with the Panel’s findings that the protection of public morals “denotes standards of right and wrong conduct maintained by or on behalf of a community or nation.” For discussion, see Paragraph 296, of the Appellate Body Report in *US- Measures affecting the cross-border supply of gambling and betting services*, *id.*

However, it would appear that in the context of transgenic plant technology regulation, there is a tendency for judicial deference to science and scientific opinions at the expense of socio-cultural and economic reservations, as exemplified by the *European Communities Biotech Products Case*,<sup>624</sup> *The European Commission v. The Republic of Poland Case*,<sup>625</sup> and *Alliance for Bio-integrity Case*,<sup>626</sup> where the primacy of science over non-scientific objections to transgenic plant technology, was affirmed.<sup>627</sup>

### 3.2.2 The Opt-out Provision of Directive 2015/412 and the Primacy of Science.

In March 2015, Directive 2015/412 was enacted by the European Parliament and the Council. Article 26b (1) of the Directive now allows a Member State to prohibit cultivation of transgenic crops in its territory.<sup>628</sup> However, such prohibition must be in conformity with the “Union law” and must be “reasoned, proportional and non-discriminatory.”<sup>629</sup> Additionally, the prohibition must be based on any of the following “compelling grounds”: environmental policy objectives; town and country planning; land use; socio-economic impacts; avoidance of GMO presence in other products without prejudice to Article 26a; agricultural policy objectives; and public policy.<sup>630</sup>

The Directive constitutes a dramatic reversal of previous regime that allows derogation from compliance only on grounds of proven scientific evidence of harm to public health or the environment, as amply demonstrated in *Land Oberosterreich and Austria v Commission of the European Communities Case*, and the *European Commission v The Republic of Poland Case*

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<sup>624</sup> See *European Communities Biotech Products Case*, *supra*, note 26, at 1-11.

<sup>625</sup> See *The European Commission v. The Republic of Poland Case*, *supra*, note 87, at 35.

<sup>626</sup> See *Alliance for Bio-integrity et al., v. Dona Shalala*, *supra*, note 107, at 166-181.

<sup>627</sup> See Taiwo A. Oriola, "The Limits of Regulatory Science in Transnational Governance of Transgenic Plant Agriculture and Food Systems," *North Carolina Journal of International and Commercial Regulation*, *supra*, note at 856-879.

<sup>628</sup> See Directive 2015/412 as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory, *Official Journal of the European Union*, (13.3.2015).

<sup>629</sup> See Article 26b (3), *id.*

<sup>630</sup> *Id.*

in section 3.2.1. Most importantly, the new grounds for derogation from compliance noted above would arguably cover ethical, religious and socio-cultural objections to transgenic plant technology, which were unsuccessfully canvassed by the Republic of Austria and the Republic of Poland before the CJEU in the above cases. Thus, the new Directive has arguably put an end to science's exclusive prerogative on the coexistence policy, and may have undermined the primacy of science and its stranglehold on transgenic plant technology governance in the European Union.

However, given that the power to opt-out of transgenic crops cultivation must comply with EU laws and be reasoned, proportional, and non-discriminatory, there is sufficient wiggle room for a legal challenge to the right to opt-out of transgenic plant technology by a Member State. Moreover, it has been argued that the new Directive is vulnerable to legal challenge under international trade rules by transgenic crops exporting countries, who could challenge the validity of the Directive under Articles 5 (1) and 5(2) of the Sanitary and Phytosanitary (SPS) Agreement,<sup>631</sup> in the same way that they successfully challenged the 1998 European Commission moratorium on transgenic plant products imports in the *European Communities Biotech Products Case*.<sup>632</sup> And given that SPS rules are entirely science-dependent, and given its ability and precedent for overriding contrarian national and regional laws, as exemplified by the *European Communities Biotech Products Case*, it is very much doubtful whether the Directive could survive any future legal challenge under international trade rules.

### **3.2.3. Coexistence Policy for Liability and Redress Regime in the European Union.**

In the European Union, Member States have national competence over liability stemming from damage caused by adventitious transgenes in the coexistence of transgenic and non-transgenic

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<sup>631</sup> See Robert G. Lee, "Humming a different tune? Commercial Cultivation of GM Crops in Europe", (2015), on file with author.

<sup>632</sup> See *European Communities Biotech Products Case*, *supra*, note 26, at 1-11.

plant agriculture.<sup>633</sup> According to the Commission Recommendation, “Liability in the event of economic damage to non-GM crops resulting from GMO admixture is a matter for civil law, which is the responsibility of Member States.”<sup>634</sup> Moreover, Article 26a of the Deliberate Release Directive 2001/18/EC, empowers Member States to take appropriate national measures on co-existence in order to avoid unintended presence of GMOs in other products.<sup>635</sup>

Responses to the devolution of liability regimes vary between Member States. Whilst some Member States like Austria, Germany and Denmark have opted for a strict liability regime to complement other civil remedies;<sup>636</sup> others like the United Kingdom have no specific liability regime at all and worst still, liability policy for the coexistence regime is devolved amongst the constituent nations in the United Kingdom.<sup>637</sup> However, in England, the Department for Environment, Food and Rural Affairs, DEFRA, conducted a public consultation in June 2006 on the introduction of possible statutory redress scheme for economic damage stemming from the presence of transgenic crops in non-transgenic crops. DEFRA later resolved not to introduce new statutory liability regime, although liability may arise under existing laws, which include product liability.<sup>638</sup> In Wales, the Genetically Modified Food (Wales) Regulations of

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<sup>633</sup> For discussion, see *Report from The Commission to the Council and the European Parliament on the coexistence of genetically modified crops with conventional and organic farming*, (Brussels, 2009), at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2009:0153:FIN:en:PDF> (accessed on 14 May 2015). See also Commission of the European Communities, *Commission Recommendation on Guidelines for the Development of National Strategies and Best Practices to Ensure the Co-existence of Genetically Modified (GM) Crops with Conventional and Organic Farming*; (Brussels, July 2003), at [http://ec.europa.eu/agriculture/publi/reports/coexistence2/guide\\_en.pdf](http://ec.europa.eu/agriculture/publi/reports/coexistence2/guide_en.pdf); and Commission of the European Communities, Communication from the Commission to the Council and the European Parliament, *Report on the implementation of national measures on the coexistence of genetically modified crops with conventional and organic farming*, (Brussels 2006), at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2006:0104:FIN:EN:PDF> (accessed on 14 May 2015).

<sup>634</sup> See *Report from The Commission to the Council and the European Parliament on the coexistence of genetically modified crops with conventional and organic farming*, (Brussels, 2009), *supra*, note 261, at 5.

<sup>635</sup> See Article 26(a) of the Deliberate Release Directive 2001/18/EC, *supra*, note 188.

<sup>636</sup> For discussion on Austrian strict liability and other civil remedies, see Manuela Weissenbacher, "Damage Caused by GMOs under Austrian Law," in Bernhard A. Koch, (editor), *Damage Caused by Genetically Modified Organisms: Comparative Survey of Redress Options for Harm to Persons, Property or the Environment*, (Berlin/New York: Walter de Gruyter Publishing, 2010) at 2.

<sup>637</sup> See Ken Oliphant, "Damage Caused by GMOs under English Law," in Bernhard A. Koch, (editor), *Damage Caused by Genetically Modified Organisms: Comparative Survey of Redress Options for Harm to Persons, Property or the Environment*, *supra*, *id*, at 86.

<sup>638</sup> See *id*; Christopher Rodgers, "DEFRA's Coexistence Proposals for GM Crops: A Recipe for Confrontation?" *Environmental Law Review*, *supra*, note 15, at 1-8.



December 2004, applies exclusively to Wales. Although Wales has yet to adopt any specific liability regime, there is a possibility that it could adopt a strict liability regime in line with the recommendations of the majority of public respondents to the Welsh Assembly Government consultation on the coexistence of transgenic and non-transgenic crops, which was launched in June 2009.<sup>639</sup>

However, given the propensity for trans-boundary or even trans-national gene-flow between transgenic and non-transgenic plant species,<sup>640</sup> and the potential for adventitious commingling of transgenic and non-transgenic crops across national and international frontiers, as exemplified by the StarLink corn from Iowa and Nebraska farms that found its way into Japanese food chain,<sup>641</sup> a splintered liability regime, within the European Union, or amongst the home nations in the United Kingdom, is bound to raise a spectre of concurrent jurisdictional oversight, conflict of laws, and concomitant differing judicial pronouncements on the extent or degree of culpabilities, liabilities, and damages that are a sure fillip for multiple litigations, and forum shopping by litigants.<sup>642</sup> Thus, the absence of a coherent and uniform liability regime in the European Union, for damage induced by adventitious transgenes, could considerably

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<sup>639</sup> See *Consultation on Proposals for Managing the Co-existence of GM, Conventional and Organic Crops in Wales*, available at <http://wales.gov.uk/docs/drah/consultation/090630managingcoexistenceofgmcropsen.pdf> (accessed on 14 May 2015). For a response to the consultation, see *Summary of Responses to the Welsh Assembly Government Consultation on Proposals for Managing the Coexistence of GM, Conventional and Organic Crops in Wales*, (December 2009), at <http://wales.gov.uk/docs/drah/consultation/090630coexistenceresponsesen.pdf> (accessed on 14 May 2015).

<sup>640</sup> See Maria Lee, *EU Regulation of GMOs: Law and Decision Making for a New Technology*, *supra*, note 223, at 105.

<sup>641</sup> See Stephanie Simon, , “Fearing a Field of Genes: The Food Industry loves engineered crops, but not when plants altered to ‘grow’ drugs and chemicals can slip into its products,” *Los Angeles Times*, (23 December, 2002), at 1; *Associated Press*, “Japan finds more Bt in shipments,” (Thursday, 18 January, 2001), at <http://archive.shomenews.com/2001/jan/20010118busi012.asp> (accessed on 14 May 2015).

<sup>642</sup> Forum shopping could occur where multiple courts have concurrent jurisdiction over a claim, thus allowing the plaintiff to ‘forum shop’ or choose the court that would treat their case most favourably. See Susanne Fruhstorfer and Felix Klement, “General Grounds on Which Courts Will Accept Jurisdiction”, in Carel Baron van Lynden, (editor) *Forum Shopping*, (Informa Law, 1998), at 150-170); Andrew Bell, *Forum Shopping and Venue in Transnational Litigation*, (Oxford University Press, USA, 2003), pp.400; Richard Fentiman, “Parallel Proceedings and Jurisdiction Agreement in Europe,” in *Pascal De Vareilles-Sommieres*, (editor), *Forum Shopping in the European Judicial Area*, (Portland: Hart Publishing, 2007), at 27-54.

weaken possible causes of action that range from strict liability, product liability, private nuisance, trespass, to negligence.<sup>643</sup>

In the United Kingdom, the current conservative government is openly in favour of transgenic plant technology and government Ministers have openly canvassed that transgenic plant agriculture and food are as safe for the environment and public health as conventional plant agriculture and food.<sup>644</sup> Whilst there is nothing intrinsically wrong in government promotional policy for new technologies; care must be taken to balance favourable promotional policies with adequate regulation. There is a danger that the political will to craft a viable liability and redress regime could be compromised whilst the government is simultaneously promoting the technology. For it is often the case that while governments around the world are keen to promote new technologies as part of national strategic social and economic development policies,<sup>645</sup> they often struggle to keep technology policy and regulatory framework abreast of new technological developments,<sup>646</sup> fuelling concerns on the propriety, adequacy, or efficacy of regulatory and governance regimes for new technologies.<sup>647</sup> Thus, while technological regulation is sacrosanct,<sup>648</sup> there is a risk that governmental technology

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<sup>643</sup> See Ken Oliphant, "Damage Caused by GMOs under English Law," in Bernhard A. Koch, (editor), *Damage Caused by Genetically Modified Organisms: Comparative Survey of Redress Options for Harm to Persons, Property or the Environment*, *supra* note 631, at 86-109.

<sup>644</sup> See Sean Poulter, "Government gives green light to growth of GM crops," *Mail Online*, (Monday, September 16, 2013), at <http://www.dailymail.co.uk/news/article-396737/Government-gives-green-light-growth-GM-crops.html> (accessed on 14 May 2015).

<sup>645</sup> See Ronald J. Herring, "The Genomics Revolution and Development Studies: Science, Poverty and Politics," in Ronald J. Herring, (editor), *Transgenics and the Poor: Biotechnology in Development Studies*, *supra*, note 248, at 2. See also Stanley M. Lemon, et al., *Globalization, Biosecurity, and the Future of the Life Sciences*, (Washington D.C: National Academies Press, 2006), at 79-81.

<sup>646</sup> See Lyria Bennett Moses, "Recurring Dilemmas: The Law's Race to Keep up with Technological Change," *University of Illinois Journal of Law, Technology, & Policy*, Volume 2007, Issue 2, (Fall 2007), at 239-285.

<sup>647</sup> See Gary E. Marchant, "The Growing Gap Between Emerging Technologies and the Law," in Gary E. Marchant, Braden R. Allenby, and Joseph R. Herkert, (editors), *The Growing Gap Between Emerging Technologies and Legal-Ethical Oversight: The pacing Problem*, (Heidelberg, London & New York: Springer Publishing, 2011), at 19-33.

<sup>648</sup> See Braden R. Allenby, "Governance and Technology Systems: The Challenge of Emerging Technologies," in Gary E. Marchant, Braden R. Allenby, and Joseph R. Herkert, (editors), *The Growing Gap Between Emerging Technologies and Legal-Ethical Oversight: The pacing Problem*, *supra*, note 274, at 7-11.

promotional policy could obfuscate effective technological regulatory regime, if a proper balance between technology promotion and regulation was not struck.<sup>649</sup>

#### **3.2.4. Conclusions.**

Chapter Three builds on the analysis in Chapter Two of the thesis by exploring the broader scientific underpinnings of the regulatory and policy framework for the coexistence of transgenic and non-transgenic plant agriculture and products in the European Union and the United States. The chapter provides an insight into the approval systems and the coexistence arrangements for transgenic and non-transgenic plant agriculture, and the inherent limitations of regulatory science for transgenic plant technology governance. Whilst Chapter Two disputes the scientific legitimacy of the substantial equivalence doctrine, and questions its undue influence on the coexistence arrangements, Chapter Three focuses exclusively on the dynamics and symbiotic relationship between “science” (in the broadest sense) and policy, and the influence and limits of scientific opinions on the regulatory and policy framework for the coexistence of transgenic and non-transgenic plant agriculture.

The aim of the chapter is to provide a deeper perspective and insight into the extent to which the current coexistence arrangements for transgenic and non-transgenic agricultural products are science-dependent, and how this dependency could impact effective liability and redress regimes, given some national governments' favourable promotional policy for plant biotechnology, and the judicial tendency to defer to scientific opinions guided by public policy. The chapter characterises science-based policy for transgenic plant technology as “regulatory science”, and explores its proprieties, legitimacy, and effectiveness, amidst on-going scientific uncertainties, claims and counter-claims on the safety science of transgenic plant technology

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<sup>649</sup> See Oliver Todt, “Regulating Agricultural Biotechnology Under Uncertainty,” *Safety Science*, Volume 42, (2004), at 144..

for public health and the environment. The chapter again draws on Anthony Giddens' pessimism on the reliability of science for the governance of "manufactured risks" in the post-industrial "risk society", and serves as a backgrounder for chapter four, which explores the reality of the science-dependent coexistence arrangements for transgenic and non-transgenic plant agriculture, and tests the effectiveness of the current coexistence laws in the European Union, the United Kingdom and the United States.

## **Chapter Four.**

### **Comparative Existential Conflicts in the Coexistence Paradigm**

#### **4.1.0. Introduction**

In Chapter Four of the thesis, scenarios of existential conflicts between transgenic and non-transgenic plant agriculture are discussed and analysed. The accounts of these existential conflicts are rendered through a mixture of descriptive and analytical narrative of real events culled from primary and secondary literature. At the heart of the coexistence debate, is the safety issues posed by the flagship ingredient of all commercially available transgenic crops: *Bacillus thuringiensis*, a bacterium which occurs naturally in the environment, and which is now in the global food chain in different approved and unapproved variants, via deliberate and adventitious releases. The chapter reviews the nature and history of this important element of transgenic plant technology, with a view to properly contextualising the conflicting safety science, claims and counter-claims on its propriety for the environment and public health. It is intended that the chapter will serve as a necessary backgrounder to Chapters Five and Six of the thesis, which deal comprehensively with a range of possible causes of action for conceivable scenarios of possible damage in the coexistence paradigm. Thus whilst highlighting the practicalities and the challenges of the conflicting rights of transgenic and non-transgenic plant farmers, and the concomitant implications for the consumers, the environment, and public health, the chapter simultaneously seeks to demonstrate the imperatives for an effective compensation regime for damage induced in the coexistence paradigm.

#### **4.1.1. *Bacillus thuringiensis* Bacterium: A Natural Pesticide.**

Generally known by its Bt. acronym, *Bacillus thuringiensis* is a species of bacteria with natural insecticide properties that are deleterious to a wide-range of insect species, ranging from moth

and butterfly caterpillars, mosquito and black fly larvae, to beetle larvae.<sup>650</sup> The bacterium was first isolated in Japan in 1901 from diseased silk-worm larvae.<sup>651</sup> In 1911, it was again isolated from Mediterranean flour moths and formally christened as *Bacillus thuringiensis*.<sup>652</sup> The bacterium was first used commercially in the United States in 1958, and by 1989, pesticide products based on *Bacillus thuringiensis* protein had captured approximately ninety to ninety-five per cent of the biopesticide market.<sup>653</sup> The market dominance of *Bacillus thuringiensis*-based pesticidal products have been attributed to their relative advantages over traditional chemical pesticides.<sup>654</sup>

The *Bacillus thuringiensis* bacterium attacks target insects by secreting spores comprising a toxic protein crystal.<sup>655</sup> If a target insect ingests the protein crystal, the crystal will instantly dissolve in insect's alkaline the gut and its digestive enzyme, activating the insecticidal component of the bacterium's spores in the process.<sup>656</sup> The insecticidal component of the bacterium's protein is known as delta-endotoxin, and it typically binds to the cells lining the midgut membrane of the target insect.<sup>657</sup> When the delta-endotoxin is securely attached to the lining of the midgut membrane of the target insect, it begins to drill holes in the membrane, consequently upsetting the gut's iron balance, stopping the target insect from feeding, and inevitably causing the target insect to starve to death.<sup>658</sup> Alternatively, if the target insect did

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<sup>650</sup> See Carrie Swadener, "Bacillus Thuringiensis (B.T.)," *Journal of Pesticide Reform*, vol. 14, No. 3, (Fall 1994), 13-20, at 13.

<sup>651</sup> *Id.*

<sup>652</sup> *Id.*

<sup>653</sup> Common brand names of *Bacillus thuringiensis* based products in the United States comprised Dipel, Foray, Thuricide, Vectobac, Mosquito Attack, and M-Track. See Carrie Swadener, "Bacillus Thuringiensis (B.T.)," at 13.

<sup>654</sup> See Madhuri Kota, Henry Daniel, Sam Varma, Stephen F. Garczynski, Fred Gould, and William J. Major, "Over expression of the *Bacillus thuringiensis* (Bt) Cry2Aa2 protein in Chloroplasts confers resistance to plants against susceptible and Bt-resistant insects," *supra*, note 663, at 1840.

<sup>655</sup> Spores are the dormant stage of the bacteria's life cycle, when the bacteria waits for better growing conditions. However, unlike other bacteria, the *Bacillus thuringiensis* spores comprise toxic protein that is the active ingredient that is deleterious to a select group of insects. For discussion, see Carrie Swadener, "Bacillus Thuringiensis (B.T.)," *supra*, note 656, at 13. .

<sup>656</sup> *Id.*

<sup>657</sup> *Id.*

<sup>658</sup> Only certain insects are susceptible to the delta-endotoxin, and at least 29 different crystals and delta-endotoxin have been identified by scientist. See generally Carrie Swadener, "Bacillus Thuringiensis (B.T.)," *id.*, at 13-14.

not succumb to the starvation regime induced by the delta-endotoxin, death could still occur if the spores secreted on the target insect's gut membrane mushroomed and infected the entirety of the target insect's body.<sup>659</sup>

Apart from the target insects, each of the approximately eight hundred strains of *Bacillus thuringiensis* may exhibit varying levels of toxicity to rodents and humans. This is exemplified by studies conducted on laboratory mice that employed the two most commonly used commercial products comprising *Bacillus thuringiensis* bacterium.<sup>660</sup> For example, while commercial products comprising *Bacillus thuringiensis var. kurstaki* (B.t.k.) strain generally have low oral acute toxicity to mice,<sup>661</sup> other forms of mice exposure to *Bacillus thuringiensis var. kurstaki* spores such as inhalation of air containing the spores by mice, resulted in respiratory depression in the experimental mice.<sup>662</sup> Furthermore, *Bacillus thuringiensis var. kurstaki* spores injected into mice's veins aggravated preexisting diseases, while *Bacillus thuringiensis var. kurstaki* was found to cause skin irritation in rabbits.<sup>663</sup> Moreover, another strain of the bacterium: *Bacillus thuringiensis var. israelensis* (B.t.i.), could cause mortality in mammals if injected into the abdomen or the brain,<sup>664</sup> while mice injected with *Bacillus thuringiensis var. israelensis* suspension, suffered from bloated and enlarged spleens.<sup>665</sup> Most significantly, laboratory mice suffered rapid paralysis and death within twelve hours of being intravenously injected with a purified form of the endotoxin of *Bacillus thuringiensis var. israelensis*.<sup>666</sup> However, when similar dosage of the endotoxin from *Bacillus thuringiensis var.*

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<sup>659</sup> Id, at 14.

<sup>660</sup> Id, at 14.

<sup>661</sup> Id, at 14.

<sup>662</sup> Id.

<sup>663</sup> Id.

<sup>664</sup> For example, in a study conducted on mice, there was 79 per cent mortality rate following a single injection of *Bacillus thuringiensis var. israelensis* into the brain. See Carrie Swadener, "Bacillus Thuringiensis (B.T.)," *supra*, note 20, at 14.

<sup>665</sup> Id.

<sup>666</sup> See Wendy E. Thomas and David J. Ellar, "Bacillus Thuringiensis Var Israelensis Crystal Delta-Endotoxin: Effects on Insect and Mammalian Cells in Vitro and in Vivo," *The Journal of Cell Science*, vol. 60 (1983), at 181-197.

*israelensis* was administered to suckling mice via the skin, death occurred within two to three hours.<sup>667</sup>

In contrast to laboratory mammals however, there have been few experimental studies on the toxicity of the *Bacillus thuringiensis var. kurstaki* (B.t.k.) strain on humans, and most of the available information emanated from accidental or occupational exposures during large scale *Bacillus thuringiensis var. kurstaki* programmes.<sup>668</sup> For example, a farmer who accidentally splashed a *Bacillus thuringiensis var. kurstaki* formulation known as *Dipel* into his eye developed an ulcer on his cornea, from which positive *Bacillus thuringiensis var. kurstaki* cultures were subsequently harvested.<sup>669</sup> Also, earlier tests conducted on the toxicity of *Bacillus thuringiensis var.*, concluded that it carried a second toxin known as beta-exotoxin, and that the application of a median lethal dose of beta-exotoxin was toxic to vertebrates,<sup>670</sup> and could cause genetic damage to human blood cells.<sup>671</sup> Furthermore, human volunteers who had eaten food contaminated with the *Bacillus thuringiensis var galleriae* strain, suffered from nausea, vomiting, diarrhea, colic-like pains, and fever,<sup>672</sup> while people with compromised immune systems or pre-existing allergies are said to be particularly susceptible to the effects of *Bacillus thuringiensis*.<sup>673</sup> The foregoing examples thus establish a clear nexus between different strains of *Bacillus thuringiensis* and disease-causing pathogens.<sup>674</sup> This probably explains why scientists are divided on the safety implications of the use of the bacterium in transgenic crops designed for human use and consumption.

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<sup>667</sup>See Carrie Swadener, "Bacillus Thuringiensis (B.T.)," *Journal of Pesticide Reform*, vol. 14, No. 3, (Fall 1994), 13-20, at 14.

<sup>668</sup> *Id.*, at 15.

<sup>669</sup> See John R. Samples and Helmut Buettner, "Ocular infection caused by a biological insecticide," *The Journal of Infectious Diseases*, vol. 148, No. 3, (1983), at 614.

<sup>670</sup> A median lethal dose could kill 50 per cent of a population of test animals. For discussion, see Carrie Swadener, "Bacillus Thuringiensis (B.T.)," *supra*, note 660, at 15.

<sup>671</sup> See Tytti Meretoja, Gunnel Carlberg, Ulla Gripenberg, Kaija Linnainmaa, and Marja Sorsa, "Mutagenicity of *Bacillus thuringiensis* exotoxin, I Mammalian tests," *Hereditas*, vol. 85 (March, 1977), at 105-112.

<sup>672</sup> See Carrie Swadener, "Bacillus Thuringiensis (B.T.)," *supra*, note 660, at 16.

<sup>673</sup> *Id.*

<sup>674</sup> *Id.*



#### 4.1.2. The Case of Swine Pharmaceutical Corn in the U.S. Food Chain.

In this section, the account of how swine pharmaceutical corn surreptitiously entered the US food chain is critical to the understanding of the nature of the existential risks posed by adventitious presence of transgenic organisms in non-transgenic crops in the coexistence paradigm, its inevitability, as well as the inherent limitations of the science that underpins on-farm segregation rules, buffer zones and plant refuge that are designed to keep transgenic and non-transgenic crops separate.

In 2001, ProdiGene Corporation, a leading biotechnological firm based in College Station, Texas, United States, commissioned a Nebraska farmer to cultivate transgenic swine vaccine corn, which embodied an insulin precursor (*Trypsin*) that had been designed to combat diarrheal, a gastrointestinal disease in piglets.<sup>675</sup> The United States Department of Agriculture had approved the cultivation of the experimental transgenic pharmaceutical corn.<sup>676</sup> The transgenic vaccine corn was to be cultivated under very restrictive conditions, which ranged from the isolation and insulation of the trial field from neighbouring farms and crops; the enclosure of the trial field by a buffer of sterile plants to blockade drifting pollens from neighbouring fields and farms; the thorough post-harvest clearance of the trial field of all leftover cornstalks and seeds; to the regular post-harvest inspections of the experimental transgenic corn field to forestall possible resurgence of ‘volunteer’ or leftover cornstalks or seeds amongst crops subsequently planted on the test field.<sup>677</sup> These restrictive measures were necessary preemptive bulwarks against plausible adventitious admixture of transgenes from

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<sup>675</sup> See Stephanie Simon, “Fearing a Field of Genes: The Food Industry loves engineered crops, but not when plants altered to ‘grow’ drugs and chemicals can slip into its products,” *Los Angeles Times*, *supra*, note 635, at 1; Bill Hord, “The Road Back: Prodigene and Other Biotech Companies Are Moving Ahead in an Environment of Increasing Fear of Crop Contamination”, *Omaha World Herald*, (19 January 2003), at 1.

<sup>676</sup> See David Winickoff, Sheila Jasanoff, Lawrence Busch, Robin Grove-White, and Brian Wynne, “Adjudicating the GM Food Wars: Science, Risk, and Democracy in World Trade Law”, *The Yale Journal of International Law*, vol. 30, (2005), 81, at 103.

<sup>677</sup> See Stephanie Simon, , “Fearing a Field of Genes: The Food Industry loves engineered crops, but not when plants altered to ‘grow’ drugs and chemicals can slip into its products,” *supra*, note 669.

the experimental swine vaccine corn with other food crops harvests.<sup>678</sup> Subsequent inspections of the trial fields by USDA officials confirmed that the anti-commingling measures were duly complied with by ProdiGene Corporation.<sup>679</sup> Due compliance was crucial because the experimental swine pharmaceutical corn was neither approved for nor intended for human consumption,<sup>680</sup> due to experts' belief that Cry9C, a key constituent of the StarLink corn, could not be easily absorbed in the human gut, and that it could potentially cause an allergic reaction.<sup>681</sup>

In the spring of 2002, following the official inspection and clearance of the trial field for re-use by farmers, the trial field was subsequently cultivated with soybeans.<sup>682</sup> However, shortly after the soybeans had been harvested and sold to food mills for processing into the food chain, a federal inspector from the United States Department of Agriculture visited the soybean farm, and discovered crumpled pharmaceutical corn amidst newly harvested soybean crop.<sup>683</sup> Unbeknown to the soybean farmer, stubborn remnants of the experimental pharmaceutical corn seeds and stalks, otherwise known as 'volunteers', had clung to earth, evaded detection and flourished alongside the newly cultivated field of soybean.<sup>684</sup>

The pharmaceutical corn incident again demonstrates the challenges of coexistence,<sup>685</sup> and casts doubts on the propriety of anti-commingling measures, that range from crop rotational

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<sup>678</sup> See United States Department of Agriculture, "USDA Coexistence Facts Sheets: Crop Production Methods," (February 2015), *supra*, note 186; United States Department of Agriculture, "USDA Coexistence Facts Sheets: Best Practices," (February 2015), *supra*, note 201.

<sup>679</sup> See Stephanie Simon, "Fearing a Field of Genes: The Food Industry loves engineered crops, but not when plants altered to 'grow' drugs and chemicals can slip into its products," *supra*, note 635.

<sup>680</sup> *Id.*

<sup>681</sup> See Patrick A. Stewart, William P. McLean, and Lucas P. Duffner, "Agricultural Bioterrorism: Dimensions of Fear and Public Perception," in James J.F. Forest, (editor), *Homeland Security: Protecting America's Targets*, *supra*, note 22, at 287- 290.

<sup>682</sup> *Id.*

<sup>683</sup> *Id.*

<sup>684</sup> In technical parlance, the resurgent transgenic swine corn is a 'volunteer' plant, a technical name given to plants from previous season, which unexpectedly emerged in a new season amongst totally different crops. For discussion, see David Winickoff, Sheila Jasanoff, Lawrence Busch, Robin Grove-White, and Brian Wynne, "Adjudicating the GM Food Wars: Science, Risk, and Democracy in World Trade Law", *supra*, note 5, at 103.

<sup>685</sup> *Id.*

system,<sup>686</sup> segregation distances, to buffer zones and refuge.<sup>687</sup> Also, the incident underscores the inevitability of adventitious presence of transgenes in non-transgenic crops in the coexistence paradigm.<sup>688</sup>

The United States Department of Agriculture subsequently ordered the incineration of approximately five hundred thousand bushels of soybean estimated at US\$3 million, which was bore by ProdiGene Corporation in addition to an unprecedented US\$250,000 fine.<sup>689</sup> Furthermore, the United States Department of Agriculture imposed stringent farm management rules that were short of the outright ban on open field trials of pharmaceutical crops canvassed for, by anti-transgenic plant agriculture activists.<sup>690</sup> The new rules, which were published in March 2003, comprised enhanced on-farm inspections requirements and limitations on the ability to rotate food crops on fields recently planted with transgenic pharmaceutical crops.<sup>691</sup>

#### **4.1.3. *Bacillus Thuringiensis*-StarLink Corn in US Food Chain.**

The pharmaceutical corn fiasco on Iowa and Nebraska farms came on the heels of the highly publicised StarLink corn debacle, in which transgenic corn that was meant for animal feed, surreptitiously entered the US food chain. The StarLink corn was a variety of transgenic corn

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<sup>686</sup> See Donald G. Bullock, "Crop Rotation," *Critical Review in Plant Sciences*, vol. 11, Issue 4, (1992), at 309-326., (noting the likelihood of the occurrence of volunteer populations of transgenic plants where seeds are inadvertently spread during harvest).

<sup>687</sup> See George Marshall, "Herbicide-Tolerant Crops: Real Farmer Opportunity or Potential Environmental Problem?" *Pesticide Science*, vol. 52, (1998), 394-402, at 398; Stephen Chandler and Jim M. Dunwell, "Gene Flow, Risk Assessment and the Environmental Release of Transgenic Plants," *Critical Review in Plant Sciences*, vol. 27, Issue 1, (2008), at 26-49.

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<sup>689</sup> See Stephanie Simon, , "Fearing a Field of Genes: The Food Industry loves engineered crops, but not when plants altered to 'grow' drugs and chemicals can slip into its products," *supra*, note 1.

<sup>690</sup> See Andrew Pollack, "U.S. Imposes Stricter Rules for Genetically Modified Crops," *New York Times*, (7 March, 2003), at A22, and Philip Brasher, "U.S. tightens rules for growing pharma crops," *Des Moines Register*, (7 March, 2002), at D1. See also Rebecca Bratspies, "The Illusion of Care: Regulation, Uncertainty, and Genetically Modified Food Crops," *New York University Environmental Law Review*, (2002), 297-355, at 323-324, (noting that the USDA did not properly exercise its oversight powers by leaving risk evaluation to the firms undertaking field trials, and by narrowly construing risk evaluation to the possibility that the transgenic crop might be a plant pest).

<sup>691</sup> See 68, Federal Register, (March 2003), at 11337.

designed to produce its own pesticidal protein, and used primarily for animal feed and other industrial non-food uses, following approval by the United States Environmental Protection Agency (EPA) in 1998.<sup>692</sup> The StarLink corn was genetically modified to produce its own pesticidal protein Cry9C, which like other *Bacillus thuringiensis* (Bt) toxins,<sup>693</sup> is designed to eliminate target corn insects such as the European corn borer, *Ostrinia nubilalis* (Hubner), and corn earthworm *Helicoverpa zea* (Boddie), without negatively impacting other non-target insects species in the environment.<sup>694</sup>

Nevertheless, the surreptitious entry of StarLink corn into the food chain was confirmed by the United States authorities in September 2000, following its discovery in corn tortillas and other processed foods.<sup>695</sup> In fact, apart from the farmers who cultivated StarLink corn, the entire grain industry ranging from other grain farmers, grain elevator operators, to grain dealers and brokers, was oblivious to its existence, as it surreptitiously made its way into the grain silos across the United States, and commingled with approximately twenty-two per cent of the grain subsequently tested by the United States Department of Agriculture.<sup>696</sup> Thus, by the time StarLink corn was outed in the food chain September 2000, it had been consumed by millions of people across the United States, precipitating an unprecedented nation-wide recall of over

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<sup>692</sup> On 22 May 1998, the U.S. Environmental Protection Agency published in the Federal Register, a final rule granting a permanent split tolerance exemption for Cry9C protein and Cry9C DNA residues, allowing their use “only in corn for feed; as well as in meat, poultry, milk, or eggs resulting from animals fed such feed.” See 63 Fed. Reg. 28252 (22 May, 1998). See also Marc Kaufman, “Modified Corn Found in Taco Shells in Tests,” *Los Angeles Times*, (18 September, 2000), at 1, (stating how the corn was detected in Taco Bell brand taco shells that were sold in groceries stores).

<sup>693</sup> See Carrie Swadener, “Bacillus Thuringiensis (B.T.),” *Journal of Pesticide Reform*, *supra*, note 661, at 14. See also Michael R. Taylor and Jody S. Tick, *The StarLink Case: Issues for the Future*, A report commissioned by the Pew Initiative on Food and Biotechnology, (October 2001), at [www.pweagbiotech.org](http://www.pweagbiotech.org), at 1.

<sup>694</sup> See Madhuri Kota, Henry Daniel, Sam Varma, Stephen F. Garczynski, Fred Gould, and William J. Major, “Over expression of the *Bacillus thuringiensis* (Bt) Cry2Aa2 protein in Chloroplasts confers resistance to plants against susceptible and Bt-resistant insects,” *Proceedings of National Academy of Science*, vol. 96, (March 1999), 1840-1845, at 1840.

<sup>695</sup> See Michael R. Taylor and Jody S. Tick, *The StarLink Case: Issues for the Future*, *supra*, note 20, at 1.

<sup>696</sup> See Jeffrey M. Smith, *Seeds of Deception: Exposing Corporate and Government Lies about the Safety of Genetically Engineered Food*, *supra*, note 94, at 49.

ten million individual food items ranging from “tacos, corn chips, corn meal, to all things corn.”<sup>697</sup>

It was a dramatic find, not least because it was precipitated by the inquisitiveness and dogged investigative efforts of the United States Chapter of Friends of the Earth, a coalition of environmental activists opposed to plant biotechnology. The group had commissioned Genetic ID Inc., to conduct a laboratory analysis on samples of taco shells, a traditional Mexican dish of corn tortillas folded around fillings comprising beef, chicken, seafood, vegetables, or cheese.<sup>698</sup> However, the incident did ostensibly undermine the US Environmental Protection Agency ability to oversee the containment of transgenes deemed unsuitable for human consumption, and arguably demonstrates the limitations of technical coexistence measures such as segregation distances and buffer zones, and the inevitability of adventitious presence of transgenes in non-transgenic crops and foods, despite the ostensibly stringent anti-commingling measures employed by the United States Environmental Protection Agency.<sup>699</sup> For While it is theoretically feasible to craft regulatory and institutional governance regimes for managing the co-existence of transgenic and non-transgenic crops, it is very challenging to obviate inadvertent commingling incidents as exemplified by the pharmaceutical corn and soybeans on Iowa and Nebraska farms.<sup>700</sup>

#### **4.1.4. Adventitious StarLink Corn in Global Food Chain.**

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<sup>697</sup> Id.

<sup>698</sup> See id, at 153. See also *Friends of the Earth*, “Serious Doubts about GM Food Safety,” Friends of the Earth Archived Press Release (18 September 2000), at [http://www.foe.co.uk/resource/press\\_releases/0918taco.html](http://www.foe.co.uk/resource/press_releases/0918taco.html).

<sup>699</sup> See Jeffrey M. Smith, *Seeds of Deception: Exposing Corporate and Government Lies about the Safety of Genetically Engineered Food*, *supra*, note *supra*, note 49, at 148 (noting the stringent conditions under which the StarLink corn was cultivated, which ranged from mandatory written undertakings by farmers to enforced 660 feet separation distances from any neighbouring maize).

<sup>700</sup> See Stephanie Simon, “Fearing a Field of Genes: The Food Industry loves engineered crops, but not when plants altered to ‘grow’ drugs and chemicals can slip into its products,” *supra*, note 1; Miguel A. Altieri, “The Myth of Co-existence: Why Transgenic Crops Are Not Compatible With Agro-ecologically Based Systems of Production,” *Bulletin of Science, Technology & Society*, Volume 25, No. 4, (August 2005), at 361-371; George Marshall, “Herbicide-Tolerant Crops: Real Farmer Opportunity or Potential Environmental Problem?” *Pesticide Science*, vol. 52, (1998), at 394-402.

There are concerns that the StarLink corn may have permeated the global food chain, due to confirmed sightings in as far afield as Bolivia in Central America and Japan in the Far East. It is also feared that StarLink corn may have been exported around the world via the US food aid programme.<sup>701</sup> Incredibly, StarLink corn has been reportedly found in Mexican landraces in Oaxaca, Mexico, a reputed centre of maize diversity.<sup>702</sup> There have been conflicting studies regarding the presence or otherwise of transgenes in Mexican Maize landraces. The initial study conducted in 2000, using samples taken from the state of Oaxaca confirmed that there were transgenes in the native Mexican landraces. The study was swiftly rebuffed and shredded. However, further studies by the Mexican government did confirm the presence of transgenes in Oaxaca maize landraces in 2000 and 2001. However, another study conducted in 2003 and 2004 proved negative and failed to find transgenes in the same area. It has been suggested that if any transgenes existed, their frequency may have declined in the interval between various conflicting studies, or that the transgenes may have disappeared altogether.<sup>703</sup>

Furthermore, in 2003, some three years after its initial discovery, StarLink corn reputedly continued to show up in more than one per cent of corn samples in the United States.<sup>704</sup> If these sporadic sightings are correct, then ostensibly, StarLink corn may have become self-perpetuating, self-replicating, and possibly irreversibly embedded in the global food chain, a frightening and foreboding prospect indeed. According to Jeffrey M. Smith, “some small amount of StarLink may linger in the human food chain forever. Although sold as a yellow feed corn, it has cross-pollinated into sweet corn, popcorn and white corn, and was identified in

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<sup>701</sup> See Andy Rees, *Genetically Modified Food: A Short Guide for the Confused*, (London & Ann Arbor, MI. Pluto Press, 2006), at 69.

<sup>702</sup> See [Mauricio R. Bellon](#) and [Julien Berthaud](#), “Traditional Mexican Agricultural Systems and the Potential Impacts of Transgenic Varieties on Maize Diversity,” *Agriculture and Human Values*, Volume 23, Number 1, (2006), at 3-14.

<sup>703</sup> See Peter H. Raven, “Transgenes in Mexican Maize: Desirability or Inevitability,” *Proceedings of the National Academy of Sciences*, Volume 102, No. 37, (September 13, 2005), at 13003-13004.

<sup>704</sup> See Andy Rees, *Genetically Modified Food: A Short Guide for the Confused*, *supra*, note 58, at 69.

the seed stock of 71 out of the 288 companies that the USDA contacted.<sup>705</sup> The full ramifications of adventitious presence of StarLink corn in the global food chain could only become evident if future scientific evidence emerged that link StarLink corn to public health or environmental problems.

#### **4.1.5. Unapproved *Bacillus thuringiensis* (Bt10) Corn in EU and UK Food Chain.**

Whilst no adverse health problems have yet been scientifically and directly linked to the alleged or assumed permanent presence of StarLink corn in the global food chain, the propensity for future linkage is arguably high, given the gradual build-up of yet another variant of *Bacillus thuringiensis* bacterium in the global food systems: Bt10 corn, an unapproved *Bacillus thuringiensis*-laden corn that was discovered in the European and United Kingdom maize supply systems in March 2005.<sup>706</sup> Significantly, an estimated fifteen thousand acres had been planted with Bt10 corn in the United States, and it was estimated that approximately fifteen thousand tones of Bt10 corn could have surreptitiously slipped into, and commingled with other edible corn in the global food chain.<sup>707</sup> Syngenta, a biotechnology firm, who was the proprietary owner of transgenic Bt10 corn, admitted that “several hundred tones” of *Bacillus thuringiensis* (Bt)10 corn, which was unapproved in the European Union, had inadvertently and mistakenly been passed on and sold in the European Union as Bt11 corn, which had been approved in the European Union for animal feed.<sup>708</sup> Also, Friends of the Earth were particularly irked by the damning evidence that Syngenta had passed on and sold the unapproved Bt10 corn as Bt11 corn in the European market for four years, ostensibly, blissfully unaware that they

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<sup>705</sup> See Jeffrey M. Smith, *Seeds of Deception: Exposing Corporate and Government Lies about the Safety of Genetically Engineered Food*, *supra*, note 49, at 155.

<sup>706</sup> See Andy Rees, *Genetically Modified Food: A Short Guide for the Confused*, *supra*, note 58, at 69.

<sup>707</sup> However, Syngenta representatives would not say which countries had inadvertently received the wrong seeds. See *Id.*, at 69. Thus, it is highly probable that most countries that import animal feeds from the United States could be affected.

<sup>708</sup> *Id.*

were selling unapproved and the wrong kind of corn to farmers.<sup>709</sup> Even after Syngenta and the United States government became cognizant of the accident, they allegedly kept it secret for four months, until the story was reported by *Nature Journal* on 22 March 2005.<sup>710</sup>

If anything, the inadvertent swapping of unapproved Bt10 corn for approved Bt11 corn in the United Kingdom and parts of the European Union,<sup>711</sup> could only serve to stoke the smoldering European skepticism and anger against transgenic plant agriculture and food products.<sup>712</sup> However, the European Union and the United Kingdom government sought to defuse the ensuing criticisms and panic by the assurances that all of Bt10 corn shipments to Europe and the United Kingdom had been used for animal feeds, and that they posed no significant harms or threats to public health.<sup>713</sup> However, the official line that Bt10 corn was safe and almost identical to Bt11 corn, was allegedly debunked by certain Syngenta documents, which indicated that there were “additional and possibly substantial differences between Bt10 and Bt11”, especially in the profiles of PAT and Cry1ab proteins, which showed that PAT levels in Bt10 appeared to be much higher than PAT levels in Bt11.<sup>714</sup> The compositional differences in the protein levels of the two *Bacillus thuringiensis* variants, were especially relevant in light of Syngenta email admission to the United Kingdom Department of Food and Rural Affairs, (which was obtained under the Freedom of Information Act), “that five Bt10 lines were a type of corn used in many processed foods”.<sup>715</sup> Thus, the Syngenta admission that Bt10 corn was routinely used in processed foods in the United Kingdom, clearly contradicted

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<sup>709</sup> Id, at 70.

<sup>710</sup> See id, at 70.

<sup>711</sup> Id, at 69.

<sup>712</sup> See Robert Lee, “GM Resistant: Europe and the WTO Panel Dispute on Biotech Products,” in Jennifer Gunning and Soren Holm, (editors), *Ethics, Law & Society: Volume I*, (Aldershot & Burlington, Ashgate Publishing, 2005), at 131-140.

<sup>713</sup> Both the European Commission and the United Kingdom authorities were criticized for their late and muted response to the crisis. See Andy Rees, *Genetically Modified Food: A Short Guide for the Confused*, *supra*, note 58, at 69.

Id, at 70.

<sup>714</sup> Id.

<sup>715</sup> Id.



the European Commission and the United Kingdom Department of Food and Rural Affairs public assurances that Bt10 corn were only used for animal feed.<sup>716</sup>

However, whether or not Bt10 corn caused any food allergens in Europe or in the United Kingdom, and the true nature of the allergens, if any, would remain purely conjectural and unknown for the foreseeable future. Similarly, whether or not the consumption of poultry and farm animals fed with Bt10 corn could have future or long term deleterious health effects on European or British populations would remain largely conjectural and speculative for now in the absence of verifiable sound science, invariably leaving the door open for possible future causes of action in product liability, strict liability, contractual liability or negligence for scientifically proven adverse or deleterious health effects on affected populations. This scenario is typified by asbestos and tobacco lawsuits, where previous exposures to asbestos fibers and tobacco were subsequently linked with numerous incidents of cancer.<sup>717</sup> With regards to the eventual linkage of asbestos to cancer, Gregory Keating described the slow process over time as a time bomb that never stopped ticking until the person exposed developed “a crippling or fatal disease- first in asbestosis and then in mesothelioma.”<sup>718</sup>

Also, and most significantly, it is yet unclear what could happen if corn carrying the StarLink *Bacillus thuringiensis* Cry9C protein strain were to commingle with corn carrying the *Bacillus thuringiensis* 10 variant? Both strains are unapproved for human consumption, and, as previously noted, there is ample evidence that both strains are already circulating in the global food chain.<sup>719</sup> The pertinent questions therefore are: could the simultaneous presence or commingling of the two variants of *Bacillus thuringiensis* bacteria in the global food chain,

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<sup>716</sup> Id.

<sup>717</sup> See Gregory C. Keating, “The Heroic Enterprise of the Asbestos Cases,” *University of Southern California Law and Economic Working Paper Series*, Paper 101, (2009), 622 at 652; Taiwo A. Oriola, “Ethical and Legal Analyses of Laws Prohibiting Tobacco Smoking in Enclosed Public Spaces,” *The Journal of Law, Medicine, & Ethics*, Volume 37, Number 4, (Winter 2009), at 828-840.

<sup>718</sup> See Gregory C. Keating, “The Heroic Enterprise of the Asbestos Cases,” *supra*, note 711, at 652.

<sup>719</sup> See Jeffrey M. Smith, *Seeds of Deception: Exposing Corporate and Government Lies about the Safety of Genetically Engineered Food*, *supra*, note 49, at 155; Andy Rees, *Genetically Modified Food: A Short Guide for the Confused*, *supra*, note 58, at 69.

precipitate mutations that could aggravate their toxicity, and thereby increase their allergenicity potentials? Similarly, could the adventitious commingling in the food chain, of corn carrying the unapproved strains of *Bacillus thuringiensis* Cry9C and *Bacillus thuringiensis* 10, with corn carrying the approved strain of *Bacillus thuringiensis* 11, lead to a cocktail of proteins so toxic that could negatively impact public health now or in the future?<sup>720</sup> Again, in the absence of sound science, there are no clear answers, even though the commingling scenarios are not far-fetched, due to the fact that the three strains of *Bacillus thuringiensis* bacterium are already directly and indirectly in commercial transgenic maize currently grown and consumed globally in twenty-eight countries across six continents.<sup>721</sup>

Indeed, possible health impacts could take two forms. The first is immediate allergic reaction by people who ate meals containing unapproved transgenes. Linking food allergies to the presence of unapproved transgenes should not be difficult provided there is conclusive science that identified the transgenes in question as the causative agency. The second possibility is a latent health problem that could manifest in the future. Thus, if there were to be proven scientific evidence in the future that positively connected or linked adventitious transgenes carrying different strains of *Bacillus thuringiensis* in the food chain or in the environment, to latent or evident debilitating allergies or illnesses, or to any environmental or proprietary damage, then arguably, it should be possible to establish a cause of action that ranged from product liability, negligence, to contractual liability.<sup>722</sup>

The possible retrospective linkage of current or evident illnesses, diseases, or harm to some distant causative agencies, or exposures to harmful substances from bygone years, is well exemplified by the asbestos cases in the United Kingdom, where diagnosis for cancer caused

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<sup>720</sup> Note that Bt11 corn is approved for use in animal feeds in the United States and the European Union. See Andy Rees, *Genetically Modified Food: A Short Guide for the Confused*, *supra*, note 58, at 69.

<sup>721</sup> See Clive James, *Global Status of Commercialized Biotech/GM Crops*, *supra*, note 1.

<sup>722</sup> See Maria Lee and Robert Burrell, "Liability for the Escape of GM Seeds: Pursuing the 'Victim'?" *The Modern Law Review*, Volume 63, Issue 2, (March 2000), at 517-535; *In re StarLink Corn Products Liability Litigation: Marvin Kramer, et al., v. Aventis CropScience USA Holding, Inc., et al.*, 212F. Supp. 2d 828 (N.D. III 2002).

by exposures to asbestos fibres dated far back to the 1940s, and is expected to peak in 2015, spanning five decades.<sup>723</sup> The legal propriety of linking the extended incubation period between exposures to cancer causing agents, and the subsequent manifestations of cancer symptoms, was given judicial imprimatur in 2012 by the UK Supreme Court in *Bai (Run Off) Limited & Others v Durham & Others*,<sup>724</sup> in which the Supreme Court retrospectively linked and backdated liability to the time of victims' first exposures to the deadly air-borne carcinogenic asbestos fibres, rather than when the consequential asbestosis or mesothelioma lung cancer symptoms became manifest or evident in the victims.<sup>725</sup> Thus, by extrapolation, if people who consumed foods containing toxic strains of *Bacillus thuringiensis* bacterium in the 2010s were to develop some debilitating diseases in the 2030s, which diseases could be scientifically linked to the consumption of *Bacillus thuringiensis* bacterium-laced foods back in the 2010s, the courts should have no difficulties in establishing a nexus, by linking and tracking the diseases back in time to their causative agents in the environment or in the foods consumed by the victims back in the 2010s.<sup>726</sup> However, as with tobacco smoking and asbestos fibres, sound science would be crucial to establishing a nexus between any diseases and the consumption of foods containing *Bacillus thuringiensis* bacterium, or any transgenic foods for that matter.<sup>727</sup>

#### **4.1.6. Adventitious Transegens and Public Health.**

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<sup>723</sup> See Kristen Griffin, "UK Supreme Court Ruling in Landmark Asbestos Case," *Mesothelioma Cancer Alliance*, (30 March, 2012), at <http://www.mesothelioma.com/news/2012/03/uk-supreme-court-ruling-in-landmark-asbestos-case.htm> (noting how the peak year for mesothelioma may differ from country to country, underscoring the extended nature of the incubation period for the disease, and how the time between asbestos exposures and to cancer symptoms manifestation could span decades). See also Owen Bowcott, "Asbestos court ruling leaves insurers facing bill of up to £5bn," *The Guardian*, (Wednesday 28 March, 2012), at <http://www.guardian.co.uk/business/2012/mar/28/asbestos-court-ruling-insurers-bill?INTCMP=ILCNETTXT3487> (accessed on 14 May 2015).

<sup>724</sup> Tracking back liability to the time of victims' exposure to the mesothelioma cancer-causing agent enabled victims to claim against the insurance companies that insured their employers at the time of exposures. See *Bai (Run Off) Limited & Others v. Durham & Others*, [2012] UKSC 14.

<sup>725</sup> See *Bai (Run Off) Limited & Others v. Durham & Others*, id, at 14.

<sup>726</sup> This scenario is clearly analogous to the Supreme Court finding in the asbestos case. See *Bai (Run Off) Limited & Others v. Durham & Others*, id, at 14.

<sup>727</sup> See James Keeley and Ian Scoones, "Contexts for Regulation: GMOs in Zimbabwe," *Institute for Development Studies (IDS) Working Paper Series* No. 190, (June 2003), pp. 1-23, at 3 and 4.

Unsurprisingly, the StarLink corn scandal immediately provoked public health concerns. For example Taco Bell's core customers were scared, whilst the US Environmental Protection Agency had to request the assistance of the Food and Drug Administration in evaluating the alleged claims of some Taco Bell's customers to adverse reactions following the consumption of foods thought to have contained Cry9C protein from *Bacillus thuringiensis* bacterium.<sup>728</sup> For example, in Oakland, California, one Grace Booth, who had eaten chicken enchiladas at a business lunch with work colleagues, allegedly developed breathing problems cum severe diarrhea within fifteen minutes of her meal, and was subsequently treated in an emergency room of a nearby hospital for anaphylactic shock.<sup>729</sup> Further down south in Florida, Keith Finger, a local optometrist fell ill within fifteen minutes of tucking into a dinner of tortillas, beans and rice.<sup>730</sup> Just like Grace Booth from California, he suffered itching, headaches, breathing difficulty, swollen tongue and acute diarrhea, all symptomatic of anaphylactic shock attacks.<sup>731</sup> There were several dozen others, who allegedly fell ill and suffered allergic reactions following a meal of tortillas or enchiladas suspected to have contained StarLink corn.<sup>732</sup>

Whilst the Food and Drug Administration and the Federal Centre for Disease Control and Prevention began inquests into the possible role that StarLink corn might have played in the mysterious food allergies sweeping across the country, some experts believed that StarLink corn was the most probable cause of the illness, on grounds that "Cry9C protein has a heightened ability to resist heat and gastric juices - giving more time for the body to overreact,"

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<sup>728</sup> See Michael R. Taylor and Jody S. Tick, *The StarLink Case: Issues for the Future: A Report Commissioned by the Pew Initiative on Food and Biotechnology*, (October 2001), at [www.pweagbiotech.org](http://www.pweagbiotech.org) at 17.

<sup>729</sup> See Marc Kaufman, "Biotech Corn Is Test Case for Industry: Engineered Food's Future Hinges on Allergy Study," *Washington Post*, (19 March, 2001), at 1 (describing how Grace Booth colleagues called for an ambulance during her ordeal).

<sup>730</sup> The account of Keith Finger's ordeal is largely based on the *Washington Post* report. See generally Marc Kaufman, "Biotech Corn Is Test Case for Industry: Engineered Food's Future Hinges on Allergy Study," *id.*

<sup>731</sup> *Id.*

<sup>732</sup> *Id.*

and that the molecular weight of Cry9C protein was consistent with something that could trigger an allergic reaction.<sup>733</sup>

Nevertheless, the test conducted on the blood samples of seventeen people who had reported allergic reactions following meals allegedly comprising StarLink corn, showed no anti-bodies that could link the StarLink corn to the alleged illness.<sup>734</sup> However, the finding patently ran counter to the thrust in literature on the inherent toxicity of Cry9C protein in *Bacillus thuringiensis* bacterium,<sup>735</sup> and the earlier insights offered by the expert panel set up by the United States Environmental Protection Agency, who opined that the molecular weight of the StarLink Cy9C protein was consistent with properties that could trigger an allergic reaction.<sup>736</sup> The contradictory findings of the expert panel were based on a new blood sample test conducted under the auspices of the United States Environmental Protection Agency within five weeks of the first test, and the findings demonstrated that the results of the earlier test could not have been conclusive, and that StarLink corn could not be completely eliminated as the source of allergic reactions suffered by people whose blood samples were tested.<sup>737</sup> The verdict on the inconclusiveness of the test results conducted by the Food and Drug Administration was hardly surprising, since some of the Cry9C protein samples provided by Aventis CropScience to the Food and Drug Administration for testing had not been taken from

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<sup>733</sup> Id.

<sup>734</sup> See Jeffrey M. Smith, *Seeds of Deception: Exposing Corporate and Government Lies about the Safety of Genetically Engineered Food*, *supra*, note 49, at 148-149. See also CDC (2001a), *FDA Evaluation of Consumer Complaints Linked to Foods Allegedly Containing StarLink Corn*. (June 13, 2001). Centers for Disease Control and Prevention (CDC) <http://www.cdc.gov/nceh/ehhe/Cry9CReport> ; CDC (2001b), *Investigation of Human Health Effects Associated with Potential Exposure to Genetically Modified Corn*. (June 11, 2001), Centers for Disease Control and Prevention (CDC) <http://www.cdc.gov/nceh/ehhe/Cry9Creport/executivesummary.htm>.

<sup>735</sup> For discussion, see Carrie Swadener, "Bacillus Thuringiensis (B.T.)", *supra*, note 20, at 16; Wendy E. Thomas and David J. Ellar, "Bacillus Thuringiensis Var Israelensis Crystal Delta-Endotoxin: Effects on Insect and Mammalian Cells in Vitro and in Vivo," *supra*, note 40.

<sup>736</sup> See EPA (2001), *White Paper on the Possible Presence of Cry9C Protein in Processed Human Foods made from Food Fractions produced through the Wet Milling of Corn*, Environmental Protection Agency, and Office of Pesticide Programs. <http://www.epa.gov/pesticides/biopesticides/otherdocs/wetmill18.pdf>. See also Marc Kaufman, "Biotech Corn Is Test Case for Industry: Engineered Food's Future Hinges on Allergy Study," *Washington Post*, (19 March, 2001), *supra*, note 81, at 1.

<sup>737</sup> See Federal Insecticide, Fungicide, and Rodenticide Act/Scientific Advisory Panel Report, "Assessment of Additional Scientific Information Concerning StarLink Corn," FIFRA Scientific Advisory Panel Meeting Report No. 201-09 (July 2001), available at <http://www.epa.gov/scipoly/sap/meetings/2001/july/julyfinal.pdf>

the StarLink corn being investigated.<sup>738</sup> Rather, some of the samples were synthesised substitutes taken by Aventis CropScience from *E. coli* bacteria, raising legitimate questions on the propriety and validity of the earlier test results, which query even the Food and Drug Administration officials deemed justifiable and legitimate.<sup>739</sup> Most significantly, using tests results based on substituted samples that were completely unrelated to the samples under investigation, arguably smack of fraud and misrepresentation, and a totally predictable outcome from a cosy system that allowed Aventis CropScience to supply virtually all of the samples used in the investigation held at the behest of the Food and Drug Administration. It was therefore unsurprising that the Scientific Advisory Report commissioned by the Environmental Protection Agency, urged for a procedure that would facilitate an independent validation of reagents and materials being tested for allergens,<sup>740</sup> while simultaneously questioning the wisdom and propriety of allowing Aventis CropScience to provide virtually all of the StarLink Cry9C protein samples used for allergy tests by the Food and Drug Administration.<sup>741</sup> Echoes of inherent conflict of interests also resonated in Jeffrey M. Smith's criticisms of the general conduct of the investigation conducted by the Food and Drug Administration into the alleged nexus between StarLink corn and food allergies:

Perhaps the gravest error was that the FDA asked Aventis, the makers of StarLink, to provide the Cry9C. If the FDA was under significant pressure to create a StarLink test, Aventis was under far more pressure to pass that test.<sup>742</sup>

Most significantly, the seeming discrepancy between the test results on the allergenicity of StarLink corn carried out by the expert panel commissioned by the United States Environmental Protection Agency, and those carried out under the auspices of the United States

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<sup>738</sup> See Richard B. Raybourne, "Development and Use of a Method for Detection of IgE Antibodies to Cry9C", FDA, (June 13, 2001), cited in Jeffrey M. Smith, *Seeds of Deception: Exposing Corporate and Government Lies about the Safety of Genetically Engineered Food*, *supra*, note 49, at 150.

<sup>739</sup> The FDA reputedly admitted that the substitution by Aventis CropScience, of the StarLink™ corn Cry9C with synthetic samples from *E. coli* bacteria could invalidate the test results. See Jeffrey M. Smith, *Seeds of Deception: Exposing Corporate and Government Lies about the Safety of Genetically Engineered Food*, *id.*, at 150.

<sup>740</sup> *Id.*

<sup>741</sup> *Id.*, at 39.

<sup>742</sup> *Id.*, at 149.

Food and Drug Administration, was arguably symptomatic of the dysfunctional Federal transgenic crops oversight regime, in which two of the three Federal agencies tasked with jurisdictional oversight of transgenic crops governance, ostensibly worked at cross-purposes, as if in direct competition with one another. The United States' multiagency governance system for transgenic crops has been severely panned by critics as "patchwork" and "haphazard", due to the perceived "inefficiencies and gaps created by the system of shared agency responsibilities" with structural vulnerability that could allow significant harms to "slip through the cracks."<sup>743</sup> *A fortiori*, the awkward multiagency regulatory structuring, and the predictably concomitant conflicting scientific reports,<sup>744</sup> could hardly inspire confidence in the Federal regulatory oversight of transgenic plant agriculture in the United States, and by extrapolation, in countries to which the United States routinely export its transgenic crops. For example, there was a significant decrease in the volume of corn purchased from the United States by the European Union, Japan and South Korea, immediately after the StarLink corn was discovered in the food chain.<sup>745</sup>

Also, the apparent inconclusiveness of the scientific enquiry into a possible nexus between StarLink corn and alleged food allergens, equally underscores the inherent scientific uncertainties that could potentially characterise any future efforts to establish a causal link between transgenic crops products and an alleged harm or damage to health or the environment, an arguably necessary normative requirement for any liability regime for adventitious commingling of transgenic and non-transgenic crops and products. As yet, there is no conclusive scientific evidence linking transgenic plant food consumption to public health

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<sup>743</sup> See Ryan C. Hansen, "Developing Internationally Uniform Liability Principles for Harms from Genetically Modified Organisms," *Bepress Legal Series*, Paper 105, (2003), at 28; Sophia Kolehmainen, "Precaution Before Profits: An Overview of Issues in Genetically Engineered Food and Crops," *Vanderbilt Environmental Law Journal*, vol. 20, (2001), 267, at 293.

<sup>744</sup> See Ryan C. Hansen, "Developing Internationally Uniform Liability Principles for Harms from Genetically Modified Organisms," *supra*, note 743, at 29.

<sup>745</sup> See Patrick A. Stewart, William P. McLean, and Lucas P. Duffner, "Agricultural Bioterrorism: Dimensions of Fear and Public Perception," in James J.F. Forest, (editor), *Homeland Security: Protecting America's Targets, Volume II: Public Spaces and Social Institutions*, *supra*, note 22, at 283-302.

problems. While new definitive scientific evidence could change our knowledge of the impacts of transgenic foods on health in future, a liability regime in tort such as negligence or nuisance, would of necessity, have to establish a causal link between an alleged harm or damage and the use, handling, or consumption of transgenic crops products.<sup>746</sup>

#### **4.1.7. New Transgenic Plant Allergens and Public Health.**

As previously discussed in Chapter One of the thesis, the transfer of desirable nucleic acid proteins (DNA), which are biological molecules, from one organism into another organism, irrespective of speciation, is the critical mass of genetic engineering techniques.<sup>747</sup> Nucleic acid proteins are found in all living things, (including humans), where they transmit, encode, and express genetic information.<sup>748</sup> In the context of plant genetic engineering techniques for example, desirable nucleic acid proteins from *Bacillus thuringiensis* bacterium with pest resistance properties, are routinely transferred into plant crops that range from maize, soybeans, canola, to cotton, with concomitant acronyms like Bt maize, Bt soybeans, and Bt cotton.<sup>749</sup>

However, there are proven possible numerous side-effects to the alteration of plant genome via the insertion of novel or foreign nucleic acid proteins. For example, some scientists believe that genetic alteration or modification of crops via novel or foreign nucleic acid proteins could affect the expression of non-target genes in the plant's genome.<sup>750</sup> Indeed, the United States

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<sup>746</sup> See Maria Lee and Robert Burrell, "Liability for the Escape of GM Seeds: Pursuing the 'Victim'?" *The Modern Law Review*, *supra*, note 78, at 530-535.

<sup>747</sup> See Jack Ralph Kloppenburg JR, *First The Seed: The Political Economy of Plant Biotechnology*, Second Edition, (Madison, Wisconsin: The University of Wisconsin Press, 2004), at 2-4; Michael J. Reiss and Roger Straugham, *Improving Nature? The Science and Ethics of Genetic Engineering*, (Cambridge: Cambridge University Press, 1996), at 1-2.

<sup>748</sup> See the views expressed by the Federal District Court of Columbia in *Alliance for Bio-integrity v. Donna Shalala*, 116 F. Supp. 2d (2000), at 176-177.

<sup>749</sup> See Madhuri Kota, Henry Daniell, Sam Varma, Stephen F. Garczynski, Fred Gould, and William J. Major, "Over expression of the *Bacillus thuringiensis* (Bt) Cry2Aa2 protein in Chloroplasts confers resistance to plants against susceptible and Bt-resistant insects," *Proceedings of National Academy of Science*, *supra*, note 21, at 1840-1845.

<sup>750</sup> See Sheldon Krimsky and Nora K. Murphy, "Biotechnology at the Dinner Table: FDA's Oversight of Transgenic Food," *The Annals of the American Academy of Political and Social Science*, Volume 584, Issue 1, (November 2002), at 84.



Food and Drug Administration acknowledged that the insertions of recombinant DNA (nucleic acid proteins) into a genetically active chromosomal location in plant genome could disrupt important genes or regulatory sequences that underpin the expression of one or several genes.<sup>751</sup> The Food and Drug Administration also acknowledged that transgenic plant developers using recombinant DNA technology could not control with precision, the ultimate location at which the inserted nucleic acid proteins would settle in the plant genome.<sup>752</sup> Furthermore, the Food and Drug Administration have acknowledged that the insertion of multiple foreign or novel genes into plant genome “to generate new metabolic pathways” could precipitate unpredictable changes or mutations in plant genome,<sup>753</sup> and dramatically alter the composition of transgenic plant crops significantly, with concomitant nutritional, toxicity and safety issues.<sup>754</sup> According to Mathilde Bourrier, the advent of transgenic plant agriculture has added a new range of food safety issues.<sup>755</sup>

New transgenic plant food allergens are a major public health scare in the coexistence paradigm. According to Samuel B. Lehrer et al, food allergens are mostly proteins or glycol-proteins.<sup>756</sup> Food allergies are said to occur from “adverse immunology reactions to proteins” and other components in food.<sup>757</sup> The commonest type of food allergies are “immediate hypersensitivity reactions, which occur when immunoglobulin E (IgE) antibodies bind to an allergen, causing symptoms that range from mild itching and diarrheal to life-threatening

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<sup>751</sup> See Food and Drug Administration, “Premarket Notice Concerning Bioengineered Foods: Proposed Rule, *Federal Register*, Volume 66, (2001), at 4706-4738.

<sup>752</sup> *Id.*, at 4710.

<sup>753</sup> *Id.*, at 4709.

<sup>754</sup> *Id.*, at 4710.

<sup>755</sup> See Mathilde Bourrier, “Applying Safety Science to Genetically Modified Agriculture,” in Michael Baram and Mathilde Bourrier, (editors), *Governing Risk in GM Agriculture*, *supra*, note 19, at 236.

<sup>756</sup> See Samuel B. Lehrer, [W. Elliott Horner](#), [Gerald Reese](#) and [Steven Taylor](#), “Why are some proteins allergenic? Implications for Biotechnology,” *Critical Reviews in Food Science and Nutrition*, Volume 36, Issue 6, (1996), at 553-564.

<sup>757</sup> See Paul R. Billings and Peter Shorett, “Coping with Uncertainty: The Human Health Implications of GE Foods,” in Iain E. P. Taylor, (editor), *Genetically Engineered Crops: Interim Policies, Uncertain Legislation*, (New York: The Haworth Press Inc, 2007), at 82.

anaphylactic shock.”<sup>758</sup> However, scientists believe that the percentage of allergenic proteins is small, and that only approximately two-hundred of the thousands of proteins that are consumed in foods are allergens.<sup>759</sup>

It is also estimated that two per cent of adults and eight per cent of children in industrialised countries suffer from food allergies, and that ninety per cent of food allergies ranging from moderate to severe are due to “a narrow range of nuts, cereal grains, seafood, soybeans, and dairy products,”<sup>760</sup> demonstrating that food allergies are common to both transgenic and conventional plant foods. According to Esther J. Kok et al., traditional plant breeding practices such as chemical mutagenesis might lead to higher rate of mutations compared with genetic changes induced by recombinant DNA technology.<sup>761</sup> However, unlike transgenic plant foods, conventionally cultivated crops have “a well-established history of safe use,”<sup>762</sup> while categories of allergenic foods such as Brazil nuts, are relatively well defined and fairly established, albeit “difficult to detect”.<sup>763</sup> But then, it has also been argued that food allergy testing is difficult and complex and most foodstuffs would never pass the test.<sup>764</sup>

With regards to allergens in transgenic plant foods, Samuel B. Lehrer et al, noted that while most transgenic plant foods were considered safe, biotechnology manipulation could affect

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<sup>758</sup> Id.

<sup>759</sup> See Trish Malarkey, “Human Health Concerns with GM Crops,” *Mutation Research*, Volume 544, (2003), at 219.

<sup>760</sup> See Paul R. Billings and Peter Shorett, “Coping with Uncertainty: The Human Health Implications of GE Foods,” in Iain E. P. Taylor, (editor), *Genetically Engineered Crops: Interim Policies, Uncertain Legislation*, *supra*, note 117, at 82.

<sup>761</sup> See Esther J. Kok and Harry A. Kuiper, “Comparative Safety Assessment for Biotech Crops,” *TRENDS in Biotechnology*, Volume 21, Number 10, (October 2003), at 443.

<sup>762</sup> Conventional plant crops are defined as “food or feed produced without the help of genetic modification and for which there is a well-established history of safe use.” See Article 2(12) Regulation (EC) No 1829/2003 of the European Parliament and the Council of 22 September 2003 on Genetically Modified Food and Feed. L268/2, *Official Journal of the European Union*.

<sup>763</sup> See Per Pinstrup-Andersen and Ebbe Schiøler, *Seeds of Contention: World Hunger and the Global Controversy Over GM Crops*, *supra*, note 117, at 42-43; Paul R. Billings and Peter Shorett, “Coping with Uncertainty: The Human Health Implications of GE Foods,” in Iain E. P. Taylor, (editor), *Genetically Engineered Crops: Interim Policies, Uncertain Legislation*, *supra*, note 117, at 82 (noting that “food allergies are difficult to detect, measure objectively and assess in terms of their impact on human health generally.”)

<sup>764</sup> See Per Pinstrup-Andersen and Ebbe Schiøler, *Seeds of Contention: World Hunger and the Global Controversy Over GM Crops*, *supra*, note 117, at 42-43.

crop allergenicity.<sup>765</sup> The authors further noted that it would be relatively easy to evaluate and minimise allergens in transgenic plant foods, if the sources of the genes responsible for the allergens were known,<sup>766</sup> and that the greatest challenge posed by allergens in transgenic plant foods was in determining whether or not a particular protein was allergenic, and what was the source of that protein.<sup>767</sup> The authors also noted that whilst there was no generally acceptable, established and definitive procedure for defining or predicting a protein's allergenicity, methods ranging from the comparison of the structures of the novel protein with known allergens, Th-2 cell simulation, to IgE antibody induction in animal models could be useful in identifying and reducing allergenic proteins in transgenic plant foods.<sup>768</sup>

In the same vein, a joint consultation policy statement between the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) formulated a “decision-tree” methodology for assessing potential allergens in transgenic plant foods.<sup>769</sup> According to the joint FAO\WHO report, the “decision-tree” approach to detecting allergens in transgenic plant foods “is a strategy which focuses on the source of the gene, the sequence homology of the newly introduced protein to known allergens, the immunochemical binding of the newly introduced protein with IgE from the blood serum of individuals with known allergies to the transferred genetic material, and the physicochemical properties of the newly introduced protein.”<sup>770</sup>

Even so, there are scientists who contend that transgenic plant foods are more prone or susceptible to allergens than conventional plant foods, but that such allergens could be more difficult to tackle because they:

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<sup>765</sup> See Samuel B. Lehrer, [W. Elliott Horner](#), [Gerald Reese](#) and Steven Taylor, “Why are some proteins allergenic? Implications for Biotechnology,” *Critical Reviews in Food Science and Nutrition*, *supra*, note 116, at 554.

<sup>766</sup> *Id.*, at 554.

<sup>767</sup> *Id.*, at 554.

<sup>768</sup> *Id.*, at 558.

<sup>769</sup> See FAO/WHO, *Evaluation of Allergenicity of Genetically Modified Foods*, Report of a Joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology, (Rome, Italy, 22-25 January, 2001), at 1-29, available at [http://www.who.int/foodsafety/publications/biotech/en/ec\\_jan2001.pdf](http://www.who.int/foodsafety/publications/biotech/en/ec_jan2001.pdf) (accessed on 14 May 2015).

<sup>770</sup> *Id.*, at 5.

Include gene transfer from biological sources with known allergenicity and the unanticipated creation of novel allergens through gene inactivation or over expression of genes that code for a minor allergen.<sup>771</sup>

Significantly, whilst Samuel B. Lehrer et al conceded that transgenic plant foods could be allergenic, they concluded that there was no evidence that recombinant proteins in transgenic plant foods were more allergenic than traditional proteins in conventionally grown plant foods.<sup>772</sup> Notably, this view is shared by several scientists, including E.J. Kok et al, who argued that transgenic plant foods were no less safe and no more allergenic than conventional plant foods, and that instead of merely relying on history of safe usage, conventionally grown plant foods should rather be subjected to comparative safety, allergenic, and toxicity tests that were the norms for transgenic plant foods.<sup>773</sup>

However, the effectiveness or conclusiveness of allergenicity and toxicity tests that E.J. Kok et al., claimed are routinely conducted on transgenic plant foods is doubtful, due to the acknowledgement of the Food and Drug Administration that the insertion of novel genes such as *Bacillus thuringiensis* bacterium proteins into the plant genome, could “generate new metabolic pathways”, precipitate unpredictable changes in the plant genome, and dramatically alter the composition of transgenic plant crops significantly, with concomitant nutritional, toxicity, and safety issues.<sup>774</sup> Moreover, the Food and Drug Administration have acknowledged that “feeding studies” and “toxicological tests”, which are the best scientific methods for testing food allergens and toxins, were extremely limited, because “feeding studies on whole foods

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<sup>771</sup> See Paul R. Billings and Peter Shorett, "Coping with Uncertainty: The Human Health Implications of GE Foods," in Iain E. P. Taylor, (editor), *Genetically Engineered Crops: Interim Policies, Uncertain Legislation*, *supra*, note 117, at 83.

<sup>772</sup> See Samuel B. Lehrer, [W. Elliott Horner](#), [Gerald Reese](#) and [Steven Taylor](#), “Why are some proteins allergenic? Implications for Biotechnology,” *Critical Reviews in Food Science and Nutrition*, *supra*, note 116, at 563-564.

<sup>773</sup> See E.J. Kok, J. Kijer, G.A. Kleter, and H.A. Kuiper, “Comparative Safety Assessment of Plant-Derived Foods,” *Regulatory Toxicology and Pharmacology*, Volume 50, (2008), at 98-113. See also Esther J. Kok and Harry A. Kuiper, “Comparative Safety Assessment for Biotech Crops,” *TRENDS in Biotechnology*, *supra*, note 121, at 439-444; Trish Malarkey, “Human Health Concerns with GM Crops,” *Mutation Research*, *supra*, note 119, at 217-221; A König et al, “Assessment of the Safety of Foods Derived from Genetically Modified (GM) Crops,” *Food and Chemical Toxicology*, Volume 42, (2004), at 1047-1088.

<sup>774</sup> See Food and drug Administration, “Premarket Notice Concerning Bioengineered Foods: Proposed Rule, *Federal Register*, Volume 66, (2001), *supra*, note 112, at 4706-4738.

have limited sensitivity” and it would be relatively difficult “to administer exaggerated doses”.<sup>775</sup> Furthermore, the hypothesis that transgenic plant foods are no more allergenic than conventional plant foods, but fails to provide compelling evidence of the superior or comparative advantages of transgenic plant foods over conventionally grown plant foods in allergens reduction terms, could hardly persuade sceptical Europeans to embrace transgenic plant foods.<sup>776</sup>

#### **4.1.8. New Transgenic Plant Foods Toxins and Public Health.**

Like food allergies, toxins are said to be an integral part of most food plants, and many common food plants are known to comprise naturally occurring toxins that could be dangerous to human health if consumed in excess.<sup>777</sup> For example, spinach and rhubarb, which are common vegetables that are routinely consumed by the general public are said to contain “oxalic acid, an anti-nutritional compound that inhibits calcium and iron absorption” and could be potentially poisonous if eaten in excess.<sup>778</sup> Furthermore, onions are known to harbour sulphuric acid, which could corrode “the upper gastrointestinal tract of humans” if eaten in excess.<sup>779</sup> Moreover, many mushrooms species are poisonous and could be “lethal in small doses”, and are often “difficult to distinguish from their edible counterparts.”<sup>780</sup> Therefore, given the reality that some well-known conventionally grown food plants have innate toxic properties, the pertinent question is: why are some scientists especially concerned about increased levels of toxins or the potential for new toxins in transgenic plant foods relative to conventionally grown plant foods? Is it because transgenic plant foods are more prone to developing new toxins other

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<sup>775</sup> For discussion, see Les Levidow, Joseph Murphy, and Susan Carr, “Recasting ‘Substantial Equivalence’: Transatlantic Governance of GM Food,” *Science, Technology, & Human Values*, *supra*, note 83, at 35.

<sup>776</sup> For discussion on safety concerns for transgenic plant foods in Europe, see Robert Lee, “GM Resistant: Europe and the WTO Panel Dispute on Biotech,” in Jennifer Gunning and Søren Holm, (editors), *Ethics, Law, and Society, Volume 1*, *supra*, note 69, at 131-139.

<sup>777</sup> *Id.*

<sup>778</sup> *Id.*

<sup>779</sup> *Id.*

<sup>780</sup> *Id.*

than naturally occurring toxins? But then, why do some scientists readily dismiss such concerns?

According to Paul R. Billings and Peter Shorett, genetic modifications of plant genome could “alter both existing and unanticipated toxicological characteristics of foods.”<sup>781</sup> Indeed, scientific literature is indicative that gene insertion could generate unexpected and unintended increases in the levels of naturally occurring toxins.<sup>782</sup> As noted in section 4.1.7 above, even the United States Food and Drug Administration, one of the three regulatory bodies for transgenic plant technological products, noted in one of its numerous policy papers that the insertion of multiple foreign genes into plant genome “to generate new metabolic pathways”, could dramatically alter the composition of transgenic plants crops significantly with concomitant nutritional, toxicity, and safety implications.<sup>783</sup> Moreover, John Godfrey observed in his letter to *The Lancet* that while there was no current evidence that transgenic plant foods were inherently harmful, it was no conclusive evidence that all applications would be harmless due to the possibility of the evolution of new allergens and toxins.<sup>784</sup> He also cautioned that while criendotoxin insecticide was not harmful when judiciously used as a spray, it was possible for the public to consume “much larger quantities” of the insecticide in transgenic plant food crops such as soybeans and maize that have been engineered to produce the inherently toxic insecticide from the DNA of *Bacillus thuringiensis* bacterium.<sup>785</sup> In support of his theory, John Godfrey referenced a 1997 study conducted on mice, which found that foreign DNA ingested by mice was not completely degraded by the digestive systems, and that the

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<sup>781</sup> See Paul R. Billings and Peter Shorett, “Coping with Uncertainty: The Human Health Implications of GE Foods,” in Iain E. P. Taylor, (editor), *Genetically Engineered Crops: Interim Policies, Uncertain Legislation*, *supra*, note 117, at 84.

<sup>782</sup> *Id.*

<sup>783</sup> See Food and Drug Administration, “Premarket Notice Concerning Bioengineered Foods: Proposed Rule,” *The Federal Register*, *supra*, note 112, at 4710.

<sup>784</sup> See John Godfrey, “Do genetically modified foods affect human health?” *The Lancet*, Volume 355, Number 9201, (January 29, 2000), at 414.

<sup>785</sup> *Id.*

undigested DNA could “reach peripheral leucocytes, spleen, and liver via the intestinal wall.”<sup>786</sup>

Whilst it could be premature to speculate on what the public health implications of undigested toxic transgenic DNA permanently lodged in the human gut could be, Susan Bardocz, a biochemist and nutritionist at the University of Debrecen, offered the following insights:

As shown in the human feeding experiment, a fully functional transgenic construct rendering Roundup Ready soya resistant to glyphosate can partially survive in the human gut, it is possible that functional Bt-toxin transgenes can survive, be taken up by bacteria resident in alimentary tract and convert us and our animals into pesticide factories.<sup>787</sup>

If the prognosis of Susan Bardocz were correct, then the digestive systems of half the world population could potentially morph “into pesticide factories” overtime, given that transgenic plant feed and food products from soybeans and maize that are genetically modified to embody and express the inherently toxic DNA of *Bacillus thuringiensis* (Bt.) bacterium have been commercially available globally since 1996 respectively for livestock and human consumption, any consequential health problems from indigestible Bt. toxins in human and animal guts could have global public health ramifications, because transgenic Bt products are available worldwide.<sup>788</sup>

However, the findings that toxins from transgenic Bt. crops could survive in the guts of humans and animals are routinely denied by pro-transgenic plant agriculture scientists. For example, Anthony Trewavas swiftly rebutted and debunked John Godfrey’s observations on the digestibility of Bt. toxins in the human gut, in a rejoinder that was published in *The Lancet*

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<sup>786</sup> Id. See also Rainer Schubert, Doris Renz, Birgit Schmitz, and Walter Doerfler, “Foreign (M13) DNA ingested in mice reaches peripheral leukocytes, spleen, and liver via the intestinal wall mucosa and can be covalently linked to mouse DNA,” *Proceedings of the National Academy of Sciences of the United States of America*, Volume 94, Number 3, (February 4, 1997), at 961-966.

<sup>787</sup> Cited in Jeffrey M. Smith, *Genetic Roulette: The Documented Health Risks of Genetically Engineered Foods*, (Fairfield, IA: Yes! Books, 2007), at 136.

<sup>788</sup> See Robert Paarlberg, *Starved for Science: How Biotechnology is Being Kept out of Africa*, supra, note 39, at 10-11. For discussion on the nature of Bt toxins, see Carrie Swadener, “Bacillus Thuringiensis (BT),” *Journal of Pesticide Reform*, supra, note 27, at 13-20.

two months following the publication of John Godfrey's letter in *The Lancet*.<sup>789</sup> In his robust defence of transgenic Bt. plant foods, Anthony Trewavas argued that transgenic Bt. plant foods had been subjected to:

thousands of compositional analyses under different growth conditions of all the major nutrients, anti-nutrients, toxic and benign alkaloids, and phyto-oestrogens to establish precise similarities to the parent. The new trait, in this case the Bt toxin, is then examined separately for possible allergic properties by tests in six different mammalian species and attempts are made to establish pharmacological properties by estimating a toxicity concentration from which safe consumption data can be estimated. To date, no toxicity concentration has been achieved, no doubt because like most proteins, Bt toxin is simply digested in the gut.<sup>790</sup>

Anthony Trewavas also observed that whilst fragments of DNA might be found in leucocytes and other cells following digestion, the inclusion of Bt. DNA should cause no concern because millions of "qualitatively different genes" were ingested daily via plant foods by the general public.<sup>791</sup> However, the problem with this analysis is that why millions of "qualitatively different genes" may be ingested daily via plant foods by the general public, DNA from the *Bacillus thuringiensis* bacterium toxins is a natural pesticide with toxic properties that could potentially cause harm to the human body if permanently lodged in the human gut.<sup>792</sup> Besides, Bt. toxin is not the sort of toxins commonly found in edible plant foods such as spinach and rhubarb vegetables, which could be managed by moderate consumption.<sup>793</sup> Rather, transgenic plant Bt. toxin is from the *Bacillus thuringiensis* bacterium that is often used to manufacture industrial pesticide,<sup>794</sup> and is never a natural component of plant foods commonly consumed

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<sup>789</sup> See Anthony Trewavas, "Toxins and genetically modified food," *The Lancet*, Volume 355, Number 9202, (March 11, 2000), at 931.

<sup>790</sup> See *id.*

<sup>791</sup> See *id.*

<sup>792</sup> See Carrie Swadener, "Bacillus Thuringiensis (BT)," *Journal of Pesticide Reform*, *supra*, note 27, at 13-20; Madhuri Kota, Henry Daniel, Sam Varma, Stephen F. Garczynski, Fred Gould, and William J. Major, "Over-expression of the Bacillus thuringiensis (Bt) Cry2Aa2 protein in Chloroplasts confers resistance to plants against susceptible and Bt-resistant insects," *Proceedings of National Academy of Science of the United States*, *supra*, note 21, at 1840-1845.

<sup>793</sup> See Paul R. Billings and Peter Shorett, "Coping with Uncertainty: The Human Health Implications of GE Foods," in Iain E.P. Taylor, (editor), *Genetically Modified Crops: Interim Policies, Uncertain Legislation*, *supra*, note 117, at 84.

<sup>794</sup> See Carrie Swadener, "Baccillus Thuringiensis (BT)," *Journal of Pesticide Reform*, *supra*, note 27, at 13-20.



by humans, until it was genetically incorporated into commercial food crops globally in 1996.<sup>795</sup>

Most significantly, a 2011 study conducted by Canadian scientists would appear to undermine Anthony Trewavas' claim that "BT toxin is simply digested in the gut."<sup>796</sup> Scientists at the Department of Obstetrics and Gynaecology, the University of Sherbrooke Hospital Centre in Quebec, Canada, tested blood samples of pregnant women, and found traces of Bt. toxins in ninety-three per cent of the pregnant mothers tested, as well as in eighty per cent of the umbilical cords studied.<sup>797</sup> Most significantly, the authors noted that the pregnant women and umbilical cords in question might have been exposed to Bt. toxins indirectly through the consumption of meat from cattle fed on transgenic Bt. corn feed.<sup>798</sup> If the findings of the scientists were correct, the implications would be that transgenic toxins could not only survive an animal's gut and digestive systems and ultimately be passed on to the animal's meat, the toxins could also survive both the cooking process to which the meat is subjected and the digestive systems of those who ultimately consume the meat.<sup>799</sup> Thus, by extrapolation, it is perfectly reasonable and logical to conclude that if pregnant women and their umbilical cords could be vulnerable to secondary or indirect exposure to transgenic Bt toxins merely by the consumption of meat from livestock fed on transgenic Bt corn feed, so could all adults and children. Also, contrary to Anthony Trewavas' claim that "Bt toxin is simply digested in the gut",<sup>800</sup> the scenario of indirect or secondary exposure also makes it highly plausible that the public could be directly and permanently exposed to Bt. toxins by eating transgenic Bt. food crops such as soybeans and corn, thus corroborating scientific opinions such as those expressed

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<sup>795</sup> See Robert Paarlberg, *Starved for Science: How Biotechnology is Being Kept out of Africa*, *supra*, note 147, at 10-11.

<sup>796</sup> See Anthony Trewavas, "Toxins and genetically modified food," *The Lancet*, *supra*, note 789, at 931.

<sup>797</sup> See Aziz Aris and Samuel Leblanc, "Maternal and foetal exposure to pesticides associated to genetically modified foods in Eastern Townships of Quebec," *Reproductive Toxicology*, (Volume 31, Issue 4, (May 2011), at 534-539.

<sup>798</sup> *Id.*

<sup>799</sup> *Id.*

<sup>800</sup> See Anthony Trewavas, "Toxins and genetically modified food," *The Lancet*, *supra*, note 789, at 931.

by John Godfrey in his letter to *The Lancet* in January 2000,<sup>801</sup> and Susan Bardocz of the University of Debrecen.<sup>802</sup>

Furthermore, numerous controversial scientific studies have linked the consumption of transgenic *Bacillus thuringiensis*-based foods to cancerous growths in laboratory mammals. This is exemplified by a 2012 study by French scientists, which demonstrated that mice fed on transgenic Bt. maize developed cancerous mammary tumours and severe liver and kidney damage.<sup>803</sup> In the study, mice were fed on a two year diet of transgenic Bt. herbicide-tolerant maize that has been approved for human consumption by authorities in the United States, Canada, the European Union, and around the world.<sup>804</sup> Prior to the two-year feeding study on mice, there had been several biotechnology industry studies comprising ninety day feeding trials on mice, although there was no legally mandated chronic animal studies on approved herbicide-tolerant transgenic plant foods.<sup>805</sup> Moreover, although there had been prior “long-term and multi-generational animal feeding trials” with contrasting safety results,<sup>806</sup> the French study was the first of its kind to have conducted an investigation on NK603 R-tolerant maize, and included evidence of “a detailed follow-up of the animals with up to 11 blood and urine samples over 2 years.”<sup>807</sup> Whilst the mice in the study suffered debilitating ailments that ranged from cancerous mammary tumours, liver damage to kidney damage, approximately fifty per

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<sup>801</sup> See John Godfrey, “Do genetically modified foods affect human health?” *The Lancet*, *supra*, note 143, at 414.

<sup>802</sup> Cited in Jeffrey M. Smith, *Genetic Roulette: The Documented Health Risks of Genetically Engineered Foods*, *supra*, note 146, at 136.

<sup>803</sup> See Gilles-Eric Séralini, Emilie Clair, Robin Mesnage, Steve Gress, Nicolas Defarge, Manuela Malatesta, Didier Hennequin, and Joël Spiroux de Vendômois, “Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize,” *Food and Chemical Toxicology*, Volume 50, Issue 11, (November 2012), at 4224-4225.

<sup>804</sup> See *id.*, at 4221.

<sup>805</sup> See *id.*, at 4221.

<sup>806</sup> See *id.*, at 4222, (noting that there had been previous “long-term and multi-generational animal feeding trials” had produced contrasting results “with some possibly providing evidence of safety, while others conclude on the necessity of further investigations because of metabolic modifications.”)

<sup>807</sup> See *id.*, at 4224-4225.

cent of males and seventy per cent of females in the groups on diet containing transgenic NK603 glyphosate maize died prematurely.<sup>808</sup>

Significantly, the French study was not the first to link the consumption of transgenic crops to debilitating diseases in mice. For example, the study on transgenic potatoes conducted by Professor Arpad Pusztai and colleagues at the Rowett Institute, under the auspices of the Scottish Office of Agriculture, Environment and Fisheries Department, demonstrated that young rats fed on diets from transgenic tomatoes had their vital organs and immune systems compromised.<sup>809</sup> Similarly, Dr. Irina Ermakova of the Institute of Higher Nervous Activity and Neurophysiology of the Russian Academy of Sciences, conducted a study, which showed that more than half of rats' offspring fed on transgenic soybeans died in the first week of life. The mortality rate was six times those of offspring born to mothers fed on normal diets. The result was characteristically disputed by Monsanto Corporation, but the United States National Institute of Health was asked to conduct an independent study by the American Academy of Environmental Medicine.<sup>810</sup>

Even so, the French study that linked Monsanto's transgenic Bt maize to cancerous tumours and liver failure in mice, was characteristically and swiftly rebutted and condemned by the European Food Safety Authority, Monsanto Corporation, and scientists from the academia. For example, in its October 2012 Press Release, the European Food Safety Authority concluded that the French study on the potential toxicity of transgenic maize NK603 containing glyphosate and its concomitant linkage to cancerous tumours and liver failures in mice, was

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<sup>808</sup> See *id.*, at 4223.

<sup>809</sup> See Mae-Wan Ho and Lim Li Ching, *GMO Free: Exposing the Hazards of Biotechnology to Ensure the Integrity of Our Food Supply*, (Ridgefield CT & London: Institute for Science in Society, 2004), at 21-22. See F. William Engdahl, *Seeds of Destruction: The Hidden Agenda of Genetic Manipulation*, (Montreal: Global Research, 2007), at 245-246.

<sup>810</sup> See F. William Engdahl, *Seeds of Destruction: The Hidden Agenda of Genetic Manipulation*, (Montreal: Global Research, 2007), at 245-246.

“of insufficient scientific quality to be considered as valid for risk assessment.”<sup>811</sup> The Press

Release noted further that:

EFSA’s initial review found that the design, reporting and analysis of the study, as outlined in the paper, are inadequate. To enable the fullest understanding of the study the Authority has invited authors Séralini et al., to share key additional information. Such shortcomings mean that EFSA is presently unable to regard the authors’ conclusions as scientifically sound. The numerous issues relating to the design and methodology of the study as described in the paper mean that no conclusions can be made about occurrence of tumours in the rats tested. Therefore, based on the information published by the authors, EFSA does not see any need to re-examine its previous safety evaluation of maize NK603 nor to consider these findings in the ongoing assessment of glyphosate.<sup>812</sup>

Unsurprisingly, the French study had an immediate impact on food regulators especially in Europe, which despite its general apathy to transgenic plant foods, remains a veritable market for approved transgenic plant food and feed.<sup>813</sup> For example, as noted earlier, the European Food and Safety Authority issued a Press Release in which they demanded for a comprehensive data from the authors, without which they could not rely on the study for risk assessment purposes.<sup>814</sup> Similarly, the Russian consumer rights watchdog, *Rospotrebnazor*, promptly ordered Russia’s Institute of Nutrition to assess the validity of the French study, while temporarily suspending import of Monsanto’s transgenic Bt maize from the United States.<sup>815</sup>

#### **4.1.9. Adventitious Gene Flow and Implications for the Environment and Biodiversity.**

The world population is in a spiral climb with concomitant concerns about food security, and the capability and sustainability of the agrochemical-dependent conventional plant agriculture to meet the world’s growing food needs.<sup>816</sup> Agrochemical is a generic term for a range of

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<sup>811</sup> See European Food Safety Authority, “EFSA publishes initial review on GM maize and herbicide study,” Press Release, (4 October 2012), at <http://www.efsa.europa.eu/en/press/news/121004.htm> (accessed on 14 May 2015).

<sup>812</sup> Id.

<sup>813</sup> See Margret Rosso Grossman, “European Community Legislation for Traceability and Labeling of Genetically Modified Crops,” in Paul Weirich, (editor), *Labeling Genetically Modified Food: The Philosophical and Legal Debate*, (Oxford & New York: Oxford University Press, 2007), at 32-62.

<sup>814</sup> See European Food Safety Authority, “EFSA publishes initial review on GM maize and herbicide study,” *Press Release*, *supra*, note 811.

<sup>815</sup> See Sean Poulter, “Russia suspends import and use of American GM corn after study revealed cancer risk,” *MailOnline*, (26 September, 2012), at <http://www.dailymail.co.uk/news/article-2208452/Russia-suspends-import-use-American-GM-corn-study-revealed-cancer-risk.html> (accessed on 14 May 2015).

<sup>816</sup> See Per Pinstrup-Andersen and Ebbe Schøler, *Seeds of Contention: World Hunger and the Global Controversy over GM Crops*, *supra*, note 123, at 1-6.

chemical products used in plant agriculture, which include pesticides, insecticides, herbicides, fungicides, and synthetic fertilizers. However, these products are not without downsides. For example, nitrogen-based synthetic fertilizer has been linked to the proliferation of nitrous oxide in the atmosphere, a principal contributor to Greenhouse gases and global warming.<sup>817</sup> Moreover, in the 1960s, American marine biologist, Rachel Carson highlighted the steep environmental and public health costs of the rampant use and misuse of synthetic chemical insecticides in commercial agriculture in her landmark and seminal work: *Silent Spring*.<sup>818</sup> Also, it has been well-documented that synthetic chemical pesticides that are routinely used in conventional plant agriculture have corrosive and poisonous effects on the environment and biodiversity.<sup>819</sup>

Therefore, given the adverse effects that agro-chemical dependency in conventional plant agriculture has on the environment, any technology that could ameliorate the problems posed by synthetic chemicals for the environment should naturally be welcome. Biotechnology Corporations such as Monsanto, Du Pont, Novartis, etc., claimed to have such a technology in the form of herbicide resistant crops and the *Bacillus thuringiensis* engineered insect-resistance crops, which they believed could benefit the environment by significantly reducing the use of agrochemical in plant agriculture.<sup>820</sup> Most significantly, the development of drought-tolerant transgenic corn and soybeans by biotechnology companies such as Monsanto, Pioneer-Dupont, and Syngenta, have been touted as a panacea for diminishing crop yields amongst forty per cent of world farmers who plough “arid and semi-arid regions marked by long dry seasons and

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<sup>817</sup> See Vandana Shiva, *The Violence of the Green Revolution*, (London & New York: Zed Books Limited, 2002), at 114-119.

<sup>818</sup> See Rachel Carson, *Silent Spring*, (London & New York: Penguin Classics, 2000), pp. 309.

<sup>819</sup> See Pamela Ronald, “Plant Genetics, Sustainable Agriculture and Global Food Security,” *Genetics*, Volume 188, (May 2011), at 11-12.

<sup>820</sup> See Miguel A. Altieri, “Transgenic Crops: Agro-biodiversity and Agro-ecosystem Function,” in Iain E. P. Taylor, (editor), *Genetically Engineered Crops: Interim Policies, Uncertain Legislation*, *supra*, note 117, at 37-38. See also Reece Walters, *Eco Crime and Genetically Modified Food*, (Oxford: Routledge, 2011), at 38.

scant rainfall even in the wet season.”<sup>821</sup> Advocates of drought-tolerant transgenic plant technology also believed that it could ameliorate drought-induced famine in Africa, costly irrigation systems, and dwindling water supply for commercial plant agriculture due largely to the effects of global warming.<sup>822</sup>

However, despite the promising and potential benefits of transgenic plant agriculture for the environment, there are scientific indications and concerns that gene flow from transgenic crops could result in adventitious presence of transgene in non-transgenic crops and the environment.<sup>823</sup> But then, gene flow is not by any means unique to transgenic plant agriculture. Rather it is a natural phenomenon through which gene from plant species could be disseminated to other plant species in the wild via pollen, seeds, and in some cases, “vegetative propagules.”<sup>824</sup> However, most transgenic plants such as those encoded with genes from *Bacillus thuringiensis* bacterium, bear DNA from micro-organisms and non-plant species that could easily be transmitted into other plant species in the wild through gene flow. Thus, there is a risk that Monsanto’s Roundup Ready glyphosate-resistant transgenic soybeans and maize plant,<sup>825</sup> which enable farmers to kill weeds without harming their crops, could pass on their genes to non-transgenic conventional or organic soybean or maize as well as weeds in the wild.<sup>826</sup>

Also, the prospects that gene flow could create stubborn “super-weeds”, have had most scientists and farmers worried. For example, the first documented case of weed resistance to

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<sup>821</sup> See Robert Paarlberg, *Starved for Science: How Biotechnology is Being Kept out of Africa*, *supra*, note 147, at 149.

<sup>822</sup> *Id.*, at 149-177.

<sup>823</sup> See Mary A. Rieger, Michael Lamond, Christopher Preston, Stephen B. Powles, and Richard T. Roush, “Pollen-Mediated Movement of Herbicide Resistance between Commercial Canola Fields,” *Science*, Volume 296, (28 June 2002), at 2386-2388.

<sup>824</sup> See Carol Mallory-Smith and Maria Zapiola, “Gene flow from glyphosate-resistant crops,” *Pest Management Science*, Volume 64, Issue 4, (April 2008), at 428 and 430.

<sup>825</sup> Glyphosate is a type of herbicide traditionally used to manage and control weeds that compete with commercial crops for soil nutrients. See Stephen O. Duke and Stephen B. Powles, “Glyphosate: a once-in-a-century herbicide: mini review,” *Pest Management Science*, Volume 68, Issue 4, (April 2008), at 319-325.

<sup>826</sup> See Carol Mallory-Smith and Maria Zapiola, “Gene flow from glyphosate-resistant crops,” *Pest Management Science*, *supra*, note 824, at 428-440.

glyphosate involved rigid ryegrass (*Lolium rigidum*), and was found near Orange in New South Wales, Australia,<sup>827</sup> whilst herbicide-resistant volunteer canola is now a major weed problem in Canada.<sup>828</sup> In the United States, farmers are said to be coping with resurgence in glyphosate Roundup resistant weeds, which as at 2010, have plagued approximately seven to ten million acres of arable farmland.<sup>829</sup> In order to combat super weeds resurgence, farmers in the East, Midwest, and South of the United States have had “to spray fields with more toxic herbicides, pull weeds by hand and return to more labor-intensive methods like regular plowing.”<sup>830</sup> For instance, one Mr. Anderson, a Tennessee farmer, had to wrestle with a notoriously tenacious species of glyphosate resistant weed known as “Palmer amaranth” or “pigweed”.<sup>831</sup> According to William Newman and Andrew Pollack, Pigweed could grow up to three inches a day and reach seven feet or more, with ability to choke out crops and damage harvesting equipments.<sup>832</sup> Thus, it is ironic that farmers had to resort to herbicide in order to combat the emergence of super-weeds. This is more so as herbicide resistant transgenic plant was designed in part to reduce the use of toxic herbicide on arable farmland in the first place.

Thus, the increased use of toxic herbicide would appear to belie the claim by biotechnology companies that herbicide-resistant transgenic plant was beneficial to the environment,<sup>833</sup> a sentiment shared by Bill Freese, a science policy analyst for the Centre for Food Safety in Washington: “The biotech industry is taking us into more pesticide-dependent agriculture when

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<sup>827</sup> See Stephen B. Powles, Debra F. Lorraine-Colwill, James J. Dellow and Christopher Preston, “Evolved Resistance to Glyphosate in Rigid Ryegrass (*Lolium rigidum*) in Australia,” *Weed Science*, Volume 46, Number 5, (September-October, 1998), at 604-607.

<sup>828</sup> See Miguel A. Altieri, “Transgenic Crops, Agro-biodiversity, and Agro-ecosystem Function,” in Iain E.P. Taylor, (editor), *Genetically Engineered Crops: Interim Policies, Uncertain Legislation*, *supra*, note 178, at 43.

<sup>829</sup> See William Newman and Andrew Pollack, “U.S. Farmers Cope with Roundup-Resistant Weeds,” *New York Times*, (4 May 2010), at B1 (citing Ian Heap, director of the International Survey of Herbicide Resistant Weeds, which is financed by the agricultural chemical industry.) Across the United States, approximately one hundred and seventy million acres are planted with corn, cotton and soybeans, the crops most affected. See *id.*

<sup>830</sup> See *id.*, at B1.

<sup>831</sup> See *id.*

<sup>832</sup> *Id.*

<sup>833</sup> See Miguel A. Altieri, “Transgenic Crops: Agro-biodiversity and Agro-ecosystem Function,” in Iain E. P. Taylor, (editor), *Genetically Engineered Crops: Interim Policies, Uncertain Legislation*, *supra*, note 178, at 37-38.

they've always promised, and we need to be going in the opposite direction.”<sup>834</sup> Even Monsanto Corporation, who are the proprietary owner of glyphosate herbicide have acknowledged that weeds resistance to the herbicide was “a serious issue.”<sup>835</sup> In fact, the company is sufficiently worried about the problem of weeds-resistant herbicide that they agreed to subsidise cotton farmers, who had to purchase herbicide from Monsanto's competitors in order to supplement Monsanto's glyphosate Roundup herbicide, in the continuing fight against super weeds in the United States.<sup>836</sup>

Furthermore, in what is set to be a perennial and daunting struggle against super weeds, Monsanto and other biotechnology companies are busy developing transgenic crops that are resistant to new types of herbicides.<sup>837</sup> For example, Bayer has started marketing transgenic cotton and soybeans that are resistant to glufosinate herbicide, whilst Monsanto's new transgenic corn is resistant both to glyphosate and glufosinate.<sup>838</sup> Furthermore, Monsanto is said to be developing transgenic crops that are resistant to dicamba herbicide, whilst Syngenta is developing soybeans that are tolerant to its Callisto product, and Dow Chemical is developing transgenic corn and soybeans that are “resistant to 2,4-D, a component of Agent Orange, the defoliant used in the Vietnam war.”<sup>839</sup> It is however doubtful whether the development of new herbicides would solve the challenge posed by super weeds. For it stands to reason and logic that if weeds could develop resistance to the current variants of commercial herbicides, they would overtime, develop resistance to new varieties of herbicides, until there is no known herbicide left to fight weeds with. It is also clear that the environment and

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<sup>834</sup> See William Newman and Andrew Pollack, “U.S. Farmers Cope with Roundup-Resistant Weeds,” *New York Times*, *supra*, note 190, at B1.

<sup>835</sup> *Id.* (citing one Rick Cole, who managed weeds resistance issues for Monsanto in the United States.)

<sup>836</sup> *Id.*

<sup>837</sup> *Id.*

<sup>838</sup> *Id.*

<sup>839</sup> *Id.*



biodiversity would be the worse for it, as weeds continually evolve resistance to all known herbicides.

#### **4.2.0. Pest Resistant *Bacillus thuringiensis*-Based Crops and Non-Target Organisms.**

Apart from weeds resistance problem, scientists have argued that targeted pests such as European corn borer could, overtime, become resistant to the *Bacillus thuringiensis* toxins in transgenic Bt. Maize or soybeans.<sup>840</sup> According to Miguel A. Altieri, over five-hundred species of pests have already evolved resistance to conventional insecticides, and there was no guarantee that pests such as the European corn borer could not develop resistance to the Bt. toxins in transgenic maize crops overtime.<sup>841</sup> Indeed, bioengineers regard insects' resistance to *Bacillus thuringiensis* toxins as inevitable overtime, and have therefore begun preparation for "resistance management plans", which included building of "refuges", and the provision of "susceptible insects for mating with resistant insects", in order to delay the evolution of resistance to Bt toxins in transgenic crops.<sup>842</sup> The real danger for the environment is that *Bacillus thuringiensis*, which is a natural toxin and insecticide, has been used in such an industrial scale that it could become virtually useless against pests overtime due to possible resistance. This could potentially disrupt the natural balance of things in nature, where the populations of certain pests and insects are naturally put in check by a bacterium that could become useless and ineffective against pest overtime, due to overuse.

Aside from possible evolution of resistance by targeted insects to Bt. toxins in transgenic crops, there is ample albeit controversial evidence that Bt. toxins in transgenic plant crops could be deleterious to non-target organisms in the environment and possibly deplete the

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<sup>840</sup> See Miguel A. Altieri, "Transgenic Crops, Agro-biodiversity, and Agro-ecosystem Function," in Iain E.P. Taylor, (editor), *Genetically Engineered Crops: Interim Policies, Uncertain Legislation*, *supra*, note 178, at 46-48.

<sup>841</sup> *Id.*

<sup>842</sup> *Id.*

biodiversity.<sup>843</sup> This is exemplified by the controversial Rosi-Marshall paper, which was based on the study of twelve streams in northern Indiana, United States.<sup>844</sup> The paper found that caddis-fly larvae (herbivorous stream insects) that were “fed only on Bt maize debris grew half as fast as those that ate debris from conventional maize.”<sup>845</sup> Moreover, caddis-flies that were “fed with high concentrations of Bt maize pollen dies at more than twice the rate of caddis-flies fed non-Bt pollen.”<sup>846</sup> In consequence of their findings, Rosi-Marshall and her colleagues summed up their research by concluding that transgenic Bt. maize “may have negative effects on the biota of streams in agricultural areas,” and that widespread planting of Bt crops has unexpected ecosystem-scale consequences.”<sup>847</sup>

But then the Rosi-Marshall paper was neither the first nor the last to link transgenic Bt. crops to negative environmental impacts.<sup>848</sup> For example, as previously observed in section 1.1.7 of the thesis, a 2012 publication in the *American Journal of Botany* found that transgenic Bt. maize, which was designed to curb traditional maize foes such as the European corn borer, could be deleterious to, or overtime, crash the populations of non-target soil organisms such as *arbuscular mycorrhizal* fungi<sup>849</sup> However, the main problem is that *arbuscular mycorrhizal* fungi are no ordinary fungi. Rather, they are important fungi that exist in a mutually beneficial and symbiotic relationship with land plants species, in which *arbuscular mycorrhizal* fungi depend on land plants for carbon nutrition, and land plants depend on *arbuscular mycorrhizal*

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<sup>843</sup> See E. J. Rosi-Marshall, J.L. Tank, T.V. Royer, M.R. Whiles, M. Evans-White, C. Chambers, N.A. Griffiths, J. Pokelsek, and M.L. Stephen, “Toxins in Transgenic Crop By-products May Affect Headwater Stream Ecosystems,” *Proceedings of National Academy of Sciences of the United States of America*, supra, note 137, at 16204-16208.

<sup>844</sup> Id.

<sup>845</sup> Id.

<sup>846</sup> Id.

<sup>847</sup> Id, at 16208.

<sup>848</sup> See Tanya E. Cheeke, Todd N. Rosentiel, and Mitchell B. Cruzan, “Evidence of reduced *arbuscular mycorrhizal* fungal conolization in multiple lines of Bt maize,” *American Journal of Botany*, Volume 99, Number 4, (April 2012), at 700-707.

<sup>849</sup> Id.

for phosphorous intake from the soil.<sup>850</sup> Thus, long term depletion in the populations of *arbuscular mycorrhizal* fungi for land plants populations could dramatically reduce the intake of natural phosphorous for land plants, with predictable long term devastating effects on the environment and the biodiversity.

It would thus appear from the foregoing discourse that the full ramifications of the advent of transgenic plant agriculture for the environment and biodiversity are at best ambivalent and as yet fully unfathomable. Also, given that the study on the effects of transgenic Bt. crops on *arbuscular mycorrhizal* fungi populations was published for the first time in 2012, more revelatory findings, whether positive or negative, could be expected in the years ahead as more and more arable farmlands are cultivated with transgenic plant crops around the world, and more and more research studies are conducted on the long term environmental impacts of transgenic plant agriculture.

#### **4.2.1. Bio-property Rights and Impacts on Farmers and Farm Businesses.**

The proprietary nature of transgenic plant seeds and crops means that intellectual property rights disputes are perhaps the most litigated till date, amongst possible disputes inherent in the coexistence paradigm for transgenic and non-transgenic plant agriculture. Intellectual property is a generic name for a range of disparate and sometimes overlapping rights that range from copyright, patents, confidential information, trademarks, plant breeders' rights, industrial designs, etc.<sup>851</sup>

The patent system confers national monopoly rights on inventors for a limited period of time, which is typically for twenty years.<sup>852</sup> Like other intellectual property rights, patents

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<sup>850</sup> See N.S. Bolan, "A Critical review on the role of mycorrhizal fungi in the uptake of phosphorous by plants," *Plant and Soil*, Volume 134, Number 2, (July, 1991), at 189-207. See also Berta Bago, "Putative sites for nutrient uptake in mycorrhizal fungi," *Plant and Soil*, Volume 226, Number 2, (November, 2000), at 263-274.

<sup>851</sup> See William Cornish, David Llewelyn, and Tanya Aplin, *Intellectual Property: Patents, Copyright, Trademarks and Allied Rights*, *supra*, note 302, at 3-4.

<sup>852</sup> See Taiwo A. Oriola, "Against the Plague: Exemption of Pharmaceutical Patent Rights as a Biosecurity Strategy," *University of Illinois Journal of Law, Technology & Policy*, Vol. 2007, Issue 2, (Fall 2007), at 311.

monopoly is inherently territorial, and can only be enforced under the national law of the country that granted the underlying patent. However, in the European Union, there are national and European patents, and both can be enforced in any European Union country. In the United Kingdom for example, a patent may be secured at the United Kingdom Intellectual Property Office in Newport, Wales, or at the European Patents Office in Munich, Germany. There is also an international application system via Patents Cooperation Treaty, which allows for one filing system that designates in which countries the patents are to be registered and enforced. Even so, there are no international patents as such, as patents protections are enforced under national laws, or in the case of European Union patents, under the European Union Patents Convention 2000 as amended.<sup>853</sup> Even so, there is an international arrangement for the protection and enforcement of patents via the World Trade Organisation's Trade Related Agreement on Intellectual Property Rights, which sets a minimum standard of protection for intellectual property rights that all signatories are expected to implement via their national patents laws.<sup>854</sup> For example, the United States and the European Union successfully challenged the provisions of Canadian patent law for non-compliance with the provisions of TRIPS that require adequate protection for pharmaceutical patents in *Canada-Patent Protection of Pharmaceutical Products Case*.<sup>855</sup> In particular, Article 27(1) of TRIPS enjoins all signatory countries to afford patents protection for "any inventions, whether products or processes, in all fields of technology, provided they are new, involve an inventive step and are capable of industrial application."<sup>856</sup>

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<sup>853</sup> See William Cornish, et al., *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights*, 8<sup>th</sup> edition, (London: Sweet & Maxwell, 2013), at 157-158.

<sup>854</sup> See Articles 1(1) and 68 of the Trade Related Agreement on Intellectual Property Rights, 1994.

<sup>855</sup> See *Canada-Patent Protection of Pharmaceutical Products*, WT/DS114/R, (17 March, 2000).

<sup>856</sup> See Article 27(1) of the WTO Trade Related Agreement on Intellectual Property Rights, 1994, *supra*, note 854. See also Debra M. Strauss, "The Application of TRIPS to GMOs: International Intellectual Property /rights and Biotechnology," *Stanford Journal of International Law*, *supra*, note 41, at 304-308.

Thus, whilst national patents laws may differ in material particulars,<sup>857</sup> no country that is a signatory to the TRIPS Agreement, could legally deny patents protection for transgenic seed and the resultant crop, which would qualify as an invention under Article 27(1) of the treaty.<sup>858</sup> Therefore, a recent proposal by the German Parliament to prohibit patents for plants and animals derived from conventional breeding,<sup>859</sup> is arguably vulnerable to legal challenge both before the WTO Council for TRIPS and the Court of Justice of the European Union, respectively for non-compliance with Article 27(1) of TRIPS,<sup>860</sup> and Article 52(1) of the European Patent Convention, which regard seeds as patentable inventions.<sup>861</sup>

Indeed, patents protection was first extended to sexually reproducing plants by the United States Patent and Trade Mark Office in 1985 in *Ex parte Hibberd*, in which the USPTO held that genetically modified maize with high levels of tryptophan was eligible for utility patents.<sup>862</sup> The United States Supreme Court subsequently affirmed the USPTO decision in 2001 in the case of *J.E.M. Ag Supply Inc., v. Pioneer Hi-Bred International*, when the United States Supreme Court held by a majority of 5-4 that sexually reproducing plants that were eligible for protection under the Plant Variety Protection Act were also eligible for utility patents.<sup>863</sup> Notably, the provisions of the United States Plant Variety Protection Act, which protect plants breeders' rights,<sup>864</sup> are *in parimaterial* with that of the United Kingdom's Plant Variety

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<sup>857</sup> See Article 30 of TRIPS Agreement, *supra*, note 854.

<sup>858</sup> See Article 27(1) of the WTO Trade Related Agreement on Intellectual Property Rights, *supra*, note 117.

<sup>859</sup> See *No Patents on Seeds*, "German Parliament prohibits patents on plants and animals from conventional breeding," Berlin, (27 June, 2013), at <http://www.no-patents-on-seeds.org/en/information/news/german-parliament-prohibits-patents-plants-and-animals-conventional-breeding> (accessed on 14 May 2015).

<sup>860</sup> See Article 27(1) of TRIPS, *supra*, note 854.

<sup>861</sup> See Article 52(1) of the European Patent Convention 2000, which provides that "European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible to industrial application."

<sup>862</sup> See *Ex parte Hibberd*, 227 USPQ 443 (Bd. Pat. App. 1985).

<sup>863</sup> See *J.E.M. Ag Supply Inc., v. Pioneer Hi-Bred International*, 534 U.S. 124 (2001).

<sup>864</sup> See the United States Plant Variety Protection Act 1970.

Protection Act,<sup>865</sup> and that of the International Union for the Protection of New Varieties of Plant, to which most countries are signatories.<sup>866</sup>

However, whilst farmers can still conditionally save and replant seeds from their harvest under the Plant Variety Protection Act,<sup>867</sup> they cannot legally do so without risking infringement under the Patent Act, as aptly exemplified by the Canadian Supreme Court decision in *Monsanto Canada Inc., v. Schmeiser*,<sup>868</sup> and the United States Supreme Court decision in case of *Vernon Hugh Bowman v. Monsanto Company*.<sup>869</sup> Thus, the relative stringency and strict liability nature of patent protection for transgenic seed and plants, and the fact that it is relatively easier to sue under the patent law than under the plant variety protection law,<sup>870</sup> make patent more attractive and preferable to seed and plant breeders such as Monsanto, DuPont, Dow, Syngenta, and Bayer, the big five multinational biotechnology corporations, who by 2009, reputedly controlled 58 percent of the world's commercial seed market.<sup>871</sup>

However, there are genuine questions of equity and fairness regarding the right and ability of transgenic crops farmers to save seeds from their harvests, and replant the saved seeds under the current national and transnational patent regimes.<sup>872</sup> There are also questions on the justice and propriety of holding non-transgenic crops farmers liable for patents infringement, following adventitious presence of transgenes in their crops via cross-pollination and other natural biological means.<sup>873</sup> This is because, unlike Plant Variety Protection law, the patent regime does not recognise farmers' right to save and reuse farm seeds, and that's the primary

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<sup>865</sup> See the United Kingdom Plant Variety Protection Act, 1997.

<sup>866</sup> See the International Union for the Protection of New Varieties of Plant (UPOV).

<sup>867</sup> For discussion, see sections 8 and 9 of the UK Plant Variety Protection Act 1997.

<sup>868</sup> See *Monsanto Canada Inc., v. Schmeiser*, *supra*, note 39, at 1.

<sup>869</sup> See *Vernon Hugh Bowman v. Monsanto Company*, *supra*, note 39, at 569.

<sup>870</sup> See *Gabriela Pechlaner, Corporate Crops: Biotechnology, Agriculture, and the Struggle for Control*, (Austin: Texas University Press, 2012), at 210-211, (noting that whilst infringement litigations were possible under the Plant Variety Act, only a limited number were ever prosecuted by seed firms. However, prosecutions for infringements of patented transgenic seed and crops were predicted to increase overtime.)

<sup>871</sup> See Debbie Barker, et al., *Seed Giant vs. U.S. Farmers, A Report by the Centre for Food Safety & Save Our Seeds*, *supra*, note 5, at 17.

<sup>872</sup> *Id.*, at 22-23.

<sup>873</sup> *Id.*

reason most transgenic seeds firms prefer patent law's exclusive monopoly to plant breeders' rights under national Plant Variety Protection laws.<sup>874</sup>

Therefore, it is patents infringement induced by adventitious transgenes that is the most controversial, and the one that is going to sorely test the mettle of the current coexistence policy for transgenic and non-transgenic plant agriculture in North America and Europe. This scenario is well exemplified by the Canadian case of *Monsanto Canada Inc v. Schmeiser*,<sup>875</sup> in which the Supreme Court of Canada held inter alia that Schmeiser, a canola farmer, was liable for patent infringement, when he saved and replanted his canola harvests.

Moreover, farm businesses could be liable for facilitating patents infringement by farmers merely by helping famers to process and clean-up their harvests. This scenario is exemplified by the United States case of *Monsanto Company & Monsanto Technology L.L.C. v. Maurice Parr*,<sup>876</sup> in which the Federal District Court held inter alia that Maurice Parr, who was running a family seeds cleaning business, was liable for infringing Monsanto's patents, for processing patented transgenic seeds and crops, because his seed cleaning business facilitated infringement of Monsanto's patents by farmers who found it cheaper to save and replant processed seeds, than to purchase new proprietary seeds from Monsanto. The full implications of the two cases for food security and coexistence policy, and what possible causes of action might be available to farmers and farm businesses in analogous positions to *Schmeiser* and *Parr*, against seed firms and neighbouring transgenic farmers, are discussed and analysed extensively in Chapters Five and Six of the thesis.

#### **4.2.2. Conclusions**

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<sup>874</sup> For example in the UK, farmers' right to save farm seeds are preserved under certain conditions. See 9(1) (2) (3) Plant Varieties Act 1977, *supra*, note 852.

<sup>875</sup> See *Monsanto Canada Inc v. Schmeiser*, *supra*, note 39, at 902.

<sup>876</sup> See *Monsanto Company & Monsanto Technology L.L.C. v. Maurice Parr*, 545, F. Supp. 2d 836 (N.D. Ind. 2008).

Chapter Four of the thesis draws largely on empirical evidence and scientific literature to highlight existential conflicts in the coexistence paradigm that could potentially adversely impact public health and the environment. There is unanimity of scientific opinions on the inevitability of gene flow between transgenic and non-transgenic plant species, with possible loss of crop purity for organic and conventional systems of agriculture, and concomitant economic loss.<sup>877</sup> In the European Union, organic and conventional crops production processes have had to be reconceptualised or redefined to accommodate the 0.9 percent maximum transgenes contents labelling threshold.<sup>878</sup> Even so, keeping adventitious transgenes below the statutory 0.9 percent transgenes contents would not guarantee access to international markets where there are lower tolerance requirements for transgenes contents in organic and conventional crops.<sup>879</sup> Also, in *Karl Heinz Bablok Case*, an organic beekeeper in Bavaria, forfeited his organic classification, when proteins from the pollens of Monsanto's transgenic maize inadvertently commingled with his organic honey, in excess of the 0.9 percent statutory labelling requirement. The CJEU held inter alia that the honey was no longer organic, and that permission would be required prior to its sale to the public.<sup>880</sup>

Furthermore, there is mounting, albeit disputed scientific evidence that *Bacillus thuringiensis* bacteria protein used in most transgenic food and feed crops, could survive the guts of humans and livestock, with as yet unknown consequences for the public health. There is also evidence that unapproved transgenes such as those from the StarLink corn Cry9C proteins may have permanently lodged in the global food chain with no clues as to how they might impact future public health. Also, recent scientific findings have suggested that *Bacillus thuringiensis* bacteria encoded in transgenic food and feed crops such as Bt maize, Bt soy, and

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<sup>877</sup> See Elena Angulo et al., "When Biotech Crosses Borders," *Nature Biotechnology*, *supra*, note 27, at 277-282.

<sup>878</sup> See paragraph 1.1 of the Preamble to Commission Recommendation of 13 July 2010 on guidelines for the development of national co-existence measures to avoid the unintended presence of GMO in conventional and organic crops, *supra*, note 164.

<sup>879</sup> See annex III, Commission Regulation (EC) No. 1235/2008, *supra*, note 217.

<sup>880</sup> See *Karl Heinz Bablok v. Freistaat Bayern*, Case C-442/09, *supra*, note 247, at 13.



Bt canola, could leach into the soil and destroy soil micro-organisms such as *arbuscular mycorrhizal* fungi populations that are critical for soil fertility.

Moreover, non-transgenic plant farmers and farm businesses are in constant peril of patent infringements due to adventitious presence of transgenes in their crops, on their land, and in their machineries. These scenarios are exemplified by *Monsanto Canada Inc v. Schmeiser*,<sup>881</sup> and *Monsanto Company & Monsanto Technology L.L.C. v. Maurice Parr*.<sup>882</sup>

Thus the coexistence paradigm poses existential challenges for organic farmers, conventional farmers, and farm businesses. There are also potential public health and environmental problems associated with adventitious presence of unapproved transgenic crops into the food chain and the environment. Furthermore, scientists are divided on the ramifications of transgenic plant technology for the environment and public health.

The pertinent question is whether current compensation regimes in national and translational laws are a good match for the challenges of coexistence? In Chapters Five and Six below, the thesis will examine the adequacy and proprieties of the current compensation regimes in the coexistence paradigm, whilst drawing on relevant laws from the UK, EU, and North America.

## **CHAPTER FIVE.**

### **Tortious Liability Framework.**

#### **5.1.0. Introduction.**

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<sup>881</sup> See *Monsanto Canada Inc v. Schmeiser*, *supra*, note 39, t 1.

<sup>882</sup> See *Monsanto Company & Monsanto Technology L.L.C. v. Maurice Parr*, *supra*, note 876.

Chapter Five of the thesis examines and discusses scenarios for tortious liability for damage caused by adventitious transgenes in the coexistence paradigm. The scenarios include possible property damage or economic loss suffered by organic or conventional plant farmers due to adventitious presence of transgenes in excess of the 0.9 percent labelling threshold in the EU, and the consequential loss of premium organic or conventional crops markets. Another scenarios include economic loss sustained by non-transgenic plant farmers and businesses, caused by patent infringements litigations or the threats of patent infringement litigations. Other scenarios include environmental damage caused by Bt toxins to non-target organisms in the ecosystems, and possible personal injury suffered by those who consume unapproved transgenes that inadvertently slipped into the food chain. All of the above scenarios have been highlighted, discussed and analysed in Chapter Four of the thesis, and in order to avoid unnecessary repetition, they would only be referenced casually unless it is absolutely necessary to repeat the scenarios for the purpose of emphasis in Chapter Five of the thesis.

As previously noted in section 1.2.1 on the scope of the thesis, some of the materials for Chapter Five and Six are drawn primarily from the United States and Canada precisely because for more than a decade, their legal systems have had to adjudicate over disputes stemming from inherent existential challenges of coexistence discussed in Chapter Four of the thesis. In the United Kingdom and the EU, there have been relatively fewer case law because only very few Member States are involved in commercial transgenic cultivation, and those few like Spain and Portugal, are focused specifically on transgenic maize, whilst the size of arable land cultivated with transgenic maize is negligible to that of the United states and Canada.<sup>883</sup>

Whilst national laws do differ significantly in some respects, there are areas of considerable similarities, especially with regards to common law remedy in torts, as well as elements of the

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<sup>883</sup> See Clive James, *Global Status of Commercialized Biotech/GM Crops*, *supra*, note 1.

patent law, through the globalising effects of the TRIPs agreement,<sup>884</sup> and the tendency of plant biotechnology companies to file for patents across multiple jurisdictions. Thus, whilst a US or Canadian judgment on a patent dispute might not be directly applicable in the UK, a similar action could be filed against defendants within jurisdiction provided the plaintiffs registered their patents in the UK.<sup>885</sup> However, it is beyond the scope of this chapter to explore key differences in the substantive patent laws of EU, UK, Canada and the US as such, except where this is pertinent to the existential problems discussed in Chapter Four of the thesis. In other words, the scope of comparison of the patent laws of the countries under study, would narrowly be focused on the specific economic problems posed by patent infringements or threats of patent infringements, and how the torts law might remedy these apparent wrongs, rather than on key differences in the substantive patent laws of the jurisdictions under consideration as such.

### **5.1.1. Economic Harm Caused by the Loss of Premium Plant Agricultural Markets.**

In Chapter Four of the thesis, one of the key existential challenges highlighted is the possible economic loss that an organic or a conventional crop farmer may suffer in the coexistence paradigm due to adventitious presence of transgenes in their harvests, and consequential loss of premium organic or conventional crops markets. In this section, relevant case law will be considered from the UK and the EU. The section will discuss these case law to highlight how they might cause economic loss for non-transgenic plant farmers. The possible remedy by the law of torts, will be discussed subsequently from section 5.1.3 of the thesis.

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<sup>884</sup> See Article 1 and Article 27(1) of the TRIPs Agreement, *supra*, note 252; *Merck Genericos Produtos Farmaceuticos v. Merck & Co. Inc.*, (Case C--431/05), *supra*, note 254; Alexander Peukert, "Territoriality and Extraterritoriality in Intellectual Property Law," in Gunther Handl & Joachim Zekoll, (editors), *Beyond Territoriality: Transnational Legal Authority in An Age of Globalization*, *supra*, note 257, at 189-227.

<sup>885</sup> For example, Monsanto was granted a patent for melon by the EPO in 2011. See European Patent Specification, "Closterovirus-Resistant Melon Plants," *supra*, note 257.

The first case that demonstrate potential economic loss for non-transgenic plant farmers in the coexistence paradigm is *R v. Secretary of State for the Environment and MAFF ex Parte Watson*.<sup>886</sup> The applicant was an organic farmer producing vegetables, which included sweet corn. He was concerned about a transgenic maize field trial that adjoined his organic farm, which was owned by the National Institute of Agricultural Botany. The UK Soil Association warned the applicant that he would lose his organic certification status, due to imminent threats of cross-pollination, if the transgenic maize trial were to continue.<sup>887</sup> Subsequently, the applicant moved his organic maize crop away from the trial site by as much as 2 kilometres. The applicant advised the respondents to discontinue the trial, but they refused. The applicant subsequently filed for a judicial review.<sup>888</sup>

The Court of Appeal held inter alia that the action for judicial review was premature, because the Ministry of Agriculture had been advised by experts that the amount of cross-pollination was "likely to be zero" because only a segregation distance of 200 metres was required, and the applicant had moved his organic farm away by as much as 2 kilometres. In the circumstances, the Court held that the assurance given regarding low risk of cross-pollination was "a reasonably confident assessment that realistically there is no more than minimal risk" of cross-pollination event.<sup>889</sup> The Court acknowledged that whilst this assurance fell short of the absolute guarantee that the applicant and Friends of the Earth wanted, yet, the Court believed that it was perfectly reasonable to strike a balance between the competing interests at play, and in the circumstances, the decision of the respondents to proceed with the field trial was not irrational.<sup>890</sup> The Court further held that if damage did eventually occur via

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<sup>886</sup> See *R v. Secretary of State for the Environment and MAFF ex Parte Watson*, *supra*, note 70, at 310.

<sup>887</sup> *Id.*, at 311.

<sup>888</sup> *Id.*, at 314.

<sup>889</sup> *Id.*, at 316.

<sup>890</sup> *Id.*

cross-pollination, then the applicant could take out an action in private nuisance and claim compensation, but not until then.<sup>891</sup>

The significance of this case is the court's recognition that the applicant has a potential cause of action in private nuisance, but he had to wait until the nuisance had occurred before he could sue. However, the real coexistence challenge for the applicant was that he was powerless to stop the transgenic maize field trial and he had no choice than to coexist with the advent of transgenic maize in the adjacent farm.

Another scenario whereby economic loss could occur due to the loss of a target market in consequence of adventitious presence of transgenes in organic or conventional products is exemplified by *Karl Heinz Bablok v. Freistaat Bayern*.<sup>892</sup> The Court of Justice of the European Union held inter alia that prior authorisation was needed before an amateur Bavarian bee farmer could sell his honey, due to adventitious presence of pollen from the DNA of Monsanto's transgenic maize MON 810.<sup>893</sup> According to the Court of Justice, the honey and food supplement containing pollen from Monsanto's transgenic maize, "constitute food for human consumption produced from ingredients produced from GMOs", within the meaning of Regulation (EC) 1828/2003.<sup>894</sup> In section 5.1.3 below, the thesis will explore possible causes of action available in torts law for the non-transgenic plant farmers who suffered economic losses in the two scenarios above.

### **5.1.2. Economic Harm Caused by Patent Infringement Litigations.**

Yet another form of possible economic loss that an organic or a conventional farmer may suffer could stem from patent infringement litigation, or a threat of patents infringement litigation occasioned by on-farm adventitious commingling of transgenic and non-transgenic plant

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<sup>891</sup> Id.

<sup>892</sup> *Karl Heinz Bablok v. Freistaat Bayern*, Case C-442/09, *supra*, note 247, at 13.

<sup>893</sup> Id, at 13.

<sup>894</sup> Id.

organisms,<sup>895</sup> or the handling of patented seeds at seeds processing and cleaning facilities.<sup>896</sup> This section is not about the substantive law on patent infringements per se, but rather on patent infringements as a veritable source of economic loss for non-transgenic plant farmers and businesses in the coexistence paradigm. The thesis deems this an existential threat, and explores how torts law might remedy this in the absence of any protection under the current national and international patent systems. The section will draw some parallels with analogous situation in the UK and EU, and how this existential challenge could be overcome by non-transgenic plant farmers and businesses.

### **5.1.3. Monsanto Canada Inc. v. Schmeiser.**

Within the context of the current coexistence paradigm for transgenic and non-transgenic plant organisms, organic or conventional crops farmers risk possible exposure to the risk of liability for patent infringement and consequential damages and economic loss.<sup>897</sup> The first patent infringement scenario in the co-existence paradigm is exemplified by *Monsanto Canada Inc. v. Schmeiser*, in which the defendant canola farmer was held liable for infringing Monsanto's patent in "Roundup Ready Canola".<sup>898</sup> The patented transgenic canola had somehow inadvertently found its way from neighbouring farms into defendant's non-transgenic canola farm. The Supreme Court of Canada found as a fact that the defendant was aware of the presence of Monsanto's patented transgenic canola in his canola harvests, but had nevertheless saved and replanted the said canola harvests, an activity that was tantamount to a "use" of the patented canola without authorisation under section 42 of the Canadian patents law, thus

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<sup>895</sup> See *Monsanto Canada Inc. v. Schmeiser*, *supra*, note 39, 20.

<sup>896</sup> See *Monsanto Company and Monsanto Technology L.L.C. v. Maurice Parr*, 545, F. Supp. 2d 836 (N.D. Ind. 2008).

<sup>897</sup> See *Monsanto Canada Inc. v. Schmeiser*, *supra*, note 39, at 33.

<sup>898</sup> See *Monsanto Canada Inc. v. Schmeiser*, *id.*, at 37.

depriving Monsanto of its monopoly on the special canola plant by saving and reusing Monsanto's transgenic canola seeds for his own commercial interests.<sup>899</sup>

Whilst interpreting the meaning of the word "use" under section 42 of the Canadian patent law, the Court noted that the plain meaning of the word "use" or "exploiter" denotes utilisation with a view to production or advantage, and that the purpose of section 42 was to define the exclusive rights granted to the patent holder. The Court noted further that the question in determining whether a defendant has "used" a patented invention was whether defendant's activities deprived the inventor in whole or in part, directly or indirectly of full enjoyment of the monopoly conferred by law. The Court further observed that if there was a commercial benefit to be derived from the invention, it belonged to the patent holder.<sup>900</sup>

The Supreme Court also noted that the defendant was not an innocent infringer, but did suggest that there might be a defence against patent infringement by farmers who were victims of volunteer crops.<sup>901</sup> Most significantly, due to the strict liability nature of patent infringement, the Supreme Court of Canada noted that a lack of knowledge of the "use" of the patented canola would not avail the defendant, because the court was not concerned "with the innocent discovery by farmers of "blow-by" patented plants on their land or in their cultivated fields."<sup>902</sup> Even if the defendant had succeeded in raising the defence of innocent infringement, the dissenting judgment in *Schmeiser* highlighted the flimsiness and weakness of such a defence thus:

A truly innocent infringer may be able to rebut the presumption of use. However, that would likely prove difficult once the innocent infringer became aware that the genetically modified crop was present – or was likely to be present – on his or her land and continued to practice traditional farming methods, such as saving seed.<sup>903</sup>

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<sup>899</sup> Id, at 905. See also Bruce Ziff, "Travel with my plant: Monsanto v. Schmeiser revisited," *University of Ottawa Law & Technology Journal*, Volume 2, Number 2, (2005), at 493-509.

<sup>900</sup> See *Monsanto Canada Inc. v. Schmeiser*, *supra*, note 39, at 48..

<sup>901</sup> See *Monsanto Canada Inc. v. Schmeiser*, *supra*, note 39, at 48.

<sup>902</sup> Id, at 905.

<sup>903</sup> Id, at paragraph 159.

Thus, by extrapolation, *Schmeiser* decision would appear to burden farmers in analogous circumstances with the additional responsibility and costs of monitoring their farms for volunteer crops and strayed transgenes, and the duty to promptly inform seed companies in order to pre-empt patent infringement litigation. Failure to do this could make it harder for farmers to rebut the presumption of use of a patented invention.<sup>904</sup>

Commercial transgenic plant agriculture is now available in some EU Member States, notably, Spain and Portugal, albeit on a smaller scale than in North America,<sup>905</sup> and the *Schmeiser Case* could easily be replicated within the European Union. The pertinent question is how would Courts in the UK and the EU rule in cases analogous to *Schmeiser Case*? Starting with the UK Patent Act 1977, the closest provision to section 42 of Canada Patent Act 1985,<sup>906</sup> is section 60(1) (a) (b) (c).<sup>907</sup> Thus, whilst section 42 of Canada Patent Act 1985 grants the patentee "the exclusive right, privilege and liberty of making, constructing and using the invention and selling it to others to be used, subject to adjudication in respect thereof before any court of competent jurisdiction,"<sup>908</sup> section 60(1)(a)(b)(c) of the UK Patent Act 1977 generally provide for the circumstances under which the use of a process or product patent would constitute an infringement if done without the consent of the patentee.<sup>909</sup>

In the *Schmeiser Case*, the majority Court applied a purposive approach to the interpretation of the word "use", noting that "the inquiry into the meaning of use under the Patent Act must be purposive."<sup>910</sup> The Court then went on to complement purposive approach with contextual interpretation, giving consideration to the other words of the provision.<sup>911</sup>

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<sup>904</sup> See Kathryn Garforth and Paige Ainslie, "When Worlds Collide: Biotechnology meets Organic Farming in Hoffman v Monsanto," *Journal of Environmental Law*, Volume 18, No. 3, (2006), at 471.

<sup>905</sup> Clive James, *Global Status of Commercialized Biotech/GM Crops*, *supra*, note 1.

<sup>906</sup> See Canada Patent Act 1985.

<sup>907</sup> See section 60(1) Patent Act 1977, Chapter 37.

<sup>908</sup> See section 42 Canada Patent Act 1985.

<sup>909</sup> See UK Patent Act 1977, *supra*, note 830.

<sup>910</sup> See *Monsanto v Schmeiser*, *supra*, note at 39, at 22.

<sup>911</sup> *Id.*



UK Courts would most certainly adopt a purposive approach to the interpretation of the analogous provisions of section 60(1)(a)(b)(c) of the Patent Act, based on the precedents established in *Catnic Components v Hill & Smith*;<sup>912</sup> *Improver Corporation v Remington Consumer Product Limited*;<sup>913</sup> and *Kirin-Amgen, Inc. v Hoechst Marion Roussel Ltd.*<sup>914</sup>

In the *Catnic Components Case*, the House of Lords, whilst applying a purposive approach to the construction of the claim, held inter alia that a bar invented for structural support of a window or a door, that extended at an upward slant of approximately 6 degrees from being vertical, did infringe the patent for a steel lintel, which patent specification required a bar "to extend vertically."<sup>915</sup> According to Lord Diplock, "A patent specification should be given a purposive construction rather than a purely literal one derived from applying to it the kind of meticulous verbal analysis in which lawyers are too often tempted by their training to indulge."<sup>916</sup> Similarly, in the *Improver Corporation Case*, the key question was whether a rubber rod with slits on its surface, did infringe a curved "helical spring" driven by a motor, and used in a depilatory device? Justice Hoffmann as he then was, adopted a purposive claim construction method, reformulated the tests for purposive construction into three, and held that the rubber rod did not infringe the "helical spring" patent on grounds that the change to a rubber rod had no material effects on the way the invention worked; that it would have been obvious to an expert that the rubber rod would work in the same way; and that the expert would have understood from the patent that the patentee meant to confine his claim to the helical spring.<sup>917</sup> In *Kirin-Amgen Case*, the key issue for determination was whether [Transkaryotic Therapies'](#) EPO was outside of Amgen's patent claims for a gene, which was exogenous to its cell, because of the difference in the way it was made? However, the genes, which expressed EPO in cells

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<sup>912</sup> See *Catnic Components v Hill & Smith*, [1982], RPC 183.

<sup>913</sup> See *Improver Corporation v Remington*, [1990] FSR 181.

<sup>914</sup> See *Kirin-Amgen, Inc. v Hoechst Marion Roussel Ltd* [2005] 1 All E.R. 667.

<sup>915</sup> See *Catnic Components v Hill & Smith*, *supra*, note 915, at 188.

<sup>916</sup> *Id.*, at 189.

<sup>917</sup> *Id.*

made by Transkaryotic Therapies' processes were not exogenous. In a judgment delivered by Lord Hoffmann, the House of Lords, whilst interpreting Article 69 of the European Patent Convention on claims construction, observed that it was consistent with the purposive approach to claims construction espoused in the *Catnic Component Case*, and held inter alia that the Transkaryotic Therapies did not infringe Amgen's patents.<sup>918</sup> Therefore, by holding that Article 69 of the EPC was consistent with the purposive approach of the *Catnic Component Case*, the House of Lords, for the first time, aligned claims construction and interpretation with that of that of the European Patent Courts in Munich.<sup>919</sup>

The pertinent question therefore is how would UK and EU Courts rule in the *Schmeiser Case*, given similar analogous circumstances? To begin with, if the Monsanto's patent in question is registered as a UK or EU patent, then UK Courts applying purposive claims construction of *Catnic Components Case* and Article 69 EPC, would likely interpret section 60(1)(a)(b)(c) similarly to section 42 of Canada Patent Act in *Schmeiser Case*, and hold that there was a "use" of the patent without authorisation. European Patent Court might come to a similar conclusion, whilst interpreting Article 69 of the EPC.<sup>920</sup>

Therefore, it is arguable that non-transgenic plant farmers in the EU could be as vulnerable as farmer Schmeiser. The pertinent question therefore is whether farmers could recoup the costs of monitoring their crops for the presence of transgenes and associated legal arrangements in torts law from either neighbouring transgenic farmers or seed companies or both? Section 5.1.3 of the chapter examines possible causes of action for farmers in analogous situations to in the *Schmeiser Case*.

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<sup>918</sup> See *Kirin-Amgen, Inc. v Hoechst Marion Roussel Ltd*, *supra*, note 914, at 670.

<sup>919</sup> *Id.*

<sup>920</sup> See *Friction Reducing additive Case*, G0002/88 (11 December 1989).

#### **5.1.4. Monsanto Company and Monsanto Technology L.L.C. v. Maurice Parr.**

The second scenario for seed patent infringement litigation that could potentially lead to economic loss for farm businesses, often involves indirect or secondary seed patent infringing activities by farm businesses, as exemplified by the U.S case of *Monsanto Company and Monsanto Technology L.L.C. v. Maurice Parr*.<sup>921</sup>

Maurice Parr was the manager of a mobile grain and seed cleaning business, known as “Custom Seed and Grain Cleaning”, with operations in and around Lafayette, Indiana, United States. Maurice Parr’s seed cleaning business involved running harvested crops “through a mechanical cleaner that sifts trash such as stems, leaves, dirt, and broken/split seed from whole seed.”<sup>922</sup> Maurice Parr’s seeds cleaning service was essential for reconditioning harvested seeds for replanting purposes, for protecting planting equipments, and for ensuring that only viable wheat or soybean seeds were replanted.<sup>923</sup> Maurice Parr often travelled with his mobile cleaning business to his customers’ farms to clean customers’ seeds on site on scheduled appointments.<sup>924</sup> In 2002, Monsanto informed Maurice Parr that it had information that Parr’s seeds cleaning business facilitated seeds replanting by soybeans farmers and encouraged and induced soybeans farmers to clean and replant soybeans, which Maurice Parr knew contained *Monsanto’s* patented technology.<sup>925</sup> In the letter informing Maurice Parr about his alleged infringing activities, *Monsanto* specifically requested him to stop:

Cleaning any seed containing Monsanto’s patented Roundup Ready Biotechnology; and advising growers (either orally or in writing) that they are entitled to save and replant seed containing Monsanto’s patented Roundup Ready biotechnology.<sup>926</sup>

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<sup>921</sup> *Monsanto Company and Monsanto Technology L.L.C. v. Maurice Parr*, *supra*, note 43, at 545.

<sup>922</sup> *Id.*, at 545.

<sup>923</sup> *Id.*, at 546.

<sup>924</sup> *Id.*, at 546.

<sup>925</sup> *Id.*, at 547.

<sup>926</sup> *Id.*, at 547.

In his reply, Maurice Parr assured Monsanto that he would make his customers aware that the act of cleaning of Monsanto's Roundup Ready seed for farmers facilitated the infringement of *Monsanto's* patent in the seed, and that he would no longer clean Monsanto's patented Roundup Ready seed for customers.<sup>927</sup>

However, following the correspondence between Maurice Parr and Monsanto, a number of transgenic soybean farmers engaged Maurice Parr's cleaning business to process their transgenic Roundup Ready soybean for replanting, contrary to the terms of the technology agreement the farmers signed with Monsanto.<sup>928</sup> Subsequently, Monsanto negotiated an out-of-court settlement with eleven of the farmers who had used Maurice Parr's cleaning business to process Roundup Ready soybean for replanting.<sup>929</sup> Monsanto then sued Maurice Parr for inducing patent infringement, by advising his customers that it was legal for farmers to save, keep, and replant patented Roundup Ready seed.<sup>930</sup> Some of Maurice Parr's previous customers with whom Monsanto had reached an out-of-court settlement, gave evidence that Maurice Parr had advised them that it was legally permissible to save and replant patented Roundup Ready seed.<sup>931</sup>

The United States District Court of Northern District of Indiana found as a fact that there was substantial likelihood that any of the soybean seed cleaned by Maurice Parr between 2002 and 2007 contained patented Roundup Ready.<sup>932</sup> This finding was predicated on the evidence that approximately 87.3 percent of the 94.3 percent of the soybeans planted in the State of Indiana between 2002 and 2007 contained Monsanto's patented Roundup Ready traits.<sup>933</sup>

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<sup>927</sup> *Id.*

<sup>928</sup> *Id.*

<sup>929</sup> *Id.*, at 548.

<sup>930</sup> *Id.*

<sup>931</sup> *Id.*, at 548-549.

<sup>932</sup> *Id.*, at 549.

<sup>933</sup> *Id.*

The United States District Court then drew on section 271(b) of the United States Patent Act, which provides *inter alia* that “whoever actively induces infringement of a patent is an infringer.”<sup>934</sup> Other elements of inducement under section 271(b) of the United States Patent Act, which the United States District Court reviewed and applied are as follows: (a) that there must have been a direct infringement; (b) there must be active aiding and abetting of direct infringement by another; and (c) that the inducer must know or should know that his actions would induce infringement.<sup>935</sup>

On the requirement of “direct infringement”, which is the first element of inducement under section 271(b) of the United States Patent Act, the U.S. District Court found that on the evidence of Mr Maurice Parr’s previous customers that he had advised them to save and replant seeds from soybean that were processed at his cleaning facility, Maurice Parr was “directly involved in the act of replanting the saved seed itself,” and was therefore liable for direct infringement of Monsanto’s patents in Roundup Ready soybeans.<sup>936</sup>

Additionally, the United States District Court noted that “the cleaning of saved seed is fundamental step in the process of replanting”, and that “Parr’s involvement is at the centre of the direct infringement by the grower.”<sup>937</sup> On the second element of inducement under section 271(b) of the U.S. Patent Act, which requires “active aiding and abetting of direct infringement,” the U.S. District Court found that Maurice Parr’s proactive and affirmative steps of advertising his cleaning services, scheduling of his cleaning appointments, and advising customers that they could save and replant their seed following cleaning process, was tantamount to actively aiding and abetting “the direct infringement of farmers who subsequently plant that seed.”<sup>938</sup> With regards to the third element of inducement under section

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<sup>934</sup> Id.

<sup>935</sup> Id, at 550.

<sup>936</sup> Id.

<sup>937</sup> Id, at 551.

<sup>938</sup> Id, at 552.

271(b) of the U.S. Patent Act which requires intent to induce infringements or knowledge that acts could induce patent infringement, the United States District Court held as follows:

The third element of inducement is a scienter requirement – a party must know or should know that their actions will induce actual infringements. Direct evidence is not required to establish the intent element of inducement – circumstantial evidence is sufficient. Actual knowledge of the patent that is being infringed is to be considered for the element of intent for the inducement cause of action. There is no dispute that Parr had actual knowledge of Monsanto’s patents in Roundup Ready crop seed. This Knowledge is direct evidence of intent to induce.<sup>939</sup>

Justice Allen Sharp of the United States District Court then ordered a permanent injunctive relief that would bar Maurice Parr and his business: *Custom Grain and Seed Cleaning*, from “cleaning or conditioning crop seed that contains Roundup Ready traits”.<sup>940</sup> Maurice Parr was also ordered to give an undertaken not to make “statements or distribute information suggesting that it is legal or otherwise permissible to save, clean, and replant Roundup Ready soybeans from an unauthorized source.”<sup>941</sup> Maurice Parr was also ordered to advise his customers that it was “illegal to save, clean, and replant Roundup Ready soybeans;” and that his future customers must certify in writing that the soybeans brought for cleaning did not contain Roundup Ready traits.<sup>942</sup>

Additionally, he was ordered to provide Monsanto with written certifications that no seeds comprising Roundup Ready had been processed, alongside samples of seeds cleaned within 30 days of the cleaning process.<sup>943</sup> Finally, Maurice Parr was ordered to pay \$40,000 as damages for past patent infringement. However, Monsanto agreed not to enforce the judgment for \$40,000 for as long as Maurice Parr complied with all the orders of the District Court. A breach of any of the District Court orders would however render the \$40,000 judgment debt payable

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<sup>939</sup> Id, at 558.

<sup>940</sup> Id.

<sup>941</sup> Id, at 558.

<sup>942</sup> Id.

<sup>943</sup> Id.

immediately to Monsanto, in addition to “any other damages or relief to which” Monsanto “may be entitled”.<sup>944</sup>

The Maurice Parr case once again demonstrates the significance of the risks of patent infringement as a putative source of economic loss or damage for farm businesses within the current coexistence paradigm. The case equally demonstrates the strict liability nature of patent infringement, and the helplessness of Maurice Parr or any other farm businesses in analogous position. For it is clear from the provisions of Section 271(b) of the United States Patent Act that Maurice Parr would still be liable for infringing Monsanto’s Roundup Ready soybean patent, even if he did not actively advertise his services, and advised his customers to save and replant soybeans seeds he helped cleaned. This is because the very act of cleaning the patented soybeans would automatically prime the seeds for replanting, which would be contrary to the provision of the technology agreement that Monsanto had with Roundup Ready soybeans farmers.

Thus, by extrapolation, the very act of cleaning the patented seeds could be tantamount to “active aiding and abetting” of patent infringement under section 271(b) of the U.S. Patents Act. Indeed, Justice Allen Sharp of the U.S. District Court directly alluded to this eventuality when he noted thus:

The purpose of cleaning the seed is to condition it for planting a new crop. The seed cleaner removes stems, leaves, gravel, dirt, and broken\split seed so that it does not impair the planting equipment and ensures that viable seed is placed into the ground. Accordingly, by ...cleaning saved Roundup Ready seed, Parr actively aid and abets the direct infringement of farmers who subsequently plant that seed.<sup>945</sup>

Moreover, and most importantly, there need not be direct evidence that Maurice Parr induced his customers to infringe Monsanto’s Roundup Ready soybean patent in order for his liability to be assured under section 271(b) of the United States Patent Act. For as Justice Allen Sharp

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<sup>944</sup> Id, at 559.

<sup>945</sup> Id, at 554.

correctly noted, “direct evidence is not required to establish intent element of inducement – circumstantial evidence is sufficient.”<sup>946</sup> Thus, by extrapolation, the very act of cleaning Roundup Ready soybeans for farmers, which facilitated replanting of soybeans seeds in contravention of Monsanto’s technology agreement with the farmers, could provide enough circumstantial evidence of Maurice Parr’s intent to induce his customers to infringe Monsanto’s patents in Roundup Ready soybeans.

If anything, the *Maurice Parr case* demonstrates that farm businesses could be vulnerable to patent infringement and concomitant economic loss, if they advertised their cleaning services to customers and proceed to actually fulfil their contractual obligations by actually cleaning customers’ seeds. The position of farm businesses such as Maurice Parr’s is even made more legally precarious by the fact that majority of seeds available for cleaning are Roundup Ready proprietary seeds in North America, due to the proliferation of commercial transgenic plant agriculture. This is exemplified by Justice Allen Sharp’s observation that approximately 87.3 percent of the 94.3 percent of the soybeans planted in the State of Indiana between 2002 and 2007 contained Monsanto’s patented Roundup Ready traits.<sup>947</sup>

It is thus inevitable that the more widespread transgenic crops are, the fewer available cleaning businesses would be for farm businesses, whose traditional seeds cleaning business model predates transgenic plant agriculture, but who might soon be permanently out of business in North America, because there are fewer non-transgenic seeds to clean, and the current regulatory framework that underpins the coexistence paradigm exposes them to patent infringement litigation and concomitant economic loss for cleaning transgenic seeds. For example, although Maurice Parr did not have to pay the \$40,000 damages awarded by the District Court to Monsanto, he reputedly incurred \$25,000 in legal fees “before even setting

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<sup>946</sup> Id.

<sup>947</sup> Id, at 549.



foot in a courtroom,” and lost 90 percent of his customers who were now afraid that business relationship with him could lead to prosecution for patent infringement.<sup>948</sup>

The pertinent question therefore is whether Maurice Parr and farm businesses in analogous situations could have a cause of action in negligence for economic damage sustained from losing customers to the proliferation of transgenic crops against transgenic farmers or seed companies? This question is particularly relevant due to the limits of innocence infringer defence and the absence of any form of protection for farm cleaning businesses such as Maurice Parr’s under the current national and international patent laws.

Most significantly, the standardised minimum requirements for the protection of patented inventions under Article 1 of the 1994 Trade Related Agreement on Intellectual Property Rights (TRIPS),<sup>949</sup> means that the general principles relied upon by the Canadian Supreme Court in the *Monsanto Canada Inc v. Schmeiser*, and the United States District Court of Northern Indiana in *Monsanto Company and Monsanto Technology L.L.C. v. Maurice Parr* are essentially similar and analogous to those under the United Kingdom and the European Union Patent laws.<sup>950</sup> Therefore, Courts in the United Kingdom and the European Union are unlikely to make conclusions that differ materially from that of the Canadian Supreme Court in the *Schmeiser Case*, or the U.S. District Court in *Maurice Parr case*, assuming of course that

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<sup>948</sup> See The Centre for Food Safety and Save Our Seeds, *Seed Giant vs. U.S. Farmers*, (2013), at 29, available at [http://www.centerforfoodsafety.org/files/seed-giants\\_final\\_04424.pdf](http://www.centerforfoodsafety.org/files/seed-giants_final_04424.pdf)

<sup>949</sup> Article 1 of the TRIPS Agreement enjoins Member states to give effect to the standardised minimum requirements for intellectual property rights protection. With regards to patents, Article 27(1) of the TRIPS Agreement requires signatories to make patents available for any inventions in all fields of technology. This would include transgenic seeds, and there would be no legal justifications for courts in the United Kingdom and the European Union to exempt transgenic seeds from patentable inventions. For discussion on the obligations of signatories to the TRIPS Agreement to comply with the provisions therein, see Taiwo A. Oriola, “Against the Plague: Exemption of Pharmaceutical Patent Rights as a Biosecurity Strategy,” *University of Illinois Journal of Law, Technology & Policy*, Volume 2007, Issue 2, (Fall 2007), at 287-343. See also Panel Report, Canada-Patent Protection for Pharmaceutical Products, WT/DS114/R, (17 March, 2000).

<sup>950</sup> See also Maria Lee and Robert Burrell, “Liability for the Escape of Gm Seeds: Pursuing the ‘Victim’?” *The Modern Law Review*, supra, note 18, at 522-523.

*Monsanto's* patents on its transgenic seeds are valid under the patent laws of the United Kingdom and the European Union.<sup>951</sup>

However, it is instructive to note that national patent laws may differ in material respects, as exemplified by the German Parliament's recent proposed amendment to the German patent law to prohibit patent on plants and animals derived from conventional breeding.<sup>952</sup> This could in theory allow German courts to disregard *Monsanto's* patent on plants and seeds, since they are all ostensibly derived from conventional breeding. Thus by extrapolation, the German legislation could protect German farmers in situations analogous to the *Monsanto Canada Inc v. Schmeiser* and *Monsanto Company and Monsanto Technology L.L.C. v. Maurice Parr*, by excluding *Monsanto's* canola or maize derived from conventional breeding from the list of patentable inventions.

However, this unilateral German parliamentary initiative is not binding on the European Patent Office in Munich, as it clearly contravenes Article 52(1) of the European Patent Convention 2000, which provides that patent shall be granted for any inventions in all fields of technology,<sup>953</sup> as well as Article 27(1) of the Agreement on Trade Related Aspects of Intellectual Property Rights, which requires that patents should be granted to all types of inventions without any discrimination.<sup>954</sup> Thus the legality of the proposed German law excluding patent for plants and animals derived from conventional breeding is arguably open to legal challenge before the Court of Justice of the European Union and the European Patent Office in Munich.

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<sup>951</sup> See Maria Lee et al., id, at 523, (noting that it was unlikely that a UK court would arrive at a different conclusion than that of the Canadian trial court, and that *Monsanto's* patent would be held valid in the UK.)

<sup>952</sup> The amendment was effected on 27 June 2013, and was in response to clamours from civil societies who were appalled European patent (EP 1597965) on "severed broccoli", which was granted by the European Patent Office in Munich on 12 June 2013, and which conferred monopoly on *Monsanto* on seeds and plants derived from conventional breeding. See No Patents on Seeds, "German Parliament prohibits patents on plants and animals from conventional breeding," Berlin, (27 June, 2013), at <http://www.no-patents-on-seeds.org/en/information/news/german-parliament-prohibits-patents-plants-and-animals-conventional-breeding>

<sup>953</sup> The European Patent Convention takes effect from 13 December 2007.

<sup>954</sup> See Article 27(1) of the WTO Trade Related Aspects of Intellectual Property Rights, 1994.

Most significantly, the State of California in the United States is the only known regulatory authority to pre-empt the scenario in *Monsanto Canada Inc. v. Schmeiser*, via its 2008 transgenic legislation, which protects non-transgenic crops farmers in situations largely analogous to the facts of *Monsanto Canada Inc., v. Schmeiser*.<sup>955</sup> Even so, the Californian transgenic legislation directly runs counter to the strict liability nature of the United States Federal Patent legislation, and therefore remains vulnerable to the pre-emptive powers of the Constitutional Commerce Clause doctrine under Article 1, section 8, clause 3 of the Constitution of the United States, which empowers the US Congress to regulate commerce nationally and internationally, and which, by extrapolation, imposes an implicit or dormant limitation on the authority of constituent states to enact legislations that could affect interstate commerce.<sup>956</sup> Thus, in the absence of a comprehensive Federal legislation on the liability of non-transgenic plant farmers and farm businesses for patent infringement in circumstances analogous to that of *Schmeiser* and *Maurice Parr*, the Constitutional Commerce Clause could theoretically be invoked by any aggrieved or interested party against the California transgenic legislation or any other similar initiatives by States, if it could be proven that the said legislation interfered with interstate commerce or trade in, or sales in patented transgenic crops.<sup>957</sup>

That patent infringement litigation is a credible economic threat to non-transgenic plant farmers is further underscored by the joint study conducted by the Centre for Food Safety and the *Save Our Seeds* campaign groups that showed that as of December 2012, Monsanto had filed 144 lawsuits against 410 farmers and 56 small farms or businesses across 27 different

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<sup>955</sup> For *Monsanto Canada Inc v. Schmeiser*, see *supra*, note 39, at 902. For the California transgenic legislation, see Bill Number AB541, section 7200, Division 4 of California Civil Code, or Article 6 section 510, Chapter 3 of Article 1 of Division 1 of the California Food and Agricultural Code relating to liability.

<sup>956</sup> See *Healy v. Beer Institute*, (1989), 491 U.S., 324, at 326, where the U.S. Supreme Court held *inter alia* that “this affirmative grant of authority to Congress also encompasses an implicit or ‘dormant’ limitation on authority of the states to enact legislation affecting interstate commerce.”

<sup>957</sup> See Taiwo A. Oriola, “Regulating Unsolicited Commercial Electronic Mails in the United States and the European Union: Challenges and Prospects,” *Tulane Journal of Technology, & Intellectual Property*, Volume 3 (2005), at 134-135.

States in the United States for alleged breach of its Technology Use Agreement and patent.<sup>958</sup> Significantly, out of the 144 patents lawsuits filed by Monsanto, 72 lawsuits were successfully prosecuted as at January 2013 with \$23,675,820.99 million in recorded damages in favour of Monsanto, 27 lawsuits ended in unrecorded (confidential) damages awarded in favour of Monsanto, while 14 lawsuits were dismissed.<sup>959</sup> Moreover, out of the over \$23 million damages awarded in favour of Monsanto in its numerous lawsuits against farmers and farm businesses, the most damages awarded in favour of Monsanto from a single judgment was \$3,052,800.00, while the least damages awarded in favour of Monsanto from a single judgement was \$5,595.00.<sup>960</sup>

Most significantly, other transgenic seed companies such as Syngenta, DuPont, Pioneer, and BASF are as keen as Monsanto to enforce their patent against farmers. For example, DuPont, the world's second largest seed company reputedly hired at least 45 farm investigators in 2012 to investigate planting and purchasing records of Canadian farmers and obtain samples from their fields for genetic analysis.<sup>961</sup> DuPont purportedly had plans to introduce the scheme into the United States in 2013, and had reputedly hired approximately 35 farm investigators most of whom were former police officers.<sup>962</sup> In the same vein, Syngenta, the third largest seed company, reputedly filed numerous lawsuits against farmers and farm businesses for patent and trademarks infringement.<sup>963</sup> For example in September 2002, Syngenta sued 6 Arkansas seed cleaners for allegedly reselling its patented Coker Wheat.<sup>964</sup> One of the cases was settled out of court with an award of \$152,000 damages in favour of Syngenta.<sup>965</sup> Another of the Syngenta cases proceeded to trial, and Syngenta successfully obtained a permanent injunction,

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<sup>958</sup> See The Centre for Food Safety and Save Our Seeds, *Seed Giant vs. U.S. Farmers*, *supra*, note 76, at 32.

<sup>959</sup> *Id.*, at 32.

<sup>960</sup> *Id.*, at 32.

<sup>961</sup> *Id.*, at 27.

<sup>962</sup> *Id.*

<sup>963</sup> *Id.*, at 31.

<sup>964</sup> *Id.*

<sup>965</sup> *Id.*

\$135,000 damages, and over \$12,000 in costs of litigation.<sup>966</sup> Similarly, Pioneer Hi-Bred International is another seed giant with a record for relentless enforcement of its intellectual property rights against small farmers.<sup>967</sup> For example in 2005, Pioneer Hi-Bred International sued two farmers who had bought 750 bags of its seeds that they had planned to save and replant.<sup>968</sup> The case was subsequently settled out of court, and the farmers “agreed to pay liquidated damages of \$50 per bag of seed equivalent saved for replanting” should the terms of the injunction be violated.<sup>969</sup> Moreover, BASF, a chemical company and seed giant, is equally renowned for suing small farmers for patent infringement. For example in 2005, BASF sued 14 rice farmers and 11 small farm businesses and partnerships in the States of Arkansas, United States.<sup>970</sup> A subsequent negotiated consent judgment found the defendants jointly and severally liable for \$2,500,000 in damages.<sup>971</sup>

The foregoing analyses amply demonstrate potential economic damage inherent in adventitious admixture of transgenic and non-transgenic plant organisms for conventional and organic farmers, as well as farm businesses. These risks are two-fold: the first is the potential loss of business and traditional market for organic or conventional crops, with concomitant economic damage. The second is the potential for patent infringement for non-transgenic farmers and farm businesses with concomitant economic damage, as amply exemplified by *Monsanto Canada Inc v. Schmeiser*, and *Monsanto Company and Monsanto Technology L.L.C. v. Maurice Parr*. The pertinent question therefore is how could the economic damage sustained by farmers and farm businesses in the coexistence of transgenic and non-transgenic crops be remedied?

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<sup>966</sup> Id.

<sup>967</sup> Id.

<sup>968</sup> Id.

<sup>969</sup> Id.

<sup>970</sup> Id.

<sup>971</sup> Id, at 32.

In the European Union, the European Commission advised Member countries in its 2003 Recommendation that in the event of economic damage resulting from adventitious admixture, any consequential liability should be remedied under national civil laws.<sup>972</sup> According to the European Commission Recommendation:

Member States are advised to examine their civil laws to find out whether the existing national laws offer sufficient and equal possibilities in this regard. Farmers, seed suppliers and other operators should be fully informed about liability criteria that apply in their country in the case of damage caused by admixture.<sup>973</sup>

Whilst Germany, Austria, and other European countries now have some form of statutory compensation regime for remedying economic damage for farmers and farm businesses in analogous position to *Schmeiser* and *Parr*,<sup>974</sup> there is currently no specific statutory civil liability in the United Kingdom.<sup>975</sup> However, following its public consultation in 2006, the Department of Environment, Food, and Rural Affairs (DEFRA), resolved that there was no need for any statutory interventions, and that the current product liability laws should provide adequate remedies for the aggrieved parties.<sup>976</sup> Thus, whilst drawing on relevant case law from North America and analogous case law from the United Kingdom, the following sections of the thesis will explore the suitability of the law of torts under the main claims of negligence, public nuisance, trespass, private nuisance, and the rule in *Rylands v Fletcher*, for remedying economic damage suffered by farmers and farm businesses in the current coexistence paradigm for transgenic and non-transgenic plant agriculture.

### **5.1.5. Negligent Liability for Economic Harm.**

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<sup>972</sup> See Recommendation 2003/556/EC.

<sup>973</sup> *Id.*

<sup>974</sup> See Austria's 2004 Gene Technology Act; Monika Hinteregger and Elke Joeining, "Economic Loss Caused by GMOs in Austria," in Bernhard A. Koch, (editor), *Economic Loss Caused by Genetically Modified Organisms: Liability and Redress for the Adventitious Presence of GMOs in Non-GM Crops*, *supra*, note 103, at 19-20.

<sup>975</sup> See Genetically Modified Organisms Bill, HC Bill 31, Session 2003-4, at <http://www.publications.parliament.uk/pa/cm200304/cmbills/031/2004031.pdf> (accessed on 14 May 2015).

<sup>976</sup> See DEFRA, Consultation on proposals for managing the coexistence of GM, conventional and organic crops, (2006), at <http://www.defra.gov.uk/environment/gm/crops/pdf/gmcoexist-condoc.pdf>. DEFRA did not believe that litigation was the best way for aggrieved parties to seek remedies. See section 161 of Report.

In a cause of action for negligence under the English common law, the plaintiff must establish that there is a duty of care; that the defendant breached the duty of care by failing to adhere to a standard of reasonable care; whilst carrying out any acts that could foreseeably harm the plaintiff, and that the plaintiff consequently suffered proximate loss.<sup>977</sup> In order to establish the existence of a duty of care, the plaintiff must satisfy the following threefold test laid down by the House of Lords in *Caparo Industries plc v. Dickman*.<sup>978</sup> First, that harm must be reasonably foreseeable; second, that the parties must be in relationship of proximity; and third, that imposition of liability must be fair, just and reasonable in the circumstances.<sup>979</sup> Whilst there is no need to resort to the three tests for guidance in situations where the duty of care is relatively standard or well-established,<sup>980</sup> it might be necessary to do so within the context of the relationship of potential parties to a cause of action in negligence for economic damage stemming from adventitious admixture of transgenic and non-transgenic plant organisms, mainly because of the novelty of the issues involved; and the fact that the parameter of the duty of care, if any, and to whom the duty of care is owed is not yet well-settled at common law in cases involving disputes relating to transgenic plant agriculture.<sup>981</sup>

#### **5.1.6. Establishing Negligence for Economic Loss.**

As previously noted, the first task of the plaintiff in a cause of action for negligence is to establish duty of care that is owed to him/her by the defendant.<sup>982</sup> However, according to Lord

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<sup>977</sup> See Ken Oliphant, "Economic Loss Caused by GMOs in the United Kingdom: England & Wales," in Bernhard A. Koch, (editor), *Economic Loss Caused by Genetically Modified Organisms: Liability and Redress for the Adventitious Presence of GMOs in Non-GM Crops*, *supra*, note 103, at 515.

<sup>978</sup> See *Caparo Industries plc v. Dickman*, [1990] AC 605.

<sup>979</sup> *Id.*, at 608.

<sup>980</sup> In *Customs and Excise Commissioners v. Barclays Bank plc*, [2006] 3 WLR 1, at 53, Lord Rodger held *inter alia* that "a court faced with a novel situation must apply the threefold test".

<sup>981</sup> See Maria Lee and Robert Burrell, "Liability for the Escape of GM Seeds: Pursuing the 'Victim'?" *The Modern Law Review*, *supra*, note 18, at 529.

<sup>982</sup> See *Caparo Industries plc v. Dickman*, *supra*, note 107, at 605.

Roger in *Customs and Excise Commissioners v. Barclays Bank plc*,<sup>983</sup> in novel circumstances where the duty of care is neither standard nor in established category, the court must apply the threefold test laid down by the House of Lords in *Caparo Industries plc v. Dickman*.<sup>984</sup>

With regards to economic loss induced by existential conflicts in the coexistence paradigm such as those that stem from the loss of premium market for organic or conventional crops, patents infringements and threats of patents infringements as discussed in sections 5.1.1; 5.1.2; 5.1.3; and 5.1.4 of the thesis, the pertinent questions are whether transgenic crop farmers or seed companies owe a duty of care to organic or conventional crop farmers to prevent adventitious presence of transgenes in their crops in order to ensure crop purity, and thereby guarantee their domestic and foreign markets, or whether neighbouring transgenic crop farmers and seed companies owe a duty of care to organic and conventional crop farmers for the associated costs of inspecting their farms for the presence of transgenes in order to avoid patent infringement litigation, or whether transgenic crop farmers or seed companies owe a duty of care to farm businesses to prevent the proliferation of transgenic crops, and the concomitant loss of market for organic or conventional crops?

In the absence of clear and direct judicial precedents in the UK, the above questions would appear to be a novel one, and as such, might not easily fit into standard or established category of duty of care.<sup>985</sup> Therefore, courts faced with such a question in the United Kingdom or other common law jurisdictions, might be inclined to apply the threefold test of reasonable foreseeability of harm or damage; relational proximity sufficient to establish a *prima facie* duty

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<sup>983</sup> See *Customs and Excise Commissioners v. Barclays Bank plc*, *supra*, note 109, at 53. (Lord Roger noted that *inter alia* that “a court faced with a novel situation must apply the threefold test.”)

<sup>984</sup> *Id.*

<sup>985</sup> See Ken Oliphant, “Economic Loss Caused by GMOs in the United Kingdom: England & Wales,” in Bernhard A. Koch, (editor), *Economic Loss Caused by Genetically Modified Organisms: Liability and Redress for the Adventitious Presence of GMOs in Non-GM Crops*, *supra*, note 103, at 515.



of care; and the fairness, justness, and reasonableness of imposing a duty of care in the circumstances.<sup>986</sup>

The Canadian Saskatchewan Court of Queen’s Bench was faced with such a novel claim in *Larry Hoffman; L.B. Hoffman Farms Inc., and Dale Beaudoin v. Monsanto Canada Inc., and Bayer Cropscience Inc.*,<sup>987</sup> in which a group of individual organic farmers sued the respondents: Monsanto Canada Inc and Bayer Cropscience for economic damage that stemmed from adventitious presence of transgenic canola in organic crops and fields, and the consequential loss of domestic and European Organic markets, due to loss of their organic canola status.<sup>988</sup> The respondents: Monsanto Canada and Bayer Cropscience were engaged in the distribution of fertilizers, pesticides, herbicides and marketing of herbicide-resistant transgenic canola, and “a variety of oilseed grown in Western Canada and North America.”<sup>989</sup> Monsanto’s transgenic “Roundup Ready” canola was genetically modified to resist glyphosate herbicides made and sold by *Monsanto* with the transgenic canola farmers.<sup>990</sup> *Bayer Cropscience* also sold their “Liberty Link” canola, which had been genetically modified to resist glufosinate ammonium-based herbicides made by the company and sold together to transgenic canola farmers.<sup>991</sup>

In their Statement of Claim, the plaintiffs alleged that they and other organic grain farmers had suffered financial losses due to the introduction and commercial use of Roundup Ready and Liberty Link transgenic canola.<sup>992</sup> In particular, they alleged that strains from respondents’ transgenic canola had inadvertently mixed-up with their organic canola via cross-pollination process, thus hindering their ability to produce and market organic canola, and forcing them to

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<sup>986</sup> See *Caparo Industries plc v. Dickman*, *supra*, note 107, at 605.

<sup>987</sup> See *Larry Hoffman; L.B. Hoffman Farms Inc., and Dale Beaudoin v. Monsanto Canada Inc., and Bayer Cropscience Inc.*, *supra*, note 19, at paragraphs 19-20.

<sup>988</sup> *Id.*

<sup>989</sup> *Id.*, at paragraph 4.

<sup>990</sup> *Id.*, at paragraph 6.

<sup>991</sup> *Id.*, at paragraph 5.

<sup>992</sup> *Id.*, at paragraph 19.

grow other types of organic crop.<sup>993</sup> The appellants' Statement of Claim further alleged that organic farmers, who were not into canola farming, were hindered from growing their organic crops by the appearance of the defendants' volunteer Roundup and Liberty transgenic canola on their farmland.<sup>994</sup> The plaintiffs also claimed damages for the costs of cleaning-up of farmlands riddled with volunteer transgenic canola crop, and the economic loss sustained in the loss of European market for their organic canola.<sup>995</sup> The plaintiffs further claimed that Monsanto Canada and Bayer Cropscience were both liable for the losses they suffered on grounds of negligence, nuisance, and trespass.<sup>996</sup>

### **5.1.7. Particulars of Duties of Care.**

The plaintiffs in *Larry Hoffmann* alleged that the defendants owed them two different duties of care, which were particularised as follows:

A duty to ensure that GM canola would not infiltrate and contaminate farmland where it was not intended to be grown, or at least the defendants 'ought to have warned growers purchasing their products of cross-pollination, and advised them of farming practices designed to limit the spread of the gene';<sup>997</sup> ... and a duty not to negligently undertake the development of export rules to ensure continued access to foreign markets, and to maintain an adequate IPP 'to preserve the European canola export market where most of the organic canola produced in Canada was sold.'<sup>998</sup>

The plaintiffs claimed that due to the defendants' breach of the aforesaid duties of care, they suffered loss of revenues caused by "(a) a loss of canola as a crop to be used within their regular rotations; (b) loss of opportunity to participate in the certified organic canola market; (c) past

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<sup>993</sup> Id.

<sup>994</sup> Id, at paragraph 20.

<sup>995</sup> Id, at paragraph 21.

<sup>996</sup> The plaintiffs also claimed that Roundup Ready and Liberty Link canola varieties constituted a "pollutant" within the meaning of The Environmental Management Protection Act, and that each of the canola varieties was "discharged" into the environment in contravention of the provisions of The Environmental Management Protection Act. See id, at paragraph 21. However, this aspect of the claim will not be discussed in paragraph 7.2.3, which deals primarily with the negligence part of the plaintiffs' statement of claim.

<sup>997</sup> See paragraph 34 of the 'Amended, Amended Statement of Claim' filed in the Saskatchewan Court of Queen's Bench in case number 67 of 2002, Saskatchewan Organic Directorate – Organic Agriculture Protection Fund, at <http://www.saskorganic.com/oapf/pdf/amended-claim.pdf>

<sup>998</sup> See *Larry Hoffman; L.B. Hoffman Farms Inc., and Dale Beaudoin v. Monsanto Canada Inc., and Bayer Cropscience Inc.*, *supra*, note 19, at paragraph 38.

and future clean-up costs caused by Roundup Ready or Liberty Link canola volunteers growing on the fields of organic farmers...”<sup>999</sup>

In light of the concession by the plaintiffs that the alleged duties of care were novel, Justice Smith had to consider whether the plaintiffs’ Statement of Claim disclosed “reasonably foreseeable harm and relational proximity sufficient to establish a *prima facie* duty of care.”<sup>1000</sup> The trial judge found that the plaintiffs’ Statement of Claim sufficiently supported the allegations that the adventitious presence of transgenic canola as volunteer crop on organic farmland, where it was not intended to be grown, was reasonably foreseeable.<sup>1001</sup> However, the judge was less certain that the plaintiffs’ Statement of Claim supported the allegation that the loss and damage claimed by the plaintiffs was foreseeable.<sup>1002</sup>

The judge’s uncertainty was predicated on the fact that organic standards at the time the defendants introduced transgenic canola did not prohibit the use of genetically modified organisms in organic agriculture.<sup>1003</sup> Nevertheless, the judge was inclined to find that the plaintiffs’ pleadings were sufficient to support their claim that adventitious presence of defendants’ transgenic canola on plaintiffs’ organic farmland was reasonably foreseeable, or that the Statement of Claim could be amended to do so.<sup>1004</sup>

However, and most importantly, the judge found that the plaintiffs’ pleadings did not support the required relational proximity to establish a *prima facie* duty of care.<sup>1005</sup> Additionally, the judge invoked the following two policy considerations to bar the imposition of the alleged duties of care on the defendants: First, that imposing a duty of care barring

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<sup>999</sup> See paragraph 44 of the Statement of Claim. *Id.*, at paragraph 36.

<sup>1000</sup> *Id.*, at paragraph 54. The tests employed by Justice Smith was generally analogous to those espoused by the U.K House of Lords in *Caparo Industries plc v. Dickman*, *supra*, note 109, at 605.

<sup>1001</sup> See *Larry Hoffman*; *L.B. Hoffman Farms Inc.*, and *Dale Beaudoin v. Monsanto Canada Inc.*, and *Bayer Cropscience Inc.*, *supra*, note 19, at paragraph 63.

<sup>1002</sup> *Id.*, at paragraphs 64-65.

<sup>1003</sup> The plaintiffs did not file their lawsuit until some 5 years after the introduction of transgenic canola by the defendants. *A fortiori*, the alleged damage or loss could not have been reasonably foreseeable. See *id.* at paragraphs 64-65.

<sup>1004</sup> *Id.*, at paragraph 66.

<sup>1005</sup> *Id.*, at paragraph 67.

defendants from unconfined release of transgenic canola into the environment, would in the circumstances, “conflict with express governmental policy” that approved unconfined release of defendants’ transgenic canola into the environment.<sup>1006</sup> In the words of the trial court:

The fact each of the defendants, after years of Canadian field testing, obtained the approval of the Government of Canada to the unconfined release of their varieties of genetically modified canola provides a powerful policy reason for not fastening on them the duty of care as pleaded. As a matter of law, this approval entailed compliance with a federal statutory scheme...<sup>1007</sup>

In the second policy consideration, the judge characterised the plaintiffs’ claim as one for a pure economic loss, because “...the alleged damage is not of physical harm to the plaintiffs’ crops, but arises from alleged inability to meet the requirements of organic certifiers or of foreign markets for organic canola.”<sup>1008</sup> Although the judgment of Justice Smith was upheld on appeal,<sup>1009</sup> the judge’s characterisation of the plaintiffs’ claim as that of a pure economic loss, rather than that in which the plaintiffs sustained physical damage to their organic crops (property), has been criticised by scholars.<sup>1010</sup>

For example, Ken Oliphant, while admitting that not every change in property would warrant the finding of damage,<sup>1011</sup> did wonder why justice Smith did not characterise an unwanted presence of transgenic canola traits in the plaintiffs’ organic canola as physical damage for which the plaintiffs’ loss was consequential, rather than one of pure economic loss?<sup>1012</sup> It would appear that the judge had no choice other than to do so, because the characterisation ostensibly complimented the other policy consideration that there could be no

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<sup>1006</sup> Id, at paragraph 71.

<sup>1007</sup> Id, at paragraph 71.

<sup>1008</sup> Id, at paragraph 72.

<sup>1009</sup> See *Larry Hoffman; L.B. Hoffman Farms Inc., v. Monsanto Canada Inc., and Bayer Cropscience Inc.*, [2007] Saskatchewan Court of Appeal, (SKCA), 47.

<sup>1010</sup> For discussion, see Ken Oliphant, “Economic Loss Caused by GMOs in the United Kingdom: England & Wales,” in Bernhard A. Koch, (editor), *Economic Loss Caused by Genetically Modified Organisms: Liability and Redress for the Adventitious Presence of GMOs in Non-GM Crops*, *supra*, note 103, at 516.

<sup>1011</sup> For the proposition that not every change to property would warrant a conclusion of damage, Ken Oliphant referenced the House of Lords decision in *Rothwell v. Chemical & Insulating Co Ltd* [2007] UKHL 39, [2008] 7 AC 281. See *id*, at 516.

<sup>1012</sup> *Id*, at 516.

imposition of a duty of care on the defendants for unconfined release of transgenic canola into the environment, because the release was dully approved by the government of Canada, approximately five years before the plaintiffs filed their lawsuit.

Perhaps the plaintiffs in *Hoffman et al., v. Monsanto et al.*, should have challenged the approval process for the transgenic canola, if they felt that the administrative process failed to fully consider environmental risks assessments by identifying adventitious presence of transgenic canola traits in organic crops via cross-pollination and volunteer transgenic canola crops? This was precisely what the plaintiffs did in *Ohana Pale Ke Ao; Kohanaiki Ohana; GMO-Free Hawai`i, and Sierra Club, Hawai`i Chapter, v. Board of Agriculture, State of Hawaii*.<sup>1013</sup> The Intermediate Court of Appeals of Hawaii affirmed the summary judgment of the Circuit Court of 6 March 2006, and found that full environmental impact assessment had not been carried out, prior to the mass introduction of transgenic strains of biopharmaceutical algae into the environment.<sup>1014</sup>

Similarly, in England, United Kingdom, Guy Watson unsuccessfully sought a judicial review of the approval process for experimental field testing of transgenic maize on land adjoining his organic maize farmland in Devon, in *R v. Secretary of State for the Environment and MAFF ex parte Watson*.<sup>1015</sup> *Guy Watson* was one of the United Kingdom's leading producers of organic fruits and vegetables, who was advised by the United Kingdom Soil Association, the organisation responsible for the certification of organic produce, that he could lose his organic status if the experimental transgenic maize trial went ahead, in light of evidence that there was a real risk of cross-pollination between his organic sweetcorn maize and the experimental transgenic maize.<sup>1016</sup>

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<sup>1013</sup> See *Ohana Pale Ke Ao; Kohanaiki Ohana; GMO-Free Hawai`i, and Sierra Club, Hawai`i Chapter, v. Board of Agriculture, State of Hawaii*, Intermediate Court of Appeals of Hawaii, 188P 3d 761(2008).

<sup>1014</sup> *Id.*, at 761-773.

<sup>1015</sup> See *R v. Secretary of State for the Environment and MAFF ex parte Watson*, [1999] Environmental Law Report, 310.

<sup>1016</sup> *Id.*, at 311.

The action was predicated on the following three grounds: First, that the Secretary of State had acted illegally in approving the experimental trialling of the transgenic maize without full risks assessments of the potential risks of cross-pollination between the organic sweetcorn maize and transgenic maize.<sup>1017</sup> However, the Court rejected this argument, and ruled that *Guy Watson* would have to wait for damage to occur to his organic sweetcorn maize before he could sue for damages in a cause of action for private nuisance.<sup>1018</sup> In other words, *Guy Watson*'s claim was premature. The second ground of the claim contended that whilst the approval for the experimental trialling of the transgenic maize was granted to *Sharpes*, the seed company which developed the transgenic maize, the actual trial was carried out by the National Institute of Botany in conjunction with the Ministry of Agriculture, Fisheries and Food.<sup>1019</sup> Consequently, the bodies carrying out the transgenic maize trial had no valid approval to release transgenic organisms into the environment, and thereby violated the provisions of EU Directive on Deliberate Release of transgenic organisms and the UK law implementing the Directive.<sup>1020</sup>

However, the Court rejected this argument, and ruled that the 1990 Environmental Protection Act did not specifically require that the party to whom approval to release transgenic organisms was granted must carry out the experimental trial, and that consent to release had not been breached.<sup>1021</sup> The third ground of the claim alleged that the transgenic maize trial had violated the provisions of the 1982 Seeds Regulations, in that the Ministry of Agriculture required the results of two replicated trials prior to considering applications for seed listings.<sup>1022</sup> Although the administrative overreach was conceded by the Ministry of Agriculture, Fisheries and Food, and the Court of Appeal berated the Minister for violating clear provisions of the

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<sup>1017</sup> *Id.*, at 315.

<sup>1018</sup> *Id.*, at 322.

<sup>1019</sup> *Id.*

<sup>1020</sup> *Id.*

<sup>1021</sup> *Id.*

<sup>1022</sup> *Id.*

Seeds Regulation, nevertheless, the Court of Appeal held that the breach was no sufficient ground to order the cessation of the experimental transgenic maize trial.<sup>1023</sup> Thus, even a judicial review challenge to clear violations of administrative procedures could fail on grounds of policy, which was arguably the case in *R v. Secretary of State for the Environment and MAFF ex parte Watson*.<sup>1024</sup> Thus, it is conceivable that the plaintiffs in *Hoffman et al* might not necessarily succeed had they sought a judicial review of the authorisation of transgenic canola by the Canadian government, if the Court ruled that the authorisation was justifiable by public policy.

Significantly, whilst *Hoffman et al., v. Monsanto et al.*, highlights the challenges faced by prospective claimants in similar circumstances in establishing a duty of care in a cause of action for negligence, it does not by any means, constitute a good law for the general proposition that claimants in common law countries in analogous situations as the plaintiffs', and others discussed earlier in sections 5.1.1; 5.1.2; 5.1.3 of the thesis, cannot succeed in a cause of action for negligence. Therefore, each case must be treated on its merit and within the context of the peculiarity of the underlying facts and juridical inclinations.

For example, *In re StarLink Corn Products Liability Litigation*,<sup>1025</sup> the plaintiffs, who were corn farmers, sued the defendant, *Aventis Cropscience USA Holdings, Inc.*, for negligence, strict liability-failure to warn, and conversion, on grounds that defendant's transgenic corn, which was not approved for human consumption, 'contaminated' plaintiffs' corn supply, depressed corn prices, and increased the general costs of farming.<sup>1026</sup> The defendant marketed their transgenic corn as StarLink corn, which was genetically modified to produce "Cry9C" protein, a variant insecticidal property in *Bacillus thuringiensis* bacterium that was not

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<sup>1023</sup> *Id.*

<sup>1024</sup> *Id.*

<sup>1025</sup> See *In re StarLink Corn Products Liability Litigation*, 121F. Supp.2d 828 (N.D. III. 2002).

<sup>1026</sup> *Id.*, at 829.

approved for human consumption due to human allergens concerns.<sup>1027</sup> It was therefore imperative to separate StarLink corn from corn meant for human consumption.<sup>1028</sup> In order to ensure an effective separation regime from production to marketing stages, the United States Environmental Protection Agency mandated segregated methods, which included a 660-foot buffer zone around StarLink corn crops to prevent cross-pollination; and labelling on StarLink corn packages.<sup>1029</sup> StarLink corn was distributed between May 1998 and October 2000 across the United States.<sup>1030</sup> In October 2000, several food manufacturers in the United States issued corn products recall, following numerous reports of the presence of Cry9C protein in human food supply.<sup>1031</sup>

In their statement of claim, the plaintiffs alleged that the ‘contamination’ occurred because the defendant, “Aventis did not include the EPA-mandated label on some StarLink packages; did not notify, instruct and remind StarLink farmers of the restrictions on StarLink use, proper segregation methods and buffer zone requirements; and did not require StarLink farmers to sign the obligatory contracts.”<sup>1032</sup> The plaintiffs further alleged that prior to the 2000 growing season, *Aventis* “instructed its seed representatives that it was unnecessary for them to advise StarLink farmers to segregate their StarLink crop or create buffer zones because Aventis believed the EPA would amend the registration to permit StarLink use for human consumption.”<sup>1033</sup>

The District Court rejected the defendants' argument that plaintiff's case was pre-empted by FIFRA, a federal law which prohibited state laws that required additional packaging and labelling requirements, but did not prohibit state laws containing identical requirements.<sup>1034</sup>

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<sup>1027</sup> The U.S. Environmental Protection Agency (EPA) did not approve StarLink corn for human consumption, due to the pesticidal properties in its Cry9C protein. See *id.*, at 834.

<sup>1028</sup> *Id.*, at 833-834.

<sup>1029</sup> *Id.*, at 834.

<sup>1030</sup> *Id.*

<sup>1031</sup> *Id.*, at 835.

<sup>1032</sup> *Id.*

<sup>1033</sup> *Id.*

<sup>1034</sup> *Id.*, at 836.



Most importantly, the defendant argued that plaintiffs' claim for damages were purely economic in nature, and therefore barred by the Economic Loss Doctrine, which would only allow for physical or property injuries; whilst denying purely economic injuries.<sup>1035</sup>

However, the District Court rejected defendants' argument, and held that to the “extent plaintiffs allege[d] that their crops were themselves contaminated, either by cross-pollination in the fields or by commingling later in the distribution chain, they ha[d] adequately stated a claim for harm to property.”<sup>1036</sup> With regards to the plaintiffs' claim for negligence, the defendant contended that there was no duty of care; that there was no proximate cause; and that the plaintiffs were not entitled to damages.<sup>1037</sup> The defendant further argued that “any effect StarLink may have had on corn markets [was] too far removed from defendants' conduct.”<sup>1038</sup> However, the District Court rejected defendant's argument and held inter alia that “Aventis had a duty to ensure that StarLink did not enter the human food supply, and their failure to do so caused plaintiffs' corn to be contaminated.”<sup>1039</sup>

Notably, with regards to plaintiffs' claim for negligence, the United States District Court found that the defendant owed plaintiffs a duty of care; that there was a proximate cause; and that the ensuing harm and concomitant claim for damages was not purely economic in nature, because the plaintiffs' corn (property) was harmed or damaged by reason of ‘contamination’ by StarLink corn via “cross-pollination in the fields or by commingling later in the distribution chain.”<sup>1040</sup> Notably, this judgment is in contradistinction to the decision in *Hoffman Case*, in which the trial Court upheld a summary judgment application for dismissal on grounds inter alia that plaintiffs' claim was for pure economic loss.<sup>1041</sup>

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<sup>1035</sup> Id, at 842.

<sup>1036</sup> Id, at 842-843.

<sup>1037</sup> Id, at 843.

<sup>1038</sup> Id.

<sup>1039</sup> Id.

<sup>1040</sup> Id, at 842-843.

<sup>1041</sup> See *Larry Hoffman; L.B. Hoffman Farms Inc., and Dale Beaudoin v. Monsanto Canada Inc., and Bayer Cropscience Inc.*, *supra*, note 19, at 225.

However, in the analogous United States case of *Frederick L. Sample, et al., v Monsanto Company et al.*,<sup>1042</sup> the United States District Court in Missouri summarily dismissed a class action lawsuit filed by *Frederick Sample* and *George Naylor* for themselves and as representatives of Missouri non-transgenic soybeans and corn crops farmers, claiming damages for negligence and public nuisance against Monsanto Corporation.<sup>1043</sup> The principal claim of plaintiffs was that they lost revenues in consequence of the rejection by the European Union markets, of transgenic seeds and boycott of all U.S corn and soybean.<sup>1044</sup> The District Court noted that it was never in dispute that plaintiffs did not suffer any ‘contamination’ or physical injury to their non-transgenic corn and soy crops, and consequently, “the economic loss doctrine precludes recovery for their nuisance as a matter of law.”<sup>1045</sup> With regards to plaintiffs’ claim for negligence, the District Court found that there was no evidence of physical injury to property, an inference drawn from court documents and the admission by plaintiffs’ counsel that there was no evidence of physical injury to property in the case.<sup>1046</sup> The District Court then held that plaintiffs’ claim for negligence must fail, in the circumstances because it was principally for alleged economic loss suffered by the closure of European corn and soybean markets, and that the claim must be barred by the economic loss doctrine.<sup>1047</sup>

Notably, the District Court ruling in *Frederick L. Sample, et al., v Monsanto Company* was similar to that of the Canadian Saskatchewan Court of Queen’s Bench in the analogous case of *Larry Hoffman; L.B. Hoffman Farms Inc., and Dale Beaudoin v. Monsanto Canada Inc., and Bayer Cropscience Inc.*,<sup>1048</sup> in which, as previously noted, Justice Smith found *inter alia* that

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<sup>1042</sup> See *Frederick L. Sample, et al., v Monsanto Company et al.*, 283 F. Supp. 2d 1088 (2003).

<sup>1043</sup> *Id.*, at 1091.

<sup>1044</sup> *Id.*, at 1093.

<sup>1045</sup> *Id.*

<sup>1046</sup> *Id.*

<sup>1047</sup> *Id.*, at 1093-1094.

<sup>1048</sup> See, *Larry Hoffman; L.B. Hoffman Farms Inc., and Dale Beaudoin v. Monsanto Canada Inc., and Bayer Cropscience Inc.*, *supra*, note 19, at 225.

the defendants had failed to establish a duty of care; and that their claim for negligence was purely economic in nature.<sup>1049</sup>

Whilst it is settled at common law that there is generally no duty of care to avoid inflicting purely economic loss on others,<sup>1050</sup> there is certainly an arguable case that plaintiffs' claim in *Hoffman case* was not purely economic, and that there was a modicum of physical damage to plaintiffs' organic crops, due to the adventitious presence of transgenic canola traits in plaintiffs' organic crops, and consequential loss of domestic and European market share.<sup>1051</sup> However, Justice Smith in *Hoffman Case* chose to emphasise and elevate policy considerations, to wit: that plaintiffs' claim was purely economic in nature, and that the government of Canada had approved unconfined dissemination of transgenic canola, while she largely glossed over the full effects of the inadvertent presence of transgenes in plaintiffs' organic crops, the presence of volunteer transgenic canola traits in fields designated for organic crops cultivation, and concomitant costs of clearing organic fields of volunteer canola crops.<sup>1052</sup> Thus, while the ruling in *Hoffman Case* was essentially similar to that in *Sample Case*, both rulings are in sharp contrast to that of the United States District Court in the *StarLink Case*.

Therefore, the contradictory judgments in the three largely analogous cases, albeit in different jurisdictions, on the point of whether or not there was physical damage to organic crops and conventional crops in order to negate the doctrine of pure economic loss, highlights the vagaries and limits of the tort of negligence as a putative instrument for remedying economic loss suffered by organic or conventional crops farmers or farm businesses in the coexistence paradigm. The major obstacles invariably would be whether a duty of care could

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<sup>1049</sup> Id, at paragraph 72.

<sup>1050</sup> See Ken Oliphant, "Economic Loss Caused by GMOs in the United Kingdom: England & Wales," in Bernhard A. Koch, (editor), *Economic Loss Caused by Genetically Modified Organisms: Liability and Redress for the Adventitious Presence of GMOs in Non-GM Crops*, *supra*, note 103, at 517, (citing the confirmation of the rule by the House of Lords in *Customs and Excise Commissioners v. Barclays Bank plc* [2006] 3 WLR 1).

<sup>1051</sup> See, *Larry Hoffman; L.B. Hoffman Farms Inc., and Dale Beaudoin v. Monsanto Canada Inc., and Bayer Cropscience Inc.*, *supra*, note 19, at 225.

<sup>1052</sup> See, *Larry Hoffman; L.B. Hoffman Farms Inc., and Dale Beaudoin v. Monsanto Canada Inc., and Bayer Cropscience Inc.*, *supra*, note 19, at paragraph 72.

be imposed in circumstances whereby approved transgenic crops were deliberately introduced into the environment? And whether the tort of negligence could exempt plaintiffs in similar circumstances from pure economic loss doctrine, because that is invariably what a farm business who is no longer able to trade in the coexistence paradigm has suffered. It is also what an organic farmer who has lost his/her premium organic market has suffered. Most importantly, it is a wrong that ought to have a legal remedy, and that cannot be left to the vagaries of the tort of negligence. In the circumstances, it is recommended that national authorities should formulate a sui generis compensatory regime that would cater to actual and potential economic losses exemplified in cases such as *Monsanto Canada Inc., v. Maurice Parr*,<sup>1053</sup> *Hoffman et al., v. Monsanto et al.*,<sup>1054</sup> and *R v. Secretary of State for the Environment and MAFF ex parte Watson*.<sup>1055</sup> This proposal is articulated in greater detail in Chapter Seven of the thesis.

#### **5.1.8. Establishing Causation in Negligence.**

The test for establishing causation in negligence is known as the “but-for” test, which posits that the defendant would only be liable for the alleged damage if it would not have occurred but for the defendant’s negligence. Conversely, the defendant would not be liable for negligence if the damage would or could on balance of probabilities, have occurred anyway regardless of the defendant’s negligence.<sup>1056</sup> However, the onus is on the plaintiff to establish that the breach of duty of care owed by defendant caused the alleged damage,<sup>1057</sup> or made a material contribution to the alleged damage,<sup>1058</sup> and that it was reasonably foreseeable at the

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<sup>1053</sup> See *Monsanto Technology L.L.C. v. Maurice Parr*, *supra*, note 46, at 545.

<sup>1054</sup> See, *Larry Hoffman; L.B. Hoffman Farms Inc., and Dale Beaudoin v. Monsanto Canada Inc., and Bayer Cropscience Inc.*, *supra*, note 19, at 225.

<sup>1055</sup> See *R v. Secretary of State for the Environment and MAFF ex parte Watson*, *supra*, note 160, at 310.

<sup>1056</sup> See *Wilsher v Essex Area Health Authority* [1988] AC 1074.

<sup>1057</sup> See *Bonnington Castings Ltd v Wardlaw* [1956] AC 613.

<sup>1058</sup> See *Fairchild v Glenhaven Funeral Services Ltd* [2003] 1 AC 32. See also Ken Oliphant, “Economic Loss Caused by GMOs in the United Kingdom: England & Wales,” in Bernhard A. Koch (editor), *Economic Loss Caused by Genetically Modified Organisms: Liability and Redress for the Adventitious Presence of GMOs in Non-GM Crops*, *supra*, note 103, at 521.

relevant time that the defendant's action or inaction would cause the said loss or damage.<sup>1059</sup> Therefore, on balance of probability and preponderance of credible evidence, the plaintiff must establish that but for the tortious actions or inactions of the defendant, the damage would never have occurred.<sup>1060</sup> Thus, duty of care, remoteness, and causation are integral elements of the tort of negligence, and courts in the United Kingdom do routinely draw on policy considerations to maintain a balance between these tests whilst weighing and evaluating relevant evidence. The central role of policy in the judicial weighting of relevant evidence relating to duty of care, proximity and causation, is succinctly put by Lord Denning thus: "The truth is that all these three – duty, remoteness and causation – are all devices by which the courts limit the range of liability for negligence . . . All these devices are useful in their way. But ultimately it is a question of policy for the judges to decide."<sup>1061</sup>

In the context of the coexistence of transgenic and non-transgenic plant agriculture, the plaintiff could prove causation by proffering evidence that link the alleged tortious activities of the defendant to the alleged economic, property, and environmental damage or personal injury. For example, an organic maize farmer suing for damage to crop allegedly caused by transgenes from neighbouring transgenic maize farm, must prove that the said transgenes emanated from the neighbouring transgenic maize farm. The organic farmer must do this by presenting evidence of the presence of transgenes in his/her crops through DNA analysis. The organic farmer must also prove that transgenes' presence in his crop exceeds the maximum 0.9 percent maximum labelling threshold that would render the organic crop transgenic and thereby constitute possible damage. In the circumstances, the supporting evidence is necessarily scientific in nature, and the onus of proof could be very difficult to discharge due to the absence of "generally accepted standard of scientific proof".<sup>1062</sup>

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<sup>1059</sup> See *Lamb v Camden LBC* (1981) QB 625.

<sup>1060</sup> See *Overseas Tankship (UK) Ltd v. Morts Dock & Engineering Co Ltd, The Wagon Mound* [1961] AC 388.

<sup>1061</sup> *Id.*, at 625.

<sup>1062</sup> See *Susan Loveday v. Renton & Wellcome Foundation Ltd*, [1990] 1 *Medical Law Report*, at 11.

This challenge is exemplified by *Susan Loveday v. Renton & Wellcome Foundation Ltd*,<sup>1063</sup> in which the plaintiff, Susan Loveday, was one of several children who suffered permanent brain damage following pertussis vaccination. A key preliminary issue for determination was whether “pertussis vaccine used in the United Kingdom and administered intramuscularly in normal dosage could cause permanent brain damage or death in young children? The plaintiff relied on clinical case reports and widely-held belief that the vaccine could, albeit rarely, cause permanent brain damage in vulnerable children.<sup>1064</sup> The plaintiff argued further that a doctor who vaccinated in breach of contraindications (guidelines issued to doctors on vaccination procedures) was negligent and would be liable for any resulting brain damage. The plaintiff also submitted that the court was only concerned to ascertain the preponderance or confluence of medical opinion, and not to decide whether that opinion was well-founded.<sup>1065</sup> The defendant argued that whilst it was possible for pertussis vaccine to cause permanent brain damage in vulnerable children, the plaintiff had failed to establish her case. Whilst drawing on the *Bolam* test, Lord Justice Stuart-Smith dismissed the defendant’s arguments, and held *inter alia* that “if a doctor acted in accordance with the practice and opinion of a respectable and responsible body of medical opinion, he was not guilty of negligence, even if another respectable and responsible body of medical opinion held different views; such a test could not, therefore, apply to the issue of causation.”<sup>1066</sup>

However, where the alleged damage was caused by combined transgenes from multiple transgenic maize farms in the neighbourhood, the plaintiff must link the alleged damage to the multiple sources, and prove that each of the transgenic maize farms made material contribution to the alleged damage. In the circumstances, damages would be awarded on the basis of defendants’ proportional contribution to the claimed injury, without the plaintiff having to

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<sup>1063</sup> *Id.*, at 11.

<sup>1064</sup> *Id.*

<sup>1065</sup> *Id.*

<sup>1066</sup> *Id.*

prove that the alleged damage would not have occurred but for the individual contribution of the defendants who owned the transgenic maize farms.<sup>1067</sup>

Notably, where there is a dispute as to the source of transgenes that caused the alleged damage in circumstances where there are multiple transgenic maize farms in the vicinity of the organic maize farm, then the plaintiff is obliged to prove each of the defendants' contribution to the claimed damage on balance of probabilities and relevant credible evidence.<sup>1068</sup> However, in certain circumstances, it might be sufficient if the plaintiff could prove that any of the defendants materially contributed to the claimed damage, even if it could not be shown on balance of probabilities that any of the defendants actually contributed to the claimed damage.<sup>1069</sup> This exception would still apply even if the plaintiff's action partly contributed to the alleged damage,<sup>1070</sup> but the plaintiff must prove that the source of transgenes that caused the alleged damage was at least under defendants' control.<sup>1071</sup>

This proposition is exemplified by *Fairchild v. Glenhaven Funeral Services Ltd*. Mr Fairchild, a subcontractor for Leeds City Council, had worked for different employers who had exposed him to asbestos, as a result of which he contracted pleural mesothelioma, and subsequently died. His wife sued his employers for negligence. It was not disputed that the inhalation of a single asbestos fibre could cause mesothelioma. It was also not disputed that increase in the risk of contracting mesothelioma and other asbestos-related diseases was relative to the number of exposures to asbestos. However, due to the long gestation or latency periods of between 25 to 50 years, it was impossible to determine the exact time when Mr Fairchild contracted the disease and which of the several employers he had worked for was responsible for the exposure. In the circumstances, the House of Lords held that the appropriate

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<sup>1067</sup> See *Bonnington Castings Ltd v. Wardlaw*, *supra*, note 203, at 613.

<sup>1068</sup> See *Wilsher v. Essex Area Health Authority* [1988] AC 1074.

<sup>1069</sup> See *Fairchild v. Glenhaven Funeral Services Ltd* [2003] 1 AC 32.

<sup>1070</sup> See *Barker v. Corus UK Ltd* [2006] 2 WLR 1027.

<sup>1071</sup> See *McGhee v. National Coal Board* [1973] 1 WLR 1.

test of causation was whether the employers had materially increased the risk of harm to the plaintiff, and that it was not possible to use the “balance of probabilities” or “but for” tests. Consequently, the House of Lords found that employers were jointly and severally liable for the illness of Mr Fairchild.<sup>1072</sup>

However, if one of the several defendants responsible for adventitious release of the transgenes that materially increased the risk of harm or damage to plaintiff’s organic maize farm had become insolvent at the time of claim, it would seem that the solvent defendant would not be obliged to compensate plaintiff for the proportion of damage caused by the insolvent defendant. This proposition was laid out in *Barker v. Corus UK Ltd*, in which plaintiffs contracted mesothelioma after working for several employers, all of whom negligently exposed plaintiffs to asbestos.<sup>1073</sup> However, due to the long gestation period of the disease, it was impossible to ascertain which of the employers actual caused the disease, although all employers apparently contributed to the risk of the occurrence of the disease. The main issue for determination was whether solvent employers should be responsible for the proportion of the damage for which the insolvent employers were liable? The House of Lords slightly departed from its earlier decision in *Fairchild*, and held that although all employers were jointly and severally liable for the damage, solvent employers were not obliged to compensate plaintiffs for the proportion of the damage caused by the insolvent employer. The concept of proportional liability was succinctly put by Lord Hoffman as follows:

In my opinion, the attribution of liability according to the relative degree of contribution to the chance of the disease being contracted would smooth the roughness of the justice which a rule of joint and several liability creates. The defendant was a wrongdoer, it is true, and should not be allowed to escape liability altogether, but he should not be liable for more than the damage which he caused and, since this is a case in which science can deal only in probabilities, the law should accept that position and attribute liability according to probabilities. The justification for the joint and several liability rule is that if you caused harm, there is no reason why your liability should be reduced because someone else also caused the same harm. But when liability is

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<sup>1072</sup> *Id.*

<sup>1073</sup> See *Barker v. Corus UK Ltd*, *supra*, note 1070, at 1033.



exceptionally imposed because you may have caused harm, the same considerations do not apply and fairness suggests that if more than one person may have been responsible, liability should be divided according to the probability that one or other caused the harm.<sup>1074</sup>

The House of Lords' judgment came under considerable criticisms, and was subsequently reversed by Parliament via section 3 of the Compensation Act 2006, which specifically deals with Mesothelioma damages, and which provides *inter alia* that the person responsible for exposing another person to asbestos shall be liable "jointly and severally with another responsible person".<sup>1075</sup>

The pertinent question therefore is: what is the relevance of section 3 of the Compensation Act 2006 to damage caused by adventitious transgenes as a result of the negligent act of several defendants? Arguably, section 3 of the Compensation Act 2006 would not apply, as it is specific to Mesothelioma illness induced by asbestos exposure. Therefore, the decision of the House of Lords on proportional liability in *Barker v. Corus UK Ltd* would apply to multiple defendants, and plaintiffs might not be able to claim damages from insolvent defendants, even though the defendants were jointly and severally liable for exposing plaintiff's crops to adventitious transgenes. This again underscores the limits of the tort of negligence for remedying damage induced by adventitious transgenes in the coexistence of transgenic and non-transgenic plant agriculture.

#### **5.1.9. The Limits of the Tort of Negligence for Environmental Damage.**

The coexistence of transgenic and non-transgenic plant agriculture paradigm also raises the prospects of adventitious escape of transgenic organisms into the environment, and possible damage to the environment and non-transgenic plant organisms. Notably, plants scientists are

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<sup>1074</sup> *Id.*

<sup>1075</sup> See section 3(2) (b). See generally section 3(1) (2) (3) (4) & (5) of the Compensation Act, 2006.

unanimous on the inevitability of gene flow between plants species,<sup>1076</sup> and even transgenic seed firms are keenly aware of the natural propensity of transgenes to escape into the environment, and do routinely employ standard terms in seed technology contracts to disclaim and exclude legal liability for the consequences of such escape.<sup>1077</sup> The full ramifications for the environment, of gene flow, super weeds, and adverse effects of *Bacillus thuringiensis* on non-target organisms have been analysed extensively in section 4.1.9 of the thesis, and will not be repeated here.

Although the tort of negligence is essentially a compensatory tool, which has been described as “a responsibility-based mechanism for repairing harm,”<sup>1078</sup> it is inherently limited as a cause of action for damage to the environment in the coexistence paradigm, because tort is essentially a private cause of action, it is inherently limited as a compensatory tool for environmental harm both by the Courts’ unwillingness to radically expand “traditional causes of action”, and the rise cum increasing dominance of statutory interventions in traditional domains of torts law.<sup>1079</sup>

### **5.2.0. Categories of Possible Physical Damage to Property.**

In the context of the coexistence of transgenic and non-transgenic plant agriculture, an organic farmer or conventional farmer may have a cause of action in negligence if they suffered physical injury to property, due to adventitious presence of transgenic organisms on their

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<sup>1076</sup> See Carol Mallory-Smith and Maria Zapiola, “Gene flow from glyphosate-resistant crops,” *Pest Management Science*, *supra*, note 15, at 428-440, (noting that gene flow is a natural phenomenon, and that gene flow from transgenic glyphosate-resistant crops can result in the adventitious presence of the transgenes in the seed lots of canola, corn and soybeans).

<sup>1077</sup> For example, Monsanto’s seed contracts with transgenic farmers carry a standard term that acknowledges that seed movements and escape of transgenes into the environment is “well known and is normal occurrence”, for which Monsanto would not be liable. See The Centre for Food Safety and Save Our Seeds, *Seed Giant vs. U.S. Farmers*, *supra*, note 41, at 7.

<sup>1078</sup> See Mark Stallworthy, “Environmental Liability and the Impact of Statutory Authority,” *Journal of Environmental Law*, Volume 15, No. 1, (2003), at 4-5.

<sup>1079</sup> *Id.*, at 5. See also Robert G Lee, “From the Individual to the Environmental: Tort Law in Turbulence,” in John. Lowry and Rod Edmunds, (editors), *Environmental Protection and the Common Law*, (Oxford: Hart Publishing, 2000), at 77-92.

land.<sup>1080</sup> However, as previously noted, every physical change in plaintiff's property would not automatically warrant the inference of damage under English common law.<sup>1081</sup>

Within the context of the coexistence of transgenic and non-transgenic plant agriculture, physical damage to property could occur via adventitious presence of transgenic traits in organic or conventional crops; or via the spread of herbicide-resistant super-weeds on land designated for organic or conventional plant agriculture. Whilst the underlying science behind the aforesaid events is largely unsettled and typically contested,<sup>1082</sup> preponderance of scientific literature, which includes that of industry researchers such as Monsanto, is indicative that inexorable spread of super-weeds and gene flow typically via crops-pollination, are a challenging environmental problems posed by the advent of transgenic plant agriculture.<sup>1083</sup> The pertinent question therefore is: what is the measure of physical damage to the property of organic or conventional crops farmer? This would invariably depend on the nature of the alleged damage. As noted previously in Chapter Four of the thesis adventitious presence of transgenic traits in organic or conventional crops in excess of the 0.9 percent statutory threshold, would automatically lead to a re-classification of the organic or conventional crops in question as transgenic.<sup>1084</sup> Ditto, the spread of herbicide resistant super-weeds to organic or conventional crops farmland, or the resurgence of volunteer transgenic crops on organic or conventional crops fields, could theoretically constitute physical damage to the farmland of the organic or conventional crops farmer, and ground a cause of action in negligence.

Whilst it may be understandable if UK Courts are reluctant to impose a duty of care on a transgenic plant farmer for introducing approved transgenic organisms into the environment,

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<sup>1080</sup> See Ken Oliphant, "Damage Caused by GMOs under English Law," in Bernhard A. Koch, (editor), *Damage Caused by Genetically Modified Organisms: Comparative Survey of Redress Options for Harm to Persons, Property or the Environment*, *supra*, note 103, at 88.

<sup>1081</sup> *Id.*

<sup>1082</sup> See generally Chapter Four of the thesis..

<sup>1083</sup> See section 4.1.9 of the thesis.

<sup>1084</sup> See Article 12(1) (a), (b), of Regulation 1829/2003 of the European Parliament and of the Council on Genetically Modified Food and Feed, *supra*, note 20.

would UK courts be willing to impose a duty of care where adventitious presence of transgenic organisms in organic or conventional crops was excess of 0.9 percent statutory labelling threshold, and thereby declare that there was a physical damage to the crops or 'property' in order to support an alleged breach of a duty of care? Similarly, would UK Courts construe the unwanted presence of super-weeds and volunteer crops on organic or conventional farmland, as physical damage to the farmland, even though the accompanying transgenic crop was duly approved for release into the environment? With regards to adventitious presence of transgenic traits in non-transgenic crops, although there is no case law precedent on this point in the European Union, it is arguable that since adventitious presence of transgenes in organic or conventional crops in excess of the 0.9 percent statutory labelling threshold would necessitate a statutory re-classification of the organic or conventional crops as transgenic, the said crops could theoretically be deemed to have been fundamentally altered to the point of physical damage, since the crops could no longer be sold as organic or conventional crops. This scenario is exemplified by *Karl Heinz Bablok Case*, in which the CJEU held that the presence of transgenic maize protein in the beehive of an organic honey farmer in excess of the 0.9 percent statutory labelling threshold, had rendered the honey transgenic, and prior authorisation would be needed for its sale to the public.<sup>1085</sup>

Even so, there is a chance that UK Courts might perceive the transformation of an organic product into a transgenic product by reason of the presence of transgenes in excess of 0.9 percent labelling threshold, as a pure economic loss that could not be remedied by the tort of negligence. It is argued that this uncertainty underscores the apparent limit of the tort of negligence for remedying environmental/property damage caused by adventitious presence of transgenic organisms in organic and conventional crops and farmland. It also demonstrates the

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<sup>1085</sup> See *Karl Heinz Bablok v Freistaat Bayern*, (Case C-442/09) *supra*, note 247.

necessity for a complementary sui generis compensation system, which is dealt with in Chapter Seven of the thesis.

### **5.2.1. The Propriety of the Tort of Private Nuisance.**

The tort of private nuisance protects against unreasonable interference with the plaintiff's use or enjoyment of land.<sup>1086</sup> Unlike the tort of negligence, private nuisance does not require that plaintiff incur physical damage to property, while mere interference with plaintiff's use or enjoyment of property would suffice to ground a cause of action in private nuisance.<sup>1087</sup> However, the interference with plaintiff's use and enjoyment of his\her property must be substantial.<sup>1088</sup> The pertinent question therefore is: what is the extent to which organic or conventional crops farmers can employ private nuisance as a compensatory tool for damages for adventitious presence of transgenes in their organic or conventional crops, or the resurgence of volunteer transgenic crops on their farmlands?

Arguably, the absence of the requirement of physical damage to property for grounding a cause of action in private nuisance, should in theory, make it easier for organic or conventional crops farmers to sue for private nuisance than for negligence. However, Ken Oliphant opined that the traditional requirement that damage must be "visible" could pose peculiar challenges for plaintiff claiming damages for adventitious presence of transgenic organisms in their organic or conventional crops.<sup>1089</sup> For example within the European Union, adventitious presence of transgenes in organic or conventional crops in excess of the 0.9 percent maximum labelling threshold would be invisible to the naked eye, and would require specialised testing equipments to verify and establish.<sup>1090</sup> Thus, if U.K courts were to follow to the letter the old

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<sup>1086</sup> Id, at 89.

<sup>1087</sup> Id.

<sup>1088</sup> Id.

<sup>1089</sup> Id, at 89.

<sup>1090</sup> The testing equipments would be beyond the reach of most farmers, and even the European Union needed the help of Monsanto to test recent shipments of U.S. white wheat for the presence of unapproved transgenes. See

dictum by James LJ that “scientific evidence, such as the microscope of the naturalist, or the tests of the chemist”, were insufficient to establish damage, and that “[t]he damage must be such as can be shown by a plain witness to a plain common jurymen”,<sup>1091</sup> then it would be nigh impossible to prove damage caused by the presence of transgenes in organic or conventional crops. However, it has also been argued that a lack of visible damage would not preclude liability, and that “visibility” of damage “is not required in a literal sense, but only in so far as the alleged damage manifest itself in some way that would be appreciable to an ordinary, informed person.”<sup>1092</sup>

Yet another advantage of private nuisance over negligence is that liability for private nuisance is “strict” if the harm is foreseeable. Thus, taking all possible reasonable precautions to avoid causing harm would not preclude liability.<sup>1093</sup> Therefore, issues on which scientists are unanimous that range from gene flow especially via plant cross-pollination process, the proliferation of super-weeds, and the proven presence of volunteer transgenic crops in organic and conventional crops fields,<sup>1094</sup> could arguably be deemed foreseeable harm to the organic or conventional crops farmers. It has also been canvassed that “private nuisance recognises harm that are less tangible than those addressed by negligence.”<sup>1095</sup> For example, it should be easier for plaintiff to establish in private nuisance that defendant’s transgenic crops field inhibited plaintiff’s ability to use their land for cultivating organic or conventional crops, and

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Anna Edwards, “America facing wheat export crisis as Europe and Japan lead the way in rejecting genetically modified crops,” *Mail Online*, *supra*, note 27.

<sup>1091</sup> See *Salvin v North Brancepeth Coal Co* [1873] LR 9 Ch App 705, 709. CF. Mellish LJ at 713. Cited in Ken Oliphant, “Damage Caused by GMOs under English Law,” in Bernhard A. Koch, (editor), *Damage Caused by Genetically Modified Organisms: Comparative Survey of Redress Options for Harm to Persons, Property or the Environment*, *supra*, note 631, at 89.

<sup>1092</sup> *Id.*

<sup>1093</sup> See Maria Lee and Robert Burrell, “Liability for the Escape of GM Seeds: Pursuing the ‘Victim?’” *The Modern Law Review*, *supra*, note 76, at 530.

<sup>1094</sup> *Id.*

<sup>1095</sup> *Id.*, at 65.

that the defendant's activities constituted substantial and unlawful interference with plaintiff's use of their land.<sup>1096</sup>

In the United States, the plaintiffs in the case of *In re StarLink Corn Products Liability Litigation* sued the defendant for private nuisance.<sup>1097</sup> The plaintiffs alleged that Defendants "created a private nuisance by distributing corn seeds with the Cry9C protein, knowing that they would cross-pollinate with neighbouring corn crops."<sup>1098</sup> The defendant argued in response that "they [could not] be liable for any nuisance caused by StarLink because they were no longer in control of the seeds once they were sold to farmers."<sup>1099</sup> However, the District Court rejected defendant's argument, and held that "residue from a product drifting across property lines present[ed] a typical nuisance claim," and "[a]ll parties who substantially contribute to the nuisance are liable."<sup>1100</sup> The District Court held further that the defendant's limited registration of StarLink corn effectively put them in a position to control the nuisance, and because they failed to do so, the plaintiffs had established a valid case for private nuisance.<sup>1101</sup>

However, under English common law, there are inherent barriers to the use of private nuisance as a cause of action for substantial and unreasonable interference with the use of own land, by aggrieved organic or conventional crops farmers. The first major barrier is the requirement of actionable nuisance, which is qualified by the concept of whether or not the defendant is an 'unreasonable user' of own land.<sup>1102</sup> Thus, although the defendant's use of own land must be unreasonable in the circumstances, the reasonableness or otherwise of defendant's use of own land cannot be adjudged independently of the effects on plaintiff's use and

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<sup>1096</sup> *Id.*

<sup>1097</sup> See *In re StarLink Corn Products Liability Litigation*, *supra*, note 170, at 844-845.

<sup>1098</sup> *Id.*

<sup>1099</sup> *Id.*, at 845.

<sup>1100</sup> *Id.*, at 847.

<sup>1101</sup> *Id.*

<sup>1102</sup> See Maria Lee and Robert Burrell, "Liability for the Escape of GM Seeds: Pursuing the 'Victim'?" *The Modern Law Review*, *supra*, note 76, at 531.

enjoyment of their land.<sup>1103</sup> Therefore, in the absence of physical damage to plaintiff's property, the reasonableness or otherwise of the interference by defendant with the use of plaintiff land is essentially a relative concept.<sup>1104</sup>

Thus, by extrapolation, if a transgenic crop farmer cultivated approved transgenic maize on own land in Devon, England, and rigorously complied with all cultivation rules, such as mandatory separation distances and required buffer zones around his transgenic maize, etc., would the use of his land in the circumstances still be considered unreasonable use of land, vis-a-vis the lawful use of land by a neighbouring organic or conventional crop farmer? The answer would inevitably depend on a number of variables. First, whether or not the land on which transgenic maize is grown is approved for that purpose. Second, whether or not transgenic maize farmer complied with all the regulatory rules and mandatory good farming practices. Third, whether or not it would be 'reasonable' for neighbouring organic or conventional maize farmer to expect cross-pollinations between crops. Fourth, whether or not the use of land by the neighbouring organic or conventional maize farmer is considered a "sensitive use", such as to preclude a nuisance claim. For according to Cotton LJ:

It would be wrong to say that the doing something not in itself noxious is a nuisance because it does harm to some particular trade in the adjoining property, although it would not prejudicially affect any ordinary trade carried on there, and does not interfere with the ordinary enjoyment of life.<sup>1105</sup>

The 'sensitive user' limitation inherent in the tort of private nuisance was re-echoed by Buxton LJ in *R v. Secretary of State for the Environment and MAFF ex parte Watson*,<sup>1106</sup> when he observed that if the applicant had brought an action in private nuisance, "difficult questions would arise as to the extent to which the Applicant was seeking to impose limitations by

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<sup>1103</sup> Id. See also *Bamford v Turnley* (1862) 3 B&S 66.

<sup>1104</sup> Id.

<sup>1105</sup> See *Robinson v Kilvert* (1888), 41 Chancery Division, 88, at 94.

<sup>1106</sup> See *R v. Secretary of State for the Environment and MAFF ex parte Watson*, *supra*, note 160, at 323.



introduction of special or specially sensitive crops.”<sup>1107</sup> Whilst commenting on the dictum by Buxton LJ, Maria Lee *et al.* opined that the defence of sensitive user would almost certainly be raised by the defendant transgenic crop farmer in a private nuisance action brought by plaintiff organic or conventional crop farmer.<sup>1108</sup> The authors then summed-up the possible challenge posed by the unpredictability of the role of ‘sensitive user’ defence to future private nuisance action by organic farmers against transgenic crop farmers as follows:

‘Sensitive use’ is simply one or more relatively open and unpredictable element of private nuisance litigation; if it applies, whether the courts deem organic agriculture to be an ‘ordinary’ use or ‘normal trade’ is probably not capable of purely doctrinal prediction.<sup>1109</sup>

Therefore, the unpredictability of the role and place of ‘sensitive user’ criterion, and the reasonable user test are putative challenges to the suitability of the tort of private nuisance as veritable compensatory tool for inherent damage in the coexistence paradigm.

The second potential limitation on the tort of private nuisance for remedying damage inherent in the coexistence paradigm, is the criteria that the tort of private nuisance would only be available to plaintiffs whose use of land was substantially and unlawfully interfered with by defendant’s transgenic plant agriculture; and its unavailability as a cause of action for personal injury. In other words, possible claimants who have no interests in land, such as Maurice Parr, the Canadian seed cleaner who was sued by Monsanto for facilitating infringements of patented seeds, would not be able to sue in private nuisance for the economic loss incurred from losing his customers and business due to the proliferation of transgenic plant agriculture, and the constant threats of patents infringements, because his business activities had nothing to with enjoyment of land *per se*.<sup>1110</sup> Furthermore, claimants who might have suffered personal injury or harm due to the consumption of unapproved transgenes in the food chain or approved

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<sup>1107</sup> *Id.*, at 323.

<sup>1108</sup> See Maria Lee and Robert Burrell, “Liability for the Escape of GM Seeds: Pursuing the ‘Victim?’” *The Modern Law Review*, *supra*, note 74, at 532.

<sup>1109</sup> *Id.*

<sup>1110</sup> See *Monsanto Company and Monsanto Technology L.L.C. v. Maurice Parr*, *supra*, note 43, at 545.

transgenes with allergenic effects, would not be able to sue in private nuisance, due to the requirement of land use.<sup>1111</sup> Thus, the possibility that farm businesses caught-up in the existential conflicts of the coexistence paradigm with genuine grievances might be left without a remedy due to the strict requirements of the common law tort of private nuisance, arguably provides a strong argument for a complementary sui generis compensatory regime that would specifically address the unique and novel grievances for which there are currently no cause of action at common law.

### **5.2.2. The Rule in *Rylands v Fletcher*.**

In *Rylands v Fletcher*,<sup>1112</sup> Blackburn J of the Court of Exchequer Chamber posited in his dissenting judgment that: “the person who for his own purpose brings on his lands and collects and keeps there anything likely to do mischief, if it escapes, must keep it in at his peril, and if he does not do so, is *prima facie* answerable for all the damage which is the natural consequence of its escape.”<sup>1113</sup> The defendant could however, be excused from liability if he could prove that the escape was either due to plaintiff’s fault, or that the escape was due to *vis major* or an act of God.<sup>1114</sup>

Rylands’ reservoir had burst open and flooded the neighbouring mine run by Fletcher, causing £937 worth of damage. *Fletcher* sued *Rylands* for negligence, but his action was dismissed in the majority judgement, which found in favour of *Rylands*.<sup>1115</sup> In a subsequent appeal to the House of Lords, the appeal was upheld and the proposition of Blackburn J was

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<sup>1111</sup> See Ken Oliphant, “Damage Caused by GMOs under English Law,” in Bernhard A. Koch, (editor), *Damage Caused by Genetically Modified Organisms: Comparative Survey of Redress Options for Harm to Persons, Property or the Environment*, *supra*, note 224, at 100.

<sup>1112</sup> See *Rylands v Fletcher*, (1866) LR 1 Exch, 265, at 279-280.

<sup>1113</sup> *Id.*

<sup>1114</sup> *Id.*

<sup>1115</sup> *Id.*

affirmed, albeit with an additional proviso by Lord Cairns, requiring that the defendant must make a “non-natural use” of land for the rule to apply.<sup>1116</sup> The proposition borders on strict liability, remains good law in England and Wales, albeit, it is no longer deemed as a separate tort, but a variant of the tort of private nuisance that is applicable to a one-off or isolated escape or event rather than a continuing escape of dangerous things that are likely to cause harm.<sup>1117</sup>

The rule in *Rylands v Fletcher* has since undergone numerous modifications and become more restrictive over the years. The first key modification is the application of the rule to only to dangerous things, which storage or presence on the defendant’s land must create “an exceptionally high risk of danger or mischief if there should be an escape, however unlikely an escape may have been thought to be.”<sup>1118</sup> The second key modification is the requirement that damage must be caused by the thing’s escape from the land, and that a mere escape of the dangerous thing from defendant’s control would not suffice.<sup>1119</sup> The third key modification to the original rule is that the defendant must have been engaged in a non-natural use of land at the time of the escape.<sup>1120</sup>

The pertinent question therefore is: to what extent could *Rylands v Fletcher* redress the concomitant damage in the coexistence paradigm? More specifically, if farmer Schmeiser had lived and farmed in Devon, England, would he be able to sue neighbouring transgenic canola famers and Monsanto for the escape of transgenic canola traits unto his non-transgenic canola farm, and the subsequent adventitious commingling of transgenic canola traits with his non-transgenic canola?<sup>1121</sup> In the same vein, to what extent could *Rylands v Fletcher* avail an organic or conventional maize farmer in Devon, England, whose farmland has been overrun

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<sup>1116</sup> See *Rylands v Fletcher*, (1868) LR 3 HL 330 at 338.

<sup>1117</sup> See *Cambridge Water v Eastern Counties Leather*, [1994], 2 AC 264.

<sup>1118</sup> See per Lord Bingham, in *Transco plc v Stockport MBC* [2004] 2 AC 1, at 10.

<sup>1119</sup> See *Read v J Lyons & Co* [1947] AC 156.

<sup>1120</sup> See *Rickards v Lothian*, [1913] AC 263.

<sup>1121</sup> See *Monsanto Canada Inc v Schmeiser*, *supra*, note 39, at 902.

and plagued by glyphosate-resistant super-weeds, which are notoriously impervious to chemical weed killers and would cost a small fortune to remove manually?<sup>1122</sup>

Significantly, the nature of the answer to the above questions would arguably partly depend on whether transgenic plant agriculture or the cultivation of approved transgenic crops is characterised as a natural or “non-natural” use of land? In *Rickards v Lothian*, Lord Moulton did offer a conceptual frame of reference when he characterised “non-natural” use of land as “some special use bringing with it increased danger to others, and must not merely be ordinary use of land or such a use as is proper for general benefit of the community.”<sup>1123</sup> However, the House of Lords in *Cambridge Water v Eastern Counties Leather*,<sup>1124</sup> discountenanced the “public benefit” qualifications of non-natural usage of land espoused by Lord Moulton in *Rickards v Lothian*,<sup>1125</sup> on grounds that it could jeopardise keeping the exception “within reasonable bounds.”<sup>1126</sup> *A fortiori*, the pertinent question is whether or not transgenic plant agricultural practice would constitute a non-natural use of land as per the definition proffered by Lord Moulton in *Rickards v Lothian*?<sup>1127</sup> Transgenic plant agriculture is highly regulated in the European Union and the United Kingdom, and the cultivation of transgenic plant seeds would only be authorised following rigorous risk assessments,<sup>1128</sup> and enforced compliance with mandated good farming practices that range from mandatory separation distances to the

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<sup>1122</sup> For the accounts on the scourge of super-weeds plaguing farmers across the United States, and in particular, in the state of Mississippi, see Tom Philpott, “Meet the weeds that Monsanto can’t beat,” *The Guardian*, (Friday 21 December 2012), *supra*, note 169. For the account of Monsanto’s acknowledgement that super-weeds was a challenging problem, see William Newman and Andrew Pollack, “US Farmers Cope with Roundup-Resistant Weeds,” *New York Times*, (4 May 2010), *supra*, note 167, at 1B.

<sup>1123</sup> See *Rickards v Lothian*, *supra*, note 271, at 280.

<sup>1124</sup> See *Cambridge Water v Eastern Counties Leather*, *supra*, note 268, at 308.

<sup>1125</sup> See *Rickards v Lothian*, *supra*, note 271, at 280.

<sup>1126</sup> See *Cambridge Water v Eastern Counties Leather*, *supra*, note 268, at 308.

<sup>1127</sup> See *Rickards v Lothian*, *supra*, note 271, at 280.

<sup>1128</sup> For the general obligations of Member states to take appropriate environmental risks assessments, and ensure that appropriate measures are taken to avoid adverse effects of transgenic agriculture on human health and the environment, see generally the provisions of Article 4 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, *Official Journal of the European Union*, *supra*, note 4.

creation of buffer zones around transgenic crop fields.<sup>1129</sup> Thus to the extent that a transgenic crop has been duly approved for cultivation, ostensibly following rigorous risk assessments, it could hardly be legally characterised as a “dangerous thing”, because its authorisation would ostensibly negate such characterisation. Thus, by extrapolation, its cultivation or presence on designated and approved agricultural farmland, could hardly be tantamount to non-natural use of land. *A fortiori*, it is highly unlikely that courts in England and Wales would hold that transgenic plant agriculture constitute a non-natural use of land.<sup>1130</sup>

However, it is also arguable that the authorisation of a transgenic crop for cultivation following rigorous risks assessments, does not by any means lessen or negate any inherent risks posed by the transgenic crop to the environment and non-transgenic crop. For example, as previously noted, there is ample scientific evidence of concomitant plague of glyphosate-resistant super-weeds;<sup>1131</sup> and the potential for cross-pollination between transgenic and non-transgenic crops,<sup>1132</sup> with concomitant damage to non-transgenic crop, by reason of loss of purity and market, should the presence of transgenic traits exceed the maximum 0.9 percent labelling threshold.<sup>1133</sup> Thus, even with evidence that there is full authorisation for cultivating transgenic crops, courts in England and Wales might not be able to ignore concomitant hard evidence relating to the proliferation of super-weeds, or the presence of volunteer transgenic crops in non-transgenic farmland, or the damage suffered by organic or conventional crops

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<sup>1129</sup> Under the E.U coexistence paradigm for transgenic and non-transgenic plant agriculture, transgenic crop farmers and farm operators are legally obliged to show evidence that they had taken appropriate steps to avoid adventitious presence of transgenic traits in non-transgenic crops. See Article 12(3) of Regulation 1829/2003 of 22 September 2003, on genetically modified food and feed, *supra*, note 11.

<sup>1130</sup> See Ken Oliphant, “Damage Caused by GMOs under English Law,” in Bernhard A. Koch, (editor), *Damage Caused by Genetically Modified Organisms: Comparative Survey of Redress Options for Harm to Persons, Property or the Environment*, *supra*, note 224, at 100.

<sup>1131</sup> See William Newman and Andrew Pollack, “US Farmers Cope with Roundup-Resistant Weeds,” *New York Times*, (4 May 2010), *supra*, note 167, at 1B.

<sup>1132</sup> See Miguel A. Alteri, “The Myth of Coexistence: Why Transgenic Crops Are Not Compatible With Agro-ecologically Based Systems of Protection,” *Bulletin of Science, Technology, & Society*, *supra*, note 15, at 363-365.

<sup>1133</sup> See Article 12(1) (a) (b) of Regulation 1829/30 of the European Parliament and of the Council on Genetically Modified Food and Feed, *supra*, note 20.

farmers due to the inadvertent presence of transgenic traits in organic or conventional crops in excess of the allowable maximum 0.9 percent labelling threshold. In the circumstances, courts might be forced to rule that transgenic plant agricultural practice is tantamount to non-natural use of agricultural land, notwithstanding that it is fully authorised by relevant regulatory authority.

Even so, the requirement stipulated by the House of Lords in *Cambridge Water v Eastern Counties Leather*,<sup>1134</sup> that the ‘escape’ of the ‘dangerous thing’ stored on land should be an ‘isolated’ or ‘one-off’ event could hardly describe how cross-pollination works or how transgenic traits flow from transgenic farmland to non-transgenic farmland. Thus as in *Cambridge Water case*, where chemical solvent was released into drinking water overtime, rather than at once, the release or escape of transgenic traits from transgenic crop fields to non-transgenic crop fields, would occur over a period of time and not at once. Thus, the tort of private nuisance would be more suited to claimants seeking damages for harm caused by adventitious release of transgenes than the rule in *Rylands v Fletcher*.<sup>1135</sup>

The foregoing analyses again demonstrate the uncertainties around the propriety and effectiveness of the rule in *Rylands v Fletcher* as a putative compensatory tool for concomitant damage to property in the current coexistence paradigm for transgenic and non-transgenic plant agricultures. It would appear that nothing short of a sui generis compensatory regime would better serve the interests and rights of non-transgenic plant farmers in the coexistence of transgenic and non-transgenic plant agricultures.

### **5.2.3. Transgenic Plant Foods and Public Harm.**

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<sup>1134</sup> See *Cambridge Water v Eastern Counties Leather*, *supra*, note 268, at 264.

<sup>1135</sup> See Christopher P. Rodgers, “Coexistence or Conflict? A European Perspective on GMOs and the Problem of Liability,” *supra*, note 282, at 242.

Whilst there is not yet any direct link between the consumption of approved transgenic plant foods and specific illnesses in North America where commercial transgenic foods have flourished since the 1990s,<sup>1136</sup> there is absolutely no reason to preclude the possibility of such occurrence in future. This is because the safety science of transgenic plant foods is primarily evolutionary and there are still several unknowns that might be discovered by future scientific evidence.<sup>1137</sup> Moreover, there is irrefutable precedence in products such as asbestos and tobacco which were previously deemed as safe until the subsequent emergence of contrarian scientific evidence, which demonstrated that asbestos and tobacco contained carcinogenic properties that could cause cancer.<sup>1138</sup> Chapter Four of the thesis provides a detailed analysis of the possible deleterious effects of transgenic plant foods toxins and allergens could have on the human body, and that there is no unanimity of scientific views on the safety science of transgenic plant foods.<sup>1139</sup> Whilst this has arguably increased the perception of risks and the need for adequate compensation regime, the pertinent question is: what sort of remedies could torts law provide and how effective could they be?

#### **5.2.4. Tortious Remedies for Personal Injuries Induced by Transgenics.**

How might the law of tort compensate possible personal injuries or harm sustained by the consumption of transgenic plant foods or exposure to transgenic plant pollens?<sup>1140</sup> A list of

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<sup>1136</sup> In the United Kingdom for example, the spokesman for the British Prime Minister, whilst refusing to answer whether or not David Cameron would feed his family with transgenic crops, was keen to emphasise the government view that there was “no credible basis for an argument that GM crops are inherently unsafe.” See Rowena Mason, “Downing Street refuses to say whether David Cameron would eat GM food,” *The Telegraph*, (Thursday 20 June, 2013), at <http://www.telegraph.co.uk/earth/environment/10132218/Downing-St-refuses-to-say-whether-David-Cameron-would-eat-GM-food.html> (accessed on 14 May).

<sup>1137</sup> See Ronald J. Herring, “The Genomics Revolution and Development Studies: Science, Poverty and Politics,” in Ronald J. Herring, (editor), *Transgenics and the Poor: Biotechnology in Development Studies*, (New York, Routledge, 2007), at 2.

<sup>1138</sup> See Taiwo A. Oriola, “Ethical and Legal Analyses of Policy Prohibiting Tobacco Smoking in Enclosed Public Spaces,” *The Journal of Law, Medicine, & Ethics*, Volume 34, Issue 4, (Winter 2009), 828-830.

<sup>1139</sup> See generally Chapter Four of the thesis.

<sup>1140</sup> See Maria Lee, *EU Regulation of GMOs: Law and Decision Making for a New Technology*, *supra*, note 67, at 130.

possible illnesses range from allergic reaction to transgenic plant foods or pollen, adverse reaction to transgenic food toxins, and a host of other possible illnesses that are currently unknown, but which might crop up as the safety science of transgenic plant foods matures.<sup>1141</sup>

Thus, in a cause of action for negligence for personal injuries, potential plaintiffs would have to establish a duty of care; that the defendant breached the duty of care; and that the plaintiffs suffered proximate loss in consequence of the breach.<sup>1142</sup> Moreover, in order to establish the existence of a duty of care, potential plaintiffs must satisfy the following threefold test laid down by the House of Lords in *Caparo Industries plc v. Dickman*.<sup>1143</sup> First, that the harm must be reasonably foreseeable; second, that the parties must be in relationship of proximity; and third, that imposition of liability must be fair, just and reasonable in the circumstances.<sup>1144</sup> Whilst there is no need to resort to the threefold test for guidance in situations where the duty of care is relatively standard or well-established,<sup>1145</sup> the pertinent is: would Courts regard alleged personal injuries from transgenic technological products as novel claims? For example, in *Customs and Excise Commissioners v. Barclays Bank plc*, Lord Roger noted that “a court faced with a novel situation must apply the threefold test.”<sup>1146</sup> However, it is unlikely that UK Courts would regard personal injuries linked to transgenic plant technology as novel because the injury or illness would most probably be consistent with familiar health problems such as food allergies, food poisoning, or any serious physical reactions to the consumption of transgenic plant food products.

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<sup>1141</sup> See chapters One and Four of the thesis for detailed analyses of the existential conflicts in the coexistence paradigm.

<sup>1142</sup> See Ken Oliphant, “Economic Loss Caused by GMOs in the United Kingdom: England & Wales,” in Bernhard A. Koch, (editor), *Economic Loss Caused by Genetically Modified Organisms: Liability and Redress for the Adventitious Presence of GMOs in Non-GM Crops*, *supra*, note 103, at 515.

<sup>1143</sup> See *Caparo Industries plc v. Dickman*, *supra*, note 780, at 605.

<sup>1144</sup> *Id.*, at 608.

<sup>1145</sup> In *Customs and Excise Commissioners v. Barclays Bank plc*, [2006] 3 WLR 1, at 53, Lord Rodger held *inter alia* that “a court faced with a novel situation must apply the threefold test”.

<sup>1146</sup> See *Customs and Excise Commissioners v. Barclays Bank plc*, *supra*, note 313, at 53.



Perhaps the greatest challenge facing potential plaintiffs, is establishing a duty of care against any of the possible defendants that range from food retailers, groceries stores, restaurants, transgenic crop farmers, to transgenic seed companies? For example, whilst it may be easier for potential plaintiffs to sue the grocery business or restaurant that sold them transgenic plant foods, it might not be so easy to sue the farmer who cultivated the transgenic plant crop in question, or the seed company who sold the farmer transgenic seed, due to a lack of relational proximity. However, in the event that potential plaintiffs managed to identify potential defendant or defendants, the next legal challenge is to establish that the defendant or defendants breached the duty of care owed to potential plaintiffs. This could in theory be established by evidence showing that defendants failed to take necessary precautions or preventive measures. Numerous scenarios for preventive or precautionary measures would for example, include a defendant restaurateur's failure to warn customers that they were serving transgenic foods; or a defendant grocer's failure to warn customers that they stocked transgenic foods, especially in the European Union where such requirements are mandated by food labelling regulations.<sup>1147</sup> These scenarios of course presume that the restaurateur or grocer knew that they were serving or stocking transgenic plant foods.

Yet another major challenge to potential plaintiffs is proving that the personal injuries or illnesses suffered were reasonably foreseeable by defendants in the circumstances. However, given the uncertain state of the safety science of transgenic plant foods, and the contradictory scientific views on whether transgenic plant food is more prone to allergens and toxins or safe for human consumption,<sup>1148</sup> it would be very difficult indeed for potential plaintiffs to prove that their personal injuries were reasonably foreseeable or to link their illnesses to the transgenic plant foods in question. This problem is underscored by the StarLink corn incident,

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<sup>1147</sup> See Regulation (EC) No [1829/2003](#) of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, *supra*, note 56.

<sup>1148</sup> See Chapter Four of the thesis.

when two different scientific panels reached contradictory conclusions as to whether the consumption of foods containing Cry9c protein led to the alleged illnesses of those whose blood samples were tested.<sup>1149</sup>

Even if the harm or personal injury was foreseeable, there is the added challenge of proving that it was caused by a particular transgenic plant food, especially if the harm or injury did not manifest until several months following the alleged causation of injury. In the circumstances, potential plaintiffs would need to retrospectively link their injury to the transgenic plant food they consumed several months or years earlier or to the transgenic plant pollen to which they were exposed months or years ago, assuming of course that they had the necessary evidence to link their injury to the alleged causative events.

The above scenario is highly plausible because potential plaintiffs might not be able to connect their current illnesses to past exposure to transgenic plant food, until the diagnosis was made possible by new or future scientific developments. This is exemplified by the UK Supreme Court decision in *Bai (Run Off) Limited & Others v Durham & Others*,<sup>1150</sup> in which the Court retrospectively linked and backdated liability to the time of victims' exposure to deadly air-borne carcinogenic asbestos fibres, rather than when the consequential illness: *asbestos or mesothelioma* lung cancer symptoms became manifest or evident in victims. Thus, by extrapolation, if people who consumed transgenic Bt plant foods in the 2010s were to develop some debilitating diseases in the 2030s, and the said diseases were scientifically linked to the consumption of transgenic Bt foods back in the 2010s, UK courts would, arguably, have no difficulties in establishing a nexus, by linking and tracing the said diseases back in time to its causative agents in the transgenic foods consumed by victims in the 2010s. However, as with tobacco smoking and asbestos fibres, sound science would be crucial to establishing a

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<sup>1149</sup> See Jeffrey M. Smith, *Seeds of Deception: Exposing Corporate and Government Lies about the Safety of Genetically Engineered Food*, *supra*, note 34, at 149.

<sup>1150</sup> See *Bai (Run Off) Limited & Others v Durham & Others*, [2012] UKSC 14.

nexus between any future diseases and the consumption of transgenic Bt foods. However, as previously noted, scientists working in the field are much divided and there is no unanimity of scientific views on issues that range from transgenic plant food allergens or toxins, or whether transgenic food is safe. *A fortiori*, it could be more legally challenging to prove that transgenic plant foods caused particular illnesses than to link asbestos fibre or tobacco to lung cancer.

Thus, theoretically, whilst potential plaintiffs might have a cause of action in negligence for compensation for personal injury from exposure to transgenic plant foods, there are legal huddles with regards establishing a duty of care, that personal injury was foreseeable, that there was relational proximity, that the duty of care was breached by the defendant, and that there was a resultant injury. The aforesaid legal challenges again demonstrate the limits and effectiveness of the tort of negligence as a compensatory tool for possible damage from exposure to transgenic plant foods.

### **5.2.5. The Tort of Trespass**

The tort of trespass is broadly divided into three categories: trespass to land, trespass to chattels, and trespass to the person. In the context of adventitious transgenes in the coexistence paradigm, trespass to land would appear to be the most appropriate cause of action for potential litigants that range from organic and conventional crops farmers to anyone who could establish the presence of adventitious transgenes in their chattel or land. The pertinent questions are: what sort of activities might constitute trespass to land or chattel in the coexistence paradigm, and how effective would the tort of trespass be in remedying the alleged wrongs?

Trespass to land deals with wrongful interference with the enjoyment or use of land, and it could occur intentionally or negligently.<sup>1151</sup> The main element of the tort of trespass is

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<sup>1151</sup> See *League Against Cruel Sports v Scott*, [1985] 2 All ER 489.

interference, which must be both direct and physical.<sup>1152</sup> Most importantly, it is unnecessary for potential plaintiffs to prove harm, because trespass is actionable per se.<sup>1153</sup>

Thus, in the coexistence paradigm, an organic crop farmer could theoretically have a cause of action against a neighbouring transgenic crop farmer, if pollens or transgenes from the latter's crops, drifted into the former's farmland, even if it is adventitious.<sup>1154</sup> For the neighbouring farmer could be for the negligence that allowed the unlawful interference in the plaintiff's use of his land.<sup>1155</sup> The transgenic crop farmer would not have to prove any damage in the circumstances provided he/she could provide evidence of unjustified interference with the enjoyment of his/her land.

However, the transgenic crop farmer could rely on certain defences, which include licence, legal justification, an Act of God, and necessity.<sup>1156</sup> For example, the farmer could draw on any of the stated defences if his transgenic crop was approved for cultivation, and he had a licence and the authorisation to cultivate the crop. After all, the European coexistence rules have acknowledged the inevitability of adventitious presence of transgenes in non-transgenic crops, and there could be no expectation of conventional or organic crop that is completely free from transgenes.<sup>1157</sup> Therefore, to the extent that these could constitute legitimate defence, the tort of trespass is also limited in its suitability for damage inherent in the coexistence paradigm.

### **5.2.6. Conclusions.**

Chapter Five of the thesis examines and discusses scenarios for tortious liability for damage caused by adventitious transgenes in the coexistence paradigm. They include possible economic loss, harm or damage to property, the environment, and personal injury. The chapter

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<sup>1152</sup> *Id.*, at 492.

<sup>1153</sup> *Id.*

<sup>1154</sup> See Catherine Elliott and Francis Quinn, *Tort Law (6th ed.)* (London: [Longman](#), 2007) at 321.

<sup>1155</sup> See *League Against Cruel Sports v Scott*, *supra* note 1151, at 490.

<sup>1156</sup> See Catherine Elliott and Francis Quinn, *Tort Law (6th ed.) supra*, note 1154, at 324.

<sup>1157</sup> See paragraph 1.1 of Commission Recommendation on Coexistence, July 2010, *supra*, note 33.

discusses the propriety of key causes of action in tort for inherent damage in the coexistence paradigm. They range from negligence, private nuisance, trespass, to the rule in *Rylands v Fletcher*. The chapter highlights scenarios of possible economic loss for organic plant farmers, conventional plant farmers, and farm businesses as a result of patent infringement that stems from adventitious presence of transgenes, as exemplified by *Monsanto Canada v Schmeiser*; *Monsanto Technology L.L.C. v Maurice Parr* case law from Canada and the US respectively. It is argued that the problem would likely be replicated in the European Union when transgenic plant technology went mainstream. The chapter notes the limitations of the tort of private nuisance and negligence in providing adequate remedy, and urges for a *sui generis* compensation regime that would specifically address the unique economic loss for farm businesses and non-transgenic plant farmers in the coexistence paradigm.

Moreover, the chapter examines the propriety of the tort of trespass as a compensatory tool for adventitious presence of transgenes in non-transgenic crops. Although trespass is promising because it is actionable *per se* without proof of any damage, the chapter notes the obvious limitations in numerous defences that range from Act of God, legal justification, and necessity. It is therefore recommended that whilst compensatory awards is possible for causes of action in tort for damage stemming from the coexistence of transgenic and non-transgenic plant agriculture, tort should be regarded as default or supplementary remedial measure to a comprehensive *sui generis* compensation system that should ideally be statutory by nature. Member States of the European Union do have the national oversight over adequate remedial measures, and some like Germany and Austria already do. But even the German and Austrian laws are not comprehensive enough, and would not cover circumstances analogous to *Schmeiser* and *Maurice Parr Cases*.

## **CHAPTER SIX.**

### **Supply Chain Liability Framework.**

#### **6.1.0. Introduction.**

Chapter Six draws on analogous case law and statutes to explore possible causes of action for the inherent damage within the supply chain for transgenic plant technology, which covers the entire life cycle of transgenic plant technology. The supply chain framework in the chapter offers two important functions. The first is a generic structural framework that allows for oversight of the life cycle of transgenic plant technology to facilitate the detection of any defects, where the defects occur, the origin of the defects, and who is responsible for the defects, with a view to properly apportioning responsibility and liability for the defective technology. The process allows for concomitant traceability of the technology from production through the supply chain gamut. The second advantage of using the supply chain generic framework is that it offers a much wider scope for the inclusion of a group of disparate but relevant causes of action such as product liability, strict liability, contractual liability, environmental liability, and the procedural Norwich Pharmacal action. Furthermore, the chapter discusses the importance of traceability for supply chain liability, and analyses the propriety of and limitations of selected causes of action, and proffers necessary reforms and recommendations, which are dealt with in greater detail in Chapter Seven of the thesis.

#### **6.1.1. General Concept of Supply Chain Liability and Traceability.**

A supply chain is the process by which a product or service is conveyed from the producer to the consumer, and typically involves a network of independent firms that range from producers of raw materials, products manufacturers, transportation firms, wholesalers to retailers.<sup>1158</sup>

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<sup>1158</sup> See John T. Mentzer, et al., "Defining Supply Chain Management," *Journal of Business Logistics*, Volume 22, Number 2, (2001), at 3.

Thus, within the context of transgenic plant agricultural economy, a typical supply chain would necessarily comprise transgenic seed breeders; transgenic seed suppliers; transgenic seed farmers; food processors; and food grocers or retailers that ultimately put transgenic crops and food products on the market for consumers. The typical supply chain for plant agricultural products is exemplified by the maize supply chain in Germany, which was broadly categorised by B. Ruther into the following three blocks: maize seed breeding companies; maize producing farms; and milling and processing industries that sell on secondary products such as starch to consumers.<sup>1159</sup>

A discourse on the supply chain for transgenic plant agricultural products from seed breeders, to farmers, and ultimately, to the consumer, is imperative as a precursor to any meaningful analysis of supply chain liability. This is primarily because the analysis of the supply chain dynamics for transgenic crops and products could help crystallise the traceability of transgenic plant products from seed breeders, farmers, food processors, to consumers, and help assign responsibility for compliance with segregation and other health and safety rules, and facilitate assignment of fault and concomitant liability. According to Linus O. Opara, the concept of agricultural traceability connotes:

Collection, documentation, maintenance, and application of information related to all processes in the supply chain in a manner that provides guarantee to the consumer and other stakeholders on the origin, location and life history of a product as well as assisting in crises management in the event of a safety and quality breach. With respect to a food product, traceability represents the ability to identify the farm where it was grown and sources of input materials, as well as ability to conduct full backward and forward tracking to determine the specific location and life history in the supply chain by means of records.<sup>1160</sup>

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<sup>1159</sup> See B. Ruther, "Risk management of unintended GMO contamination in the supply chain of maize and processed maize products," Paper prepared for presentation at the 113<sup>th</sup> EAAE Seminar "A resilient European food industry and food chain in a challenging world", Chania, Crete, Greece, (3-6 September, 2009), at 4.

<sup>1160</sup> See Linus U. Opara, "Traceability in agriculture and food supply chain: a review of basic concepts, technological implications, and future prospects," *Journal of Food, Agriculture, and Environment*, Volume 1, Issue 1, (2003), at 102.

The following six important elements of traceability have been identified: The first is “product traceability”, which helps determine the physical location of a product at any stage in the supply chain.<sup>1161</sup> Thus, in the context of transgenic plant agricultural products, “product traceability” could facilitate the physical location of transgenic crop in its different forms from seed to crop and secondary products in the supply chain.

The second important element of traceability is “process traceability”, which helps determine the type and sequence of activities that have affected agricultural product during the growing and post-harvest activities that “include interactions between the product and physical/mechanical, chemical, environmental and atmospheric factors, which result in the transformation of the raw material into value-added products; and the absence or presence of contaminants.”<sup>1162</sup> Thus, by extrapolation, “process traceability” for transgenic crop and associated products could facilitate retrospective monitoring of the numerous processes that transgenic crop and products have gone through prior to market debut, right from seed breeders, to farmers, and to food processors. The retrospective insights gleaned from “product traceability” could help determine the exact stage in the life-cycle of transgenic crop and concomitant products that a particular defect occurs, and who amongst numerous actors responsible for processing transgenic crop and associated products in the supply chain was responsible for the defect.

The third important element of traceability is “genetic traceability”, which helps ascertain the genetic composition of agricultural product.<sup>1163</sup> Genetic traceability is especially crucial for transgenic crop and products liability discourse, because genetic compositional information would necessarily include the type of seed and the constituent novel organisms, (such as *Bacillus thuringiensis*) with which the seed under investigation has been genetically modified;

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<sup>1161</sup> Id.

<sup>1162</sup> Id, at 102-103.

<sup>1163</sup> Id, at 103.



as well as the degree of toxicity and allergenicity of the novel organisms in the transgenic seed in question.<sup>1164</sup> Thus, for example, genetic analysis of constituent novel organisms of transgenic plant food, could help identify the defect in transgenic plant food, and how the defect resulted in personal injury in a product liability litigation.<sup>1165</sup>

The fourth element of traceability is “inputs traceability”, which is indicative of source or supplier of agricultural inputs such as seeds, chemical pesticides, etc.<sup>1166</sup> Inputs traceability in the supply chain is no doubt significant in the determination of the source and quality of transgenic seed and agro-chemical pesticides inputs for the purposes of assigning responsibility and liability for any defects in a cause of action for breach of contract, product liability or strict liability. For example, for the purposes of determining contractual liability for defective or ineffective product, or patent infringement for use of transgenic canola without licence or permission, it should be possible for Monsanto to employ “inputs traceability” mechanism such as genetic testing, to determine whether or not a transgenic canola farmer actually used its transgenic canola and its complementary glyphosate herbicides. Similarly, Bayer routinely test seed and crop samples taken from transgenic and non-transgenic farmers’ fields to check for the presence of proprietary transgenic seed and crop that had been cultivated without licence or permission. Furthermore, in Canada, DuPont, the world’s second largest seed company hired dozens of investigators in 2012 to examine planting records of and take samples of seeds from farms across Canada for genetic analysis for the purposes of determining patents infringement.<sup>1167</sup>

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<sup>1164</sup> See Paul R. Billings and Peter Shorett, “Coping with Uncertainty: The Human Health Implications of GE Foods,” in Iain E.P. Taylor, (editor), *Genetically Engineered Crops: Interim Policies, Uncertain Legislation*, supra, note 38.

<sup>1165</sup> Article 6 of the EC Product Liability Directive, which is imparimaterial with section 3(1) of the UK Consumer Protection Act 1987, requires plaintiffs to prove products defects and then link the defects to damage allegedly incurred. See Article 6, Product Liability Directive 85/347/EEC (as amended by 1999/34/EC).

<sup>1166</sup> See Linus U. Opara, “Traceability in agriculture and food supply chain: a review of basic concepts, technological implications, and future prospects,” *Journal of Food, Agriculture, and Environment*, supra, note 1160, at 103.

<sup>1167</sup> See Debbie Barker et al., *Giants vs. U.S. Farmers: A Report by the Centre for Food Safety & Save Our Seeds*, (2013), at 29.

The fifth element of traceability is “disease and pest traceability”, which could facilitate the tracing of “epidemiology of pests, and biotic hazards such as bacteria, viruses and other emerging pathogens that may contaminate food and other ingested biological products derived from agricultural raw materials.”<sup>1168</sup> Again, the ability to trace diseases and pests in the supply chain for transgenic crops is crucial for any liability discourse, as it could facilitate the point at which constituent novel bacterium mutated, or the point at which the mutated or infected transgenic crop and products entered the food chain, and who, amongst numerous actors in the supply chain, was or were responsible for introducing the diseased transgenic crop and products in question into the food chain.

### **6.1.2. Social and Legal Imperatives for Traceability in the Supply Chain.**

However, whilst traceability is crucial for the supply chain liability discourse for transgenic crops, its continuing relevance for agricultural products in general, is underscored by the rise in consumer demands for traceability, due to inherent food safety issues in the supply chain system, which over the years, have ranged from foot-and-mouth disease to mad-cow disease in the United Kingdom and Europe.<sup>1169</sup> With regards to transgenic crops, the recurring incidences of adventitious presence of transgenic in non-transgenic crops,<sup>1170</sup> or adventitious presence of unapproved transgenic organisms in the food chain,<sup>1171</sup> arguably legitimised consumer demands for labelling,<sup>1172</sup> a normative traceability mechanism, which the European Union

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<sup>1168</sup> Linus U. Opara, “Traceability in agriculture and food supply chain: a review of basic concepts, technological implications, and future prospects,” *Journal of Food, Agriculture, and Environment*, *supra*, note 1160, at 103.

<sup>1169</sup> *Id.*, at 103.

<sup>1170</sup> See Erik Stokstad, “A Little Pollen Goes a Long Way,” *Science*, *supra*, note 42, at 2314.

<sup>1171</sup> See *In Re StarLink Corn Products Liability Litigation: Marvin Kramer, et al., v. Aventis CropScience USA Holding, Inc., et al.* 212 F.Supp. 2d 828 (N.D. III 2002); Stephanie Simon, “Fearing a Field of Genes: The Food Industry loves engineered crops, but not when plants altered to ‘grow’ drugs and chemicals slip into its products,” *supra*, note 43, at 1.

<sup>1172</sup> See Robert Lee, “GM Resistant: Europe, and the WTO Panel Dispute on Biotech,” in Jennifer Gunning and Soren Holm, (editors), *Ethics, Law, and Society*, *supra*, note 5, at 131-140; Ambuj Sagar, Arthur Daemrich, and Mona Ashiya, “The Tragedy of the Commoners: Biotechnology and Its Publics,” *Nature Biotechnology*, Volume 18, (1 January 2000), at 2-4; Mark L. Winston, *Travels in the Genetically Modified Zone*, *supra*, note 38; Les

embraced via its labelling and traceability regulations for transgenic crops, which primarily aims to facilitate consumer choice by assurance of on-farm and market separation of transgenic and non-transgenic crops and food products.<sup>1173</sup>

Perhaps, no incident better exemplifies the imperatives for viable normative and technical traceability mechanisms for supply chain liability purposes, than the StarLink corn scandal in the United States, when unapproved experimental transgenic corn was found in the United States food chain and in the United States food aid to Bolivia and Central America in the 2000s.<sup>1174</sup> The unapproved transgenic StarLink corn was not only traced back to Aventis CropScience who were the breeder of StarLink corn, but also, the estimated 135 acres on which the unapproved StarLink corn was cultivated in Iowa, were identified.<sup>1175</sup> Furthermore, and most significantly, the proportion of the unapproved transgenic StarLink corn in the United States food chain was also traced, quantified and measured. For example, according to the Economic Research Service of the United States Department of Agriculture, the StarLink corn was found in an estimated 123 million bushels of corn in 2000, whilst Aventis CropScience, the owner of StarLink corn, estimated that approximately 430 bushels of corn were found to have contained StarLink corn between 1999 and 2000.<sup>1176</sup> These estimates in turn facilitated a massive nation-wide recall of an estimated 300 food corn product types, which included 70 types of corn chips, 80 types of taco shells, and nearly 100 restaurant food products.<sup>1177</sup> Overall,

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Levidow, Joseph Murphy, and Susan Carr, "Recasting Substantial Equivalence": Transatlantic Governance of GM Food," *Science, Technology & Human Values*, *supra*, note 105, at 36.

<sup>1173</sup> See Directive 2001/18/EC No. 1829/2003, and Regulation (EC) No. 1830/2003; Margret Rosso Grossman, "European Community Legislation for Traceability and Labelling of Genetically Modified Crops, Food, and Feed," in Paul Weirich, (editor), *Labelling Genetically Modified Food: The Philosophical and Legal Debate*, (Oxford: Oxford University Press, 2007), at 32-62.

<sup>1174</sup> See Knight Ridder, "Biotech Firm Executive Says Genetically Engineered Corn Is Here to Stay," *Tribune*, (19 March, 2011), at 1; Andy Rees, *Genetically Modified Food: A Short Guide for the Confused*, *supra*, note 118, at 69.

<sup>1175</sup> See Jerry Perkins, "Aventis Pays \$9.2 Million to Iowa Farmers for StarLink," *Des Moines Register*, *supra*, note 120, at D1.

<sup>1176</sup> See Patrick A. Stewart, William P. McLean, and Lucas P. Duffner, "Agricultural Bioterrorism: Dimensions of Fear and Public Perception," in James J.F. Forest, (editor), *Homeland Security: Protecting America's Targets, Volume 2*, (Westport, CT: Greenwood Publishing Group, 2006), at 287.

<sup>1177</sup> *Id.*

an estimated 10 million individual food items that ranged from “tacos, corn chips, corn meal, to all things corn”, were reputedly recalled nationally in the United States.<sup>1178</sup>

The StarLink corn food scandal naturally inflicted damage on farmers, food processors and food exporters. For example, the concomitant economic damage from the loss of the United States corn export markets in the European Union, Japan, and South Korea was enormous,<sup>1179</sup> whilst the United States food industry reportedly lost an estimated \$1 billion to the StarLink corn debacle.<sup>1180</sup> Moreover, the tracing of the StarLink corn in the food chain, and the subsequent identification of the damaged wrought and the party responsible for its inadvertent presence in the food chain, facilitated the subsequent but predictable class action lawsuit that was filed by corn farmers from across the United States against Aventis CropScience *In re StarLink Corn Products Liability Litigation: Marvin Kramer, et al., v. Aventis CropScience USA Holding, Inc., et al.*<sup>1181</sup> The StarLink corn case thus exemplifies the significance of traceability in the attribution of fault and concomitant liability in the supply chain for transgenic plant products. Conversely, it also exemplifies the significance and centrality of supply chain to the apportionment of liability by facilitating traceability of transgenic products from seed breeders, to farmers and ultimately, to the consumer.

Similarly, in the summer of 2001, in Nebraska, United States, traceability in the supply chain facilitated the discovery of the source of experimental adventitious transgenic swine pharmaceutical corn found amidst soybean harvested from Nebraska fields, which had been previously used for cultivating pharmaceutical corn.<sup>1182</sup> The significance of traceability for

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<sup>1178</sup> See Jeffrey M. Smith, *Seeds of Deception: Exposing Corporate and Government Lies about the Safety of Genetically Modified Food*, (Foxhole, Darlington: Green Books Ltd, 2004), at 153.

<sup>1179</sup> See Patrick A. Stewart, William P. McLean, and Lucas P. Duffner, “Agricultural Bioterrorism: Dimensions of Fear and Public Perception,” in James J.F. Forest, (editor), *Homeland Security: Protecting America’s Targets, Volume 2, supra*, note 14, at 287.

<sup>1180</sup> *Id.*

<sup>1181</sup> See *In re StarLink Corn Products Liability Litigation: Marvin Kramer, et al., v. Aventis CropScience USA Holding, Inc., et al., supra*, note 12, at 828.

<sup>1182</sup> See Stephanie Simon, “Fearing a Field of Genes: The Food Industry loves engineered crops, but not when plants altered to ‘grow’ drugs and chemicals can slip into its products,” *supra*, note 28, at 1.

supply chain liability is further exemplified by the discovery of unapproved experimental transgenic white wheat growing on farms in the West Coast of Oregon in the United States in the Spring of 2013.<sup>1183</sup> The unapproved transgenic white wheat was thought to have subsequently entered the United States food chain, and prompted urgent review of wheat imports from the United States by the European Union, Japan and other Asian countries.<sup>1184</sup> It also prompted the European Union authorities to test wheat shipments from the United States for traces of the unapproved transgenic white wheat.<sup>1185</sup>

The significance of traceability in the supply chain for transgenic plant agricultural products is further underscored by the globalised nature of industrial transgenic agricultural economy, which is inherently fragmented and characterised by a few transnational seed companies, contract farming,<sup>1186</sup> and intensive and highly technical agricultural practices that are heavily reliant on proprietary transgenic seed and complementary agro-chemicals herbicides inputs such as Monsanto's glyphosate and Bayer Cropscience' glufosinate.<sup>1187</sup> In the United States for example, the vast majority of commodity crops such as cotton, soybean, corn and canola are transgenic, are owned by a few transnational agrichemical firms such as Monsanto, DuPont, Syngenta, Dow and Bayer Cropscience.<sup>1188</sup> These few seed companies and their proxies are also the primary suppliers of transgenic seed and complementary agrochemical inputs to millions of farmers, who reputedly cultivated approximately 181.5 million hectares with transgenic crops across 28 countries on 6 continents in 2014, an

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<sup>1183</sup> See Anna Edwards, "America facing wheat export crisis as Europe and Japan lead the way in rejecting genetically modified crops," *The Mail Online*, (31 May 2013), at <http://www.dailymail.co.uk/news/article-2333381/GM-wheat-crops-America-facing-wheat-export-crisis-Europe-Japan-lead-way-rejecting-genetically-modified-crops.html> (accessed on 14 May 2015).

<sup>1184</sup> *Id.*

<sup>1185</sup> *Id.*

<sup>1186</sup> See Linus U. Opara, "Traceability in agriculture and food supply chain: a review of basic concepts, technological implications, and future prospects," *Journal of Food, Agriculture, and Environment*, *supra*, note 1160, at 101.

<sup>1187</sup> See *Larry Hoffman et al., and Monsanto Canada Inc, and Bayer Cropscience Inc.*, *supra*, note 980, at 225.

<sup>1188</sup> See Debbie Barker, et al., *Seed Giant vs. U.S. Farmers*, A Report by the Centre for Food Safety & Save Our Seeds, (2013), at 16-17.

unprecedented 100-fold increase from the global 1.7 million hectares cultivated with transgenic crops in 1996.<sup>1189</sup> Thus, an analysis of the supply chain for transgenic seed from major seed breeders to farmers, and ultimately to the consumer around the world, should theoretically facilitate the traceability of transgenic seed breeders and suppliers, the traceability of the farms or farmers to whom approved transgenic seed was supplied; and the traceability of the breeder, country of origin, and the farmers to whom unapproved transgenic seed was supplied; as well as the point at which unapproved transgenic seed entered the food chain. Therefore, and by extrapolation, the ability to trace the nature and origin of transgenic seed in the supply chain should in turn, facilitate the identification of necessary parties to possible causes of action in product liability, strict liability, or contractual liability, as well as attribution of legal responsibility and concomitant liability for non-compliance with mandatory regulations on transgenic plant governance.<sup>1190</sup>

Most crucially, since patents infringement poses inherent liability risk to farmers in the coexistence of transgenic and non-transgenic plant agriculture, traceability of transgenic seed in the supply chain from seed breeders to farmers, could also aid seed firms in enforcing their intellectual proprietary right and exerting their monopoly stranglehold over transgenic seed via the instrumentality of the patent law and technology contract agreements that prohibit seed saving and sharing by farmers.<sup>1191</sup> For example, in order to detect whether farmers were saving and sharing seed and thereby infringing its patents and technology agreement, DuPont, the world's second largest seed firm reputedly hired at least 45 farm investigators in 2012 to investigate planting and purchasing records of Canadian farmers, and obtain samples from their

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<sup>1189</sup> Given that the annual growth rate for global transgenic crops adoption is approximately 6 percent, the 170.3 million acres 2012 estimate is bound for inexorable future increase, as is the case since the commercial debut of transgenic crops in 1996. For discussion, see Clive James, *Global Status of Commercialized Biotech/GM Crops: 2014*, *supra*, note 1.

<sup>1190</sup> See Jerry Perkins, "Aventis Pays \$9.2 Million to Iowa Farmers for StarLink," *Des Moines Register*, *supra*, note 14, at D1; *In re StarLink Corn Products Liability Litigation: Marvin Kramer, et al., v. Aventis CropScience USA Holding, Inc., et al.*, *supra*, note 20, at 828.

<sup>1191</sup> See Debbie Barker, et al., *Seed Giant vs. U.S. Farmers*, A Report by the Center for Food Safety & Save Our Seeds, *supra*, note 5, at 22-26.

fields for DNA analysis, that would show whether or not farmers were cultivating illegal transgenic seed.<sup>1192</sup>

### **6.1.3. Technological Challenges to Traceability of Transgenics in The Supply Chain.**

In the context of transgenic plant agricultural products, traceability is technically challenging as products identification, and genetic analysis of products, would require technical expertise, the absence of which could be a huddle to establishing a cause of action for product or contractual liability in the supply chain. According to Linus O. Opara:

To implement traceable agricultural supply chains, technological innovations are needed for product identification, process and environmental characterization, information capture, analysis, storage and transmission, as well as overall system integration. These technologies include hardware (such as measuring equipment, identification tags and labels) and software (computer programmes and information systems).<sup>1193</sup>

With regards to transgenic crops, the technology needed for product identification, genetic analysis, environmental monitoring, and quality and safety measurements, is highly specialised and governments and farmers may have to ironically rely on seed firms or authorised laboratories to help detect adventitious presence of both approved and unapproved transgenic plant organisms in the food chain. For example, in the spring of 2013, regulatory authorities in the European Union purportedly sought the help of Monsanto Corporation to test incoming shipments of United States white wheat for traces of unapproved transgenic organisms.<sup>1194</sup> However, there are obvious potential pitfalls and conflicts of interests in placing reliance on the technology of seed firms for tracing adventitious presence of approved or unapproved transgenic organisms in the food chain, for the purpose of establishing supply chain liability.

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<sup>1192</sup> Id, at 27.

<sup>1193</sup> See Linus U. Opara, "Traceability in agriculture and food supply chain: a review of basic concepts, technological implications, and future prospects," *Journal of Food, Agriculture, and Environment*, *supra*, note 1060, at 103-104.

<sup>1194</sup> See Anna Edwards, "America facing wheat export crisis as Europe and Japan lead the way in rejecting genetically modified crops," *The Mail Online*, (31, May 2013), *supra*, note 32.

This is exemplified by the inconclusive results of the tests conducted on blood samples of people who allegedly suffered allergies following the consumption of food purportedly containing Cry9C protein of *Bacillus thuringiensis* bacterium in the StarLink corn.<sup>1195</sup> The United States Food and Drug Administration and the Centre for Disease Control and Prevention had relied on the Cry9C protein samples supplied by Aventis CropScience, the seed firm under investigation, to determine whether or not there was a nexus between the consumption of food containing StarLink corn and the allergies suffered by the people whose blood samples were tested.<sup>1196</sup> It was subsequently alleged that the samples submitted by Aventis CropScience for testing, were synthesised substitutes from *E. Coli* bacteria, rather than Cry9C protein from *Bacillus thuringiensis* bacterium, raising legitimate questions on the propriety and validity of the test conducted on the blood samples and the subsequent results that exonerated the StarLink corn.<sup>1197</sup>

#### **6.1.4. The Costs of Technical Traceability of Transgenes in The Supply Chain.**

Even where testing facilities are readily available and not compromised, there is also the additional problem of who bears the costs of testing food and feed crops for traces of adventitious presence of approved and unapproved transgenes. For example, would the European Union pay Monsanto Corporation for testing shipments of United States white wheat imports for unapproved transgenes, or would the costs be passed on to the food importer?<sup>1198</sup> In Serbia, which is aspiring to join the European Union, the government has a mandatory policy of testing and analysing seed, maize, soybean and feed products that are transported over the

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<sup>1195</sup> See Marc Kaufman, “Biotech Corn Is Test Case for Industry: Engineered Food’s Future Hinges on Allergy Study,” *Washington Post*, *supra*, note 17, at 1; Jeffrey M. Smith, *Seeds of Deception: Exposing Corporate Government Lies about the Safety of Genetically Engineered Food*, *supra*, note 17, at 148-149.

<sup>1196</sup> See Jeffrey M. Smith, *Seeds of Deception: Exposing Corporate Government Lies about the Safety of Genetically Engineered Food*, *id*, at 150.

<sup>1197</sup> *Id*, at 150.

<sup>1198</sup> See Anna Edwards, “America facing wheat export crisis as Europe and Japan lead the way in rejecting genetically modified crops,” *The Mail Online*, (31, May 2013), *supra*, note 32.



state border, for the presence of approved and unapproved transgenes at authorised laboratories, while the costs are passed on to products importers.<sup>1199</sup> The main problem with the Serbian system however, is that importers of food and feed crops would eventually internalise the costs of genetic analyses and pass it on to the consumer via food and feed crops products pricing, an inevitable price that consumers have to pay in the coexistence paradigm.<sup>1200</sup>

On the other hand, if a national government or a supra-national authority such as the European Union funded genetic testing of food and feed crops for the presence of transgenes, the funding would arguably constitute an indirect tax on the consumer, whose tax money would invariably be used for the exercise. Alternatively, if regulatory authorities were to pass on the costs of testing food and feed crops for the presence of transgenes to transgenic seed firms via licensing fees or other regulatory charges, seed firms could in turn internalise the costs as production costs, which they could then pass on to farmers, who would in turn pass the costs on to the consumer. Thus, the market economy of the technical aspects of traceability of approved and unapproved transgenes in the supply chain for transgenic crops would appear skewed against the consumer, with obvious implications for global food affordability and food security.

In sections 6.1.0, 6.1.1, 6.1.2, and 6.1.3 above, the chapter highlights the nexus between transgenic crops and products traceability, supply chain, and consequential liability for damage stemming from the coexistence of transgenic and non-transgenic plant agriculture. It is noted that traceability mechanisms could be at once normative and technical, and are crucial for establishing supply chain liability that range from strict liability, product liability, and contractual liability for possible environmental, economic, or health damage that could stem

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<sup>1199</sup> See David Duthie and Liina Eek, “National Biosafety Regulatory Systems in Central and Eastern Europe,” in Marie-Claire Cordonier Segger, Frederic Perron-Welch, and Christine Frison, *Legal Aspects of Implementing the Cartagena Protocol on Biosafety*, (Cambridge & New York: Cambridge University Press, 2003), at 242.

<sup>1200</sup> See the analysis of literature in section 1.1.8 and Chapter Four of the thesis.

from adventitious presence of transgenic traits in non-transgenic food products. However, the technicality involved in genetic analysis and product identification for traceability of transgenic crop and products in the supply chain could be a barrier to establishing supply chain liability, as the technical expertise required could be beyond the reach of regulatory authorities and farmers, who might need to establish product or contractual liability for adventitious presence of transgenic organisms in non-transgenic crops and products. It is also noted that relying on seed firms to supply technical data or expertise required could compromise results and defeat supply chain liability; and that ultimately, it is the consumer that pays for the costs of technical traceability of transgenes in food and feed crops.

#### **6. 2.0. General Concept of Strict Liability.**

Strict liability is generally predicated on the theory of liability without fault,<sup>1201</sup> which subsists in criminal and civil contexts, and is in contradistinction to the “no liability without fault” mantra that is the general hallmark of the tort of negligence.<sup>1202</sup> Thus, by virtue of the strict liability doctrine, the defendant could be legally liable in criminal or civil court for damage or loss caused by an act or omission regardless of fault in a civil litigation, or culpability (*mens rea*) in a criminal litigation. However, whilst strict liability exists under the tort of private nuisance in England and Wales, and generally at common law in criminal libel and blasphemy,<sup>1203</sup> the concept of strict liability in civil or criminal law often manifests in civil or quasi-criminal statutory or regulatory provisions across common and civil law countries.<sup>1204</sup> In

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<sup>1201</sup> See Charles O. Gregory, “Trespass to Negligence to Absolute Liability,” in David Campbell and Robert Lee, (editors), *Environmental Law and Economics, Volume II*, (Aldershot, England & Burlington, USA: Ashgate Publishing, 2007), at 30.

<sup>1202</sup> See Richard A. Epstein, “A Theory of Strict Liability,” in David Campbell and Robert Lee, *Environmental Law and Economics, Volume I*, (Aldershot, England & Burlington, USA: Ashgate Publishing, 2007), at 228-229, (noting that the aphorism “no liability without fault” was a moral oppositional battle cry against strict liability.)

<sup>1203</sup> See for example *Whitehouse v. Lemon Gay News*, [1979] 2 WLR 281.

<sup>1204</sup> This is exemplified by *Pharmaceutical Society of Great Britain v Storkwain* (1986) 2 ALL ER 635, in which a pharmacist was held criminally liable for supplying prescription drugs to a patients who used a forged doctor’s prescription note. The court justified the imposition of strict liability on the premise that drugs misuse was a social

continental Europe for example, Germany,<sup>1205</sup> Austria,<sup>1206</sup> Switzerland,<sup>1207</sup> and Norway,<sup>1208</sup> all have statutory strict liability regimes for damage or loss stemming from adventitious presence of transgenic plant organisms in non-transgenic crop and products, which shall be analysed in Chapter Seven.

### 6.2.1. Judicial Presumption of Strict Liability in the UK.

Perhaps, with the exception of the United Kingdom Patent Act 1977, which protects patented seeds and imposes strict liability for patents infringements,<sup>1209</sup> and the Consumer Protection Act, which imposes strict liability for defective products,<sup>1210</sup> there is as yet, no statutory law in England and Wales or any part of the United Kingdom that specifically imposes strict liability on potential defendants for damage or loss stemming from adventitious presence of transgenic organisms in non-transgenic plant materials, unlike continental European countries such as Austria and Germany.<sup>1211</sup> The pertinent question therefore, is whether courts in England and Wales could imply or construe strict liability into any of the cognate legislations governing the coexistence of transgenic and non-transgenic plant agriculture and concomitant damage? In other words, could courts in England and Wales hold a transgenic crop farmer strictly liable for non-compliance with relevant provisions of the law governing deliberate release of transgenic plant organisms into the environment, or hold a grocery store manager strictly liable for non-compliance with labelling rules for transgenic plant food? For example, according to

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evil, and that pharmacists must be encouraged to take unreasonable care to verify the authenticity of prescription notes.

<sup>1205</sup> See generally the German Gene Technology Act 1990 (as amended).

<sup>1206</sup> See generally the Austrian Gene Technology Act 510, 1994 (as amended).

<sup>1207</sup> See generally the Swiss Law on Genetic Engineering, 2003.

<sup>1208</sup> See generally the Norwegian Gene Technology Act, Act 38 of 23 April, 1993.

<sup>1209</sup> See Patents Act 1977, (as amended); *Monsanto Canada Inc., v. Schmeiser*, *supra*, note 76, at 902

<sup>1210</sup> See the Consumer Protection Act Chapter 43, 1987, which implemented the EC Product Liability Directive 85/374/EEC as amended.

<sup>1211</sup> See DEFRA, Consultation on proposals for managing the coexistence of GM, conventional and organic crops, (2006), at <http://www.defra.gov.uk/environment/gm/crops/pdf/gmcoexist-condoc.pdf> (accessed on 14 May 2015).

the key provisions of Genetically Modified Organisms (Deliberate Release) Regulations 2002, which implemented the Deliberate Release Directive 2001/18/EC in England and Wales, the cultivation of transgenic plant seeds in England and Wales is prohibited without prior authorisation. Moreover, organic or conventional crops and products that contain transgenic organisms in excess of the 0.9 maximum labelling thresholds must be labelled as containing transgenic organisms.<sup>1212</sup>

There are indeed numerous legislations, which courts in England and Wales have routinely, albeit inconsistently, interpreted to presume strict liability or imply *mens rea* or guilty mind, whenever legislative provisions are silent on the requirement of strict liability or *mean rea*.<sup>1213</sup> The rationale or justification for judicial presumption of strict liability or importation of *mens rea* into statutory provisions in the absence of express Parliamentary intent, was reiterated in *Sweet v. Parsley*, in which a school teacher was charged under section 5(6) of the Dangerous Drug Act 1965, for renting out her house to students who used it to smoke cannabis without her knowledge or consent. However, the statute did not require *mens rea* for the offence. The House of Lords observed that the common law required knowledge prior to the enactment of the statute, and that *mens rea* could only be presumed when the offence is a true crime as opposed to a regulatory offence. Whilst quashing her conviction, Lord Reid observed thus:

There is for centuries been a presumption that Parliament did not intend to make criminals of persons who were in no way blameworthy in what they did. That means that whenever a (legislative provision) is silent as to *mens rea*, there is a presumption that in order to give effect to the will of parliament we must read in words appropriate to require *mens rea*.<sup>1214</sup>

It does follow that there would likely be a very strong, albeit rebuttable presumption of strict liability or *mens rea*, especially when courts are dealing with offences that are inherently criminal in nature or character, as opposed to offences that are merely regulatory in nature,

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<sup>1212</sup> See Article 12(2) and 24(2) of Regulation (EC) No. 1829/2003, *supra*, note 12.

<sup>1213</sup> See *Gamon v. AG for Hong Kong*, (1984), 2 All ER 503.

<sup>1214</sup> See *Sweet v. Parsley*, (1970) AC 132..

since “Parliament did not intend to make criminals of persons who were in no way blameworthy in what they did.”<sup>1215</sup> Thus, by extrapolation, courts in England and Wales that are faced with interpreting cognate statutory provisions governing the coexistence of transgenic and non-transgenic plant agriculture and concomitant damage, which are currently largely devoid of strict liability provisions,<sup>1216</sup> would have to make a distinction between non-compliance that are inherently criminal in nature and non-compliance that are merely regulatory in nature. In making the critical determination, courts would have to be guided by the wording of the statutory provisions under consideration and the nature of the offence. For example, could failure to comply with strict segregation rules by a transgenic maize farmer warrant a criminal conviction? It is highly unlikely, because this is not expressly stipulated in the coexistence rules, and the nature of the behaviour is at best negligent and non-criminal. .

According to Lord Nicholls in *B v. DPP*,<sup>1217</sup> in the absence of express provision in the applicable statute requiring a rebuttable presumption of *mens rea*, courts could imply a rebuttable presumption of *mens rea* in circumstances where the wording of the statute in question made it compellingly clear that presumption of *mens rea* was rebuttable, taking into consideration the nature of the offence, the mischief, which the statute was designed to rectify, and other circumstances that could help ascertain legislative intentions.<sup>1218</sup> In other words, courts in England and Wales are obliged to thoroughly examine the overall purpose of the

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<sup>1215</sup> See *Sweet v. Parsley*, *id.*, at 140.

<sup>1216</sup> The 2006 DEFRA consultation proposals recommended that existing regulatory regime such as product liability should continue to apply to redress damage emanating from the coexistence of transgenic and non-transgenic plant agriculture. See DEFRA, *Consultation on proposals for managing the coexistence of GM, conventional and organic crops*, (2006), *supra*, note 65.

<sup>1217</sup> See *B v. DPP*, [2000] 2 AC 428. A 14 year old boy was charged with the offence of inciting a 13 year old girl to commit an act of gross indecency, when he repeatedly asked the underage girl to perform oral sex on him, an act that is contrary to section 1(1) of the Indecency with Children Act 1960. The boy had believed that the girl was over 14 years old. The key question for determination was whether the offence under section 1(1) required strict liability with regards to the age of the victim of sexual harassment? The court held that strict liability could not be presumed in the circumstances, and the earlier conviction was quashed.

<sup>1218</sup> *Id.*, at 440.

statute in question, and should not conclude lightly that an offence is of a strict liability by nature, as exemplified by the following dictum by Lord Goddard in *Brend v. Wood*:

It is of utmost importance for the protection of the liberty of the subject that a court should always bear in mind that, unless a statute clearly or by necessary implication rules out mens rea as a constituent part of the crime, the court should not find a man guilty of an offence against the criminal law unless he has a guilty mind.<sup>1219</sup>

Moreover, judicial presumption of strict liability or *mens rea* into statutory interpretation is rebuttable when the underlying issues pertain to public safety, and the imposition of strict liability or means rea in the circumstances would only be necessary to accomplish the goals of the legislation in question. For example, in *Pharmaceutical Society of Great Britain v Storkwain*, a pharmacist was held criminally liable for supplying prescription drugs to a patient who used a forged doctor's prescription note. The court justified the imposition of strict liability on the premise that drugs misuse was a social evil, and that pharmacists must be encouraged to take unreasonable care to verify the authenticity of prescription notes.<sup>1220</sup> Similarly, in *R v. Brockley*,<sup>1221</sup> the key issue for determination before the Court of Appeal for England and Wales, was whether the presumption of strict liability would fulfil the primary goal of the statute that prohibited undischarged bankrupts from acting as a company director? The Court of Appeal construed the offence of an undischarged bankrupt acting as a company director, as being of strict liability in nature, because such interpretation would help achieve the primary goal of the legislation, which was to ensure that bankrupts must take necessary steps to be discharged from bankruptcy prior to taking up appointments as company directors.<sup>1222</sup>

By extrapolation, in the absence of strict liability provisions in the current regulatory framework on liability arising from the coexistence of transgenic and non-transgenic plant agriculture in the United Kingdom, the pertinent question is whether courts would be inclined

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<sup>1219</sup> See *Brend v. Wood*, (1946), 62 T.L.R. 462, at 475.

<sup>1220</sup> See *Pharmaceutical Society of Great Britain v. Storkwain*, *supra*, note 61, at 635.

<sup>1221</sup> See *R v. Brockley*, (1994) 99 Criminal Appeal Report, 385.

<sup>1222</sup> *Id.*, at 390.

to import strict liability into cognate legislations and hold a transgenic maize farmer strictly liable for non-compliance with statutory separation distances or the maintenance of a buffer zone between his transgenic maize farm and neighbouring non-transgenic maize farms for example?<sup>1223</sup> Or would courts in England and Wales be inclined to presume strict liability, and hold a grocer strictly liable for failure to label food products that contain transgenic organisms, whilst interpreting the provisions of the traceability and labelling rules, which enjoin labelling of transgenic plant food and products?<sup>1224</sup> There is no certain or clear answer, as the outcome would invariably depend on the wording of the statutory provisions in question, the nature of the infraction, and whether or not public safety is compromised in the circumstances.<sup>1225</sup>

It is thus clear from the foregoing analysis that judicial presumption of strict liability by courts in England and Wales is largely uncertain and clearly dependent on the factual circumstances of each case. Thus, unless Parliament specifically intended strict liability for harm or damage caused by adventitious admixture of transgenic and non-transgenic plant materials in England and Wales, as some legislative authorities in continental European countries have done, courts might be reluctant to presume strict liability or construe *mens rea* into applicable statutes on the coexistence of transgenic and non-transgenic plant agriculture, unless the offence leading to the harm or damage is inherently criminal in nature. Thus to the extent that the outcome of judicial presumption of strict liability in the interpretation of cognate legislative provisions governing damage arising from adventitious presence of transgenic

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<sup>1223</sup> See National Institute of Agricultural Botany, Report on the separation distances required to ensure GM content of harvested material from neighbouring fields is below specified limits in non-seeds crops of oil rape, maize and sugar beet, (Cambridge: January 2006), at 9. Available at <http://randd.defra.gov.uk/Default.aspx?Menu=Module&Module=More&Location=None&ProjectID=13261&FromSearch=Y&Publisher=1&SearchText=CB02039&SortString=ProjectCode&SortOrder=Asc&Page=10#Description> (accessed on 14 May 2014).

<sup>1224</sup> See Article 12(1) (a) (b) and 2(2) of Regulation (EC) No. 1829/2003 of the European Parliament and of the Council on Genetically Modified Food and Feed, OL L268/1 (18/10/2003).

<sup>1225</sup> See *Pharmaceutical Society of Great Britain v Storkwain*, *supra*, note 61, at 635, in which a pharmacist was held criminally liable for supplying prescription drugs to a patients who used a forged doctor's prescription note. The court justified the imposition of strict liability on the premise that drugs misuse was a social evil, and that pharmacists must be encouraged to take unreasonable care to verify the authenticity of prescription notes. See also *R v. Brockley*, *supra*, note 1221, at 390.

organisms in non-transgenic crops is far from certain, judicial presumption of strict liability or *mens rea* could hardly be a viable or reliable cause of action for potential plaintiffs who might sue for damage caused by adventitious admixture of transgenic and non-transgenic plant organisms.

*A fortiori*, it is recommended that Parliament in the United Kingdom should enact legislations governing the coexistence of transgenic and non-transgenic plant agriculture and the concomitant damage, which are similar to that of Austria, Norway, Germany and other continental European countries that specifically impose strict liability for damage or harm that stem from adventitious admixture of transgenic and non-transgenic plant materials, rather than leave the situation to the vagaries of rebuttable judicial presumption of strict liability or *mens rea* in the interpretation of relevant statutory provisions governing the coexistence of transgenic and non-transgenic plant agriculture. This is especially imperative because the current practice of judicial presumption of strict liability or *mens rea* is largely arbitrary, uncertain, and thus inadequate for possible causes of action under currently applicable transgenic laws in the United Kingdom, such as those on labelling or segregation rules for example.<sup>1226</sup> Thus, in the absence of express statutory provisions in England and Wales that impose strict liability for damage or harm caused by adventitious presence of transgenic organisms in non-transgenic crops, potential plaintiffs would have to rely on the rule in *Rylands v. Fletcher*, a variant of the tort of private nuisance, which is inherently limited due to the requirements of land use and reasonable foreseeability of harm or damage.<sup>1227</sup>

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<sup>1226</sup> See 12(1) (a) (b) and 2(2) of Regulation (EC) No. 1829/2003 of the European Parliament and of the Council on Genetically Modified Food and Feed, *supra*, note 79.

<sup>1227</sup> For comprehensive discussion on the applicability of the tort of private nuisance to damage emanating from the coexistence of transgenic and non-transgenic plant agriculture, see generally chapter seven of thesis. See also Ken Oliphant, "Economic Loss Caused by GMOs in the United Kingdom: England & Wales," in Bernhard A. Koch, (editor), *Economic Loss Caused by Genetically Modified Organisms: Liability and Redress for the Adventitious Presence of GMOs in Non-GM Crops*, *supra*, note 68, at 518-519.



### 6.2.3. Sui Generis Statutory Strict Liability for Damage Caused by Transgenics.

Unlike the United States,<sup>1228</sup> and the United Kingdom, most continental European countries such as Germany, Austria, Switzerland, etc., have a *sui generis* strict liability regime for damage that stem from the co-existence of transgenic and non-transgenic plant agriculture. This section will briefly review the significance of the statutory strict liability regimes in Austria, Germany and Norway, and the implications for transgenic plant agriculture governance system in Europe.

In Norway, the 1993 Norwegian Act on Genetic Technology<sup>1229</sup> regulates liability and redress regime for damage emanating from the co-existence of transgenic and non-transgenic plant agriculture.<sup>1230</sup> Of particular significance is section 23 of the Act, which imposes strict liability for damage resulting from the coexistence of transgenic and non-transgenic plant agriculture:

One who is responsible for activity under the scope of this statute is liable without fault when the activity by placing or emitting genetically modified organisms in the environment causes damage, inconvenience or loss.<sup>1231</sup>

According to Bjarte Askeland, the above provision would cover situations where non-transgenic crops were contaminated by genetically modified crops.<sup>1232</sup> Thus, in situations analogous to *Schmeiser case*,<sup>1233</sup> Norwegian non-transgenic farmers could arguably counter-claim for economic and property damage in a cause of action for strict liability.

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<sup>1228</sup> See A. Bryan Endres, “Damage Caused by GMOs under US Law,” in Bernhard A. Koch, (editor), *Damage Caused by Genetically Modified Organisms: Comparative Survey of Redress Options for Harm to Persons, Property or the Environment*, (Berlin & New York: Walter de Gruyter GmbH & Co. KG, 2010), at 733.

<sup>1229</sup> See Norwegian Act on Genetic Technology [gentekol] No. 38, 2 April 1993, cited in Bjarte Askeland, “Damage Caused by GMOs under Norwegian Law”, in Bernhard A. Koch, (editor), *Damage Caused by Genetically Modified Organisms: Comparative Survey of Redress Options for Harm to Persons, Property or the Environment*, id, at 427.

<sup>1230</sup> Id.

<sup>1231</sup> Id.

<sup>1232</sup> The author noted that the Norwegian government was yet to finalise liability rules for the co-existence of transgenic and non-transgenic plant agriculture, even though the Ministry of Agriculture had been planning to do so for some years. See id, at 427-428.

<sup>1233</sup> See *Monsanto Canada Inc., v. Schmeiser*, *supra*, note 48, at 902.

In Austria, the Gene Technology Act regulates liability and redress regime for damage emanating from the coexistence of transgenic and non-transgenic plant agriculture.<sup>1234</sup> In particular, sections 79a-j of the Gene Technology Act (GTG) imposes strict liability on the operator of transgenic organisms for risks associated with “the production, use, increase, storage, destruction or disposal of genetically modified organisms, as well as their intentional and unintentional release.”<sup>1235</sup> Thus, under the Austrian Gene Technology Act, a transgenic maize farmer whose crop cross-pollinated or commingled with neighbouring organic or conventional maize, could be strictly liable for property or economic damage, even though the cross-pollination was not his fault, but a natural biological process.

Also, if the definition of the “operator” includes transgenic seed breeder or firm, then presumably, transgenic seed firms such as Monsanto could also be strictly liable for damage caused by unwanted transgenes in the environment following intentional or unintentional release. According to Manuela Weissenbacher, a subsequent amendment to the Austrian Gene Technology Act in 2004, introduced a new section 79k paragraph 1, which provides for an injunctive relief for “the owner of land in agricultural use, or the holder of another property right”, against “emissions from neighbouring land provided the neighbour cultivates products that consist of or contain GMOs.”<sup>1236</sup> The nature and scope of the injunction injunctive relief is described thus by Manuela Weissenbacher:

An injunction will be granted in case of contamination by GMOs originating from agriculturally used land which was either caused directly (e.g. by sowing or planting) or by indirect effects during the growth phase, the harvest or even later. Furthermore, the interference must exceed a certain tolerance threshold and cause a substantial impairment of the use of the affected farmland. If the above described interference results in damage to person and/or property, the neighbour who caused the interference is liable regardless of fault vis-a-vis the affected landowner or holder of the property

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<sup>1234</sup> See the Gene Technology Act (Gentechnikgesetz, GTG), Bundesgesetzblatt (BGBl) 1994 as amended by BGBl I 2006/13, cited in Manuela Weissenbacher, “Damage Caused by GMOs under Austrian Law,” in Bernhard A. Koch, (editor), *Damage Caused by Genetically Modified Organisms: Comparative Survey of Redress Options for Harm to Persons, Property or the Environment*, id, at 2.

<sup>1235</sup> Id.

<sup>1236</sup> Id, at 3.

right.<sup>1237</sup>

Furthermore, an operator of transgenic plant organisms would also be liable regardless of fault for harm, death, personal injury or damage to health suffered by a person or persons.<sup>1238</sup> Most importantly, the operator would still be liable even if the transgenic organisms that caused damage to property or harm was authorised.<sup>1239</sup>

In Germany, the Act on Genetic Engineering (GenTG) was enacted in 1990 to provide special liability and redress regime for damage emanating from the release of genetically modified organisms.<sup>1240</sup> According to Jorg Fedtke, the Act provides for strict liability for harm caused by research and development, but does not exclude parallel or alternative causes of action in nuisance, and “the fault-based general rule of tort law, whilst losses caused by licensed genetically modified organisms are covered by the Product Liability Act.<sup>1241</sup> According to Jorg Fedtke, the applicability of strict liability depends on whether or not “a particular GMO may be circulated freely”.<sup>1242</sup> Thus, if a genetically modified organism has not been authorised for free circulation or release into the environment, then concomitant “losses of life, health, or property are covered by the *Gentechnikgesetz*, which establishes strict liability for harm caused by research and development.”<sup>1243</sup> However, if a genetically modified organism was licensed or authorised for free circulation or release into the environment, then concomitant damage could only be remedied by product liability and other parallel remedies in tort.<sup>1244</sup>

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<sup>1237</sup> *Id.*, at 3.

<sup>1238</sup> See Section 79a, paragraph 1 of the Gene Technology Act, cited in Manuela Weissenbacher, “Damage Caused by GMOs under Austrian Law,” *id.*

<sup>1239</sup> *Id.*, at 3 and 4.

<sup>1240</sup> The Act has been amended several times with major amendments made in 1993, 2004, 2006, and 2008. See Gesetz zur Regelung der Gentechnik of 20 June 1990, Bundesgesetzblatt (BGBl.) 1990 I 1080 ff. Cited in Jorg Fedtke, “Damage Caused by GMOs under German Law,” in Bernhard A. Koch, (editor), *Damage Caused by Genetically Modified Organisms: Comparative Survey of Redress Options for Harm to Persons, Property or the Environment*, *id.* at 212.

<sup>1241</sup> *Id.*, at 212-213.

<sup>1242</sup> *Id.*, at 212.

<sup>1243</sup> *Id.*

<sup>1244</sup> *Id.*

Limiting the application of strict liability to harm or damage caused by transgenic organisms in the research and development phase, and prior to authorised commercial release or circulation, is significant in that only seed firms and institutions engaged in confined laboratory or field trials could be strictly liable for concomitant damage to public health and property under the German Genetic Engineering Act. Thus, by extrapolation, whilst transgenic crop farmers could be liable for nuisance or other fault-based rule in tort, they could not be strictly liable to organic or conventional crop farmers for damage caused by the adventitious presence of transgenes in organic or conventional crops, provided that transgenic crop farmers had authorisation or licence to cultivate their crops. This is in contradistinction to the Austrian Gene Technology Act, under which an operator, which presumably include transgenic crop farmers with a valid growing licence, could be strictly liable for damage caused to neighbouring conventional or organic crops in the coexistence of transgenic and non-transgenic plant agriculture.<sup>1245</sup>

### **6.3.0. General Concept of Product liability.**

A cause of action in product liability is open to aggrieved consumers who might want to sue products manufacturers for defective products. In the European Union and the United Kingdom, product liability is a statutory strict liability remedy, respectively under the Product Liability Directive,<sup>1246</sup> and the Consumer Protection Act.<sup>1247</sup> The preamble to the European Economic Community Product Liability Directive rationalised the justification for its strict liability nature thus: "Liability without fault on the part of the producer is the sole means of

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<sup>1245</sup> See Manuela Weissenbacher, "Damage Caused by GMOs under Austrian Law," in Bernhard A. Koch, (editor), *Damage Caused by Genetically Modified Organisms: Comparative Survey of Redress Options for Harm to Persons, Property or the Environment*, *supra*, note 170, at 3.

<sup>1246</sup> See Product Liability Directive 85/347/EEC (as amended by 1999/34/EC), *supra*, note 70.

<sup>1247</sup> See section 1(1) of the Consumer Protection Act, Chapter 43, 1987, which implemented the provisions of the Product Liability Directive in the United Kingdom.

adequately solving the problem, peculiar to our age of increasing technicality, of a fair apportionment of the [risks](#) inherent in modern technological production."<sup>1248</sup>

In the UK, the Department of Environment, Agriculture and Rural Affairs (DEFRA), suggested in its 2006 Consultation Report on coexistence and liability, that reliance should be had on existing statutory remedies such as “product liability”, rather than formulating special liability regimes for damage arising from the coexistence of transgenic and non-transgenic plant agriculture.<sup>1249</sup> The extent of the effectiveness of product liability law for inherent damage in the coexistence paradigm will be discussed in section 6.3.1. B of the thesis.

### **6.3.1. Establishing Product Liability in the Supply Chain: The US, UK& EU.**

#### **A. The United States.**

In the United States, product liability rules vary from state to state and there is no single federal statute or legislation that is comparable to the European Community Product liability Directive. Rather, “product liability” remedy is subsumed under a variety of judge-made consumer protection laws that range from the tort of negligence, strict liability tort, and breach of warranties.<sup>1250</sup> The landmark case that established the boundary of product liability doctrine, which was subsequently incorporated into the American Law Institute’s *Restatement of the Law, Third Torts: Product Liability*,<sup>1251</sup> was *Greenman v. Yuba Power Products*,<sup>1252</sup> in which Justice Roger J. Traynor of the Supreme Court of California, whilst referencing his earlier judgement in [Escola v. Coca-Cola Bottling Co.](#),<sup>1253</sup> observed thus:

We need not recanvass the reasons for imposing strict liability on the manufacturer. The purpose of such liability is to insure that the costs of injuries resulting from defective products are borne by the manufacturers that put such products on the market

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<sup>1248</sup> See Preamble to Product Liability Directive, *supra*, note 70.

<sup>1249</sup> See DEFRA, Consultation on proposals for managing the coexistence of GM, Conventional and Organic Crops, (2006), *supra*, note 65.

<sup>1250</sup> See James A. Henderson, Jr., and Aaron D. Twerski, *The American Law Institute, Restatement of the Law Third, Torts: Product Liability*, (The American Law Institute, 1998). (This is a publication of the American Law Institute, which is essentially a codification of case law. It is neither a Congressional legislation nor states laws).

<sup>1251</sup> See *id.*

<sup>1252</sup> See *Greenman v. Yuba Power Products*, [59 Cal. 2d 57](#) (1963).

<sup>1253</sup> See [Escola v. Coca-Cola Bottling Co.](#), [24 Cal. 2d 453, 462](#) (1944).

rather than by the injured persons who are powerless to protect themselves... To establish the manufacturer's liability it was sufficient that plaintiff proved that he was injured while using the Shopsmith in a way it was intended to be used as a result of a defect in design and manufacture of which plaintiff was not aware that made the Shopsmith unsafe for its intended use.<sup>1254</sup>

In 1986, the United States Supreme Court adopted the doctrine of strict liability for defective product espoused in 1963 by Justice Traynor in *Greenman*, as part of federal admiralty law in *East River S.S. Corp. V. Transamerica Delaval Inc.*,<sup>1255</sup> whilst the principle of product liability as espoused in *Greenman*, and as subsequently codified in the *Restatement of the Law, Third Torts: Product Liability*,<sup>1256</sup> remains the cornerstone and a standard reference point in product liability litigations both by the Bar and courts across the United States.

Section 7 of the *Restatement of the Law, Third Torts: Product Liability* deals with the liability of commercial seller or distributor of food products for harm caused by defective food products, and provides thus:

One engaged in the business of selling or otherwise distributing food products who sells or distributes a food product that is defective under § 2, § 3, or § 4 is subject to liability for harm to persons or property caused by the defect. Under § 2(a), a harm-causing ingredient of the food product constitutes a defect if a reasonable consumer would not expect the food product to contain that ingredient.<sup>1257</sup>

Arguably, the above provision should cover food derived from transgenic plant, and the seller or distributor could be liable for harm caused to persons or property. Thus, if a person suffered from food poisoning or allergy, or got sick following consumption of defective food derived from transgenic plant, he or she could theoretically have a cause of action in product liability against the grocer, restaurateur, or eatery, or the farmer who sold the food product, for any harm or personal injury sustained. Transgenic plant food product could be defective, if “at the

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<sup>1254</sup> See *Greenman v. Yuba Power Products*, *supra*, note 1252, at 63-64.

<sup>1255</sup> See *East River S.S. Corp. V. Transamerica Delaval Inc.*, 476 U.S. 858 (1986).

<sup>1256</sup> See James A. Henderson, Jr., and Aaron D. Twerski, *The American Law Institute, Restatement of the Law Third, Torts: Product Liability*, *supra*, note 1250.

<sup>1257</sup> See section 7, *id.*

time of sale or distribution, it contains a manufacturing defect, is defective in design, or is defective because of inadequate instructions or warnings.”<sup>1258</sup>

There are conceivable scenarios in which transgenic plant food product could contain manufacturing defect, be defective in design, or defective by lack of inadequate instructions or warnings. For example, transgenic plant food could have manufacturing defect, if the constituent novel genes such as the eponymous *Bacillus thuringiensis* bacterium that is routinely used to modify plant crops like Bt maize, Bt canola, Bt cotton, etc, radically affected the expression or behaviour of other genes in the host plant genome. This scenario is plausible due to the acknowledgement of the United States Food and Drug Administration, that the insertions of recombinant DNA (nucleic acid proteins) such as *Bacillus thuringiensis*, into genetically active chromosomal location in plant genome could disrupt or hamstring important genes or regulatory sequences that underpin the expression of one or several genes.<sup>1259</sup>

The strict liability nature of product liability is underscored by section 3 of the *Restatement of the Law, Third Torts: Product Liability*, which permits the inference of product defect from circumstantial evidence:

It may be inferred that the harm sustained by the plaintiff was caused by a product defect existing at the time of sale or distribution, without proof of a specific defect, when the incident that harmed the plaintiff (a) was a kind that ordinarily occurs as a result of product defect; and (b) was not, in the particular case, solely the result of causes other than product defect existing at the time of sale or distribution.<sup>1260</sup>

Thus, if diners in a particular restaurant regularly got sick following a particular meal based on transgenic plant product; or if patrons of a grocer got sick following the purchase of transgenic maize or canola, there should be ample circumstantial evidence linking the sickness of patrons to their purchase, and the patrons might have a cause of action in product liability against the

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<sup>1258</sup> See Sheldon Krimsky and Nora K. Murphy, “Biotechnology at the Dinner Table: FDA’s Oversight of Transgenic Food,” *The Annals of the American Academy of Political and Social Science*, supra, note 43, at 84.

<sup>1259</sup> See the Food and Drug Administration, “Premarket Notice Concerning Bioengineered Foods: Proposed Rule”, *Federal Register*, supra, note 93, at 4706-4738.

<sup>1260</sup> See section 3, *Restatement of the Law, Third Torts: Product Liability*, id.

restaurateur or grocer, without having to prove specific defect in the underlying transgenic plant products used by the restaurateur for his dishes, or prove specific defect in the transgenic maize or canola stocked and sold by the grocer.

The former scenario is amply exemplified by the StarLink corn incident, where people allegedly suffered from food allergies, and got sick across cities in the United States, following a meal suspected of comprising StarLink corn product.<sup>1261</sup> Although blood sample test results proved inconclusive,<sup>1262</sup> the United States Environmental Protection Agency concluded that the evidence was such that StarLink corn could not be completely eliminated as the source of food allergy across the United States.<sup>1263</sup>

However, it is unclear whether a third party affected by the defective transgenic plant product would be able to sue the seller or distributor, who is defined by section 20 to include the manufacturer of the product.<sup>1264</sup> This question is especially pertinent for liability arising from the coexistence of transgenic and non-transgenic plant agriculture, where an organic farmer's crop is damaged by the neighbouring transgenic crop due to cross-pollination for example. The pertinent question therefore is: could an organic maize farmer sue a transgenic seed manufacturer such as Monsanto, for damage caused to his organic maize by the neighbouring transgenic maize via cross-pollination, even though the organic maize farmer did not buy the transgenic maize from Monsanto?

In order to answer this question, it is necessary to analyse section 21 of *Restatement of the Law, Third Torts: Product Liability*:

Harm to persons or property includes economic loss if caused by harm to (a) the plaintiff's person; or (b) the person of another when harm to the other interferes with an interest of the plaintiff protected by tort law; or (c) the plaintiff's property other than the defective product.

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<sup>1261</sup> See Marc Kaufman, "Biotech Corn Is Test Case for Industry: Engineered Food's Future Hinges on Allergy Study," *Washington Post*, *supra*, note 53, at 1.

<sup>1262</sup> See Jeffrey M. Smith, *Seeds of Deception: Exposing Corporate and Government Lies about the Safety of Genetically Engineered Food*, *supra*, note 54, at 150.

<sup>1263</sup> This conclusion was reached following a parallel test on the blood samples of victims. See *id.*

<sup>1264</sup> See section 20 of the *Restatement of the Law, Third Torts: Product Liability*, *supra*, note 1250.



Based on the assumption that the necessary plaintiff under section 20 would be the transgenic maize farmer who purchased the defective product from the manufacturer, or seller or distributor, it would seem from the provision of section 20 cited above that whilst harm to the plaintiff's (transgenic maize farmer) person or property is compensable, only harm to "the person of another" (organic maize farmer) would be compensable, provided the harm interfered with the plaintiff's (transgenic maize farmer) interest.<sup>1265</sup>

In other words, whilst harm to the person of the organic maize farmer may trigger a cause of action by the transgenic maize farmer against the transgenic seed firm, any harm to the property of the organic maize farmer would trigger no such cause of action. Even so, harm to the person of the organic farmer caused by the defect in the neighbouring transgenic crop is highly unlikely.

Perhaps, the most plausible scenario is where members of the public became ill due to the adventitious presence of defective transgenic crop in the food chain. This scenario of harm caused to the persons of others (members of the public), other than the transgenic crop farmer, could trigger a cause of action in product liability for defective product, by the transgenic crop farmer against the seed firm, who sold or supplied the defective transgenic seed, if members of the public who got sick from consuming the defective transgenic crop, threatened the interest of the transgenic crop farmer by compensation claims.

It thus seems that the cause of action in product liability under the *Restatement of the Law, Third Torts: Product Liability* is ill-suited to an organic or conventional crop farmer, whose crop suffered damage due to adventitious presence of transgenes from the neighbouring transgenic crop farm, because section 21 only covers harm caused by a defective product to the person of a third party and not harm caused to the property of a third party.

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<sup>1265</sup> See *id.* Presumably, the harm may interfere with the plaintiff's interest if the third party threatens to sue the plaintiff for harm to his or her person.

The above analysis is further reinforced by the combined readings of sections 7 and 16 of the *Restatement of the Law, Third Torts: Product Liability*, which provide that harm or damage to person or property must arise from the inherent defect in the transgenic maize product.<sup>1266</sup> This would necessarily exclude an organic or conventional crop farmer, because the damage caused by cross-pollination of transgenic and non-transgenic crops would not necessarily be occasioned by inherent defect in the transgenic crop, but by externalities such as natural cross-pollination and other biological processes.

The defendant could raise an affirmative defence under section 17 of *Restatement of the Law, Third Torts: Product Liability*, which provides that “a plaintiff’s recovery of damages for harm caused by a product defect may be reduced if the conduct of the plaintiff combines with the product defect to cause harm and the plaintiff’s conduct fails to conform to the generally applicable rules establishing appropriate standard of care.”<sup>1267</sup> Thus, by extrapolation, if the illness of members of the public who consumed defective transgenic plant products was occasioned by their failure to properly cook the defective transgenic plant food in question, then damages payable to them would be reduced accordingly. Significantly however, no defence of disclaimers, waivers, or contractual exculpations would avail the defendant in a cause of action for product liability.<sup>1268</sup>

## **B. The United Kingdom and the European Union.**

In the United Kingdom, the producer of a product, or any person who use their name to sell a product, or the importer of the product into the European Union or United Kingdom, could be held strictly liable for any damage caused wholly or partly by the defective product,<sup>1269</sup> provided the person who suffered damage, had requested the supplier to identify the producer,

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<sup>1266</sup> See sections 7 and 16 of the *Restatement of the Law, Third Torts: Product Liability*, id.

<sup>1267</sup> See section 17 of the *Restatement of the Law, Third Torts: Product Liability*, id.

<sup>1268</sup> See section 18 of the *Restatement of the Law, Third Torts: Product Liability*, id.

<sup>1269</sup> See generally section 2(1) (2) (a) (b) (c) (3), of the Consumer Protection Act, *supra*, note 188.

trader or importer of the product; that the request was made within a reasonable period following the occurrence of the damage, and at a time when it was not reasonably practicable for the person making the request to identify the producer, trader or importer of the product; and the supplier failed within a reasonable period following receipt of the request, either to comply with the request or identify the person who supplied the product to him.<sup>1270</sup>

Thus, transgenic seeds and crops suppliers, importers, and transgenic plant farmers could be potentially liable for damage caused by transgenic plant organisms. In the context of the coexistence of transgenic and non-transgenic plant agriculture, there are conceivable scenarios under which inherent defect in transgenic seed or crop could cause damage, which could range from environmental, economic, to property damage. For example, inherent defect in transgenic maize that has been genetically modified to be resistant to pests or weeds could theoretically lead to the deployment of more herbicides or pesticides than would ordinarily be necessary. In the circumstances, the proliferation of use of chemical pesticide or herbicide could in turn, degrade the environment and cause environmental or property damage both to transgenic farmland and the adjoining non-transgenic farmland.<sup>1271</sup>

Moreover, transgenic food processors or producers could potentially be liable for food defect in the form of transgenic toxins that could cause food poisoning; or transgenic allergens that could cause anaphylactic shock, itchy, severe diarrhoea, and breathing difficulty, all of which would constitute personal injury under section 5(1) of the Consumer Protection Act.<sup>1272</sup>

### **6.3.2. Meaning of Defective Product in the Context of Transgenic Crop and Food.**

The general provision of section 3(1) of the Consumer Protection Act on the meaning of product “defect” is particularly relevant for transgenic seed or crop:

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<sup>1270</sup> See section 2(3) (a) (b) (c), of the Consumer Protection Act, *id.*

<sup>1271</sup> Section 5(1) of the Consumer Protection Act defines damage that would give rise to liability as “death or personal injury, or any loss of or damage to property.” See *id.*

<sup>1272</sup> See section 5(1) Consumer Protection Act, *supra*, note 188.

There is a defect in a product for the purposes of this Part if the safety of the product is not such as persons generally are entitled to expect; and for those purposes “safety”, in relation to a product, shall include safety with respect to products comprised in that product and safety in the context of risks of damage to property, as well as in the context of risks of death or personal injury.<sup>1273</sup>

The provision is analogous to Article 6 of the Product Liability Directive,<sup>1274</sup> which was interpreted by the High Court of England and Wales in *A & Others v National Blood Authority*.<sup>1275</sup> A class action lawsuit was filed by a group of 114 individuals who had contracted Hepatitis C from blood transfusions containing the virus. It was in evidence that although the blood producers and medical practitioners were aware of the risk since the 1970s, yet, the blood was never screened for the presence of Hepatitis C virus at the relevant time. The court had to consider whether the public knew and accepted the risk of infection. The court found that the general public had neither been warned nor was the risk of infection publicised. The court held *inter alia* that the public never accepted any risk that any percentage of transfused blood would be infected, and that the plaintiffs were legitimately entitled to expect that the blood transfusions were free from infection. The court held further that given the facts of the case, it was irrelevant to consider avoidability of the defect, impracticality, cost, and the difficulty of adopting precautionary measures. The court further held that the benefit and utility of the product to the society would only be relevant or considered where the public had full information and knowledge of the risks.<sup>1276</sup>

The pertinent question therefore is how would courts in England and Wales interpret section 3 of the Consumer Protection Act, or Article 6 of the Product Liability Directive in the context of transgenic plant food? By extrapolation, courts would have to consider the risks, if any of

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<sup>1273</sup> See section 3(1) of the Consumer Protection Act, *supra*, note 188.

<sup>1274</sup> Article 6 of the EC Product Liability Directive provides that “A product is defective when it does not provide the safety which a person is entitled to expect, taking all circumstances into account, including: (a) the presentation of the product; (b) the use to which it could be reasonably be expected that the product would be put; and (c) the time when the product was put into circulation.” See EC Product Liability Directive, *supra*, note 70.

<sup>1275</sup> See *A & Others v. National Blood Authority*, [2001] 3 All ER 289.

<sup>1276</sup> *Id.*, at 292.

public consumption of transgenic plant food, which has been available commercially in North America and Europe since the 1990s.<sup>1277</sup> Courts would also consider whether the general public were aware of any risks, the nature of the risks, and whether such risks were duly publicised.

In North America and Europe, transgenic plant crops and food are subject to rigorous risk assessments to ensure public health safety.<sup>1278</sup> Most significantly, transgenic plant food is deemed to be substantially equivalent to organic and conventional food,<sup>1279</sup> and there is as yet no evidence that transgenic plant food is unsafe for human consumption. Nevertheless there are fears of unknown risks and much uncertainty surrounding the safety of transgenic plant food, which have been exacerbated by conflicting scientific opinions and literature on the safety of transgenic plant food, especially with regards to transgenic toxins and allergens.<sup>1280</sup> Also there is a great deal of public scepticism of transgenic plant food in Europe and the United Kingdom where the public loath and generally shun transgenic plant food.<sup>1281</sup> Therefore, if someone were to fall ill or suffer a debilitating illness that is scientifically linked to the consumption of transgenic plant food, courts in England and Wales would have to consider whether the public were fully apprised of the risks and whether the public were generally entitled to expect safety in the circumstances. It is highly likely that courts would find the producer of transgenic plant food liable for supplying defective product.

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<sup>1277</sup> See Jack Ralph Kloppenburg, *First the Seed: The Political Economy of Plant Biotechnology*, Second Edition, *supra*, note 45, at 296.

<sup>1278</sup> See Article 4(1) of the Deliberate Release Directive, which enjoins Member States to “ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment which might arise from the deliberate release or placing on the market of GMO.” The section provides further that GMOs may only be released after compliance with the provisions of Articles 5 and 6 on risks assessments.

<sup>1279</sup> See Les Levidow, Joseph Murphy, and Susan Carr, “Recasting ‘Substantial Equivalence’: Transatlantic Governance of GM Food,” *Science, Technology & Human Values*, *supra*, note 107, at 36.

<sup>1280</sup> See Paul R. Billings and Peter Shorett, “Coping with Uncertainty: The Human Health Implications of GE Foods,” in Iain E. P. Taylor, (editor), *Genetically Engineered Crops: Interim Policies, Uncertain Legislations*, *supra*, note 45, at 75-79; Trish Malarkey, “Human Health Concerns with GM Crops,” *Mutation Research*, volume 544, (2003), at 217-221, (discussing the potential for transgenic plant food allergens and toxins).

<sup>1281</sup> See Robert Lee, “GM Resistant: Europe and the WTO Panel Dispute on Biotech,” in Jennifer Gunning and Soren Holm, (editors), *Ethics, Law, and Society, Volume 1*, *supra*, note 15, at 131-140; Ambuj Sagar, Arthur Daemrich, and Mona Ashiya, “The Tragedy of the Commoners: Biotechnology and Its Public,” *Nature Biotechnology*, *supra*, note 15, at 2-4.

### 6.3.3. Discharging the Burden of Proof that Transgenic Technology is Defective.

According to Article 4 of the Product Liability Directive, “The injured person shall be required to prove the damage, the defect and the causal relationship between defect and damage.”<sup>1282</sup>

The Directive does not provide any guidance on the standard of proof, but under the evidentiary rule in the United Kingdom, in civil cases, the burden is on the plaintiff to prove by preponderance of credible evidence and balance of probability that he or she has suffered the alleged damage, and to link the alleged damage to the defective product.<sup>1283</sup>

Article 4 of the Product Liability Directive has been interpreted by courts in several cases. For example, in *Richardson v. LRC Products*,<sup>1284</sup> the plaintiff alleged that the teat end of a condom became detached during sexual intercourse, leading to an unwanted pregnancy, which the plaintiff alleged was due to the defective condom. The court observed that the failure of the condom was not sufficient, even in the circumstances where “naturally enough, the users’ expectation is that a condom will not fail.”<sup>1285</sup> The court further held that a condom user was not legitimately entitled to expect a condom to be hundred percent effective, because it was a common knowledge that a condom could fail. The court held further that the condom had not failed in any way that defeated legitimate expectations, and that the plaintiff had failed to prove the defect that caused the teat to detach during sexual intercourse.<sup>1286</sup>

Another relevant case, in which Article 4 of the Product Liability Directive was interpreted, was the Belgian case of *Riboux -v- S.A. Schweppes Belgium*.<sup>1287</sup> The plaintiff suffered injuries when a bottle of Schweppes soft drink exploded. Although the plaintiff did not provide any specific evidence of defect in the bottle, nevertheless, the District Court held that it was

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<sup>1282</sup> See Article 4 of the EC Product Liability Directive, *supra*, note 70.

<sup>1283</sup> For discussion, see *Re B (A Child)* [2008] UKHL 35.

<sup>1284</sup> See *Richardson v. LRC Products*, [2000] Lloyd’s Rep. Med. 280.

<sup>1285</sup> *Id.*, at 286.

<sup>1286</sup> *Id.*, at 287.

<sup>1287</sup> See *Riboux -v- S.A. Schweppes Belgium*, 21.11.96, Civ. Namur, 5e. Ch.

prepared to infer that the bottle was defective, because the plaintiff would not expect a soft drink bottle to explode.<sup>1288</sup>

The pertinent question therefore is how would a plaintiff claiming damages for personal injuries allegedly suffered from the consumption of transgenic plant food discharge the burden of proof in courts? It should be sufficient if the plaintiff could link the injuries to the transgenic plant food in question. This process would necessitate a heavy reliance on scientific evidence that would establish a causal link between the consumption of transgenic food and the alleged illness or personal injuries. However, the process is fraught with much uncertainty due to the conflicting scientific opinions and literature on the propriety and safety of transgenic plant food,<sup>1289</sup> and the yet unknown risks involved in the consumption of transgenic plant food.<sup>1290</sup> Moreover, marshalling scientific evidence could be challenging and expensive for the average plaintiff, and proving the causal link between the consumption of transgenic plant food and an alleged illness may be more difficult than it appears.

#### **6.3.4. The Significance of “Development Risk Defence”.**

Under the Consumer Protection Act, possible defences to product liability litigation range from claim that the defect was attributable to compliance with European Community regulations, that the defendant did not supply the defective product to the plaintiff, that the supply of the defective product was not made in the course of business, that the defect did not exist in the product at the relevant time of supply, “that the state of scientific and technical knowledge at the relevant time was not such that a producer of products of the same description as the product in question might be expected to have discovered the defect if it had existed in his products

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<sup>1288</sup> *Id.*

<sup>1289</sup> See Trish Malarkey, “Human Health Concerns with GM Crops,” *Mutation Research*, *supra*, note 241, at 217-221.

<sup>1290</sup> See Paul R. Billings and Peter Shorett, “Coping with Uncertainty: The Human Health Implications of GE Foods,” in Iain E. P. Taylor, (editor), *Genetically Engineered Crops: Interim Policies, Uncertain Legislations*, *supra*, note 45, at 75-79.

while they were under his control”, (the development risk defence), that the defect was a defect in a product in which the product in question had been comprised, to the defence that the defect “was wholly attributable to the design of the subsequent product or to compliance by the producer of the product in question with instructions given by the producer of the subsequent product.”<sup>1291</sup>

In the context of transgenic plant agriculture, it is instructive to note the possible significance or impacts of the “development risk defence” in section 4(1) (e) of the Consumer Protection Act, which is to the effect “that the state of scientific and technical knowledge at the relevant time was not such that a producer of products of the same description as the product in question, might be expected to have discovered if it had existed in his products while they were under his control.”<sup>1292</sup> This provision is analogous to Article 7(e) of the European Community Product Liability Directive, which provides that “the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered.”<sup>1293</sup>

In *A & Others v. National Blood Authority*,<sup>1294</sup> the development risk defence was raised to the product liability claim of the 114 individuals who contracted Hepatitis C via blood transfusion. The court observed that “existence of the defect” in Article 7(e) of the Product Liability Directive referred to knowledge of a generic defect in a product. The court held further that once there was knowledge of an existing defect in a product, then there was knowledge of the risk that the defect could materialise in a specific product. The court held noted that once a producer had notice of a potential problem, but nevertheless continued to supply the product, the producer would be doing so at their own risk. Most importantly, the court noted that it would defeat the purpose of the Directive, if a producer who knew about certain risks but

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<sup>1291</sup> See generally section 4(1) (a) (b) (c) (d) (e) & (f) of the Consumer Protection Act, *id.*

<sup>1292</sup> *Id.*

<sup>1293</sup> See Article 7(1) of the Product Liability Directive, *supra*, note 70.

<sup>1294</sup> *A & Others v. National Blood Authority*, *supra*, note 214, at 289.



nevertheless continued to supply the product, was allowed to raise the development risk defence to the consequential injuries from the use of the product. The court further held that the development risk defence would only protect the producer from unknown risks.<sup>1295</sup>

Furthermore, in *The Commission v. The United Kingdom*,<sup>1296</sup> the Court of Justice of the European Union held inter alia that the burden of proof is on the defendant relying on the development risk defence to show that at the time the product was put into circulation, the objective state of scientific and technical knowledge was such that, on the basis of reasonableness test, the product defects could not have been discovered.<sup>1297</sup>

In the context of defective transgenic plant technological products, the High Court's interpretation of Article 7(e) of the development risk defence in *National Blood Authority case*, which is *imparimaterial* with section 4(e) of the Consumer Protection Act,<sup>1298</sup> poses particular challenges for potential plaintiffs suing for personal injuries or property damage in the United Kingdom and European Union. To start with, all commercially available transgenic food products in the European Union have ostensibly undergone rigorous risks assessments and approved for public consumption.<sup>1299</sup> The risks assessments are necessarily predicated on available scientific evidence.<sup>1300</sup> Moreover, despite conflicting scientific literature on the safety of transgenic plant food for public health,<sup>1301</sup> there is currently no evidence that someone got sick from the consumption of dully approved transgenic plant food and product.<sup>1302</sup> Therefore, producers of transgenic plant food such as Monsanto and DuPont; and food grocers and

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<sup>1295</sup> *Id.*, at 289.

<sup>1296</sup> See *The Commission v. The United Kingdom*, Case C-203/99.

<sup>1297</sup> *Id.*

<sup>1298</sup> Note that the European Commission challenged the UK implementation of the development risks defence in *The Commission v. The United Kingdom*, *id.* However, the Court of Justice of the European Union observed that the UK legislation that implemented the Product Liability Directive was not manifestly contrary to the Directive, but did give guidance as to how the defence should be interpreted.

<sup>1299</sup> See Articles 5, 6, and 7 of the Deliberate Release Directive 2001/18/EC.

<sup>1300</sup> See the Preamble to the Deliberate Release Directive 2001/18/EC.

<sup>1301</sup> See Jeffrey M. Smith, *Seeds of Deception: Exposing Corporate and Government Lies about the Safety of Genetically Engineered Food*, *supra*, note 54, at 150.

<sup>1302</sup> See Marc Kaufman, "Biotech Corn Is Test Case for Industry: Engineered Food's Future Hinges on Allergy Study," *Washington Post*, *supra*, note 232, at 1.

suppliers might theoretically be able to raise the “development risk defence” to personal injuries claims linked to the consumption of transgenic plant food, on grounds that there was no known defect, and the existence of any defect was theoretically impossible. This is especially so in light of the controversial substantial equivalence policy, which equates transgenic plant food with organic and conventional plant food, and hold that both are substantially equivalent.<sup>1303</sup>

However, the main challenge for potential plaintiffs vis-a-vis development risk defence is that it could be theoretically raised against an illness or personal injury that manifested long after “the state of scientific and technical knowledge” had changed or evolved. This is especially so for the science of transgenic plant agriculture, which is at best evolving and evolutionary. For example, a recent study by Canadian scientists found traces of *Bacillus thuringiensis* bacterium in unborn children, which their mothers had apparently injected by eating cow beef fed on Bt maize feed.<sup>1304</sup> The study proved that *Bacillus thuringiensis* could not only survive the guts of the livestock fed with Bt feed, but could also survive the guts of humans who consumed the livestock fed on Bt feed.<sup>1305</sup> In other words, it is possible for a person to contract residual *Bacillus thuringiensis* toxin from eating livestock fed with Bt feedstuff, even if they had never consumed transgenic plant food directly. The main problem however is that scientists are yet to fully fathom the long term implications for public health, of residual Bt toxin in the human gut, especially as some scientists continue to dispute the findings that *Bacillus thuringiensis* bacterium protein can survive the human gut.<sup>1306</sup>

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<sup>1303</sup> See Chapter Two of the thesis. See also Les Levidow, Joseph Murphy, and Susan Carr, “Recasting ‘Substantial Equivalence’: Transatlantic Governance of GM Food,” *Science, Technology & Human Values*, *supra*, note 238, at 36.

<sup>1304</sup> See Aziz Aris and Samuel Leblanc, “Maternal and foetal exposure to pesticides associated to genetically modified foods in Eastern Townships of Quebec,” *Reproductive Toxicology*, *supra*, note 78, at 534-539.

<sup>1305</sup> *Id.*

<sup>1306</sup> See Anthony Trewavas, “Toxins and genetically modified food,” *The Lancet*, *supra*, note 34, at 931.

Thus, it is theoretically possible that an illness or disease linked to the consumption of transgenic plant food might not manifest fully until much later in time. For example, if someone were to develop cancer that was scientifically linked to the consumption of transgenic plant food some twenty years back, when “the state of scientific and technical knowledge” at the time the plaintiff consumed the transgenic plant food in question did not reveal any defect in the food, the defendant could theoretically successfully raise “the development risk defence” to potential claim for product liability for the injury sustained. This prospect or possibility shows the relative weakness of product liability as a cause of action for personal injury sustained from the consumption of transgenic plant food. In the circumstances, potential plaintiffs would be well advised to sue under a different cause of action, other than product liability, as exemplified by *Bai (Run Off) Limited & Others v. Durham*,<sup>1307</sup> in which the U.K Supreme Court retrospectively linked and backdated liability to the time when the plaintiffs were exposed to the deadly airborne carcinogenic asbestos fibres, rather than when the consequential asbestosis or mesothelioma lung cancer symptoms became manifest or was diagnosed in victims.<sup>1308</sup>

#### **6.4.0. Contractual liability for Damage Caused by Adventitious Transgenes.**

The conveyance of transgenic plant crops and food products from the producer to the farmer and ultimately to the consumer through a network of independent firms in the supply chain, would of necessity involve contractual obligations, breach of which could incur liability.<sup>1309</sup> For example, transgenic seed firm and transgenic seed farmer would have to enter into a contract of sale before the latter could buy transgenic plant seed for cultivation. Also, the fulfilment of the contract of sale might necessitate another contract between the transgenic seed firm and a transportation firm, or between the transgenic seed farmer and a transportation firm,

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<sup>1307</sup> See *Bai (Run Off) Limited & Others v. Durham*, *supra*, note 1198, 14.

<sup>1308</sup> *Id.*

<sup>1309</sup> See Jill Poole, *Textbook on Contract Law*, 9<sup>th</sup> edition, (Oxford: Oxford University Press, 2008), at 349-488.

for the transportation of the said transgenic seed to the farm of the transgenic seed farmer. Moreover, the transgenic seed farmer might have to enter into contractual obligations with food processors or grocers for the sale of his transgenic crops. Finally, food processors or food grocers would then sell on the transgenic plant crops or any secondary products from the original crops to the consumer. This is the typical supply chain for transgenic plant crops and food products that shows the crucial role of contractual obligations within the supply chain.<sup>1310</sup>

The law of contracts generally enforces contractual obligations between parties to a contract, provided they had the legal capacity to enter into the contract,<sup>1311</sup> and there were no vitiating elements such as duress, illegality, and fraudulent misrepresentation.<sup>1312</sup> Most importantly, third parties who are not privy to the terms of contractual agreements are generally barred from enforcing the terms of the contract.<sup>1313</sup> Thus, in the context of supply chain contractual liability, due to the principle of privity of contract, an organic farmer might not be able to sue a transgenic seed firm for damage stemming from adventitious presence of transgenes in his organic crop, if the said transgenes came from the neighbouring transgenic farm supplied by the transgenic seed firm. The above scenario is exemplified by the case of *Dunlop Tyre Company v. Selfridge*.<sup>1314</sup> The plaintiffs sold tyres to Dew & Company, a wholesale distributor of tyres, on terms that Dew & Company would obtain an undertaking from retailers that they would not undersell or sell below the plaintiff's price list. However, the defendants purchased tyres from Dew & Company, and subsequently retailed the tyres below the stipulated Plaintiff's price list. The plaintiffs sought an injunction and damages, however, the action failed because the plaintiffs were not a party or privy to the contract that the defendants

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<sup>1310</sup> See B. Ruther, "Risk management of unintended GMO contamination in the supply chain of maize and processed maize products," Paper prepared for presentation at the 113<sup>th</sup> EAAE Seminar, *supra*, note 2, at 4.

<sup>1311</sup> *Id.*, at 646.

<sup>1312</sup> *Id.*, at 541-581, 588—623, and 625-631.

<sup>1313</sup> See *id.*, at 443-487.

<sup>1314</sup> See *Dunlop Tyre Company v. Selfridge*, [1915] AC at 847.

had with Drew & Company. Lord Haldane held *inter alia* that “only a person who is a party to a contract can sue on it.”<sup>1315</sup>

There are however, exceptions to the privity doctrine, which range from collateral contracts,<sup>1316</sup> agency,<sup>1317</sup> trusts,<sup>1318</sup> restrictive covenants,<sup>1319</sup> to the provisions of the Contract (Rights of Third Parties) Act 1999.<sup>1320</sup> Nevertheless, none of these exceptions are particularly useful for an organic or conventional crop farmer, who might want to sue transgenic seed firms for damage stemming from adventitious presence of transgenes amidst his or her crop, due to cross-pollination or other biological processes. For example it is highly unlikely that an organic farmer would have any contractual interest in the transgenic seed contract between his neighbouring transgenic farmer and a transgenic seed firm. Rather transgenic seed firms have actively sought to exclude liability from any damage that might result from adventitious presence of transgenes in organic or conventional crops fields that border the fields where their proprietary transgenic seeds are cultivated.<sup>1321</sup> This is exemplified by Syngenta’s technology agreement with transgenic plant farmers, which excludes liability despite recognising that “a certain amount of pollen movement occurs, and it is not possible to achieve 100 percent purity of seed or grain in any crop production system.”<sup>1322</sup> Ditto, it is also unlikely that any sort of agency relationship could exist between neighbouring organic and transgenic farmer with regards to the terms of transgenic seed contract with transgenic seed firms.

However, contractual liability would be relevant as a cause of action between transgenic seed firms and transgenic crop farmers, and the remedy has been used effectively by transgenic

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<sup>1315</sup> *Id.*, at 848.

<sup>1316</sup> See *Shanklin Pier v. Detel Products* [1951] 2 KB 854.

<sup>1317</sup> See *Scruttons Ltd v. Midland Silicones Ltd* [1962] AC 446.

<sup>1318</sup> See the House of Lords decision in *Les Affreteurs Reunis v. Leopold Walford*, [1919] AC 801.

<sup>1319</sup> See *Strathcona SS Company v. Dominion Coal Company*, [1926] AC 108.

<sup>1320</sup> See generally Contract (Rights of Third Parties) Act 1999.

<sup>1321</sup> See Debbie Barker et al., *Giants vs. U.S. Farmers: A Report by the Centre for Food Safety & Save Our Seeds*, *supra*, note 10, at 25.

<sup>1322</sup> *Id.*

seed firms to enforce their technology agreements against transgenic seed farmers.<sup>1323</sup> For example, it is standard practice for Monsanto Corporation, who are the industry leader, to require transgenic farmers to sign a “technology use and stewardship agreement”, which the company uses to compliment the protection of its intellectual property rights.<sup>1324</sup> The terms of the technology use agreement are typically onerous, and range from the requirement that farmers should not save and replant harvested transgenic seeds; that farmers should not transfer transgenic seeds to others; to the requirement that farmers should not conduct research on the proprietary seeds “other than to make agronomic comparisons and conduct yield testing for Grower’s own use.”<sup>1325</sup> However despite their patently onerous and arguably unconscionable terms, courts in North America have upheld the validity of the terms of the technology agreements. For example in *Monsanto Company and Monsanto Technology L.L.C. v. Maurice Parr*, the United States District Court held *inter alia* that Maurice Parr was liable for patent infringement for actively encouraging transgenic crop farmer to flout Monsanto’s technology agreement and save seeds from their harvests.<sup>1326</sup>

The foregoing discourse highlights the limits of contractual liability as a supply chain liability remedy, for parties that are most likely to be affected by the damage caused by adventitious presence of transgenes in non-transgenic organisms. However, it is a favoured cause of action by transgenic seed firms such as Monsanto and Syngenta who have used onerous terms of technology agreements to compliment the protection offered by patent law.

#### **6.5.0. Environmental Liability Framework.**

Chapter Four of the thesis examines and analyses in relative detail, the implications of the advent of transgenic plant technology for the environment and biodiversity, especially with

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<sup>1323</sup> *Id.*, at 22-26.

<sup>1324</sup> *Id.*, at 22.

<sup>1325</sup> See *id.*, at 25.

<sup>1326</sup> See *Monsanto Company and Monsanto Technology L.L.C. v. Maurice Parr*, *supra*, note at 545.

regards to the inevitability of transgenes flow into the environment,<sup>1327</sup> (even with coexistence best practices),<sup>1328</sup> as well as the virtual irreversibility of transgenics from the ecosystems.<sup>1329</sup> Whilst scientists appear to agree on the aforesaid events, there is no scientific consensus on myriads of issues that range from the effects of *Bacillus thuringiensis* proteins on non-target organisms in the eco-systems,<sup>1330</sup> to the growing problems of "super-weeds" and the concomitant proliferation of chemical pesticides and herbicides uses, which transgenic plant technology was supposed to eliminate or minimise.<sup>1331</sup> In this section, the thesis will examine statutory framework for environmental liability for inherent damage in the coexistence paradigm, drawing on UK, EU and US laws. The section will analyse the nature of possible harm and consequential remedies, as well as the limitations of the current statutory regimes, and why a sui generis regime might be well suited to securing the types remedies that are not readily available under the environmental liability laws of the UK, EU and US.

In the European Union, the regulatory framework for the protection of the environment is the Environmental Liability Directive 2004/35/EC, which came into force in Member States in 2009, and was implemented nationally by England, Northern Ireland, Scotland and Wales in 2009.<sup>1332</sup> The Directive aims to draw businesses to the environmental impacts of their activities,

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<sup>1327</sup> See Miguel A. Altieri, "Transgenic Crops: Agro-biodiversity and Agro-eco-system Function," in Iain E.P. Taylor, (editor), *Genetically Engineered Crops: Interim Policies, Uncertain Legislation*, *supra*, note 117, at 37-38; Mary A. Rieger, et al., "Pollen-Mediated Movement of Herbicide Resistance between Commercial Canola Fields," *Science*, *supra*, note 823, at 2386-2388.

<sup>1328</sup> See Petra Kozjak, Jelka Sustar-Volzlic and Vladimir Meglic, "Adventitious Presence of GMOs in Maize in View of Coexistence," *Acata Agriculturae Slovenica*, *supra*, note 223, at 283.

<sup>1329</sup> See Recital 4, of the Preamble to Directive 2001/18/EC of the European Parliament and the Council, *supra*, note 4.

<sup>1330</sup> See E.J. Rosi-Marshall, et al., "Toxins in Transgenic Crop By-Products May Affect Headwater Stream Ecosystems," *Proceedings of National Academy of Sciences*, *supra*, note 137, at 16204-16208.

<sup>1331</sup> See Stephen B. Powles, et al, "Evolved Resistance to Glyphosate in Rigid Ryegrass (*Lolium rigidum*) in Australia," *Weeds Science*, *supra*, note 827, at 604-607; William Newman and Andrew Pollack, "US Farmers Cope with Roundup-Resistant Weeds," *New York Times*, *supra*, note 190, at B1.

<sup>1332</sup> See Directive 2004/35/EC of the European Parliament and the Council of April 2004, *Official Journal of the European Union*, 30.4.2004; The Environmental Damage (Prevention and Remediation) (England) Regulations 2015, (2015 No. 810); The Environmental Liability (Scotland) Regulations 2009 N. 266; The Environmental Liability (Prevention and Remediation) Regulations (Northern Ireland) 2009; The Environmental Damage (Prevention and Remediation) Wales Regulations 2009 (as amended).

and to take proactive measures to remediate any consequential damage to the environment.<sup>1333</sup>

Most significantly, the Directive is based on the "polluter-pay" principle, to ensure that the original polluter pays for environmental remediation rather than the tax payers.<sup>1334</sup>

The Directive defines environmental damage as "damage to protected species and natural habitats, which is any damage that has significant adverse effects on reaching or maintaining the favourable conservation status of such habitats and species..."<sup>1335</sup> Significantly, environmental damage to land or "land damage" is defined as "any land contamination that creates a significant risk of human health being adversely affected as a result of the direct or indirect introduction, in, on or under land, of substances, preparations, organisms or micro-organisms,"<sup>1336</sup> whilst "water damage" is defined as "any damage that significantly adversely affects the ecological chemical and/or quantitative status and/or ecological potential..<sup>1337</sup> the word "damage" is then defined as "a measurable adverse change in a natural resource or measurable impairment of a natural resource service which may occur directly or indirectly."<sup>1338</sup>

The pertinent question is whether Directive 2004/35/EC could be used to remedy environmental damage caused by transgenic plant technology? If it is proven that *Bacillus thuringiensis* is depleting non-target organisms in the environment, or that the emergence of "super-weeds" is due to the proliferation of the use of glyphosate and other complementary chemicals by transgenic plant farmers, either of these events could constitute "damage" to the environment within the meaning of Article 2(2) of the Directive. However, there must be a causal link between the alleged damage and the activities of the alleged operators.<sup>1339</sup>

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<sup>1333</sup> See Article 8(1), Directive 2004/35/EC, *supra*, note 1332.

<sup>1334</sup> See Article 8(1), and paragraph 18 of the Preamble to the Environmental Liability Directive, *id.*

<sup>1335</sup> See Article 2(1)(a), *id.*

<sup>1336</sup> See Article 2(1)(c), *id.*

<sup>1337</sup> See Article 2(1)(b), *id.*

<sup>1338</sup> See Article 2(2), *id.*

<sup>1339</sup> See Article 4(5), *id.*



In the circumstances, transgenic seed firms, and transgenic seed farmers would constitute the "operator" under Article 2(6), which means "any natural or legal, private or public person who operates or controls the occupational activity..."<sup>1340</sup> Also environmental damage could be pre-empted through intervention by competent authority that require the operator to take necessary preventive actions.<sup>1341</sup> Thus, transgenic seed manufacturers or farmers could be asked by a competent authority to stop the manufacture, dissemination and use of glyphosate for example, if it is found to cause damage to the water system. Similarly, the competent authority could request the withdrawal of a particular Bt. crop, if its constituent toxic protein is found to cause damage to deplete or undermine the populations of non-target organisms in the soil. Furthermore, under the "polluter pay" principle of the Directive, the operator would be responsible for the prevention and remediation costs,<sup>1342</sup> unless the operator could prove that the imminent damage or damage was caused by a third party, or occurred despite appropriate pre-emptive measures.<sup>1343</sup>

Thus, transgenic seed firms or farmers may still escape responsibility for preventing an imminent damage or liability for damage caused to the environment via transgenes' flow into the environment, if they could establish that the escapes occurred despite taking appropriate preventive measures such as the stipulated segregation distances, erection of buffer zones, etc. They are most likely to succeed due to scientific consensus that not even the best is coexistence practices could pre-empt transgenes' flow or escape into the environment.<sup>1344</sup> Arguably, this possibility undermines the effectiveness of the "polluter pays" objective of the Directive.

Moreover, it is very doubtful if approved transgenic seeds and crops that had undergone rigorous risk and safety assessments could be regarded as pollutants under the Directive? Also,

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<sup>1340</sup> See Article 2(6), *id.*

<sup>1341</sup> See Article 5(1)(2)(3)(4), *id.*

<sup>1342</sup> See Article 8(1)(2), *id.*

<sup>1343</sup> See Article 8(1)(3)(a).

<sup>1344</sup> See Petra Kozjak, Jelka Sustar-Volzlic and Vladimir Meglic, "Adventitious Presence of GMOs in Maize in View of Coexistence," *Acata Agriculturae Slovenica*, *supra*, note 223, at 283.

given the virtual irreversibility of transgenes in the environment,<sup>1345</sup> it is extremely doubtful whether any remediation measures could overcome technical obstacles of transgenes removal from the environment.

Furthermore, the limitation period of five years within which the competent authority must initiate recovery costs from the operator or relevant third party, arguably undermines the effectiveness of the Directive as a compensatory tool for damage caused to the environment and the ecosystems in the coexistence paradigm.<sup>1346</sup> Moreover, the provisions of the Directive do not apply to personal injury, damage to property or to any economic loss.<sup>1347</sup> Thus, organic and conventional farmers are unable to use the Directive as a cause of action for consequential economic loss and property damage incurred in the coexistence paradigm. This is a major limitation on the effectiveness of the Directive in balancing conflicting rights in the coexistence paradigm.

Under the UK Environmental Protection Act, there are specific provisions that address possible damage from transgenic plant technology and how these could be dealt with.<sup>1348</sup> Section 107(2) defines "environment" as including "land, air and water and living organisms supported by any of those media."<sup>1349</sup> Damage to the environment "is caused by the presence in the environment of genetically modified organisms which have...escaped or been released from a person's control and are capable of causing harm."<sup>1350</sup> "Harm" is defined as "adverse effects as regards the health of humans or the environment."<sup>1351</sup>

In order to prevent harm to humans and the environment, the Secretary of State may order an inspector to search premises, and where the inspector has reason to believe that genetically

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<sup>1345</sup> See Recital 4, of the Preamble to Directive 2001/18/EC of the European Parliament and the Council, *supra*, note 4.

<sup>1346</sup> See Article 10, Directive 2004/35/EC, *supra*, note 1332.

<sup>1347</sup> See paragraph 14 of the Preamble to the Directive, *id.*

<sup>1348</sup> See Environmental Protection Act 1990, Chapter 43.

<sup>1349</sup> See section 107(1), *id.*

<sup>1350</sup> See section 107(3), *id.*

<sup>1351</sup> See section 107((6), *id.*

modified organisms could cause imminent damage to the environment, he may seize it and cause it to be rendered harmless.<sup>1352</sup> Section 118 of the Act stipulates a range of offences for non-compliance with risks assessment and notification requirements under section 108 of the Act.<sup>1353</sup> Upon conviction for the offences under section 118 of the Act, a person could be fined up to £20,000 or be imprisoned for a term not exceeding six months or both.<sup>1354</sup> Moreover, following any convictions under section 118 of the Act, the Secretary of State may arrange for any reasonable steps to be taken towards remedying the harm, and recover the costs of taking those steps.<sup>1355</sup> Presumably the recovery of the costs for remedying harm caused by the offender would be in a subsequent civil proceedings filed by the Secretary of State against the offender.

The foregoing analysis demonstrates that the provisions of the UK Environmental Protection Act 1990, are unsuitable as cause of action for aggrieved organic or conventional farmers or farm businesses in the UK., who have incurred economic losses and property damage in the coexistence paradigm. Just like the provisions of Environmental Liability Directive 2004/35/EC, the overriding message from the UK Environmental Protection Act 1990, is that it is unsuitable as a cause of action for potential litigants seeking remedy for damage incurred in the coexistence paradigm.

In the United States, there are disparate statutory environmental liability regimes, and the only Federal law regulating liability and compensation for liability is the Comprehensive Environmental Response Compensation and Liability Act 1980.<sup>1356</sup> the law was designed to facilitate the cleaning up of sites contaminated with hazardous substances that are broadly

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<sup>1352</sup> See section 117(1), *id.*

<sup>1353</sup> See sections 108 and 118, *id.*

<sup>1354</sup> See section 118(3), *id.*

<sup>1355</sup> See section 121(1)(2), *id.*

<sup>1356</sup> See Comprehensive Environmental Response Compensation and Liability Act 1980. Title 42 USC 9601.

defines as "pollutants" and "contaminants".<sup>1357</sup> The Act also empowers federal and states agencies to restore natural resource damaged by hazardous substances.<sup>1358</sup>

A possible polluter includes the current owner or operator of a site, the owner or operator of a site as at the time the pollution occurred, a person who arranged the disposal of a hazardous substance, pollutant or contaminant, and a person who transported a hazardous substance, pollutant or contaminant.<sup>1359</sup> Also, the parties responsible for the pollution is expected to pay for the costs of remediation under the Act, and historically, over 70 percent of remediation activities were paid for by the pollutants.<sup>1360</sup>

It is however doubtful whether transgenic plant seeds or crops would qualify as "pollutants" or "contaminants", and whether manufacturers of transgenic plant seeds and crops and transgenic plant farmers would be regarded an "operator" under the Act. This is because of the US doctrine of the substantial equivalence doctrine and official pro-plant biotechnology policy.<sup>1361</sup> Therefore, the US Comprehensive Environmental Response Compensation Liability Act 1980, is patently unsuitable as a cause of action for potential litigants who incurred economic costs and property damage in the coexistence paradigm.

#### **6.6.0. The Cartagena Protocol on Biosafety.**

The Cartagena Protocol on Biosafety to the Convention on Biodiversity,<sup>1362</sup> is a supplementary international agreement to the Convention on Biological Diversity, which was finalised in Nairobi, Kenya, in May 1992.<sup>1363</sup> The Protocol was negotiated pursuant to Article 19 of the Convention on Biological Diversity (CBD), and provides an international legal framework for

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<sup>1357</sup> See section 107(14) & (33), id.

<sup>1358</sup> Id.

<sup>1359</sup> See section 107(2)(a), id.

<sup>1360</sup> See USGAO, "Superfund Program: Updated Appropriation and Expenditure Data," (February 18, 2014), at <http://www.gao.gov/new.items/d04475r.pdf> (accessed on 14 May 2015).

<sup>1361</sup> See generally the discussion and analysis in Chapter One of the thesis.

<sup>1362</sup> See The Cartagena Protocol on Biosafety to the Convention on Biodiversity, (Montreal, 2000), at <http://www.biodiv.org> (accessed on 14 May 2015).

<sup>1363</sup> Id.

adequate level of protection for 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 into account risks to human health, and specifically, focusing on transboundary movements.<sup>1364</sup>

Living modified organism is defined as "any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology."<sup>1365</sup> The definition undoubtedly includes transgenic plant organisms, which is a product of modern biotechnology.<sup>1366</sup> The Protocol urges precautionary principle approach to the governance of products of modern biotechnology,<sup>1367</sup> due to "lack of scientific certainty... insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism in the conservation and sustainable use of biological diversity...taking also into accounts risks to human health..."<sup>1368</sup>

The Protocol is especially relevant to the supply chain framework, because it applies to transboundary movement, transit handling and use of all living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking into account risks to human life," whilst seeking to ensure biosafety, by prescribing procedures and rules for safe transboundary transfer and movements of living modified organisms.<sup>1369</sup>

Most significantly, Article 27 of the Protocol enjoins contracting parties to establish a process of negotiation for "international rules and procedures in the field of liability and redress for damage resulting from transboundary movements of living modified organisms", taking into account the provisions of relevant international laws.<sup>1370</sup>

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<sup>1364</sup> See Article 1, id.

<sup>1365</sup> See Article 3(g), id.

<sup>1366</sup> See the analyses and discussion in sections 1.1.2, 1.1.3, 1.1.4 and 1.1.5 of the thesis.

<sup>1367</sup> See Article 1, id.

<sup>1368</sup> See Article 10(6) and 11(8), id.

<sup>1369</sup> See Article 4, id.

<sup>1370</sup> See Article 27, id.

Following six years of protracted negotiations, the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety was adopted (The Supplementary Protocol).<sup>1371</sup> The Supplementary Protocol "applies to damage resulting from living modified organisms, which find their origin in transboundary movement."<sup>1372</sup> The living modified organisms covered are those intended for direct use as food or feed, or for processing, those destined for contained use, and those intended for intentional introduction into the environment.<sup>1373</sup> The supplementary Protocol equally applies to damage arising from any unauthorised use of the living modified organisms designed for food, feed, release into the environment, or contained use.<sup>1374</sup> Thus, by extrapolation, in the context of damage relating to transgenic plant technological products, the Supplementary Protocol would cover all approved transgenic plant products, any adventitious release and unauthorised uses.

Damage is defined in Article 2(2) (b) as "an adverse effect on the conservation and sustainable use of biological diversity, taking into account risks to human health".<sup>1375</sup> Damage must also be "measurable or otherwise observable taking into account scientifically-established baselines recognized by a competent authority that takes into account any other human induced variation and natural variation."<sup>1376</sup> This provision effectively subjects the standard of proof of damage to scientific standards, which would invariably depend on the prevailing scientific opinions at any point in time. Significantly, Article 4 provides that a causal link must be established between damage and the living modified organism in question in accordance with domestic law.

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<sup>1371</sup> See Gurdial Singh Nijar, "The Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety: An Analysis of Implementation," *International Environmental Agreement: Policy, Law and Economic*, *supra*, note 16, at 272.

<sup>1372</sup> See Article 3, Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety, (Montreal 2011).

<sup>1373</sup> See Article 3(1)(a)(b)(c), *id.*

<sup>1374</sup> See Article 3(2), *id.*

<sup>1375</sup> *Id.*

<sup>1376</sup> See Article 2(2)(b)

The Supplementary Protocol provides for two legal framework for liability and redress regime. The first is administrative approach under Article 5, whilst the second is civil liability approach under Article 12. The administrative liability framework details procedure for notifying the competent authority about the damage, the evaluation of the damage by the competent authority, and the implementation of appropriate "response measures" by the competent authority.<sup>1377</sup> "Response measures" are defined as "reasonable actions to prevent, minimise, contain, mitigate, or otherwise avoid damage as appropriate," It also include the restoration of biological diversity to its previous condition prior to the occurrence of the damage, or to its nearest equivalent, thus acknowledging that it might not be practical to attain full restoration of the ecosystems. For this reason, the competent authority might order the replacement of the lost biodiversity with equivalents either at the same location or alternative location.<sup>1378</sup>

However, whilst there is a detailed administrative procedure for identifying the operator that caused the damage, evaluating the damage, and determining appropriate compensatory responses for restoration and damages, the legal framework for civil liability, which could afford a private cause of action for economic loss and property damage in the coexistence paradigm, is left deliberately vague under Article 12 of the Supplementary Protocol on civil liability and redress. Article 12(1) enjoins contracting parties to provide in their "domestic law, for rules and procedures that address damage."<sup>1379</sup> Parties are also enjoined to apply their domestic law and general rules of procedural liability, and to develop civil liability rules and procedures, or a combination of both.<sup>1380</sup> Furthermore, whilst considering appropriate civil

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<sup>1377</sup> See Article 5(1)(2)(3)(4).

<sup>1378</sup> See Article 2(2)(d), *id.*

<sup>1379</sup> See Article 12(1), *id.*

<sup>1380</sup> See Article 12(1)(a)(b)(c), *id.*

liability, parties are enjoined to address the following elements: damage, standard of liability, including strict or fault-based liability, channelling of liability, and the right to bring claims.<sup>1381</sup>

The failure of the Supplementary Protocol to implement comprehensive civil liability regime following six years of protracted negotiations has been criticised.<sup>1382</sup> According to Gurdial Singh, the Supplementary Protocol "is spectacularly deficient in providing for an effective civil liability regime...an opportunity was missed to advance international environmental liability jurisprudence by crafting an effective international liability and redress regime that could speak across jurisdictions with widely divergent legal systems, especially with regards to civil liability, traditional and socio-economic damage in the specific modern biotechnology sector."<sup>1383</sup> However, this failure was not unexpected because the biotechnology industry and the United States were opposed to a detailed civil liability framework; and Article 12 of the Supplementary Protocol was no more than a compromise.<sup>1384</sup> It is argued however that the provisions of Article 12 could only reinforce the current disparate liability and redress regime, and unless there is a uniform civil liability and redress regime, the balancing of rights and confronting of the existential threats in the coexistence paradigm would remain an illusion. Chapter Seven of the thesis sets out in some detail how the imbalance between administrative and civil liability and redress regime could be remedied.

#### **6.7.0. Norwhich Pharmacal Actions.**

A Norwhich Pharmacal order is typically granted against an innocent third party for discovery and disclosure of documents or information that could help the applicant to seek redress against other individuals. The order was first granted by the House of Lords in 1974 in [Norwich](#)

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<sup>1381</sup> See Article 12(3)(a)(b)(c)(d), *id.*

<sup>1382</sup> See Gurdial Singh Nijar, "The Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety: An Analysis of Implementation," *International Environmental Agreement: Policy, Law and Economic*, *supra*, note 16, at 276-278.

<sup>1383</sup> *Id.*, at 277-278.

<sup>1384</sup> *Id.*, at 278-279.



[Pharmacal Co. v Customs and Excise Commissioners](#), which involved the owner and exclusive licensee of a patent for an antibacterial called furazolidone.<sup>1385</sup> Between 1960 and 1970, unlicensed copies of the product were shipped to Britain, without the consent of Norwich Pharmacal Com.<sup>1386</sup>

The Commissioners for customs & Excise had information that could identify the importers of the products but refused to disclose the information to Norwich. In an action by Norwich against the Commissioners, the House of Lords held inter alia that "if through no fault of his own a person gets mixed up in the tortious acts of others so as to facilitate their wrong doing he may incur no personal liability, but he comes under a duty to assist the person who has been wronged by giving him full information and disclosing the identity of the wrong doers."<sup>1387</sup> The procedure for the issuance of the order has since been codified in England & Wales in the Civil Procedure Rules.<sup>1388</sup>

In the context of supply chain liability, the Norwich Pharmacal order could be applied for by any of the litigants to secure critical information held by innocent parties within the supply chain to help establish their cause of action either in tort, contract, product liability or patents infringements.

### **6.8.0. Conclusions.**

Chapter Six uses the supply chain framework to explore a range of causes of action that include strict liability, product liability, contractual liability, environmental liability, and the procedural rule Norwich Pharmacal order. The chapter draws on tangent and analogous case law and statutes from the United Kingdom, the European Union, North America, and the provisions of

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<sup>1385</sup> See [Norwich Pharmacal Co. v Customs and Excise Commissioners](#), [1974] AC 133.

<sup>1386</sup> *Id.*, at 138.

<sup>1387</sup> See Per Lord Reid, *id.*, at 143.

<sup>1388</sup> See Rules 31.18, Civil Procedure Rules Act 1997.

the Cartagena Protocol on Biosafety, to explore possible causes of action for enforcing supply chain liability that may arise in the coexistence paradigm.

The importance of traceability in for supply chain liability is analysed in the context of conceivable scenarios for strict liability, product liability, and contractual liability. The chapter highlights the weaknesses and proprieties of these causes of action, and argues for a more coherent and effective compensation regime that would supplement existing causes of action. The imperatives and the modalities for the complementary *sui generis* law is canvassed for in relative detail in Chapter Seven of the thesis.

## Chapter Seven.

### Conclusions: Problems, Solutions and Recommendations for Law Reform

#### 7.1.0. The Existential Problems of Coexistence.

Since the advent of commercial transgenic plant agriculture in North America in the 1990s, approximately 181.5 million of hectares of arable farmland have been cultivated with transgenic crops, such as maize, soybeans, wheat, and cotton etc., across twenty-eight countries on six continents.<sup>1389</sup> Transgenic plant food and industrial crops are genetically engineered by scientists to develop resistance to weeds and pests,<sup>1390</sup> to improve nutrition,<sup>1391</sup> to increase yields,<sup>1392</sup> and to thrive amidst the harshness of arid farmlands and inhospitable drought conditions.<sup>1393</sup> However, whilst transgenic plant agricultural technology has been variously touted as the panacea to global food security problems by scientists and proponents alike, there are also scientists and opponents who have urged caution due to unknown risks and its possible adverse effects on public health and the environment.<sup>1394</sup> Most significantly, scholarly and public debates on the propriety of transgenic plant agriculture for public health and the environment are often tendentious and acrimonious, whilst the science on issues that range from the nature of transgenic plant food toxins and allergens, adventitious gene-flow, and the

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<sup>1389</sup> See Clive James, ISAAA, *Global Status of Commercialized Biotech/GM Crops: 2014*, ISAAA Brief No. 49, *supra*, note 1.

<sup>1390</sup> See Jikun Huang, Ruifa Hu, Scott Rozelle and Carl Pray, "Insect-Resistant GM Rice in Farmers' Fields: Assessing Productivity and Health Effects in China," *Science*, *supra*, note 38, at 688-690; Robert Paarlberg, *Starved for Science: How Biotechnology is Being Kept Out of Africa*, *supra*, note 38, at 149-150.

<sup>1391</sup> See Taiwo A. Oriola, "Consumer Dilemmas: The Right to Know, Safety, Ethics, and Policy of Genetically Modified Food," *Singapore Journal of Legal Studies*, *supra*, note 298, at 516.

<sup>1392</sup> See Guanming Shi, Jean Paul Chavas and Joseph Lauer, "Commercialized Transgenic Traits: Maize Productivity and Yield Risk," *Nature Biotechnology*, *supra*, note 39, at 111-114.

<sup>1393</sup> See Jeff Tollefson, "Drought-tolerant maize gets US debut: Seed companies race to tap multibillion dollar market," *Nature*, *supra*, note 37 at 8; Eleonora Cominelli, "Transgenic Crops Coping with Water Scarcity," *New Biotechnology*, *supra*, note 37 at 473-477.

<sup>1394</sup> See generally the discussions and analyses in Chapter Four of the thesis on comparative existential conflicts in the coexistence paradigm.

long-term impacts of transgenic plant agriculture on the environment and public health, remain uncertain, sometimes conflicting and often inconclusive.<sup>1395</sup>

However, despite the lack of unanimity of views in scientific literature on the propriety and safety of the science of transgenic plant agriculture for public health and the environment, national transgenic plant food policy in the United States, and to some extent in the European Union, is largely underpinned by the “substantial equivalence” doctrine, which posits that foods derived from transgenic plant technology are substantially equivalent to those derived from organic and conventional plant agriculture. Thus, by extrapolation, transgenic plant agriculture is substantially equivalent to organic and conventional plant agricultural systems.<sup>1396</sup> It is hypothesised in the thesis that the substantial equivalence policy partly undermined the imperatives for a coherent and adequate compensation regime, because it would be unreasonable to expect damage from adventitious commingling of products of essentially similar genetic properties, and also because it could give the impression that the technology was inherently unsafe. This analysis is supported by the initial opposition by the plant biotechnology company to any form of compensation regime.<sup>1397</sup>

Even so, some nations, especially in Europe, are fiercely opposed to transgenic plant technology and products, a stance that arguably informed official precautionary approach and regulatory measures, which include a traceability and labelling regime designed primarily to facilitate informed consumer choice in the general marketplace for plant agricultural food products.<sup>1398</sup> Other precautionary measures include the European Commission official moratorium on the approval of new transgenic crops, and importation of transgenic crops and

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<sup>1395</sup> See generally Chapters Four of the thesis for the discussion on the comparative existential conflicts in the coexistence paradigm.

<sup>1396</sup> See the discussion in Chapter Two of the thesis on substantial equivalence doctrine, and Chapter Three of the thesis on the regulatory science that underpin the governance of transgenic plant agriculture.

<sup>1397</sup> See Gurdial Singh Nijar, "The Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety: An Analysis of Implementation," *International Environmental Agreement: Policy, Law and Economic*, *supra*, note 16, at 279.

<sup>1398</sup> See Regulation (EC) 1830/2003 of the European Parliament and of the Council on the traceability and labelling of genetically modified organisms, Official Journal of the European Union, *supra*, note

products in 1998. However, this measures were overruled by the WTO Panel in *European Communities Biotech Products Case*, in a trade dispute initiated by transgenic crops producing and exporting countries that included Canada, the United States and Argentina,<sup>1399</sup> underscoring the trans-nationality of the coexistence regulatory framework, and the limits of national and regional regulatory framework in achieving a coherent compensatory regime that could balance the conflicting rights in the coexistence paradigm, and help ensure compliance with coexistence rules.

Yet, the inexorable spread of transgenic plant agriculture and food around the world, and the cultural, social, political, economic, and environmental imperatives for continuing parallel existence of transgenic, conventional and organic plant agriculture, make coexistence of transgenic and non-transgenic plant agriculture inevitable and assured. However, empirical and scientific evidence suggest that the coexistence paradigm is far from harmonious, as exemplified by the rare unanimity of scientific views on the natural propensity for gene-flow between transgenic and non-transgenic crop varieties,<sup>1400</sup> with possible loss of crop purity and concomitant economic damage to organic or conventional crops.<sup>1401</sup> Even the European Commission had to admit that there could be no expectation of hundred percent purity for organic and conventional crops, and a new standard of 0.9 percent maximum transgenes contents was set for organic and conventional crops.<sup>1402</sup> The thesis argues that this was perhaps a necessary sacrifice by organic farmers, conventional farmers, and the consumer, to accommodate transgenic plant technology in the coexistence paradigm, in light of increasing world population and corresponding global food security scares. However, the conflicting

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<sup>1399</sup> See *European Communities Biotech Products Case*, *supra*, note 27.

<sup>1400</sup> See generally the discussion in Chapter Four of the thesis on the existential conflicts in the coexistence paradigm.

<sup>1401</sup> See discussion in Chapter Two of the thesis.

<sup>1402</sup> See Article 12(2) and 24(2) of Regulation (EC) No. 1829/2003, *supra*, note 12.

rights ought to be moderated and balanced by a coherent and effective compensatory regime, which is currently lost amidst disparate national laws on coexistence arrangements.

In terms of the implications of the advent of transgenic plant technology for the environment, and the imperatives for adequate compensation regime, the thesis highlights the mounting evidence that complementary chemical herbicides for transgenic Bt. crop varieties, such as Monsanto's glyphosate, and Bayer CropScience's ammonium-based glufosinate, are kindling resistance in, and morphing targeted weeds into super-weeds that require even more chemical herbicides to eliminate, with dire and negative long-term consequences for the environment.<sup>1403</sup> Moreover, recent scientific findings have suggested that *Bacillus thuringiensis* bacterium encoded in transgenic maize and other Bt. crops could leach into the soil, and deplete non-target soil micro-organisms such as *arbuscular mycorrhizal* fungi population that are critical for improving soil fertility.<sup>1404</sup> Whilst most of the science that underpin these findings are hotly disputed, the disputes and contestations, the thesis argues, could only raise the level of public perception of risk, and increase demands for adequate compensation, which could help enforce compliance and dampen public anxieties about the technology.

With regards to public health implications of transgenic plant technology, more worryingly, unapproved transgenes are routinely found in the food chain, and some scientists are genuinely apprehensive that Cry9C protein, a natural toxic pesticide from *Bacillus thuringiensis* bacterium, which was never approved for use in food crop, may have permanently permeated the global food chain via the StarLink corn scandal, which precipitated health scares and unprecedented nation-wide corn food products recall in the United States.<sup>1405</sup> There is also the hotly contested scientific evidence that *Bacillus thuringiensis* bacterium, which is encoded in

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<sup>1403</sup> See Chapter Four of the thesis.

<sup>1404</sup> *Id.*

<sup>1405</sup> *Id.*

virtually all transgenic food crops, may be able to survive the human gut, with as-yet-unknown ramifications for future global public health.<sup>1406</sup>

Significantly, the aforementioned existential challenges and conflicting rights inherent in the coexistence paradigm have precipitated new and unique legal challenges, and opened-up new legal frontiers and liability scenarios, which range from the likelihood of patent infringement by non-transgenic plant farmers due to adventitious gene flow; farmers' right to save and replant seeds from their harvests; damage caused to organic or conventional crops by adventitious transgenes; environmental damage caused by the emergence of herbicide-resistant super-weeds, and the concomitant rise in the use of chemical herbicides; possible environmental damage from the depletion of invaluable soil micro-organisms critical for renewal of soil fertility; possible personal injury or harm caused by unique and unfamiliar transgenic plant food allergens and toxins; or by unapproved transgenes in the food chain; to economic damage caused by the loss of organic or conventional crop purity and premium markets.<sup>1407</sup> These legal battles are already being fought in Canada and the United States where commercial transgenic plant agriculture has flourished since the mid 1990s. However, the widespread adoption of transgenic plant agriculture, and the globalization of agricultural trade in transgenic plant products, make the spread of the legal battles to other parts of the world inevitable, hence the need for a coherent compensatory regime that is globally accepted and enforceable.

Whilst drawing on Ulrich Beck and Anthony Giddens' socio-legal theory on risks and responsibility, it is hypothesised and argued in the thesis that the pervasive climate of uncertainty on the safety science of transgenic plant technology for the environment, public

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<sup>1406</sup> See Aziz Aris and Samuel Leblanc, "Maternal and foetal exposure to pesticides associated to genetically modified foods in Eastern Townships of Quebec," *Reproductive Toxicology*, *supra*, note 797, at 534-539; John Godfrey, "Do genetically modified foods affect human health?" *Lancet*, *supra*, note 143, at 414.

<sup>1407</sup> See generally the discussion in Chapter Four of the thesis on the existential challenges posed by the coexistence of transgenic and non-transgenic plant agriculture.

health as well as the technology's possible adverse economic effects on organic and conventional agricultural markets, have accentuated the nature of inherent risks for which there should be a corresponding legal responsibility.<sup>1408</sup> It is further argued that transgenic plant technology is a technology of risk due in part to the uncertainties that underpin its safety science, and that like all "technology of risk" in the post-industrial risk society, there must of necessity, be a corresponding legal responsibility that could simultaneously help ensure compliance with coexistence rules, moderate and balance inherent conflicting rights, and build public confidence in the technology, rather than undermine its promise. For it remains clear from the available evidence that there are economic imperatives for the continuing existence of transgenic plant technology, given the continuing dependence of the European livestock feed on transgenic plant crops.

### **7.1.1. Why Current Compensatory Regimes Are Inadequate.**

The thesis draws largely on relevant and analogous case law and statutes from Canada, the United States, the United Kingdom, and the European Union, on the liability regimes for damage stemming from the coexistence of transgenic and non-transgenic plant agriculture, with particular focus on liability induced by adventitious presence of approved and unapproved transgenes in non-transgenic plant crop and food products. The central argument of the thesis is that the current national and transnational liability regimes for damage induced by adventitious transgenes are ill-suited to the unique existential challenges and legal problems posed by the coexistence of transgenic and non-transgenic plant agriculture.

In Chapter One, the thesis reviews relevant literature and provides an insight into the existential conflicts and conflicting rights in the coexistence paradigm. In Chapter Two, the

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<sup>1408</sup> See Ulrich Beck, *Risk Society: Towards a New Modernity*, *supra*, note 10; at 51-84; Anthony Giddens, "Risk and Responsibility," *Modern Law Review*, *supra*, note 7, at 8.



thesis discusses the significance of the substantial equivalence doctrine, and how the international recognition of the doctrine by the World Health Organization; the Food and Agricultural Organization; and the OECD ultimately legitimised transgenic plant agriculture, and paved the way for the internationalisation of trades in transgenic plant agricultural products.<sup>1409</sup> It is hypothesised that the non-regulatory policy espoused by the substantial equivalence doctrine for transgenic plant food, is implicated in the absence of coherent, effective, and viable compensatory regime in the coexistence paradigm. The hypothesis is premised on the logic that if regulators truly thought that transgenic plant food was substantially equivalent to conventional plant food, then, by extrapolation, transgenic plant agriculture would be substantially equivalent to conventional plant agriculture, and therefore, any regulatory regime for the coexistence of transgenic and non-transgenic plant agriculture would be moot.

Arguably, this is why most national regulators like the UK DEFRA are happy for the existing liability regime such as product liability to apply to damage induced by adventitious transgenes in the coexistence of transgenic and non-transgenic plant agriculture.<sup>1410</sup> Thus, the influence of the substantial equivalence doctrine is palpable in the lack of proactive national and transnational liability regimes designed to address the unique legal problems thrown-up by the coexistence of transgenic and non-transgenic plant agriculture. This is so, even though the “science” that underpins the substantial equivalence doctrine has been faulted by critics who decry the doctrine as an ideological and political constructs originally designed by the United States government to facilitate and expedite transgenic plant agricultural business and limit federal bureaucracy.<sup>1411</sup>

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<sup>1409</sup> See generally the discussion in Chapter One of the thesis.

<sup>1410</sup> See Christopher Rodgers, “Defra’s Coexistence Proposals for GM Crops: A Recipe for Confrontation?” *Environmental Law Review*, *supra*, note 27, at 1-8.

<sup>1411</sup> See Michael Baram, “Governance of GM Crop and Food Safety in the United States,” in Michael Baram and Mathilde Bourier, (editors), *Governing Risk in GM Agriculture*, *supra*, note 45, at 26-44.

Chapter Three discusses the science-centric national and transnational regulatory and policy framework for transgenic plant agriculture and the coexistence of transgenic and non-transgenic plant agriculture. Even so, the ‘science’ that underpins the current regulatory framework for the coexistence paradigm is at best evolutionary, hotly contested, and largely uncertain.<sup>1412</sup> Arguably, disparate regulatory science regime for the coexistence of transgenic and non-transgenic plant agriculture, is symptomatic of the current disparate and largely ineffectual compensatory regimes for the unique existential and legal challenges thrown-up by the practicalities of the coexistence of transgenic and non-transgenic plant agriculture. Even the Cartagena Protocol on Biosafety failed to agree on commensurate civil liability regime.<sup>1413</sup>

Yet, these generalised and disparate redress regimes are inherently limited, as amply demonstrated by Chapters Five and Six of the thesis. Chapter Five explores the propriety of tortious liability for remedying damage induced by adventitious transgenes in the coexistence of transgenic and non-transgenic plant agriculture, and highlights the limits of the cause of action in negligence and private nuisance for environmental damage, economic damage, property damage, and personal harm.<sup>1414</sup> Chapter Six also examines the concept of supply chain liability, explores and highlights the propriety and limits of the cause of action in contract, strict liability, environmental liability, and product liability for economic, environmental, property, and personal harm induced by adventitious transgenes in the coexistence of transgenic and non-transgenic plant agriculture.

### **7.1.2. Recommendations for Law Reform.**

Therefore, in light of the inherent limitations in the current national and transnational liability and redress framework, the thesis recommends a *sui generis* international legislative

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<sup>1412</sup> See the discussions in Chapter Three of the thesis on comparative regulatory science.

<sup>1413</sup> See the discussion in section 6.6.0 of the thesis.

<sup>1414</sup> See Chapter Five of thesis.

framework for a civil liability regime that would complement the current regime, and address some of the unique challenges of coexistence.

These range from the vulnerability of organic and conventional crops farmers to patents infringement and the concomitant economic loss, as exemplified by *Monsanto Canada Inc v. Schmeiser*.<sup>1415</sup> Similarly, farm businesses that operate seed processing and cleaning businesses are at risk of secondary patents infringement for cleaning proprietary transgenic seeds and crops, an act that was held tantamount to aiding transgenic farmers to save and replant proprietary seeds in breach of the terms of their technology agreements in *Monsanto v. Maurice Parr*.<sup>1416</sup> The strict liability nature of the patent regime is particularly burdensome in circumstances exemplified by *Monsanto Canada Inc v. Schmeiser and Monsanto v. Maurice Parr*, and there is a strong case for national and international patent exception rights that would protect non-transgenic plant farmers and farm businesses in analogous circumstances.

The case for law reform in this field of law is especially pertinent and exigent, in light of the inexorable global spread of transgenic plant agriculture, and the likelihood that the oligopolistic transgenic seed firms would enforce their patents with equal force in any part of the world, given their tendency for filing patents in multiple jurisdictions. Besides, there is a strong case for patents exemption right for non-transgenic crops farmers and farm businesses in the circumstances on grounds of equity and fairness, and in the interest of global food security and mutual coexistence of transgenic and non-transgenic plant agriculture. The State of California in the United States is the only known regulatory authority to exempt non-transgenic farmers from liability in circumstances analogous to the *Schmeiser Case*. Even so, the Californian patents liability exemption law does not cover seeds processing and cleaning businesses like that of *Maurice Parr*, and is still vulnerable to federal pre-emption laws.<sup>1417</sup>

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<sup>1415</sup> See *Monsanto Canada Inc v. Schmeiser*, *supra*, note 302, at 902.

<sup>1416</sup> See *Monsanto Company v. Maurice Parr*, *supra*, note 798, at 836.

<sup>1417</sup> See generally the discussions in section 4.2.1 of the thesis.

The proposed *sui generis* legislation would also help potential plaintiffs who are excluded by the current crop of liability regimes such as negligence, private nuisance, product liability, for reasons that range from a lack of interest in land, privity of contract, to the economic nature of the damage caused by adventitious transgenes in the coexistence of transgenic and non-transgenic plant agriculture.<sup>1418</sup>

### 7.1.3. The Nature and Form of Proposed *Sui Generis* Legislative Framework.

According to the *Oxford English Dictionary*, *sui generis* is a Latin phrase that means "of its (his, her, or their) own kind; in a class by itself; unique"<sup>1419</sup> In law, *sui generis* is used to denote the classification or categorisation of a group of rights that exist independently of other similar rights, due to their uniqueness or the need to create new entitlements that could not fit into the existing legal framework for similar group of rights.<sup>1420</sup> A very good example of a *sui generis* regime in the EU is the Database Directive **96/9/EC**, which was crafted to create a new group of statutory rights in database that failed to meet the minimum copyright originality threshold.<sup>1421</sup>

In this section, an international *sui generis* compensation regime is proposed that would set out clear and uniform civil liability rules for implementation by signatories in their domestic laws. It is proposed that the *sui generis* law should be administered by the Montreal Secretariat of the Convention on Biological Diversity, alongside the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety, which implemented detailed administrative liability framework, but failed to agree on a

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<sup>1418</sup> These issues are highlighted and discussed in Chapters Five and Six of the thesis.

<sup>1419</sup> See *Oxford English Dictionary*, (3<sup>rd</sup> edition) (Oxford: Oxford University Press, September 2005).

<sup>1420</sup> See Mawson, C. O. Sylvester, "sui generis", *Dictionary of Foreign Terms* (2 ed.), (New York: Thomas Y. Crowell Company, 1975), at 328.

<sup>1421</sup> See **Directive 96/9/EC of the European Parliament and of the Council of 11 March 1996 on the legal protection of databases**; Taiwo A. Oriola, "Electronic Database Protection and the Limits of Copyright: What Options for Developing Countries?" *The Journal of World Intellectual Property*, Volume 7, (March 2004), pp. 201-228.

coherent civil liability regime, due largely to the opposition by the biotechnology industry and transgenic crops exporting countries.<sup>1422</sup> However, the biotechnology industry subsequently relented and proposed an alternative civil compensation framework known as *The Compact: A Contractual Mechanism for Response in the Event of Damage to Biological Diversity Caused by A Release of Living Modified Organism*.<sup>1423</sup>

It is however important that the proposed *sui generis* regime should not be perceived as a check on the global growth of transgenic plant technology. Rather, it should be seen as a system for balancing the conflicting rights in the coexistence paradigm, which are already skewed in favour of transgenic plant technology as it were. For example, in Europe and elsewhere, organic and conventional farmers have had to contend with the inevitable adventitious presence of transgenes in their harvests, and a redefinition of what constitute organic or conventional crops, effectively losing the purity of their crops. Thus, it is only when the level of transgenes in their crops exceed 0.9 percent that they would be obliged to label their harvest as transgenic.<sup>1424</sup>

It is proposed that the key features of the proposed *sui generis* compensatory regime should include the following: First, an ‘intellectual property infringement exemption clause’ that guarantees immunity from patents prosecution, for organic or conventional crop farmers as well as farm businesses in analogous circumstances like in *Schmeiser Case* and *Maurice Parr Case*.<sup>1425</sup> The proposed intellectual property infringement exemption clause should also allow farmers to save their seeds for replanting, notwithstanding adventitious presence of transgenes in the seeds. However, the right to save and replant contaminated seeds, should be without prejudice to the right of the organic or conventional plant farmers to pursue a separate cause of action in private nuisance or negligence against whoever is responsible for the presence of

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<sup>1422</sup> See section 6.6.0 of the thesis.

<sup>1423</sup> See *The Compact: A Contractual Mechanism for Response in the Event of Damage to Biological Diversity Caused by A Release of Living Modified Organism*, at <https://croplife.org/wp-content/uploads/2014/05/First-Amended-Text-of-the-Compact.pdf> (accessed on 14 May 2015).

<sup>1424</sup> See the general discussion in Chapter Four of the thesis.

<sup>1425</sup> See the discussion in section 4.2.1 of the thesis.

transgenes in their crops. It is proposed that this intellectual property exemption clause would correct the current anomaly exemplified by Schmeiser and Maurice Parr in the coexistence paradigm.

The second key feature of the proposed *sui generis* regime is a compulsory insurance scheme for all systems of plant agriculture that would cover possible damage in the coexistence paradigm. Currently, the insurance industry is reluctant to insure transgenic plant agriculture. However, making it mandatory would increase the pool of insurers and the insured, even as the stock of the technology continues to rise globally. It is argued that overtime, insurance premiums would decrease as more and more farmers subscribe. Arguably, a compulsory insurance scheme would help instil public confidence in the technology and lead to greater adoption by farmers.

The third key feature of the proposed *sui generis* compensation scheme is an international compensation fund set up by governments as a contingency for cross-border damage. The fund could be administered by the Secretariat of the Convention on Biological Diversity in Montreal.

The fourth key feature of the proposed *sui generis* regime is a transnational civil procedural regime that would establish uniform procedural standards to be followed by national courts, and that would allow nationals of Member States to sue in the court of any Member states for compensation for damage cause in the coexistence paradigm. This would allow national courts to apply their substantive laws, whilst following standard procedures that would guarantee access to local court and recognise as justiciable, compensation claims relating to damage caused by transgenic plant technology in the coexistence paradigm. In fact, Denmark, Norway and Sweden already employ this practice under the 1974 Nordic Convention.<sup>1426</sup> The immediate challenge to such a uniform trans-national procedural rule is that the courts in a Member State may decline jurisdiction on ground of *forum non conveniens* (not the most

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<sup>1426</sup> See the Nordic Convention, 1974 1092 U.N.T.S. 279.

suitable forum). However, this is unlikely to happen once states have signed up to the sui generis compensation regime.

The fifth key feature of the proposed compensation regime is the principle of national treatment. This is a common feature of international treaties that allows Member States to treat nationals from other Member States as if they were their nationals under domestic laws. This would allow potential litigants to overcome potential jurisdictional huddles, and sue in any Member State provided the alleged damage could be linked to the territory or national of the Member State.

The sixth key feature of the proposed sui generis regime is a uniform private law regime. This would establish a binding agreement, stipulating a body of substantive liability laws that are enforceable in domestic courts. For example, the body of laws could allow anyone to sue for private nuisance whether they have an interest in land or not as long as they could establish damage. It could also contain provisions that would overcome all the obstacles posed by product liability, negligence, and contractual liability, discussed in Chapters Five and Six of the thesis. The body of laws would also harmonise causes of actions and the standards of proof. An example of a uniform private law regime is the Convention on Civil Liability for Oil Pollution Damage, which deals with liability for pollution caused by oil spills,<sup>1427</sup> and the Basel Protocol on Liability and Compensation resulting from the Transboundary Movement of Hazardous Wastes and Disposal.<sup>1428</sup>

The seventh key feature of the proposed sui generis regime is international arbitral system that would act as an international arbitral regime for intergovernmental dispute resolution. This would allow governments to challenge each other on their policies or non-compliance with the provisions of the sui generis compensation regime before international arbitration. It could also

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<sup>1427</sup> See International Convention on Civil Liability for Oil Pollution Damage of 29 November 1969 (as amended).

<sup>1428</sup> See Protocol on Liability and Compensation for Damage resulting from Transboundary Movements of Hazardous Wastes and their Disposal, Basel, (10 December 1999).

allow governments to challenge each other for failure to allow access to national courts or for failure to maintain agreed uniform standards. The international arbitral system would set up a suite of substantive and procedural rules relating to membership, nature of disputes, etc. There are comparative international rules such as the Trade Related Aspects of Intellectual Property, which is managed by the WTO TRIPS Council, and which provisions are binding and enforceable against countries that failed to comply.<sup>1429</sup> Also, *The European Communities Biotech Products Case*, is a testament to the binding force of the international Agreement on the Application of Sanitary and Phytosanitary Measures.<sup>1430</sup>

The said *sui generis* compensation regime would be administered by the Secretariat of the Convention on Biological Diversity in Montreal, who would be tasked with oversight and enforcement by national governments. The *sui generis* law should be binding and enforceable against erring national governments.

#### **7.1.4. The Limits of the Proposed *Sui Generis* Legislative Framework.**

There are obvious difficulties to the realisation of the proposed *sui generis* redress regime for damage induced by adventitious transgenes in the coexistence of transgenic and non-transgenic plant agriculture. First, the proposed *sui generis* law could be opposed by transgenic seed firms and countries with vested economic interests in commercial transgenic plant agriculture. However, this sort of resistance is not unprecedented, as exemplified by the historical resistance of the tobacco industry to legislative curbs. It is common knowledge that the tobacco industry even initially denied any link between tobacco smoking and cancer.<sup>1431</sup> Moreover, countries and governments with vested economic interests in transgenic plant agriculture could most

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<sup>1429</sup> See The TRIPS Agreement 1994, *supra*, note 48.

<sup>1430</sup> See the WTO Agreement on the Application of Sanitary and Phytosanitary Measures at [http://www.wto.org/english/tratop\\_e/sps\\_e/spsagr\\_e.htm](http://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm)

<sup>1431</sup> For discussion, see R.D. Tollison and R.E. Wagner, *Smoking and the State: Social Costs, Rent Seeking, and Public Policy*, (Massachusetts and Toronto: Lexington Books, 1998), at 19-37.



likely be opposed to the proposed *sui generis* redress regime. Indeed, this was the main reason countries could not agree on effective civil compensation mechanism under the Nayoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety.<sup>1432</sup>

Furthermore, such a law could be deemed as an attempt to stifle international trade in transgenic plant products, and most crucially, the proposed law could be perceived as prejudicial or discriminatory to transgenic seed firms and transgenic plant farmers, unless of course, there is scientific evidence to justify such a special redress regime.

Nevertheless, a *sui generis* redress regime that would complement existing liability and redress regimes is the most effective means of establishing an inclusive, effective, and viable compensatory measure for the existential challenges in the coexistence paradigm. It would introduce some balance into the conflicting rights, ensure compliance with coexistence rule, and bring about responsible transgenic governance system. It is only fitting that the current wrongs in the coexistence paradigm be righted, simply because non-transgenic plant farmers have as much right as transgenic plant farmers to subsist in the coexistence paradigm.

### **7.1.5. Conclusions**

Chapter Seven of the thesis reiterates the existential problems of the coexistence paradigm to justify the proposal for a *sui generis* compensatory regime that would complement existing national laws. One of the two central hypotheses that underpin the thesis' proposal for a *sui generis* compensation regime is that transgenic plant technology is a 'technology of risk' in the post-industrial society, and that the high level of uncertainty surrounding its safety science for the environment and public health, ultimately increases the perception of its attendant risks. The thesis then draws on the socio-legal theory espoused by Ulrich /Beck and Anthony Giddens

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<sup>1432</sup> See the discussion in section 6.6.0 of the thesis.

that risks and responsibility are correlatives, and that within the coexistence paradigm, responsibility connotes legal liability for attendant risks, and that like all technologies of risk such as nuclear technology, it is fitting that there should be adequate compensation regime, not merely as a deterrent, but as a tool to incentivise compliance with coexistence rules and balance the conflicting rights which are increasingly been skewed against non-transgenic plant farmers and businesses.

## BIBLIOGRAPHY

### BOOKS.

Allenby, B. R., "Governance and Technology Systems: The Challenge of Emerging Technologies," in Gary E. Marchant, Braden R. Allenby, and Joseph R. Herkert, (editors), *The Growing Gap Between Emerging Technologies and Legal-Ethical Oversight: The pacing Problem*, (Heidelberg, London & New York: Springer Publishing, 2011).

Altieri, M. A., "Transgenic Crops: Agro-biodiversity and Agro-ecosystem Function," in Iain E. P. Taylor, (editor), *Genetically Engineered Crops: Interim Policies, Uncertain Legislation*, (New York: Haworth Food & Agricultural Products Press, (2007).

Anderson, J. D., *Fundamentals of Aerodynamics*, 5<sup>th</sup> edition, (McGraw-Hill Higher Education, 1 June, 2011).

Askeland, B., "Damage Caused by GMOs under Norwegian Law", in Bernhard A. Koch, (editor), *Damage Caused by Genetically Modified Organisms: Comparative Survey of Redress Options for Harm to Persons, Property or the Environment*, ((Berlin & New York: Walter de Gruyter GmbH & Co. KG, 2010).

Baram, M., "Governance of GM Crop and Food Safety in the United States," in Baram, M. and Bourier, M., (editors), *Governing Risk in GM Agriculture*, (Cambridge: Cambridge University Press, 2011).

Baram, M. and Bourier, M. (editors), *Governing Risk in GM Agriculture*, (Cambridge: Cambridge University Press, 2011).

Beck, U., *'Ecological Politics in an Age of Risk'*, (Oxford: Blackwell Publishers, 1995).

Beck, U., *Risk Society: Towards a New Modernity*, (London: Sage Publications, 1992).

Bell, A., *Forum Shopping and Venue in Transnational Litigation*, (Oxford University Press, USA, 2003).

Bernard, C., *An Introduction to the Study of Experimental Medicine*, (Dover Publications, 1st June, 1957).

Bernauer, T., *'Genes, Trade, and Regulation: The Seeds of Conflict in Food Biotechnology'*, (Princeton and Oxford: Princeton University Press, 2003).

Billings, P. R. and Shorett, P., "Coping with Uncertainty: The Human Health Implications of GE Foods," in Taylor, I. E. P., (editor), *Genetically Engineered Crops: Interim Policies, Uncertain Legislation*, (New York: Haworth Food & Agricultural Products Press, (2007).

Bodiguel, L. and Cardwell, M., (editors), *The Regulation of Genetically Modified Organisms: Comparative Approaches*, (Oxford: Oxford University Press, 2010).

Bourier, M., "Applying Safety Science to Genetically Modified Agriculture," in Michael Baram and Mathilde Bourier, (editors), (Cambridge: Cambridge University Press, 2011).

Burt, D. S., *The Biography Book: A Reader's Guide to Non-fiction, Fictional and Film Biographies of More than 500 of the Most Fascinating Individuals of All Time*, (Westport, CT & Oxford: Greenwood Publishing Group Inc, 2001).

Campbell, D. and Lee, R., (editors), *Environmental Law and Economics, Volume II*, (Aldershot, England & Burlington, USA: Ashgate Publishing, 2007).

Cardwel M. N., Crossman, M.R., and Rogers, C.P., (eds.) *Agriculture and International Trade Law, Policy and the WTO*, (Oxford: U.K, Cambridge: Massachusetts: CABI Publishing, 2003).

Cordonier Segger, M. C., Perron-Welch, F. and Frison, C., *Legal Aspects of Implementing the Cartagena Protocol on Biosafety*, (Cambridge & New York: Cambridge University Press, 2003).

Cornish, W., Llewelyn, D., and Aplin, T., *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights*, 8<sup>th</sup> edition, (London: Sweet & Maxwell, 2013).

Dano, E. D., "Potential Socio-Economic, Cultural and Ethical Impacts of GMOs: Prospects for Socio-Economic Impact Assessment," in Terje Traavik and Lim Li Ching, (eds.) *Biosafety First: Holistic Approaches to risk and Uncertainty in Genetic Engineering and Genetically Modified Organisms*, (Tromso: Tapir Academic Press, 2007).

[De Vareilles-Sommieres](#), P., (editor), *Forum Shopping in the European Judicial Area*, (Portland: Hart Publishing, 2007).

Duthie, D., and Eek, L., "National Biosafety Regulatory Systems in Central and Eastern Europe," in Marie-Claire Cordonier Segger, Frederic Perron-Welch, and Christine Frison, *Legal Aspects of Implementing the Cartagena Protocol on Biosafety*, (Cambridge & New York: Cambridge University Press, 2003).

Eastman, K. and Sweet, J., *Genetically Modified Organisms (GMOs): The significance of gene flow through pollen transfer*, (Copenhagen: European Environmental Agency, 2002).

Ebert, I. and Lahstein, C., "GMO Liability: Options For Insurers", in Bernhard A. Koch, (editor), *Economic Loss Caused by Genetically Modified Organisms: Liability and Redress for the Adventitious Presence of GMOs in Non-GM Crops*, (Wien & New York: Springer, 2008).

Elliott, C., and Quinn, F., *Tort Law* (6th edition) (London: Longman, 2007).

Endres, A. B., "Damage Caused by GMOs under US Law," in Bernhard A. Koch, (editor), *Damage Caused by Genetically Modified Organisms: Comparative Survey of Redress Options for Harm to Persons, Property or the Environment*, (Berlin & New York: Walter de Gruyter GmbH & Co. KG, 2010).

Engdahl, F. W., *Seeds of Destruction: The Hidden Agenda of Genetic Manipulation*, (Montreal: Global Research, 2007).

Epstein, R. A., "A Theory of Strict Liability," in David Campbell and Robert Lee, *Environmental Law and Economics, Volume I*, (Aldershot, England & Burlington, USA: Ashgate Publishing, 2007).

Fedtke, J., “Damage Caused by GMOs under German Law,” in Bernhard A. Koch, (editor), *Damage Caused by Genetically Modified Organisms: Comparative Survey of Redress Options for Harm to Persons, Property or the Environment* (Berlin & New York: Walter de Gruyter GmbH & Co. KG, 2010).

Fentiman, R., “Parallel Proceedings and Jurisdiction Agreement in Europe,” in [Pascal De Vareilles-Sommieres](#), (editor), *Forum Shopping in the European Judicial Area*, (Portland: Hart Publishing, 2007).

Forest, J. J. F., (editor), *Homeland Security: Protecting America’s Targets*, (volume 2, (Westport, CT., Greenwood Publishing Group, 2006).

Fowler, C., *Unnatural Selection: Technology, Politics, and Plant Evolution* (Amsterdam: Gordon and Breach, 1994).

Fruhstorfer, S. and Klement, F., “General Grounds on Which Courts Will Accept Jurisdiction”, in Carel Baron van Lynden, (editor) *Forum Shopping*, (Informa Law, 1998).

Garforth, K. and Ainslie, P., “Liability and Redress in Canadian Case Law: Hoffman v. Monsanto Canada Inc.”, in Marie-Claire Cordonier Segger, Frederic Perron-Welch, and Christine Frison, (editors), *Legal Aspects of Implementing the Cartagena Protocol on Biosafety*, (Cambridge & New York: Cambridge University Press, 2013).

Gregory, C. O., “Trespass to Negligence to Absolute Liability,” in David Campbell and Robert Lee, (editors), *Environmental Law and Economics, Volume II*, (Aldershot, England & Burlington, USA: Ashgate Publishing, 2007).

Gunning J. and Holm S., (editors), *Ethics, Law and Society: Volume 1*, (Aldershot: Ashgate Publishing, 2005).

Henderson, Jr., J. A., and Twerski, A. D., *The American Law Institute, Restatement of the Law Third, Torts: Product Liability*, (The American Law Institute, 1998).

Herring, R. J., “The Genomics Revolution and Development Studies: Science, Poverty and Politics,” in Ronald J. Herring, (editor), *Transgenics and the Poor: Biotechnology in Development Studies*, (Abingdon, Oxon & New York: Routledge Publishing, 2007).

Herring, R. J., (editor), *Transgenics and the Poor: Biotechnology in Development Studies*, (Abingdon, Oxon & New York: Routledge Publishing, 2007).

Hinteregger, M. and Joening, E., “Economic Loss Caused by GMOs in Austria,” in Bernhard A. Koch, (editor), *Economic Loss Caused by Genetically Modified Organisms: Liability and Redress for the Adventitious Presence of GMOs in Non-GM Crops* (Wien & New York: Springer, 2008).

Ho, M. W. and Ching L.L., *GMO Free: Exposing the Hazards of Biotechnology to Ensure the Integrity of Our Food Supply*, (Ridgefield, CT & London: Institute for Science in Society, 2004).

Jasanoff, S., *The Fifth Branch: Science Advisers as Policymakers*, (Cambridge Massachusetts: Harvard University Press, 1994).

Kerr, W. and Hobbs, J., “Consumers, Cows and Carousels: Why the Dispute over Beef Hormones is Far More Important than its Commercial Value’ in Nicholas Perdikis and Robert Read (eds), *The WTO and the regulation of international trade : recent trade disputes between the European Union and the United States*, (Edward Elgar Publishing Limited, 2005).

Kloppenburg Jr , J.R., *First The Seed: The Political Economy of Plant Biotechnology*, Second Edition, (Madison, Wisconsin: University of Wisconsin Press, 2004).

Koch, B. A., (editor), *Damage Caused by Genetically Modified Organisms: Comparative Survey of Redress Options for Harm to Persons, Property or the Environment*, (Berlin & New York: Walter de Gruyter GmbH & Co. KG, 2010).

Koch, B. A., (editor), *Economic Loss Caused by Genetically Modified Organisms: Liability and Redress for the Adventitious Presence of GMOs in Non-GM Crops*, (Wien & New York: Springer, 2008).

Lee, M., *EU Regulation of GMOs: Law and Decision Making for a New Technology*, (Cheltenham, UK & Northampton, MA, USA: Edward Elgar Publishing, 2008).

Lee, M., “Multi-level Governance of Genetically Modified Organisms in the European Union: Ambiguity and Hierarchy,” in Luc Bodiguel and Michael Cardwell, (editors), *The Regulation of Genetically Modified Organisms: Comparative Approaches*, (Oxford: Oxford University Press, 2010).

Lee, R. G., “From the Individual to the Environmental: Tort Law in Turbulence,” in John Lowry and Rod Edmunds, (editors), *Environmental Protection and the Common Law*, (Oxford: Hart Publishing, 2000).

Lee, R. G., “GM Resistant Europe and the WTO Panel Dispute on Biotech Products,” *Ethics, Law and Society: Volume 1*, (Aldershot: Ashgate Publishing, 2005).

Lemon, S. M., et al., *Globalization, Biosecurity, and the Future of the Life Sciences*, (Washington D.C: National Academies Press, 2006).

Lightbourne, M., *Food Security, Biological Diversity and Intellectual Property Rights*, (Surrey, England & Burlington, USA: Ashgate, Publishing, 2009).

Lowry, J. and Edmunds, R., (editors), *Environmental Protection and the Common Law*, (Oxford: Hart Publishing, 2000).

Marchant, G. E., “The Growing Gap Between Emerging Technologies and the Law,” in Gary E. Marchant, Braden R. Allenby, and Joseph R. Herkert, (editors), *The Growing Gap Between Emerging Technologies and Legal-Ethical Oversight: The pacing Problem*, (Heidelberg, London & New York: Springer Publishing, 2011).

Marchant, G. E., Allenby, B. R. and Herkert, J. R., (editors), *The Growing Gap Between Emerging Technologies and Legal-Ethical Oversight: The pacing Problem*, (Heidelberg, London & New York: Springer Publishing, 2011).

Maury, J. P., Newton: *Understanding the Cosmos*, New Horizon Series, (London: Thames & Hudson, 1992).

McHughen, A., Smyth, S. J., "Regulation of Genetically Modified Crops in USA and Canada: American Overview," in Chris A. Wozniak and Alan McHughen, (editors), *Regulation of Agricultural Biotechnology: The United States and Canada*, (Heidelberg, New York & London: Springer, 2013), at 4146.

Mellon M. And Rissler J., *Gone to Seed: Transgenic Contaminants in the Traditional Seed Supply*, USC Publications, Cambridge, MA, 2004).

Nottingham, S., *Eat Your Genes, How Genetically Modified Food Is Entering Our Diet*, 2<sup>nd</sup> updated edition, (London, Zed Books Ltd., 2003).

Oliphant, K., "Damage Caused by GMOs under English Law," in Bernhard A. Koch, (editor), *Damage Caused by Genetically Modified Organisms: Comparative Survey of Redress Options for Harm to Persons, Property or the Environment* (Walter de Gruyter: Berlin/New York: 2010).

Oliphant, K., "Economic Loss Caused by GMOs in the United Kingdom: England & Wales," in Bernhard A. Koch, (editor), *Economic Loss Caused by Genetically Modified Organisms: Liability and Redress for the Adventitious Presence of GMOs in Non-GM Crops* (Springer: Vienna/New York, 2008).

Olsen, J. K. B., Pedersen, S. A. and Hendricks, V. F., (editors), *A Companion to the Philosophy of Technology*, (Chichester, England: Blackwell Publishing, 2009).

Paarlberg, R., *Starved for Science: How Biotechnology is Being Kept Out of Africa*, (Harvard: Harvard University Press, 2009).

Papineau, D., (General Editor), *Philosophy*, (London: Duncan Bird Publishers, 2009)  
Pechlaner, G., *Corporate Crops: Biotechnology, Agriculture, and the Struggle for Control*, (Austin: Texas University Press, 2012).

Perdikis, N. and Read, R., (eds), *The WTO and the regulation of international trade : recent trade disputes between the European Union and the United States*, (Edward Elgar Publishing Limited, 2005).

Peukert, A., "Territoriality and Extraterritoriality in Intellectual Property Law," in Gunther Handl & Joachim Zekoll, (editors), *Beyond Territoriality: Transnational Legal Authority in An Age of Globalization*, (Leiden/Boston: Brill Academic Publishing, 2012).

Pielke Jr. R. A., *The Honest Broker: Making Sense of Science in Policy and Politics*, (Cambridge: Cambridge University Press, 2007).

Pinstrup-Andersen, P. and Schiøler, E., *Seeds of Contention: World Hunger and the Global Controversy over GM Crops*, (Baltimore & London: John Hopkins University Press, 2001).

Poole, J., *Textbook on Contract Law*, 9<sup>th</sup> edition, (Oxford: Oxford University Press, 2008).

Prescott, C., *Oxford Science Study Dictionary*, (Oxford: Oxford University Press, 1999).

Radder, H., "Science and Technology: Positivism and Critique," in Jan Kyrre Berg Olsen, Stig Andur Pedersen, and Vincent F. Hendricks, (editors), *A Companion to the Philosophy of Technology*, (Chichester, England: Blackwell Publishing, 2009).

Rees, A., *Genetically Modified Food: A Short Guide for the Confused*, (London & Ann Arbor, Michigan: Pluto Press, 2006).

Reiss, M. J. and Straughan, R., *Improving Nature? The Science and Ethics of Genetic Engineering*, (Cambridge: Cambridge University Press, Canto Edition, 2001).

Robinson, S., Pool, R. and Giffin, R., *Emerging Safety Measures: Workshop Summary, Forum on Drug Discovery, Development, and Translation*, (Washington DC: National Academy of Sciences, 2008).

Rosso Grossman, M., "European Community Legislation for Traceability and Labeling of Genetically Modified Food," in Paul Weirich, (editor), *Labeling Genetically Modified Food: The Philosophical and Legal Debate*, (Oxford: Oxford University Press, 2007).

Rosso Grossman, M., "Genetically Modified Crops and Food in the United States: The Federal Regulatory Framework, State Measures, and Liability in Tort," in Luc Bodiguel and Michael Cardwell, (editors), *The Regulation of Genetically Modified Organisms: Comparative Approaches*, (Oxford: Oxford University Press, 2010).

Shiva, V., *Protect or Plunder? Understanding Intellectual Property Rights*, (London & New York: Zed Books Ltd, 2001).

Shiva, V., *The Violence of the Green Revolution*, (London & New York: Zed Books Limited, 2002).

Smith, J. M., *Genetic Roulette: The Documented Health Risks of Genetically Engineered Foods*, (Fairfield, IA: Yes! Books, 2007).

Smith, J. M., *Seeds of Deception: Exposing Corporate and Government Lies about the Safety of Genetically Engineered Food*, (Foxhole, Dartington, UK, 2004).

Steel, J., *Risks and Legal Theory*, (Oxford: Hart Publishing, 2004).

Stewart, P. A., McLean, W. P. and Duffner, L. P., "Agricultural Bioterrorism: Dimensions of Fear and Public Perception," in James J.F. Forest, (editor), *Homeland Security: Protecting America's Targets*, (volume 2, (Westport, CT., Greenwood Publishing Group, 2006).

Taylor, I. E. P., (editor), *Genetically Engineered Crops: Interim Policies, Uncertain Legislation*, (New York: The Haworth Press, Inc, 2007).

Sylvester, M., "Sui Generis", *Dictionary of Foreign Terms* (2 ed.), (New York: Thomas Y. Crowell Company, 1975), at 328.

Thomas W. E., and Ellar, D. J., "*Bacillus Thuringiensis Var Israelensis* Crystal Delta-Endotoxin: Effects on Insect and Mammalian Cells in Vitro and in Vivo," *The Journal of Cell Science*, vol. 60 (1983).



Thorson, W., "International Trade in Genetically Altered Agricultural Products: Impact of the Biosafety Protocol" in *Agriculture and International Trade Law, Policy and the WTO*, (Oxford: U.K, Cambridge: Massachusetts: CABI Publishing, 2003).

Tollison, R. D. and Wagner, R. E., *Smoking and the State: Social Costs, Rent Seeking, and Public Policy*, (Massachusetts and Toronto: Lexington Books, 1998).

Traavik, T. and Ching, L. L., (eds.) *Biosafety First: Holistic Approaches to risk and Uncertainty in Genetic Engineering and Genetically Modified Organisms*, (Tromso: Tapir Academic Press, 2007).

Van den Bossche, P. and Zdouc, W., *The Law and Policy of the World Trade Organization: Text, Cases and Materials*, (Cambridge: Cambridge University Press, 2013).

Van Lynden, C. B., (editor) *Forum Shopping*, (Informa Law, 1998).

Wei, G., *An Introduction to Genetic Engineering, Life Sciences and the Law*, (Singapore: Singapore University Press, 2002).

Weirich, P., (editor), *Labeling Genetically Modified Food: The Philosophical and Legal Debate*, (Oxford: Oxford University Press, 2007).

Weissenbacher, M., 'Damage Caused by GMOs under Austrian Law', in Bernhard A. Koch (ed.) *Damage Caused by Genetically Modified Organisms: Comparative Survey of Redress Options for Harm to Persons, Property or the Environment*, (Berlin/New York, Walter de Gruyter GmbH: 2010).

Winston, M. L., *Travels in the Genetically Modified Zone*, (Cambridge, Massachusetts: Harvard University Press, 2002).

## **JOURNAL ARTICLES**

Altieri, M. A., "Genetically Engineered Crops: Separating the Myths from Reality", *Bulletin of Science, Technology & Society*, Volume 21, No. 2 (April 2001).

Altieri, M. A., "The Myth of Coexistence: Why Transgenic Crops Are Not Compatible with Agro-ecologically Based Systems of Protection," *Bulletin of Science, Technology & Society*, Volume 25, Number 4, (August 2005).

American Seed Trade Association, What Is Adventitious Presence? Cited in Serina Vandegrift and Christine Gould, "Issues Surrounding the International Regulation of Adventitious Presence and Biotechnology," *Jurimetrics: The Journal of Law, Science & Technology*, vol. 44, (2003).

Angulo, E., and Gilna, B., "When Biotech Crosses Borders," *Nature Biotechnology*, Volume 26, Number 3, (March 2008), at 277-282.

Aris, A. and Leblanc, S., "Maternal and foetal exposure to pesticides associated to genetically modified foods in Eastern Townships of Quebec," *Reproductive Toxicology*, Volume 31, Issue 4, (May 2011).

Bago, B., "Putative sites for nutrient uptake in mycorrhizal fungi," *Plant and Soil*, Volume 226, Number 2, (November, 2000).

Barnard, C. and Odudu, O., (editors), *Cambridge Year Book of European Legal Studies*, Volume 13, (2010-2011).

[Bellon](#), M. R. and [Berthaud](#), J., "Traditional Mexican Agricultural Systems and the Potential Impacts of Transgenic Varieties on Maize Diversity," *Agriculture and Human Values*, Volume 23, Number 1, (2006).

Bellon, M. R. and Berthaud, J., "Transgenic Maize and the Evolution of Landrace Diversity in Mexico: The Importance of Farmers' Behavior," *Plant Physiology*, Volume 134, (2004).

Bennett Moses, L., "Recurring Dilemmas: The Law's Race to Keep up with Technological Change," *University of Illinois Journal of Law, Technology, & Policy*, Volume 2007, Issue 2, (Fall 2007).

Blancke, S., et al., "Fatal Attraction: The Intuitive Appeal of GMO Opposition," *Trends in Plant Science*, (April 2015).

Bolan, N. S., "A Critical review on the role of mycorrhizal fungi in the uptake of phosphorous by plants," *Plant and Soil*, Volume 134, Number 2, (July, 1991).

Bratspies, R., "The Illusion of Care: Regulation, Uncertainty, and Genetically Modified Food Crops," *New York University Environmental Law Review*, (2002).

Bratspies, R. M., "Myths of Voluntary Compliance: Lessons from the StarLink Corn Fiasco," *William & Mary Environmental Law & Policy Review*, vol. 27 (2003).

Brundrett, M., "Co-evolution of roots and mycorrhizas of land plants," *New Phytologist*, Volume 154, Issue 2, (May 2002).

Buchanan, R. B., "Genetic Engineering and the Allergy Issue," *Plant Physiology*, Volume 126, Number 1, (May 2001).

Bullock, D. G., "Crop Rotation," *Critical Review in Plant Sciences*, vol. 11, Issue 4, (1992).

Carson, L. and Lee, R., "Consumer Sovereignty and the Regulatory History of the European Market for Genetically Modified Foods," *Environmental Law Review*, Vol. 7, (2005).

Chandler, S. and Dunwell, J. M., "Gene Flow, Risk Assessment and the Environmental Release of Transgenic Plants," *Critical Review in Plant Sciences*, vol. 27, Issue 1, (2008).

Cheeke, T. E., Rosentiel, T. N. and Cruzan, M. B., "Evidence of reduced arbuscular mycorrhizal fungal colonization in multiple lines of Bt maize," *American Journal of Botany*, Volume 99, Number 4, (April 2012).

Cunningham, R., "The ABC of GMOs, SPS & The WTO: An analysis of the Application of the Agreement on Sanitary and Phytosanitary Measures within the context of

biotechnology and International Trade,” *Australian Southern Cross University Law Review*, Volume 9, (2005).

d'Espagnat, B., “Is Science Cumulative? A Physicist Viewpoint,” *Boston Studies in the Philosophy of History of Science*, Volume 255, Number 5, (2008).

Duke, S. O. and Powles, S. B., “Glyphosate: a once-in-a-century herbicide: mini review,” *Pest Management Science*, Volume 68, Issue 4, (April 2008).

Enders, A. B., “GMO”: Genetically Modified Organism or Gigantic Monetary Obligation? The Liability Schemes for GMO Damage in the United States and the European Union”, *Loyola of Los Angeles International and Comparative Law Review*, Volume 22 (2000).

Ernstmeyer, J., "Does Strict Territoriality Toll the End of Software Patents?" *Boston University Law Review*, Volume 89, (2009).

Fang, F. C., Steen, R. G. and Casadevall, A., “Misconduct accounts for the majority of retracted scientific publications,” *The Proceedings of the National Academy of Sciences*, (1 October, 2012).

Garforth, K. and Ainslie, P., “When Worlds Collide: Biotechnology meets Organic Farming in Hoffman v Monsanto,” *Journal of Environmental Law*, Volume 18, No. 3, (2006).

Geghard, F., and Smalla, K., “Monitoring Field Releases of Genetically Modified Sugar Beets for persistence of Transgenic Plant DNA and Horizontal Gene Transfer,” *FEMS Microbiology Ecology*, Volume 28, Issue 3, (1999).

Giddens, A., “Risk and Responsibility,” *The Modern Law Review*, Volume 62, No. 1, (January 1999).

Gleick, P. H., et al., “Climate Change and the Integrity of Science,” *Letters, Science*, Volume 328, (7 May 2010).

Godfrey, J., “Do genetically modified foods affect human health?” *The Lancet*, Volume 355, Number 9201, (January 29, 2000).

Hansen, R. C., “Developing Internationally Uniform Liability Principles for Harms from Genetically Modified Organisms,” *Bepress Legal Series*, Paper 105, (2003).

Herring, R. J., “Epistemic Brokerage in the Bio-property Narrative: Contributions to Explaining Opposition to Transgenic Technologies in Agriculture,” *New Biotechnology*, Volume 27, Number 5 (November 2010).

Herring, R. J., “Stealth Seeds: Bioproperty, Biosafety, Biopolitics,” *Journal of Development Studies*, Volume. 43, Issue 1, (2007).

Holt-Giménez, E. and Altieri, M. A., “Agroecology, Food Sovereignty, and the New Green Revolution,” *Agroecology and Sustainable Food Systems*, Volume 37, Issue 1, (2013).

Hunt, J., "Ploughing Their Own Furrow: Subnational Regions and the Regulation of GM Crop Cultivation," in Catherine Barnard and Okeoghene Odudu, (editors), *Cambridge Year Book of European Legal Studies*, Volume 13, (2010-2011).

Ioannidis, J. P. A., "Why Most Published Research Findings Are False," *PLoS Medicine*, Volume 2, Issue 8, (August 2005).

Irwin, A., Rothstein, H., Yearley, S. and McCarthy, E., "Regulatory Science: Towards a Sociological Framework," *Futures: The Journal of Policy, Planning and Futures Studies*, Volume 29, No. 1 (1997).

Keating, G. C., "The Heroic Enterprise of the Asbestos Cases," *University of Southern California Law and Economic Working Paper Series*, Paper 101, (2009).

Keeley, J. and Scoones, I., "Contexts for Regulation: GMOs in Zimbabwe," *Institute for Development Studies (IDS) Working Paper Series No. 190*, (June 2003).

Kershen, L. D., "Trade and Commerce in Improved Crops and Food: An Essay on Food Security," *New Biotechnology*, Volume 27, Number 5, (5 November 2010).

Kok, E. J. and Kuiper, H. A., "Comparative Safety Assessment for Biotech Crops," *Trends in Biotechnology*, Volume 21, Number 10, (October 2003).

Kok, E. J., Kijer, J., Kleter G. A. and Kuiper, H. A., "Comparative Safety Assessment of Plant-Derived Foods," *Regulatory Toxicology and Pharmacology*, Volume 50, (2008).

Kolehmainen, S., "Precaution Before Profits: An Overview of Issues in Genetically Engineered Food and Crops," *Vanderbilt Environmental Law Journal*, vol. 20, (2001).

Kota, M., Daniel, H., Varma, S., Garczynski, S. F., Gould, F. and Major, W. J., "Over expression of the *Bacillus thuringiensis* (Bt) Cry2Aa2 protein in Chloroplasts confers resistance to plants against susceptible and Bt-resistant insects," *Proceedings of National Academy of Science*, Volume 96, (March 1999).

König, A., et al, "Assessment of the Safety of Foods Derived from Genetically Modified (GM) Crops," *Food and Chemical Toxicology*, Volume 42, (2004).

Kozjak, P., Sustar-Volzlic, J., and Meglic, V. "Adventitious Presence of GMOs in Maize in the View of Coexistence," *Acta Agriculturae Slovenica*, Volume 97, (3 September 2011).

Krimsky, S. and Murphy, N.K., "Biotechnology at the Dinner Table: FDA's Oversight of Transgenic Food," *The Annals of the American Academy of Political and Social Sciences*, Volume 584, Issue 1, (November 2002).

Krishna, V., Quam, M. and Zilberman, D., "Transgenic Crops, Production Risk and Agrobiodiversity," *European Review of Agricultural Economics*, (4 June 2015).

Kuparinen, A., Schurr, F., Tackenberg, O. and O'Hara, R. B., "Air-Mediated Pollen Flow from Genetically Modified to Conventional Crops," *Ecological Applications*, Vol. 17, No. 2 (2007).

Lee, D. and Natesan, E., "Evaluating genetic containment strategies for transgenic plants," *TRENDS in Biotechnology*, Volume 24, Number 3, (March 2006).

Lee, M. and Burrell, R., "Liability for the Escaped GM Seeds: Pursuing the 'Victim'?" *The Modern Law Review*, Volume 65, Number 4, (July 2002).

Lee, R. G., "Humming a different tune? Commercial cultivation of GM crops in Europe," (unpublished article: on file with author, 2015).

Lee, R. G., "Look at Mother Nature on the Run in the 21st Century: Responsibility, Research and Innovation," *Transnational Environmental Law*, vol. 1, Issue 1, (April 2012).

Lehrer, S. B., [Horner](#), W. E., [Reese](#), G. and [Taylor](#), S., "Why are some proteins allergenic? Implications for Biotechnology," *Critical Reviews in Food Science and Nutrition*, Volume 36, Issue 6, (1996).

Levidow, L., Murphy, J. and Carr, S., "Recasting "Substantial Equivalence": Transatlantic Governance of GM Food," *Science, Technology & Human Values*, Volume 32, Number 1, (January 2007).

Losey, J. E., Rayor, L. S., and Carter, M. E., "Transgenic pollen harms monarch larvae," *Nature*, Volume 399, (20 May 1999).

Malarkey, T., "Human Health Concerns with GM Crops," *Mutation Research*, Volume 544, (2003).

Mallory-Smith, C. and Zapiola, M., "Gene flow from glyphosate-resistant crops," *Pest Management Science*, vol. 64, (2008).

Markowitz, G. and Rosner, D., "Corporate Responsibility for Toxins," *The Annals of the American Academy of Political and Social Science*, Volume 284, Issue 1, (2002).

Marshall, G., "Herbicide-Tolerant Crops: Real Farmer Opportunity or Potential Environmental Problem?" *Pesticide Science*, vol. 52, (1998).

Mentzer, J. T., et al., "Defining Supply Chain Management," *Journal of Business Logistics*, Volume 22, Number 2, (2001).

Meretoja, T., Carlberg, G., Gripenberg, U., Linnainmaa, K. and Sorsa, M., "Mutagenicity of *Bacillus thuringiensis* exotoxin, I Mammalian tests," *Hereditas*, vol. 85 (March, 1977).

Moar, W., Roush, R., Sheldon, A., Ferre, J., MacIntosh, S., Leonard, B. R. and Abel, C., "Field-evolved Resistance to Bt Toxins," *Nature Biotechnology*, Volume 26, (2008).

Moonesinghe, R., Khoury, M. J. and A.Cecile J.W. Janssens, "Most Published Research Findings Are False: But a Little Replication Goes a Long Way," *PLoS Medicine*, Volume 4, Issue 2, (February 2007).

Nijar, G. S., "The Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety: An Analysis and Implementation Challenges",

*International Environmental Agreements: Policy, Law and Economics*, Volume 13, Issue 3, (September 2013).

Opara, L. U., "Traceability in agriculture and food supply chain: a review of basic concepts, technological implications, and future prospects," *Journal of Food, Agriculture, and Environment*, Volume 1, Issue 1, (2003).

Oriola, T. A., "The Limits of Regulatory Science in Transnational Governance of Transgenic Plant Agriculture and Food Systems," *North Carolina Journal of International Law and Commercial Regulation*, Volume 39, Number 3, (Spring 2014).

Oriola, T.A., "Against the Plague: Exemption of Pharmaceutical Patent Rights as a Biosecurity Strategy," *University of Illinois Journal of Law, Technology & Policy*, Volume 2007, Issue 2, (Fall 2007).

Oriola, T.A., "Consumer Dilemmas: The Right to Know, Safety, Ethics, and Policy of Genetically Modified Food," *Singapore Journal of Legal Studies*, (December 2002).

Oriola, T. A., "Ethical and Legal Analyses of Laws Prohibiting Tobacco Smoking in Enclosed Public Spaces," *The Journal of Law, Medicine, & Ethics*, Volume 37, Number 4, (Winter 2009).

Oriola, T. A., "Regulating Unsolicited Commercial Electronic Mails in the United States and the European Union: Challenges and Prospects," *Tulane Journal of Technology, & Intellectual Property*, Volume 3 (2005).

Oriola, T. A., "Strong Medicine: Patents, Market, and Policy Challenges for Managing Neglected Diseases and Affordable Prescription Drug," *Canadian Journal of Law and Technology*, Volume 7, Number 1, (April 2009).

**Oriola, T. A., "Electronic Database Protection and the Limits of Copyright: What Options for Developing Countries?"** *The Journal of World Intellectual Property*, Volume 7, (March 2004).

Perez, O., "Anomalies at the Precautionary Kingdom: Reflections on the GMO Panel's Decision," *International Law Forum, The Hebrew University of Jerusalem, Research Paper No. 13-06*, (October 2006).

Powles, S. B., Lorraine-Colwill, D. F., Dellow J. J., and Preston, C., "Evolved Resistance to Glyphosate in Rigid Ryegrass (*Lolium rigidum*) in Australia," *Weed Science*, Volume 46, Number 5, (September-October, 1998).

Raven, P. H., "Transgenes in Mexican Maize: Desirability or Inevitability," *Proceedings of the National Academy of Sciences*, Volume 102, No. 37, (September 13, 2005).

Redick, T. P., "Stewardship for Biotech Crops: Strategies for Improving Confidence," *Jurimetrics, The Journal of Law, Science, and Technology*, Volume 44, No. 1 (Fall 2003).

Rieger, M. A., Lamond, M., Preston, C., Powles, S. B. and Roush, R. T., "Pollen-Mediated Movement of Herbicide Resistance between Commercial Canola Fields," *Science*, Volume 296, (28 June 2002).

Rodgers, C. P., "Coexistence or Conflict? A European Perspective on GMOs and the Problem of Liability," *Bulletin of Science, Technology, & Society*, Volume 27, No. 3, (June 2007).

Rodgers, C., "DEFRA's Coexistence Proposals for GM Crops: A Recipe for Confrontation?" *Environmental Law Review*, Volume 10 (2008).

Ronald, P., "Plant Genetics, Sustainable Agriculture and Global Food Security," *Genetics*, Volume 188, (May 2011).

Rosi-Marshall, E. J., Tank, J. L., Royer, T. V., Whiles, M. R., Evans-White, M., Chambers, C., Griffiths, N. A., Pokelsek J., and Stephen, M. L., "Toxins in Transgenic Crop By-products May Affect Headwater Stream Ecosystems," *Proceedings of the National Academy of Sciences of the United States of America*, Volume 104, Number 41, (October 9, 2007).

Ruther, B., "Risk management of unintended GMO contamination in the supply chain of maize and processed maize products," Paper prepared for presentation at the 113<sup>th</sup> EAAE Seminar "A resilient European food industry and food chain in a challenging world", Chania, Crete, Greece, (3-6 September, 2009).

Sagar, A., Daemmrich, A. and Ashiya, M., "The Tragedy of the Commoners: Biotechnology and Its Publics," *Nature Biotechnology*, Volume 18, (1 January 2000).

Samples J. R. and Buettner, H., "Ocular infection caused by a biological insecticide," *The Journal of Infectious Diseases*, vol. 148, No. 3, (1983).

Schiermeiser, Q., "German Universities Bow to Public Pressure Over GM Crops," *Nature*, Volume 453, (14 May 2008).

Schroeder, C. H., "Corrective Justice: Liability for Risks and Tort Law," *University of California Law Review*, Volume 38, (1990).

Schubert, D., "A different Perspective on GM Food", *Nature Biotechnology*, Volume 20, (2002).

Schubert, R., Renz, D., Schmitz, B. and Doerfler, W., "Foreign (M13) DNA ingested in mice reaches peripheral leukocytes, spleen, and liver via the intestinal wall mucosa and can be covalently linked to mouse DNA," *Proceedings of the National Academy of Sciences of the United States of America*, Volume 94, Number 3, (February 4, 1997).

Scriber, J. M., "Bt or not Bt: Is that the question?" *Proceedings of the National Academy of Sciences of the United States of America*, Volume 98, Number 22, (23 October, 2001).  
Séralini, G. E., Clair, E., Mesnage, R., Gress, S., Defarge, N., Malatesta, M., Hennequin, D. and Spiroux de Vendômois, J., "Long term toxicity of a Roundup herbicide and a

Roundup-tolerant genetically modified maize,” *Food and Chemical Toxicology*, Volume 50, Issue 11, (November 2012).

Shivanand, P. and Noopur, S., “Recombinant DNA Technology: Applications in the Field of Biotechnology and Crime Sciences,” *International Journal of Pharmaceutical Sciences Review and Research*, Volume 1, Issue 1, (March-April 2010).

Smyth S. J. and Kershen, D. L., “Agricultural Biotechnology: Legal Liability Regimes from Comparative and International Perspectives,” *Global Jurist Advances*, Vol. 6, Issue 2 (2006).

Stallworthy, M., “Environmental Liability and the Impact of Statutory Authority,” *Journal of Environmental Law*, Volume 15, No. 1, (2003).

Stokstad, E., “A Little Pollen Goes a Long Way,” *Science*, Vol. 296, (28 June, 2002).

Strauss, D. M., “The Application of TRIPS to GMOs: International Intellectual Property Rights and Biotechnology,” *Stanford Journal of International Law*, Volume 45, (2009).

Sullia, S. S., S. B. & Swamy, S., G. “Peer Review Contestations in the Era of Transgenic Crops”, *Current Science*, Volume 95, Number 2, (25 July 2008).

Subramanian, S., "EU Obligation to the TRIPS Agreement: EU Microsoft Decision," *The European Journal of International Law*, Volume 21 Number 4, (2011).

Swadener, C., “Bacillus Thuringiensis (BT),” *Journal of Pesticide Reform*, Volume 14, No. 3 (Fall 1994).

Swaminathan, M.S., "Achieving Food Security in Times of Crisis," *New Biotechnology*, Volume 27, Number 5, (5 November 2010).

Tabashnik, B. E., Gasmann, A. G., Crowder, D. W. and Carriere, Y., "Insect Resistance to Bt Crops: Evidence Versus Theory," *Nature Biotechnology*, Volume 26, (7 February, 2008).

Todt, O., “Regulating Agricultural Biotechnology Under Uncertainty,” *Safety Science*, Volume 42, (2004).

Tollefson, J., “Drought-tolerant maize gets US debut: Seed companies race to tap multibillion dollar market,” *Nature* (11 January 2011).

Trewavas, A., “Toxins and genetically modified food,” *The Lancet*, Volume 355, Number 9202, (March 11, 2000).

Tsioumani, E., "Genetically Modified Organisms in the EU: Public Attitudes and Regulatory Developments," *RECIEL*, Volume 13, Number 3, (2004).

Uchtmann, D. L., “STARLINK: A Case Study of Agricultural Biotechnology Regulation”, *Drake Journal of Agricultural Law*, Volume 7, (2002).



Vandegrift, S. and Gould, C., "Issues Surrounding the International Regulation of Adventitious Presence and Biotechnology," *Jurimetrics: The Journal of Law, Science & Technology*, vol. 44, (2003).

Waltz, E., "GM Crops: Battlefield: Papers suggesting that biotech crops might harm the environment attract a hail of abuse from other scientists," *Nature*, Volume 461, Number 7260, (3 September 2009).

Wilmot, I., Schnieke, A.E., McWhir, J., Kind, A.J., and Campbell, K.H., "Viable offspring derived from fetal and adult mammalian cells", *Nature*, Volume 385, Issue 6619, (1997).

Winickoff, D., Jasanoff, S., Busch, L., Grove-White, R. and Wynne, B., "Adjudicating the GM Food Wars: Science, Risk, and Democracy in World Trade Law", *The Yale Journal of International Law*, vol. 30, (2005).

Ziff, B., "Travel with my plant: Monsanto v. Schmeiser revisited," *University of Ottawa Law & Technology Journal*, Volume 2, Number 2, (2005).

## REPORTS.

Barker, D., (editor), *Seed Giants vs. U.S. Farmers: A Report by the Center for Food Safety & Save Our Seeds*, (2013).

BRS, AHIS, USDA, *User's Guide: Notification*, (5 February 2008).  
Centre for Disease Control and Prevention, *Investigation of Human Health Effects Associated with Potential Exposure to Genetically Modified Corn*. (June 11, 2001).

Commission of the European Communities, Communication from the Commission to the Council and the European Parliament, *Report on the implementation of national measures on the coexistence of genetically modified crops with conventional and organic farming*, (Brussels 2006).

Communication from the Commission on the Precautionary Principle (COM (2001).  
*Consultation on Proposals for Managing the Co-existence of GM, Conventional and Organic Crops in Wales*, (2006).

Czarnak-Klos, M., and Rodriguez-Cerezo, E., "European Coexistence Bureau: Best Practice Documents for Coexistence of Genetically Modified Crops with Conventional and Organic Crop Farming," *European Commission /JTC Scientific and Technical Reports*, (2010).

EFSA Panel on Genetically Modified Organisms, European Food Safety Authority: *Scientific Opinion: Guidance on the Environmental Risk Assessment of Genetically Modified Plants*, *EFSA Journal*, (2010).

Environmental Protection Agency, *White Paper on the Possible Presence of Cry9C Protein in Processed Foods Fractions produced through the Wet Milling Corn*, (Environmental Protection Agency and Office of Pesticide Programs, 2001).

EPA, *White Paper on the Possible Presence of Cry9C Protein in Processed Human Foods made from Food Fractions produced through the Wet Milling of Corn*, Environmental Protection Agency, and Office of Pesticide Programs, (2001).

European Food Safety Authority, “EFSA publishes initial review on GM maize and herbicide study,” Press Release, (4 October 2012).

European Food Safety Authority, Scientific Opinion on application (EFSA-GMO-DE-2011-95) for placing on the market of genetically modified maize 5307 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Syngenta Crop Protection AG, *European Food Safety Authority Journal*, Volume 13, No. 5 (2015).

European Union Research Directorate, *GMOs: Are There Any Risks?* (Brussels: EU Commission Press Briefing, 9 October, 2001).

Federal Insecticide, Fungicide, and Rodenticide Act/ Scientific Advisory Panel Meeting Report No. 201-09 (July 2001).

Food and Agriculture Organization/World Health Organization (FAO/WHO), *Evaluation of Allergenicity of Genetically Modified Foods*, Report of a Joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology, (Rome, Italy, 22-25 January, 2001).  
Food and Agriculture Organization/World Health Organization (FAO/WHO), *Report of a Joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology*, (Geneva: September 2001).

Food and Agriculture Organization/World Health Organization (FAO/WHO), Report of a Joint FAO/WHO Expert Consultation, *Strategies for Assessing the Safety of Foods Produced by Biotechnology*, (Rome: FAO/WHO, 1991).

Food and Drug Administration (FDA), Centre for Food Safety and Applied Nutrition, “Guidance on Consultation Procedures: Foods Derived from New Plant Varieties, (1997).  
Food and Drug Administration, *Evaluation of Consumer Complaints Linked to Foods Allegedly Containing StarLink Corn*. (June 13, 2001).

Food and Drug Administration (FDA), Joint CSAN/CVM Advisory Committee Meeting, “Procedures for industry-FDA interaction prior to commercial distribution of foods derived from new plant varieties developed using recombinant DNA techniques,” (1994).  
Government Accountability Office, (GAO) *Genetically Engineered Crops: Agencies Are Proposing Changes to Improve Oversight, but Could Take Additional Steps to Enhance Coordination and Monitoring*, (GAO-09-60 November 2008).

Guidance Document on European Union Organic Standards, (January 2010), at <https://www.gov.uk/government/organisations/department-for-environment-food-rural-affairs>.

House of Commons Science and Technology Committee, *Advance Genetic Techniques for Crop Improvement: Regulation, Risk and Precaution*, (Fifth Report of Session 2014-15).

International Federation of Organic Agricultural Movements (IFOAM), Position on Genetic Engineering and Genetically Modified Organisms, (adopted by IFOAM World Board, Canada, May, 2002).

International Federation of Organic Agriculture Movements - EU Regional Group, "Co-existence between GM and Non-GM Crops: Necessary Anti-contamination and Liability Measures," (Position Paper, October 2003).

Ministry of Agriculture, *Fisheries and Food, Advisory Committee on Novel Foods and Processes, Annual Report*, (1998).

National Institute of Agricultural Botany, Report on the separation distances required to ensure GM content of harvested material from neighbouring fields is below specified limits in non-seeds crops of oil rape, maize and sugar beet, (Cambridge: January 2006).

Organization for Economic Cooperation and Development, *Safety Evaluation of Foods Derived from Biotechnology: Concepts and Principles*, (Paris: OECD, 1993).

OTA, *Commercaill Biotechnology: An International Analysis*, (Washington, D. C.: U.S. Congress, Office of Technology Assessment, OTA-BA-218, January 1984).

*Report from The Commission to the Council and the European Parliament on the coexistence of genetically modified crops with conventional and organic farming*, (Brussels, 2009).

*Summary of Responses to the Welsh Assembly Government Consultation on Proposals for Managing the Coexistence of GM, Conventional and Organic Crops in Wales*, (December 2009).

Taylor, M. R. and Tick, J. S., *The StarLink Case: Issues for the Future*, A report commissioned by the Pew Initiative on Food and Biotechnology, (October 2001).

Technical Services Division 2, *Summary of Responses to the Welsh Assembly Government Consultation on Proposals for Managing the Coexistence of GM, Conventional and Organic Crops in Wales*, (December 2009).

The GM Science Review Panel, *GM Science Review (Second Report): An Open Review of the Science Relevant to GM Crops and Food based on Interests and concerns of the Public*, (January 2004).

The Royal Society, *Genetically Modified Plants for Food Use and Human Health*, (2002).

United States Department of Agriculture, "USDA Coexistence Facts Sheets: Crop Production Methods," (February 2015).

United states Department of Agriculture, "USDA Coexistence Facts Sheets: Best Practices," (February 2015).

United States Department of Agriculture, "USDA Coexistence Facts Sheets: Conventional Farming," (February 2015).

United States Department of Agriculture, "USDA Coexistence Fact Sheets: Organic Farming," (February 2015).

United States Department of Agriculture, "Field testing of Plants engineered to produce pharmaceutical and industrial compounds," *Federal Register*, Volume 68, Number 46, (Monday, 10 March, 2003/Proposed Rule)

United States Department of Agriculture, "USDA Coexistence Facts Sheets: Corn," (February 2015).

USDA and Biotechnology Services, "Minimum Separation Distances to Be Used for Confined Field Tests of Certain Genetically Engineered Plants," available at [http://www.aphis.usda.gov/biotechnology/downloads/sep\\_dist\\_table\\_0813.pdf](http://www.aphis.usda.gov/biotechnology/downloads/sep_dist_table_0813.pdf).

World Health Organization/Food and Agriculture (WHO/FAO), *Biotechnology and Food Safety: Report of a Joint FAO/WHO Consultation*, (Rome: Italy, September 30- October 4, 1996).

World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures.

#### **ONLINE RESOURCES.**

ABC News, "organic farmer to sue over GM contamination," *ABC News*, (Thursday, January 13, 2011), at <http://www.abc.net.au/news/2011-01-13/organic-farmer-to-sue-over-gm-contamination/1904328>

Associated Press, "Japan finds more Bt in shipments," (Thursday, 18 January, 2001), at <http://archive.shomenews.com/2001/jan/20010118busi012.asp>

BBC News, "Britain's wheat 'down by third after extreme weather'", at <http://www.bbc.co.uk/news/uk-22866982>

Bowcott, O., "Asbestos court ruling leaves insurers facing bill of up to £5bn," *The Guardian*, (Wednesday 28 March, 2012).

Brasher, P., "U.S. Tightens rules for growing Parma crops," *Des Moines Register*, (7 March, 2002).

Brown, P., "Insurers refuse to cover GM farmers: Leading companies liken risk to thalidomide and terrorism." *The Guardian*, (8 October, 2003).

Cookson, C., "Food Battle Looms on Hertfordshire Fields," *Financial Times*, (25 May, 2012).

Edwards, A., "America facing wheat export crisis as Europe and Japan lead the way in rejecting genetically modified crops," *Mail Online*, (31 May 2013).

Friends of the Earth, "Serious Doubts about GM Food Safety," Friends of the Earth Archived Press Release (18 September 2000).

Genetic Engineering Policy Alliance, "California's First Law Protecting Farmers From Threats of Genetic Engineering Signed by Governor," available at [http://www.gepolicyalliance.org/action\\_alert\\_support\\_ab541.htm](http://www.gepolicyalliance.org/action_alert_support_ab541.htm)

Griffin, K., "UK Supreme Court Ruling in Landmark Asbestos Case," *Mesothelioma Cancer Alliance*, (30 March, 2012).

Hord, B., "The Road Back: Prodigene and Other Biotech Companies Are Moving Ahead in an Environment of Increasing Fear of Crop Contamination," *Omaha World Herald*, (19 January 2003).

Institute for Responsible Technology, *GMOs in Food*, available at <http://www.responsible-technology.org/GMFree/GMODangers/GMOsinFood/index.cfm>

James, C., '*Global Status of Commercialized Biotech/GM Crops*'. (New York: ISAAA Brief No: 49), at <http://www.isaaa.org/resources/publications/pocketk/16/>

Kaufman, M., "Biotech Corn Is Test Case for Industry: Engineered Food's Future Hinges on Allergy Study," *Washington Post*, (19 March, 2001).

Kaufman, M., "Modified Corn Found in Taco Shells in Tests," *Los Angeles Times*, (18 September, 2000).

Lehrer, J., "The Truth Wears Off: Is there Something Wrong with the Scientific Method?" *The New Yorker*, (13 December, 2010).

Mason, R., "Downing Street refuses to say whether David Cameron would eat GM food," *The Telegraph*, (Thursday 20 June, 2013).

Moghisi, A., *Institute for Regulatory Science*, "Best Available Science: Metrics for Evaluation of Scientific Claims," at <http://www.nars.org/bas.html>

Newman, W. and Pollack, A., "U.S. Farmers Cope with Roundup-Resistant Weeds," *New York Times*, (4 May 2010).

No Patents on Seeds, "German Parliament prohibits patents on plants and animals from conventional breeding," Berlin, (27 June, 2013), at <http://www.no-patents-on-seeds.org/en/information/news/german-parliament-prohibits-patents-plants-and-animals-conventional-breeding>

Perkins, J., "Aventis Pays \$9.2 Million to Iowa Farmers for StarLink," *Des Moines Register*, (17 September, 2001).

Philpott, T., "Meet the weeds that Monsanto can't beat," *The Guardian*, (Friday 21 December 2012).

Pollack, A., "U.S. Imposes Stricter Rules for Genetically Modified Crops," *New York Times*, (7 March 2003).

Poulter, S., "Government gives green light to growth of GM crops," *Mail Online*, (Monday, September 16, 2013).

Poulter, S., "Russia suspends import and use of American GM corn after study revealed cancer risk," *MailOnline*, (26 September, 2012).

Ridder, K., "Biotech Firm Executive Says Genetically Engineered Corn Is Here to Stay," *Tribune*, (19 March, 2011).

Simon, S., "Fearing a Field of Genes: The Food Industry loves engineered crops, but not when plants altered to 'grow' drugs and chemicals can slip into its products", *Los Angeles Times*, (23 December 2001).

The Centre for Food Safety and Save Our Seeds, *Seed Giant vs. U.S. Farmers*, (2013), at [http://www.centerforfoodsafety.org/files/seed-giants\\_final\\_04424.pdf](http://www.centerforfoodsafety.org/files/seed-giants_final_04424.pdf).