The Limits of Regulatory Science in Transnational Governance of Transgenic Plant Agriculture and Food Systems

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I. Introduction: The Technological Society[1]

The disruptive propensity of new technologies on existing social, economic, moral, and cultural milieus is no less sacrosanct than it is ancient and topical.[2] For example, the technique of metallurgy, which involves the extraction of metals from naturally occurring ores, is an ancient technological feat, which the apocryphal book of Enoch dated back to at least 3300 B.C.E.[3] However, the advent of metallurgy was greatly disruptive of a tranquil way of life, as metallurgical technology was simultaneously pressed into worthwhile agricultural pursuits and the service of disruptive warfare and strife.[4] Moreover, the advent of ornaments and bracelets, which were, of course, by-products of

1 *The Technological Society* is the title of Jacques Ellul's 1954 seminal work on the downsides of society's increasing dependency on technology. Since the book's publication in 1954, we have become ever more dependent on technology, and the title is used in this article to highlight and contextualise the dual use dilemmas posed by our continuing dependency on technology generally and transgenic plant technology especially. For further discussion, see generally JACQUES ELLUL, THE TECHNOLOGICAL SOCIETY (1973).

2 *See* Charles Harding, *Threadbearers: The Disseminators of Technology*, 6 INT'L J. TECH. KNOWLEDGE & SOC'Y, no. 2, 2010, at 141, 141-49 (citing the account in the apocryphal book of Enoch).

3 *Id.* at 143.

4 *Id.* at 143-44.

metallurgy, led to undue fixation on personal grooming at the expense of divine pursuits, and very much to the displeasure of God.[5] The apocryphal account of the origin of metallurgy in the book of Enoch in chapter 8, verses 1 and 2, aptly notes the disruptive effects of metallurgical technology on existing socio-cultural milieus:

> And Azazel taught men to make swords, and knives, and shields, and breastplates, and taught them about metals of the earth and the art of working them, and bracelets, and ornaments, and the use of antimony, and the beautifying of the eyelids, and all kinds of precious stones, and all coloring and dyes . . . . And there was a great impiety, they turned away from God, and committed fornication, and they were led astray, and became corrupt in all their ways.[6]

However, in retrospect, metallurgy would not be the only technology with inherent propensity for unpredictable disruptiveness,[7] and while most readers might readily, and perhaps rightly, dismiss Enoch's apocryphal account of the origin of metallurgy as a myth,[8] the moral of the story remains palpably tangent and topical with uncanny resonance in contemporary technologies with dual-use potentials, capabilities, and unpredictable tendencies.[9] After all, the technologies that

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5 *Id.* at 144.

6 *Id.* (citing JOSEPH LUMPKIN, THE FIRST AND SECOND BOOKS OF ENOCH: THE ETHIOPIC AND SLAVONIC TEXTS 28 (2009)).

7 *See* Braden R. Allenby, *Governance and Technology Systems: The Challenge of Emerging Technologies*, *in* THE GROWING GAP BETWEEN EMERGING TECHNOLOGIES AND LEGAL-ETHICAL OVERSIGHT: THE PACING PROBLEM 3, 3-7 (Gary E. Marchant, Braden R. Allenby & Joseph R. Herkert eds., 2011) (citing the revolutionary impacts of railways on the social, cultural, and economic institutions of the United States in the early 17th century).

8 In fact, there are more rational historical accounts of the origin and use of metallurgy over the centuries dating from the Neolithic Iron Age, a third principal period of the three-age system, which was characterised by the manufacture of iron implements such as weapons and agricultural tools. *See* RONALD FRANK TYLECOTE, A HISTORY OF METALLURGY (2d ed. 2002).

9 The dual-use research dilemma deals with managing technologies that are capable of hostile and positive uses, such as nuclear installations. The dual use research dilemma is especially prevalent in biotechnological products, which could be used for terrorist activities. *See* Taiwo A. Oriola, *Against the Plague: Exemption of Pharmaceutical Patent Rights as a Biosecurity Strategy*, 2007 U. ILL. J.L. TECH. & POL'Y, 287, 289-93 (2007) (discussing the challenges posed by hostile use of biological

facilitated the industrial revolution, the Green Revolution, penicillin, and the computer, amongst others, also heralded the age of environmental pollution, sundry high technological risks, chemical, germ, biological, and nuclear warfare.[10] These technologies are mostly high-profiled and ubiquitous, and include a broad array of diverse fields including, for instance, nuclear technology, nanotechnology, biotechnology, robotics, information technology, and communication technology.[11] A notable high profile technology with far-reaching implications for public health and safety, and which is often a target of public anxiety, opposition, and intense regulation, is nuclear technology.[12] It is a technology that is perhaps loathed and loved almost in equal measure, due to its ability to harness the awesome power of uranium simultaneously for useful nuclear energy and destructive nuclear weaponry, with concomitant nuclear waste disposal challenges.[13] Yet another high profile technology, which is the subject of discourse in this article, is the product of agricultural biotechnology or recombinant DNA in plant agriculture, otherwise known as genetically modified organisms, or transgenic plant or

inventions for bioterrorism). The National Science Advisory Board for Biosecurity is routinely convened in the United States by the Office of Biotechnology Activities to advise on dual use potentials of biotechnological inventions. *See Dual Use Research*, NATIONAL INSTITUTES OF HEALTH-OFFICE OF SCIENCE POLICY, http://oba.od.nih.gov/biosecurity/biosecurity.html.

10 *See* David Beckmann, *Foreword* to PER PINSTRUP-ANDERSEN & EBBE SCHIØLER, SEEDS OF CONTENTION: WORLD HUNGER AND THE GLOBAL CONTROVERSY OVER GM CROPS viii (John Hopkins Univ. Press 2001).

11 Nanotechnology, biotechnology, robotics, information technology, and communication technology were described as "the five horsemen of emerging technologies." *See* Allenby, *supra* note 7, at 7-11.

12 *See* Koos Van Der Bruggen, *Nuclear Ethics*, *in* A COMPANION TO THE PHILOSOPHY OF TECHNOLOGY 462, 462-65 (Jan Kyrre Berg Olsen, Stig Andur Pedersen & Vincent F. Hendricks eds., 2009) (discussing the United States' deployment of nuclear weapons twice against Japan in 1945, and the polarised opinions on the propriety and ethics of nuclear weapons).

13 *See* Helen Caldicott, *Prof. Gordon Edwards on the Perils of Nuclear Technology, Uranium Mining, and Weapons Proliferations*, COTO REPORT (Mar. 17, 2011), http://coto2.wordpress.com/2011/03/17/prof-gordon-edwards-on-the-perils-of-nuclear-technology-uranium-mining-and-weapons-proliferation/ (providing an interview on the perils of nuclear technology, in which Professor Gordon Edwards was quoted as follows: "[y]ou get electricity for maybe 20 or 30 years if you're lucky, then you have plutonium forever").

crops.[14] Like nuclear technology, it has been a subject of relentless public anxiety, intense scrutiny, regulation, and opposition, since its commercial debut in 1996,[15] amidst continuing, often acrimonious, conflicting scientific data on its susceptibility to new toxins and allergens, and its full ramifications for public health and the environment.[16]

However, it is sacrosanct that, for better or worse, ours is a "technological society,"[17] to which we are irrevocably bound and dependent, and as Martin Heidegger rightly noted, "[e]verywhere we remain unfree and chained to technology, whether we passionately affirm or deny it."[18] Most significantly, the growing ascendancy of technology, and our growing technological dependency over the past century, were largely facilitated by strategic governmental interventions in the forms of promotions and regulations of new technologies.[19] For example, most cutting-

14 Transgenic plants or crops are those that have been genetically modified to host and express certain desirable characteristics, such as pest and drought resistance. Examples include transgenic Bt cotton, corn, soybeans, and canola. *See* MICHAEL J. REISS & ROGER STRAUGHAN, IMPROVING NATURE? THE SCIENCE AND ETHICS OF GENETIC ENGINEERING 131-64 (1996).

15 Calgene's "Flavr Savr" tomato was the first transgenic plant to reach the market in 1994, but it was quickly withdrawn because its "anti-sense" gene for delayed ripening did not confer any on-field or market advantage on the tomato. Several varieties of transgenic corn incorporating Bt toxins were subsequently commercialised in 1996. These were followed by transgenic soy, cotton, and canola. *See* JACK RALPH KLOPPENBURG JR., FIRST THE SEED: THE POLITICAL ECONOMY OF PLANT BIOTECHNOLOGY 296 (Univ. of Wisconsin Press, 2d ed. 2004).

16 Scientific research into the safety of transgenic crops for public health and the environment tends to be divisive and acrimonious. For example, research completed in 1999 by a laboratory in the United States finding that monarch caterpillars died following consumption of pollen from a new variety of genetically modified corn was subsequently discredited by new research, which showed that monarch caterpillars and butterflies did not suffer any harm in their natural habitat. *See* PER PINSTRUP-ANDERSEN & SCHIØLER, SEEDS OF CONTENTION: WORLD HUNGER AND THE GLOBAL CONTROVERSY OVER GM CROPS 47-48 (Johns Hopkins Univ. Press 2001).

17 Our society is arguably more dependent and reliant on technology than Jacques Ellul feared in the 1950s, when he published his seminal work on the impacts of technology on the society in 1954. *See* Ellul, *supra* note 1.

18 *See* Martin Heidegger, THE QUESTION CONCERNING TECHNOLOGY AND OTHER ESSAYS 4 (1977).

19 *See* Oliver Todt, *Regulating Agricultural Biotechnology Under Uncertainty*, 42 SAFETY SCIENCE 143, 144 (2004) (noting regulation and promotion as two fundamental governmental interventionist activities for technology development and describing the

edge technologies are rooted in research conducted at publicly funded universities in Europe and North America,[20] whilst the intellectual property regime, which is openly promoted by governments of industrialized countries, is primarily designed to safeguard investments in applied research and innovations.[21] Thus, there is a symbiotic relationship between governmental technology regulation and promotion that range from laws safeguarding property rights, tax breaks, and government subsidies, to direct public funding for start-up and established firms.[22]

However, while governments around the world are keen to promote new technologies as part of national strategic social and economic development policies,[23] they often struggle to keep

challenges of balancing the two activities).

20 *See* Taiwo A. Oriola, *Strong Medicine: Patents, Markets, and Policy Challenges for Managing Neglected Diseases and Affordable Prescription Drug*, 7 CANADIAN J.L. & TECH. 57, 72-78 (2009) (discussing how pioneering and breakthrough prescription drugs are often rooted in basic research conducted at publicly funded universities and research institutes in the United States, Canada, United Kingdom, and Europe, and arguing for the reflection of taxpayers' investments in the pricing of privately owned pharmaceuticals); *see also* Mark Henderson, THE GEEK MANIFESTO: WHY SCIENCE MATTERS 114-17 (2012) (discussing science's serendipity and how important inventions such as fibre optic cable technology were borne out of publicly funded university research); *see also* KLOPPENBURG, *supra* note 15, at 195-96 (noting how new genetic technologies were developed by publicly funded research at universities and institutes).

21 The *quid pro quo* for the legal protection of intellectual property rights is primarily to incentivise innovation and technology developments by the grant of a limited monopoly to rights owners, which in turn allows for the recoupment of investments in new technologies. *See generally* David I. Bainbridge, INTELLECTUAL PROPERTY 17-19 (6th ed. 2007) (discussing the rationale and justifications for intellectual property rights protection).

22 In the United Kingdom, for example, tax advantages for start-up or new businesses set up in one of the twenty-one new enterprise zones could amount to one hundred percent business rates discounts for five years. The discounts could be worth up to £275,000 over a five year period. *See* Tom Bawden, *Budget 2011: Selected Enterprise Zones Designed to Encourage New Investment*, THE GUARDIAN (Mar. 23, 2011), http://www.theguardian.com/uk/2011/mar/23/budget-2011-enterprise-zones-designed-to-encourage-new-investment.

23 For example, the administration of Prime Minister Atal Bihari Vajpayee in India perceived and promoted biotechnology as a pro-poor national development 'precision' tool with which to create wealth, "fight obdurate diseases, increase agricultural production, combat nutritional deficiencies and protect the environment." *See* Ronald J. Herring, *The Genomics Revolution and Development Studies: Science, Poverty and Politics*, 43 J. DEV. STUD. 3 (2007) [hereinafter *Genomics Revolution*] (discussing the

technology policy and regulatory framework abreast of new technological developments,[24] fueling concerns on the propriety, adequacy, or efficacy of regulatory and governance regimes for new technologies.[25] Thus, while technological regulation is sacrosanct,[26] there is a risk that governmental technology promotional policy could obfuscate an effective technological regulatory regime in the absence of a proper balance between technology promotion and regulation.[27] For example, a government that is overly enthused by the endearing promise of transgenic plant agricultural technology could, in all probability, have a more favourable promotional policy regime[28] than a government less enthused due to national developmental policy objectives or social, economic, cultural, or political imperatives.[29] There is arguably a parallel between this hypothesis and the dichotomies in transgenic plant agricultural regulatory and policy frameworks in the United States, with its proactive and laissez-faire regulatory and policy regime,[30] as exemplified by its official

economic, political, and social forces that were driving innovations in life-sciences-related technologies).

24 *See* Lyria Bennett Moses, *Recurring Dilemmas: The Law's Race to Keep Up with Technological Change*, 2007 U. ILL. J.L. TECH. & POL'Y 239, 239-85 (2007).

25 *See* Gary E. Marchant, *The Growing Gap Between Emerging Technologies and the Law*, *in* THE GROWING GAP BETWEEN EMERGING TECHNOLOGIES AND LEGAL-ETHICAL OVERSIGHT: THE PACING PROBLEM 19-33 (Gary E. Marchant, Braden R. Alleaby & Joseph R. Herkent eds. 2011).

26 *See* Allenby, *supra* note 7, at 7-11.

27 *See* Todt, *supra* note 19, at 144 (discussing how governments have to balance their promotional and regulatory interests in technology governance regimes).

28 Agricultural biotechnology is routinely touted as a panacea to food scarcity and world hunger by its adherents. *See* PER PINSTRUP-ANDERSOEN & EBBE SCHIØLER, *supra* note 15, at 86-105 (discussing the potential of transgenic crops to solve world hunger, especially in Africa).

29 Some analysts believe that the continuing European public resistance to transgenic crops, which stemmed from mistrust of environmental and safety agencies, largely informed the precautionary principle that currently predominates the regulatory framework for transgenic crops in Europe. *See* Ambuj Sagar, Arthur Daemmrich, & Mona Ashiya, *The Tragedy of the Commoners: Biotechnology and Its Publics*, 18 NATURE BIOTECHNOLOGY 2, 2-4 (2000); Robert Lee, *GM Resistant: Europe and the WTO Panel Dispute on Biotech*, *in* 1 ETHICS, LAW & SOCIETY 131, 131-39 (Jennifer Gunning & Søren Holm eds., 2005).

30 *See* George Gaskell et al., *Transatlantic Tensions over GM Crops and Food*, *in* GENOMICS & SOCIETY: LEGAL, ETHICAL & SOCIAL DIMENSIONS 197, 197-211 (George Gaskell & Martin W. Bauer, eds., 2006).

aversion for labeling transgenic plant food products,[31] and countries of the European Union, where popular resistance to transgenic plant agricultural technology endures and defines its relatively stringent policies that regulate the technology.[32]

Yet, while transgenic plant agriculture is perhaps one of the most regulated technologies of our time, its regulatory framework, characterized in this Article as "regulatory science"[33] is arguably molded almost entirely by evolutionary or evolving "science"[34] on

31 Despite overwhelming support for the labeling of transgenic plant products as exemplified by a 2003 survey and the aborted states' legislative initiatives such as that of Oregon, the FDA has refused to endorse labeling of transgenic plant food products. This policy starkly contrasts with that of the countries of the European Union, where labeling of transgenic food products is mandatory. *See* ROBERT PAARLBERG, STARVED FOR SCIENCE: HOW BIOTECHNOLOGY IS BEING KEPT OUT OF AFRICA 17 (2009) (noting how domestic pressure forced the European Union to introduce a compulsory labeling rule for all transgenic crops products sold within the European Union).

32 In contradistinction to the United States, regulators in the European Union took the view that transgenic plant agriculture and products posed uncertain risks that warranted special regulation, such as the Directive 90/220 on Deliberate Release of Genetically Modified Organisms into the Environment, which was designed to prevent "adverse effects on human health or the environment." *See* Les Levidow, Joseph Murphy & Susan Carr, *Recasting "Substantial Equivalence": Transatlantic Governance of GM Food*, 32 SCI., TECH. & HUM. VALUES at 26, 36 (Jan. 2007); *see also* Sheila Jasanoff, DESIGNS ON NATURE: SCIENCE AND DEMOCRACY IN EUROPE AND THE UNITED STATES 274-80 (2007) (discussing how the differing framing of biotechnological risks led to policy differences between the United States and the European Union. While the United States' "product-based" approach drew heavily on scientific accounts, extolling the merits and promises of genetic engineering "as a highly specific intervention, grounded in molecular biology" with untold benefits and minimal risks to public health and the environment, the European Union and Member states adopted a "process-based" approach, which took cognizance of ecological implications and inherent uncertainties of the technology as exemplified by their normative precautionary regulatory approach).

33 For a discussion on the concept of regulatory science and various definitions, see YEONWOO LEBOVITZ ET AL., BUILDING A NATIONAL FRAMEWORK FOR THE ESTABLISHMENT OF REGULATORY SCIENCE FOR DRUG DEVELOPMENT: WORKSHOP SUMMARY 5-11 (2011). Also it is worthwhile to consult regulatory decisions for the best scientific knowledge available.

34 The word "science" is defined by the Oxford Dictionary as "an organised body of knowledge on a subject." *See* THE OXFORD DICTIONARY AND THESAURUS 1350 (American ed. 1996). The term "evolutionary science" is used contextually in this essay to denote an evolving body of knowledge as opposed to an exact, evolved, standardised, or established knowledge. For example, while the knowledge that water, iron, gold, and copper are electricity conductors is sacrosanct, the science on the full implications of transgenic agriculture for public health and the environment is arguably evolutionary and not as well established, due to innumerable unknowns that range from horizontal gene

issues that range from transgenic plant food allergens and toxins, to the coexistence of transgenic and non-transgenic plants, to the safety of transgenic plant agriculture and food respectively for the environment and public health.[35] In general terms, regulatory science connotes science-based regulation, policy, or decision-making processes[36] and has been defined as "a unique application of science, at all levels, to the societal decision process[,]"[37] or as "[t]he development and use of new tools, standards and approaches to more efficiently develop products and to more effectively evaluate product safety, efficacy and quality."[38] Significantly, a distinction is often made between "regulatory science" and "research science," with the latter being regarded as qualitatively superior to the former.[39] According to Sheila Jasanoff: "[w]hereas, 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."[40]

Whilst it is beyond the remit of this article to join the fray on the contested theoretical and empirical distinctions between "regulatory" and "research" science,[41] it would suffice to argue

flow, to new allergens, to new toxins from novel proteins. *See Genomics Revolution*, *supra* note 23, at 2.

35 It is axiomatic that scientists are divided on what the full implications of transgenic agriculture could be for the public health and the environment. *See* MAE-WAN HO, GMO FREE: EXPOSING THE HAZARDS OF BIOTECHNOLOGY TO ENSURE THE INTEGRITY OF OUR FOOD SUPPLY 21-25 (2004) (branding the "substantial equivalence" doctrine on which the safety of transgenic crops was premised as "unscientific," and noting how the contrarian findings of Professor Puszai on the dangers posed by transgenic crops to public health and the environment were attacked within the scientific establishment).

36 *See* Alan Irwin et al., *Regulatory Science: Towards a Sociological Framework*, 29 FUTURES 17, 17-31 (1997).

37 *See* LEBOVITZ ET AL., *supra* note 33, at 6 (citing Alan Moghissi). While there is no official definition of regulatory science, there are numerous contextual definitions, especially in the context of biopharmaceutical products governance.

38 *Id*. (citing NIH-FDA definition).

39 *See* SHEILA JASANOFF, THE FIFTH BRANCH: SCIENCE ADVISERS AS POLICYMAKERS 76-83 (1994).

40 *Id.* at 77.

41 For example, no distinction was made between research and regulatory science by Alan Irwin et al., in their paper on the role of regulatory science in the governance of

that there is no evidence to suggest that "research science" is either infallible[42] or sacrosanct as such,[43] 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.[44] Rather, an audit of scientific literature on transgenic plant technology, which was commissioned by the United Kingdom Department of Environment Food and Rural Affairs (DEFRA) and published by the GM Science Review Panel in 2004, showed that most of the literature by both academic and industry researchers was in peer-

toxic chemicals in the European Union, which relied on works of university-based researchers, private laboratories conducting large-scale regulatory compliance texts, industrial scientists assessing health and environmental benefits of chemical products, and government institutions tasked with assessing scientific evidence submitted by industry. *See* Irwin et al., *supra* note 36, at 17-31; *see also* LEBOVITZ ET AL., *supra* note 33, at 1-78 (discussing 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).

42 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% were attributable to errors, while a whopping 67.4% were attributable to misconduct including fraud or suspected fraud. *See* Ferric C. Fang, R. Grant Steen & Arturo Casadevall, *Misconduct Accounts for the Majority of Retracted Scientific Publications*, 149 PROC. NAT'L ACAD. SCI. 17028, 17028-33 (2012).

43 In a corporate sense, "research science," even if superior, is arguably organic, cumulative, dynamic, and progressive. The state of the art of a technology is inherently variable depending on the underlying scientific discoveries and understanding of new materials such as nano-materials for example. *See* Bernard d'Espagnat, *Is Science Cumulative? A Physicist Viewpoint*, 255 BOSTON STUD. IN PHIL. & HIST. SCI. 145, 145-51 (2008). 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 (Dec. 13, 2010), http://www.newyorker.com/reporting/2010/12/13/101213fa_fact_lehrer.

44 For example, the Second Report of GM Science Review Panel, commissioned by DEFRA UK, was premised on a review of academic (research) and industry scientific literature on issues of public concerns ranging from GM food safety to gene flow. *See 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*, Jan. 2004, *available at* http://www.bis.gov.uk/files/file14992.pdf.

reviewed and refereed journals.[45] 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 "[r]esearch 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."[46] It is instructive to note that the report released by the European 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.[47] Thus, the hypothesis that regulatory science is inferior to research science ostensibly smacks of an arbitrary distinction and categorization because, invariably, regulatory science is premised on an amalgam of scientific knowledge from industry and academia. This is so irrespective of publication medium or the quality of publication outlet. Regulatory science differs as much from country to country as it does from one type of technology to the other, with concomitant variations in its fundamental constituents, a point well adumbrated by Alan Irwin et al., who state:

> [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.[48]

Thus, in the context of transgenic plant agricultural technology policy, for example, cross-country variations in the regulatory and policy science framework are exemplified by the European Union precautionary principle,[49] which arguably informed legislation

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45 *See id*.

46 Press Release, European Union Research Directorate, GMOs: Are There Any Risks? (Oct. 9, 2001) (*available at* http://ec.europa.eu/research/biosociety/pdf/gmo_press_release.pdf) (noting on 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").

47 *See id.*

48 The term "academic science" as used in this context, connotes "research science." *See* Irwin et al., *supra* note 36, at 20.

49 The precautionary principle involves applying provisional risk management

such as the transgenic food products labeling rules, to which the United States did not subscribe,[50] despite a survey suggesting that ninety-four percent of Americans in 2003 preferred the labeling of transgenic plant food products.[51] A fortiori, in this Article, 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 or quality of the publication medium.[52]

Most significantly, it is arguable that the regulatory and policy framework for transgenic plant agricultural technology is largely underpinned by science.[53] This is exemplified by the European Food and Safety Authority's guidance document on the environmental risk assessment of genetically modified plants, which, inter alia, enjoins the conduct of risk assessment as follows: "in a scientifically sound manner based on available scientific and technical data and on common methodology for identification, gathering and interpretation of the relevant

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 Communication from the Commission on the Precautionary Principle*, COM (2000) 14 final (Feb. 2, 2000).

50 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 the mid 2000's. *See* Margaret Rosso Grossman, *European Community Legislation for Traceability and Labeling of Genetically Modified Food*, *in* LABELING GENETICALLY MODIFIED FOOD: THE PHILOSOPHICAL AND LEGAL DEBATE 32, 32-62 (Paul Weirich ed., 2007).

51 *See* Paarlberg, *supra* note 31, at 23.

52 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 frameworks in the governance of transgenic plant agricultural technology.

53 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 & Nora K. Murphy, *Biotechnology at the Dinner Table: FDA's Oversight of Transgenic Food*, 584 ANNALS AM. ACAD. POL. & SOC. SCI. 80, 82 (2002).

data . . . . Sufficient scientific data must be available in order to arrive at qualitative/quantitative risk estimates."[54] Furthermore, Articles 5(1) and 5(2) of the Agreement on the Application of Sanitary and Phytosanitary Measures of the Uruguay Round (SPS Agreement), require that all food safety measures must be based on risk assessment and scientific evidence.[55]

However, while the ostensible science-centric policy disposition of 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.[56] Regulatory science is an arguably putative and interpretive policy tool for defining, delimiting, and deconstructing the relationship between virtually all forms of technology and nature, a point aptly adumbrated by Robert G. Lee as follows: "[w]hile nature is inevitably interpreted and technically constructed through science, it is now also shaped by its deliberative intrusion."[57] Notably, regulatory science and the policy framework through which science's "deliberative intrusion" in, or deconstruction of, nature is often accomplished could either be legislative or judicial.[58] The juridical element of regulatory science is arguably exemplified by the landmark United States Supreme Court decision in *Diamond v. Chakrabarty*,[59] in which Justice Warren E. Burger, while delivering the Court's five-four judgment held, inter alia, that a genetically modified live micro-organism was patentable subject matter, a "manufacture or

54 *See* EFSA Panel on Genetically Modified Organisms, *Scientific Opinion: Guidance on the Environmental Risk Assessment of Genetically Modified Plants*, 8 EFSA J, Nov. 2010, at 1, 3.

55 *See* Agreement on the Application of Sanitary and Phytosanitary Measures, Apr. 15, 1994, Final Act Embodying the Results of the Uruguay Round of Multilateral Trade negotiations, Annex 1A, Legal Instruments-Results of the Uruguay Round vol. 27, *available at* http://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm.

56 Regulatory science is routinely employed in the governance of pharmaceuticals and new drug development. *See* LEBOVITZ ET AL., *supra* note 33, at 5-11.

57 *See* Robert G. Lee, *Look at Mother Nature on the Run in the 21st Century: Responsibility, Research and Innovation*, 1 Transnat'l Envtl. L. 105, 107 (2012).

58 *See* Taiwo A. Oriola, *Ethical and Legal Issues in Singapore Biomedical Research*, 11 PAC. RIM L. & POL'Y J. 497, 497-529 (2002) (discussing legislative and juridical examples of pro-biotechnology research policies).

59 *See* Diamond v. Chakrabarty, 447 U.S. 303 (1980).

composition of matter" under United States patent legislation.[60] The micro-organism in question was a bacterium, which had been genetically modified to break down crude oil as a means to clean up oil spills.[61] The Office of the United States Patents Commissioner, Sidney Diamond, had rejected a patent application for the bacterium on grounds that living things, such as a live bacterium, could not be patented under United States patent law.[62] While rejecting the Patents Commissioner's arguments, the United States Supreme Court held the U.S. Congress had intended patentable subject matter to "include anything under the sun that is made by man,"[63] and that the genetically altered bacterium was "a nonnaturally occurring manufacture or composition of matter–a product of human ingenuity having a distinctive name, character[, and] use."[64]

However, even with our ingenuity, prowess, and current cutting-edge technological sophistication, we have yet to create life from scratch, notwithstanding the Craig Venter Institute's synthetic bacteria.[65] Yet, due mainly to the pioneering *Chakrabarty* decision, scientists have secured proprietary rights in micro-organisms merely for the discovering, isolating, shuffling,

60 *See id.* at 309. The provision of the Patent Act that the Court was interpreting was § 101, which provides that "[w]hoever invents or discovers any new useful process, machine, or manufacture, or composition of matter, or any new or useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirement of this title." 35 U.S.C. § 101 (1952).

61 *See Chakrabarty*, 447 U.S. at 303.

62 *See id*. at 306.

63 *Id.* at 309.

64 *Id*. at 309-10 (internal quotation marks omitted).

65 For example, in July 2010, Dr. Craig Venter, a synthetic biologist, and his colleagues published a research article in *Science* magazine, reporting that they had created a synthetic life, by replacing the genome of a natural cell with a different genome created by gene synthesis, resulting in a new bacterial, which Venter and colleagues described as "*Mycoplasma laboratorium*." *See* Daniel G. Gibson et al., *Creation of a Bacterial Cell Controlled by a Chemically Synthesized Genome*, 329 SCIENCE 52, 52-56 (2010). Following the publication of the experiment, the J. Craig Venter Institute refuted the media's suggestion that the Institute was playing God, and that the experiment was not tantamount to "creating life from scratch." They also maintained that they had merely created "new life out of already existing life using synthetic DNA." *See First Self-replicating Bacterial Cell: Frequently Asked Questions*, J. CRAIG VENTER INSTITUTE, http://www.jcvi.org/cms/research/projects/first-self-replicating-synthetic-bacterial-cell/faq (last visited Oct. 1, 2013).

and transferring of useful genes from one organism into another, as exemplified by the Myriad Genetics' controversial patents for isolated human breast and ovarian cancer genes.[66] The significance of the *Chakrabarty* decision was that it, arguably single-handedly, opened the floodgates for patents on life, as exemplified by subsequent proliferation of patents for mere gene shuffling and gene transfer.[67] Thus, albeit juridical, the *Chakrabarty* decision exemplifies science's "deliberative intrusion" into nature, typically via the tendentious regulatory science and policy regime that often exhibits pro-science leanings and biases, a stance ostensibly necessitated by the policy imperatives for promotion of innovations and new technologies on grounds of public interest and technological progress.[68]

66 Myriad Genetics and the University of Utah discovered, isolated, and patented breast and ovarian cancer genes, which they christened BRCA1 and BRCA2. They subsequently developed diagnostic tests for which they charged over $3,000, to examine extracted DNA from the genes for mutations that could be indicative of high predisposition to ovarian or breast cancer. However, because the monopoly conferred by Myriad's patents prevented other laboratories from performing similar tests, the patents were challenged by the American Civil Liberties Union and Public Patent Foundation on behalf of numerous medical groups, researchers and laboratories, on grounds that human genes could not be patented because they were products of nature, and that the consequential monopoly on diagnostic tests for breast and ovarian cancer aggravated medical costs. In 2010, the patents were invalidated by the United States District Court, Southern District of New York. *See* Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 702 F. Supp. 2d 181 (S.D.N.Y. 2010). However, in a subsequent appeal filed by Myriad Genetics, the Court of Appeals for the Federal Circuit reversed the District Court's ruling on grounds that an isolated DNA from the human body could be patented because it was "markedly different" from the DNA inside the body. *See* Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 653 F.3d 1329 (Fed. Cir. 2011). In a subsequent appeal to the United States Supreme Court, the Supreme Court remanded the case to the Court of Appeals with instructions to review its decision validating the patents in light of the new Supreme Court ruling invalidating medical diagnostic patents in Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 182 L. Ed. 2d 321 (2012). *See* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 132 S. Ct. 1794, 182 L. Ed. 2d 613 (2012). For discussion, see Samantak Ghosh, *Gene Patents: Balancing the Myriad Issues Concerning the Patenting of Natural Products*, 27 BERKELEY TECH. L.J. 241, 241-72 (2012).

67 *See* Taiwo A. Oriola, *Genes for Sale: Ethical Reflections on Donors Proprietary Rights in Human Genetic Derivatives*, *in* 3 ETHICS, LAW & SOCIETY 159, 166-67 (Jennifer Gunning & Soren Holm, eds., 2007).

68 Albeit juridical in nature, the *Chakrabarty* decision was actually premised on the Supreme Court's interpretation of § 101 of the U.S. Patent Act, which of course is a regulatory instrument enacted by the U.S. Congress. In the *Chakrabarty* decision for example, the argument that the "invented" bacterium and similar genetic research could

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 systematized observation of an experiment with phenomena, [especially] concerned with the material and functions of the physical universe,"[69] or as "an organized body of knowledge on a subject."[70] According to Francis Bacon, experimental observation of materials and the concomitant inductions or deductions thereof are the hallmarks of science.[71] Thus, observable, verifiable, and replicable scientific knowledge arguably should be preferable to ethical, religious, conscientious, cultural, whimsical, subjective, or idiosyncratic rationales for regulating technological inventions,[72] precisely because of science's perceived neutrality, objectivity, rationality, agnosticism, and relative certitude.[73] This point is aptly summed

"spread pollution and disease" or "result in a loss of genetic diversity" or "depreciate the value of human life" was dismissed by the court on grounds that only the U.S. Congress had the legislative oversight to do so. For discussion, *see* Chakrabarty, 447 U.S. 303, 316-17 (1980). Thus, the *Chakrabarty* case demonstrates how policy objectives for promotion of new technologies for the common good could shape the outcome of a judicial decision. Similarly, in the *Harvard Onco-mouse* case, patents examiners drew on the public benefits inherent in the advancement of cancer research, to find that the Harvard Onco-mouse invention did not contravene the provisions of Article 53(a) of the European Patent Convention, which excluded inventions that were contrary to public policy, public order, or morality from being patentable. *See* Decision on *Onco-mouse/Harvard,* 1992 O.J. EPO (10) 593; *see also* Oriola, *supra* note 58, at 497-529 (discussing deliberative and public policy-induced legislative and juridical examples of pro-biotechnology research policies).

69 *See* THE OXFORD DICTIONARY AND THESAURUS, *supra* note 34, at 1350.

70 *See id.*

71 *See* CLAUDE BERNARD, AN INTRODUCTION TO THE STUDY OF EXPERIMENTAL MEDICINE 6 (1957). 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* DAVID PAPINEAU, PHILOSOPHY 96 (2009).

72 *See, e.g.,* Case C-165/08, Comm'n v. Poland, 2009 E.C.R. I-6843 [hereinafter *Poland*]. 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.

73 *See* Hans Radder, *Science and Technology: Positivism and Critique*, *in* A

up by David Papineau as follows:

> The uniqueness of scientific knowledge seems to derive from two factors. First, scientific theories are not wild speculations. Unlike theological or metaphysical claims, scientific theories 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.[74]

But then the pertinent recurring question, which is at the core of this Article, is the extent to which "science" 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.[75] After all, if the general public were to rely on "science" to the exclusion of ethical, religious, or cultural imperatives for regulating technologies both old and new,[76] then the general public certainly should have legitimate expectations of "science" to deliver a relative degree of reliability, neutrality, and certitude in the governance of transgenic plant agriculture and foods.[77] Otherwise, what would be the

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COMPANION TO THE PHILOSOPHY OF TECHNOLOGY 61-65 (Jan Kyrre Berg Olsen et al. eds., 2009) (discussing how "[s]cience and technology are seen as yielding universally valid knowledge and objectively working tools that are normatively neutral and acquire value only when applied for specific social purposes"). However, the author also noted recent studies, which question science neutrality and universal validity. *See id*. at 61-62.

74 *See* PAPINEAU, *supra* note 71, at 98; *see also* ROGER A. PIELKE, JR., THE HONEST BROKER: MAKING SENSE OF SCIENCE IN POLICY AND POLITICS 43-44 (2007) (discussing how society tends to ascribe high value to scientific information and regard it as authoritative, while non-scientific information is perceived negatively).

75 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, "[s]o long as there exist . . . different, valid scientific perspectives, some degree of uncertainty will always exist." Pielke, *supra* note 74, at 61.

76 For example, the ethical, religious, and cultural oppositional grounds to transgenic plant agriculture and foods were discountenanced by the court in the U.S. case of Alliance for Bio-Integrity v. Donna Shalala, 116 F. Supp. 2d 166 (2000). *See also Poland*, *supra* note 72.

77 Indeed, it has been proven that many scientific ideas generate conflicting results, and that not all scientific studies are replicable. *See* Lehrer, *supra* note 43; *see also* John P.A. Ioannidis, *Why Most Published Research Findings Are False*, 2 PLOS MEDICINE 0696, 0696-701 (2005).

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?[78] This question is particularly tangent and relevant to any general academic inquiry into the limits and propriety of regulatory science in the governance of transgenic plant agricultural technology in light of the hotly contested safety science of transgenic plant agriculture,[79] and the recent assertion by approximately 250 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."[80]

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 irreplicable or false.[81] Yet, replicability of scientific results is crucial to the validation or affirmation of their reliability, as aptly expressed by Jonah Lehrer as follows:

> The test of replicability, as it's known, is the foundation of modern research. Replicability is how the community enforces itself. It's a safeguard for the creep of subjectivity. Most of the time, scientists know what results they want, and that can influence the results they get. The premise of replicability is that the scientific community can correct for these flaws.[82]

However, aside from replicability problems inherent in most scientific research results, the claim that "science never absolutely

78 *See* Papineau, *supra* note 71, at 98.

79 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 22-24 (2007). For a contrarian account on the promise of the technology, see Paarlberg, *supra* note 31, at 1-80.

80 *See* Peter H. Gleick et al., Letter to the Editor, *Climate Change and the Integrity of Science*, 328 SCIENCE 689, 689 (2010).

81 *See* Lehrer, *supra* note 43; *see also* Ioannidis, *supra* note 77, at 0696-0701; *see also* Ramal Moonesinghe, Muin J. Khoury & A. Cecile J.W. Janssens, *Most Published Research Findings Are False: But a Little Replication Goes a Long Way*, 4 PLOS MEDICINE 0218, 0218-21 (2007) (noting how a lack of replication in research findings especially in the field of genetics, was due mostly to publication and selection bias).

82 *See* Lehrer, *supra* note 43.

proves anything"[83] could also be justified partly by the theory that science, which typically underpins regulatory policy for technologies, could either be "proven" science or "evolving" science.[84] For example, the science that underpins aerodynamics technology,[85] and the constitution of human genetic material,[86] would appear relatively settled. However, 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.[87]

Significantly, the central hypothesis in this Article, which posits that the current underlying science on the full ramifications of transgenic plant agriculture and food products respectively for the environment and public health is evolutionary, is not entirely unfounded, as scientific knowledge is arguably generally organic and tends to be incremental and cumulative over time, despite contrarian claims.[88] Arguably, current scientific knowledge is invariably built on past or cumulative scientific studies, as aptly exemplified by the famous statement of "the greatest and most

83 *See* Gleick et al., *supra* note 80, at 689.

84 Science is generally classified into two categories: proven and evolving science. *See* A. Alan Moghisi, *Best Available Science: Metrics for Evaluation of Scientific Claims*, INSTITUTE FOR REGULATORY SCIENCE, http://www.nars.org/bas.html (last visited Oct. 2, 2013).

85 Aerodynamics deals with the study of the interaction of air with solid objects, and knowledge is crucial for designing and calculating the speed of aircrafts relative to their weights and sizes. *See* JOHN D. ANDERSON, FUNDAMENTALS OF AERODYNAMICS 11-14 (5th ed. 2011).

86 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 1-53 (2001).

87 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. *See* Robert B. Buchanan, *Genetic Engineering and the Allergy Issue*, 126 PLANT PHYSIOLOGY 5, 5-7 (2001).

88 *See* d'Espagnat, *supra* note 43, at 145-51 (dismissing Kuhn's theory or its interpretation thereof to the effect that science is not cumulative).

influential scientist who ever lived,"[89] Isaac Newton, who wrote that "[i]f I have seen further, it is by standing on the shoulders of the giants."[90] 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."[91] For example, whilst the science of aerodynamics technology facilitated the flight of the first powered aircraft by the Wright brothers in 1903, the scientific knowledge that underpinned their work was arguably largely predicated on the accumulated body of knowledge garnered over time from numerous earlier abortive experimental powered flights.[92] Even so, the science of aerodynamics technology has since progressed considerably, as exemplified by subsequent emergence of crucial knowledge on the interactive dynamics of aircraft designs, weight, and speeds that inevitably impacted flight safety and performance in the latter part of the 20th Century.[93] Thus, arguably, the science that underpinned the supersonic Concorde airplane was far superior to that of the first powered-aircraft flown by the Wright brothers. But then, there is no denying that the Concorde airplane and all modern jets incorporated and built on the basic science that powered the Wright brothers' maiden flight. Thus, over time, the evolving or evolutionary science that underpins aerodynamics technology has become relatively proven or standardized, in light of the current state of the art in civilian and military aircrafts, vis-a-vis the state of the art of the science that underpinned aerodynamics technology in the formative years leading up to the epochal first powered-flight by the Wright brothers.[94]

89 *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 315 (2001).

90 *See* JEAN-PIERRE MAURY, NEWTON: UNDERSTANDING THE COSMOS, NEW HORIZON SERIES 117 (1992).

91 *See* Moghisi, *supra* note 84.

92 For discussion on the history of aviation see OCTAVE CHANUTE, PROGRESS IN FLYING MACHINES 308 (Dover 2003).

93 *See* Anderson, *supra* note 85, at 10-37.

94 This is not to suggest that there is no scope for further improvements or possibility for future breakthroughs in aerodynamics science, especially with regards to hypersonic flights, aerospace technology, and safer and more efficient flights. The aerodynamics technology example is meant to demonstrate the relative advancements of aviation science since the Wright brothers, and to underscore the general evolutionary

Indeed, 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 either aerodynamics or transgenic plant technology. Moreover, and most crucially, the central hypothesis in this article—that the science of 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 2012 publication on the impact of transgenic Bacillus thuringiensis maize on non-target soil organisms.[95] 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.[96] 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 contributed to the growing and evolutionary body of knowledge on the "unanticipated effects of Bt. crop cultivation on non-target soil organisms."[97]

Therefore, within the context of the evolutionary or evolving nature of the safety science underpinning transgenic plant agricultural technology, as well as the current scientific uncertainties pervading its full ramifications for public health and the environment, what follows are pertinent questions, central to the theme of this article. First, could the current contested, unsettled, and arguably evolutionary science on the implications of transgenic plant agriculture and new transgenic plant food toxins and allergens respectively for the environment and public health definitively change overtime? In other words, 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

nature of science and its resultant technology.

95 *See* Tanya E. Cheeke, Todd N. Rosentiel & Mitchell B. Cruzan, *Evidence of Reduced Arbuscular Mycorrhizal Fungal Colonization in Multiple Lines of Bt Maize*, 99 AM. J. BOTANY 700, 700-707 (2012).

96 *See id.*

97 *See id.* at 700.

recent findings on the probable debilitating impacts of transgenic Bt crops on arbuscular mycorrhizal fungi populations? Second, in light of the pervasive uncertainties dogging the long-term safety science of transgenic plant agriculture and food respectively for the environment and public health, should science continue to trump alternative, albeit non-scientific, premises or rationales for transgenic plant technology governance, including, among others, ethical, religious, cultural, and conscientious considerations, when the said science is notoriously susceptible to irreplicability, and arguably neither precise nor exact, and no more than an evolutionary work in progress? Third, assuming arguendo that the central hypothesis in this article, which posits that the underlying "science" of regulatory science is overly tendentious and deterministic in its putative oversight of transgenic plant agricultural technology is grossly exaggerated, flawed, or unfounded, to what extent is the "science" that underpins transgenic plant agricultural technology governance inclusive of extraneous non-scientific values, considerations, and socio-cultural influences? Answering these questions could arguably highlight the strengths, weaknesses, and limits of regulatory science, and aid policy makers to better understand the propriety of regulatory science in the governance of transgenic plant agriculture.

The article is divided into five parts. Part I is the introduction, which defines and reviews the literature on the central problems. It discusses the dilemmas inherent in regulatory science oversight of transgenic plant agriculture focusing on the uncertainty of its underlying science within the broader context of "the technological society," as well as the concomitant challenges posed by regulatory science oversight of new technologies. Part II reviews the literature on the theory of science and the symbiotic relationship between science and technology, with a view to underscoring the intimate nexus between science, technology, and policy, and, particularly, how the science of transgenic plant agriculture ultimately informs the regulation and policy framework for the technology. Part III examines the limits of regulatory science for transgenic plant agriculture governance, with specific focus on the propriety of the substantial equivalence doctrine, the validity and reliability of the science that underpins transgenic plant allergens and toxins, and the validity of the

science that underpins in situ gene flow and adventitious commingling of transgenic and non-transgenic plant materials. The primary aim is to join issues on the propriety and limits of regulatory science in transgenic plant agriculture governance, by highlighting the frailty and uncertainty of its underlying science. Part IV discusses selected case law to highlight what the Article characterizes as science determinism or centralism, and the ostensibly visceral grip of science over transgenic plant agriculture policy, at the expense of alternative, albeit non-scientific governance systems including ethical, religious, to cultural values. Part V concludes the Article, by urging for a more inclusive regulatory regime that takes cognizance of non-scientific externalities and considerations in the governance of transgenic plant agricultural technology.

II. The Science and Technology of Transgenic Plant Agriculture

Arguably, there is no technology without an underlying science. But then, while it may seem that modern science is separable from its resultant technology, modern science is indeed "instrumentally embodied" or technologically dependent.[98] Therefore, in order to grasp the full ramifications of the limits of regulatory science in transgenic plant agricultural technology governance, it is important to review the literature on the distinctions and dynamics between science and technology generally. In particular, it is imperative to consider how the underlying science of transgenic plant agricultural technology ultimately informs the concomitant regulatory and policy regimes for transgenic plant technology. This analysis is crucial to understanding the role and limits of regulatory science in national and transnational transgenic plant agricultural technology governance.

A. Definitional, Conceptual, and Theoretical Framework for Transgenic Plant Agriculture

Every organism, including bacteria, fungi, plants, animals, and humans, is imbued by nature with genes, which are no more than

98 *See* Don Ihde, *Technology and Science*, *in* A COMPANION TO THE PHILOSOPHY OF TECHNOLOGY, *supra* note 12, at 52.

"codes or messages," programmed by nature to instruct organisms about which chemicals or proteins are needed for survival, reproduction, and growth.[99] 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 move genes from one species or organism to another, across natural structural barriers that separate, define, and distinguish species or organisms.[100] The procedure or technique for moving, recombining, or shuffling of genes from one organism into another organism is known as "genetic engineering,"[101] and it is typically undertaken to confer a desirable trait from one organism unto another organism. The recipient organism typically is able to manifest the desirable trait via the chemical produced by the transferred genes.[102] This procedure is exemplified by the StarLink™ transgenic corn produced by Aventis CropScience Corporation, which was a progeny of the convergence of genes between Bacillus thuringiensis, a bacterium micro-organism, and corn, which is of course a plant organism.[103] Bacillus thuringiensis is naturally imbued with insecticide properties, and it is routinely used to eliminate unwanted insects in agriculture, forests, and urban areas.[104] Thus, scientists at Aventis CropScience Corporation inserted proteins from Bacillus thuringiensis into the corn genome, which imbued the corn with immunity against its traditional insect foes, such as the European corn borer and corn earthworm, thus

99 *See* Reiss & Straughan, *supra* note 14, at 1-2.

100 *See* Mark L. Winston, Travels in the Genetically Modified Zone 1 (2002); *see also* KLOPPENBURG, *supra* note 15, at 2-4 (discussing the superiority of recombinant DNA technology over conventional plant breeding techniques, and how the new technology was tantamount to "outdoing evolution").

101 *See* REISS & STRAUGHAN, *supra* note 14, at 1; *see also* Mae-Wan Ho & Lim Li Ching, GMO Free: Exposing the Hazards of Biotechnology to Ensure the Integrity of Our Food Supply 15 (2004).

102 REISS & STRAUGHAN, *supra* note 14, at 1-2.

103 For discussion on Aventis CropScience StarLink™ corn, which was approved by the United States Environmental Protection Agency on May 22, 1998, see Bacillus Thuringiensis Subspecies Tolworthi Cry9C Protein and the Genetic Material Necessary for its Production in Corn; Exemption from the Requirement of a Tolerance, 63 Fed. Reg. 28258 (May 22, 1998).

104 For discussion on Bacillus thuringiensis, see Carrie Swadener, *Bacillus Thuringiensis (Bt)*, 14 J. PESTICIDE REFORM, FALL 1994, 13, 13-20.

obviating the need for the use of insecticide.[105]

Technically, genetic engineering techniques for intra and trans-species genes transfer as typified by the process for making StarLink™ transgenic corn, is broadly defined as "a technique of altering an organism's genotype by inserting genes from another organism into its DNA."[106] The resultant product, as in StarLink™ corn, is known technically as transgenic organisms,[107] or in general parlance, as genetically modified organisms or (GMOs).[108] A GMO 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."[109]

The European Community and similar international official documents, such as the Food and Agriculture Organization of the United Nations, routinely use the phrase genetically modified organisms (GMOs) to describe transgenic plant organisms that are products of intra and trans-species genes transfer.[110] However, the term has been described as no more than 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" allegedly bent on undermining transgenic plant agriculture and stifling its

105 *See* Madhuri Kota, Henry Daniell, Sam Varma, Stephen F. Garczynski, Fred Gould & William J. Major, *Over Expression of the Bacillus Thuringiensis (Bt) Cry2Aa2 Protein in Chloroplasts Confers Resistance to Plants Against Susceptible and Bt-resistant Insects*, 96 PROC. NAT'L ACAD. SCI. 1840, 1840-45 (1999).

106 CHRIS PRESCOTT, OXFORD SCIENCE STUDY DICTIONARY 101 (1999).

107 *See* Ronald J. Herring, *Epistemic Brokerage in the Bio-property Narrative: Contributions to Explaining Opposition to Transgenic Technologies in Agriculture*, 27 NEW BIOTECHNOLOGY 614, 614-22 (2010) (expressing preference for transgenic technology for its neutrality in describing products of Recombinant DNA technologies, rather than GMOs, which is a "political terminology").

108 The term GMOs is used by Article 2(2) of 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. *See* Council Directive 2001/18/EC, art. 2(2), 2001 O.J. (L 106) 1, 4.

109 *See id.*

110 *See id.*; *see also* Food and Agriculture Organization of the United Nations, *Weighing the GMO Arguments*, FAONEWSROOM (Mar. 2003), http://www.fao.org/english/newsroom/focus/2003/gmo8.htm.

concomitant promise and potential contribution to human development.[111] For instance, while affirming preference for the term "transgenic organisms," due to its supposedly neutral and apolitical connotations,[112] Ronald J. Herring decried what he considered as negative, inflammatory, or discriminatory political connotations inherent in the use of the terms "genetically modified organisms" or "GMOs":

> 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.[113]

In this article, the term "transgenic" plant agriculture is preferred to "genetically modified organism" or "GMOs," precisely in order to transcend the alleged political and negative connotations attributed to these terms, and the increasingly deeply partisan nature of the debates that have come to characterize recent scholarship on the legal, ethical, and scientific proprieties of the use of recombinant rDNA technology in plant agriculture.[114] Indeed, as Ronald J. Herring rightly noted, genetic engineering is widely used and unquestioningly accepted in medicine, pharmaceuticals, and numerous industrial applications,[115] and it remains the arrowhead of modern biotechnology, which the Cartagena Protocol on Biosafety defines as the application of:

> [i]n vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells, or [. . .] [f]usion of cells beyond the taxonomic family, that overcome natural physiological reproductive or

111 One of the prominent critics of opponents of transgenic plant agriculture is Ronald J. Herring, a resolute believer in the promise and potentials of transgenic plant agriculture to eradicate hunger in poor and developing countries, who strongly believes that anti-transgenic plant agriculture activists are undermining the technology and its potentials by disseminating exaggerative and inflammatory knowledge, which invoke negative connotations. For discussion, see Herring, *supra* note 107, at 614-15.

112 *See id.* at 614-15, 618.

113 *Id.* at 614-15.

114 *See id*.

115 *See id*.

recombination barriers and that are not techniques used in traditional breeding and selection.[116]

In the same vein, a 1984 definition by the United States Congressional Office of Technology conceptualises 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 microorganisms for specific uses."[117]

Historically, modern biotechnology, as opposed to traditional biotechnology,[118] dates from the mid-1970's and involves the use of genetic engineering techniques[119] to shuffle or transfer genes between and among plant and animal species, with the aim of passing on certain desirable hereditary traits to the host plants or animals.[120] In plant agriculture, for example, such hereditable desirable traits range from delayed fruits-ripening,[121] drought

116 Cartagena Protocol on Biosafety to the Convention on Biological Diversity art. 3(i), Jan. 29, 2000, 2226 U.N.T.S. 208. The Protocol was made pursuant to Articles 8(g), 17, and 19, paragraphs 3 and 4, of the 1992 Rio Convention on Biological Diversity. *See* Convention on Biological Diversity arts. 8(g), 17, 19, June 9, 1992, 1760 U.N.T.S. 79.

117 *See* CONGRESSIONAL OFFICE OF TECHNOLOGY ASSESSMENT, COMMERCIAL BIOTECHNOLOGY: AN INTERNATIONAL ANALYSIS 3 (1984).

118 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* REISS & STRAUGHAN, *supra* note 14, at 2-5. For example, traditional plants breeding dates from over 10,000 years ago, and precipitated the evolution of thousands of land races in several plants species. Land races have been defined as "genetically variable populations that exhibit different responses to pests, diseases, and fluctuations in environmental conditions." Genetic diversity in land races, which emanated from the complex interactions between artificial selection, natural selection, and plants cultivation outside of their centre of origin, was to become the very foundation of modern agriculture. *See* KLOPPENBURG, *supra* note 15, at 46. *See* STEPHEN NOTTINGHAM, EAT YOUR GENES, HOW GENETICALLY MODIFIED FOOD IS ENTERING OUR DIET 10-26 (2d ed. 2003); *see also* CARY FOWLER, UNNATURAL SELECTION: TECHNOLOGY, POLITICS, AND PLANT EVOLUTION 3 (1994).

119 *See* REISS & STRAUGHAN, *supra* note 14, at 2.

120 *See* NOTTINGHAM, *supra* note 118, at 10-26.

121 In 1994, the United States Food and Drug Administration approved the first transgenic plant food, which was a transgenic tomato with the trade name of "Flavr Savr." The DNA sequence of the key gene: the polygalacturonase enzyme, which is 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. For discussion, see Krimsky & Murphy, *supra* note 53, at 81.

tolerance,[122] to pest and herbicide resistance properties.[123] 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, used restriction enzymes,[124] to successfully splice "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."[125] The feat earned the duo a U.S. patent in 1980 and precipitated a genetic engineering revolution and patent gold rush, as industry and university laboratories became embroiled in the highly competitive and lucrative race to discover and shuffle useful and desirable hereditable genetic information between higher and lower organisms into microbes and vice versa.[126] Indeed, 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 (FDA) gave approval for the use of human insulin, produced by a genetically modified bacterium.[127] This was swiftly followed by genetically engineered animals, such as Dolly the sheep,[128] and genetically engineered agricultural crops, such as Bt maize, soybeans, and canola, which,

122 *See* PAARLBERG, *supra* note 31, at 149-77 (discussing the usefulness of drought-tolerant transgenic plant crops especially in Africa).

123 Examples of pest-resistant transgenic food crops include Bt. maize, Bt. soybeans, and Bt. canola, all of which had nucleic acid proteins from Bacillus thuringiensis, a bacterium that is naturally toxic to pests, grafted into their genome. *See* Taiwo A Oriola, *Consumer Dilemmas: The Right to Know, Safety, Ethics, and Policy of Genetically Modified Food*, 2002 SING. J. LEGAL STUD. 514, 516 (2002).

124 Restriction enzymes are culled from bacteria and are used by bacteria as a natural defence mechanism against invading viruses. Scientists employ restriction enzymes as "molecular scissors" to cut out DNA strands with accuracy and precision. *See* Wei, *supra* note 86, at 28.

125 KLOPPENBURG, *supra* note 15, at 193-94.

126 *See id.*

127 *See* PAARLBERG, *supra* note 31, at 10-11.

128 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. For discussion, see I. Wilmut, A. E. Schnieke, J. McWhir, A. J. Kind & K. H. S. Campbell, *Viable Offspring Derived from Fetal and Adult Mammalian Cells*, 385 NATURE 810, 810–13 (1997).

first debuted commercially in 1996 in North America, Argentina, and Europe.[129]

Perhaps the most significant difference between traditional plant breeding technique and plant genetic engineering technique is the latter's capability for trans-species genes transfer, a feat that is patently beyond conventional plant breeding technique.[130] Thus, due mainly to its inherent capability to breach "the walls of speciation," plant genetic engineering breeding technique surpasses, and is qualitatively superior to conventional plant breeding methodology, which is inherently limited by sexual compatibility constraints.[131] This superiority is two-dimensional. First, genetic engineering operates at the cellular and molecular levels.[132] Second, genetic engineering technique dispenses with sexual reproduction and allows for the transfer of genes between totally unrelated organisms.[133] A typical example of trans-species gene transfer is the transgenic Bt maize, which was genetically modified to carry genes from Bacillus thuringiensis bacterium, in order to avoid the use of "synthetic pesticides for the control of certain caterpillars."[134]

Thus, in the context of transgenic plant agricultural technology, the underlying science covers not only the production process for the technology in accordance with the technique pioneered by Cohen and Bayer or any of its modern variants,[135] but

129 *See* PAARLBERG, *supra* note 31, at 12; *see also* KLOPPENBURG, *supra* note 15, at 296.

130 Norman W. Thorson, *International Trade in Genetically Altered Agricultural Products: Impact of the Biosafety Protocol*, *in* AGRICULTURE AND INTERNATIONAL TRADE LAW, POLICY AND THE WTO 239, 240 (Michael N. Cardwell, Margret R. Crossman & Christopher P. Rogers eds., 2003).

131 *See* KLOPPENBURG, *supra* note 15, at 2-3, 192.

132 *Id.* at 3.

133 *Id.*

134 *Id.* at 315.

135 *See id.* at 193-94. In plant genetic engineering, for example, at least two different methods are used to transfer DNA into plants. Alan McHughen, *Learning from Mistakes: Missteps in Public Acceptance Issues with GMOs*, *in* WHAT CAN NANOTECHNOLOGY LEARN FROM BIOTECHNOLOGY: SOCIAL AND ETHICAL LESSONS FOR NANOSCIENCE FROM THE DEBATE OVER AGRIFOOD BIOTECHNOLOGY AND GMOS 38 (Kenneth David & Paul B. Thompson eds., 2008). The first is a biological method that uses a bacterium known as *Agrobacterium tumefaciens* as a naturally occurring genetic engineering agent. *Id.* The second possible method comprises "a purely physical

includes the safety science governing the use of the technology to protect public health and the environment, which ranges from allergen and toxin reduction to combating in situ gene flow between transgenic and non-transgenic plants in the wild.[136] In other words, the underlying science of transgenic plant agricultural technology would range from understanding plant recombinant deoxyribonucleic acid (rDNA); the technique of gene transfer from a donor plant or micro-organism to the cell or genome of a host plant;[137] to safety issues, such as the management of transgenic plant food allergens and toxins, as well as the stemming of gene flow between transgenic and non-transgenic plants. A fortiori, the science of transgenic plant agricultural technology is divisible into two broad categories: the scientific knowledge that underpins the production process for transgenic plant crops and that which underpins environmental and public health safety. The following section, will consider the theoretical and conceptual distinctions between science and technology. Then, the Article will further explore the interactive dynamics between the science and technology of transgenic plant agriculture, focusing on how the former ultimately impacts the regulatory and policy framework of the latter.

B. Theorising Science and Technology: A Separate, Separable, and Symbiotic Relationship

Deconstructing the interactive dynamic between "science" and its resultant "technology" is imperative to unraveling how the underlying science of a technology ultimately informs the regulatory and policy framework for that technology. Thus, in order to understand how the current governance systems for transgenic plant technology work, it is imperative to examine the nature of its underlying science, which is far from settled and often contested by scientists working in the field.[138] Even so, the

method" involving "biolistic or particle acceleration." *Id.*

136 *See* Carol Mallory-Smith & Maria Zapiola, *Gene Flow from Glyphosate-Resistant Crops*, 64 PEST MGMT. SCI. 428, 428 (2008) (discussing how one of the challenges posed by transgenic plant agriculture to the environment is in preventing adventitious commingling of genes between transgenic and non-transgenic plant in the wild).

137 *See* KLOPPENBURG, *supra* note 15, at 193-94.

138 *See infra* Sec. II, pt. c (providing an analysis on the contested science of

underlying science of transgenic plant technology continues to trump possible non-scientific governance systems that include ethical or cultural imperatives, as exemplified by *Alliance for Bio-integrity v. Donna Shalala*[139] and the *Commission of the European Communities v. Republic of Poland*.[140] Thus, within the general context of the discourse on science and technology scholarship, this section seeks to highlight how the interactive dynamics of the relationship between the science and technology of transgenic plant ultimately informs the governance systems for the technology.

Arguably, the relationship between science and technology is at once separate, separable, and symbiotic. The symbiotic element of the relationship is implicit in their definitions. "Science" simultaneously connotes knowledge and the pursuit of knowledge in a way that is "systematic and formulated" and is often used synonymously with "natural and physical science."[141] Thus, scientific theories are markedly different from ethical, theological or metaphysical claims because they are subject to controlled tests, experiments, and observation.[142] However, in contradistinction, "technology" is defined as "the application of scientific knowledge for practical purposes."[143] Therefore, science would appear to embody the knowledge that ultimately finds practical expression in technology. But then, technology historians have always opined that technology transcends science "ontologically and epistemologically" and that technology "is not merely applied science."[144] Even so, the distinction between science and

transgenic plant technology).

139 *See* Alliance for Bio-Integrity v. Donna Shalala, 116 F. Supp. 2d 166 (D. D.C. 2000) (granting deference to an agency policy that merely stated that genetically engineered foods were presumptively not harmful, thereby denying any impingement on plaintiff coalition's rights).

140 *See Poland*, *supra* note 72, at 220/10 (rejecting national legislation which prohibited the marketing of genetically modified seed varieties).

141 THE OXFORD DICTIONARY AND THESAURUS 746 (American ed. 1996). Natural sciences is defined as "sciences used in the study of the physical world." *Id.* at 550. Physical science is defined as "sciences used in the study of inanimate natural objects." *Id.* at 621.

142 *See* PAPINEAU, *supra* note 71, at 98.

143 The Oxford Dictionary and Thesaurus, *supra* note 34, at 860 ("Study or use of the mechanical arts and applied sciences.").

144 Thomas J. Misa, *History of Technology*, *in* A COMPANION TO THE PHILOSOPHY

technology often is not clear-cut, and overlap conceptually and symbiotically, as demonstrated by the following definition of "technology" by the United Nations Conference on Trade and Development (UNCTAD): "[t]echnology is bought and sold as capital goods including machinery and productive systems, human labour usually skilled manpower, management and specialised scientists. Information of both technical and commercial character, including that which is readily available, and that subject to proprietary rights and restrictions."[145]

Indeed, modern conception of technology now routinely uses "technology interchangeably with know-how," especially in the context of technology transfer discourse.[146] This is again exemplified by the term "techno-science," a hybrid concept embodying science and technology, which is favored by contemporary science and technology scholars.[147] Perhaps these scholars, such as Bruno Latour, who coined the concept "technoscience," were persuaded by the ostensible symbiotic relationship and overlapping concepts of science and technology,[148] which is aptly framed by Martin Heidegger as follows:

> It is said that modern technology is something incomparably different from all earlier technologies because it is based on modern physics as an exact science. Meanwhile we have come to understand more clearly that the reverse holds true as well: [m]odern physics, as experimental, is dependent upon technical apparatus and upon progress in the building of apparatus.[149]

Thus, while technology may have historically predated modern science historically,[150] modern science, such as physics and

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OF TECHNOLOGY, *supra* note 12, at 7.

145 Richard Li-Hua, *Definitions of Technology*, *in* A COMPANION TO THE PHILOSOPHY OF TECHNOLOGY, *supra* note 12, at 19.

146 *Id.*

147 *See* Don Ihde, *Technology and Science*, *in* A COMPANION TO THE PHILOSOPHY OF TECHNOLOGY, *supra* note 12, at 51.

148 *See* Kristian Hvidtfelt Nielsen, *We Have Never Been Scientists*, 67 ANNALS OF SCI. 561, 561 (2010), *available at* http://www.tandfonline.com/doi/pdf/10.1080/00033790902788055.

149 HEIDEGGER, *supra* note 18, at 14.

150 *See* DON IHDE, *Technology and Science*, *in* A COMPANION TO THE PHILOSOPHY OF TECHNOLOGY, *supra* note 12, at 52 (noting that Homo sapiens, or our pre-modern

genetics, are said to be "instrumentally embodied" or technologically dependent.[151] For example, in the field of biotechnology, geneticists are heavily reliant on "interventional" microscopic instrumentations for key experiments such as "gene splicing,"[152] without which it would be impossible to create transgenic organisms, such as the Chakrabarty bacterium[153] or transgenic crops, such as Bt. maize.[154] However, while the relationship between science and technology may be symbiotic and interdependent, the two concepts are arguably notionally and theoretically separable. Thus, within the specific context of transgenic plant agricultural technology for example, the underlying science would be the knowledge of plant rDNA techniques used in transference, recombination, or modification of genes, while the technology would be the resultant transgenic crops that are born out of the application of the knowledge of plant rDNA techniques.[155]

Significantly, the underlying knowledge or science of technology also informs best practices for optimal functionality and safety, which is typically built into the technology with accompanying operational manuals (*i.e.* washing machines) or prescription medications that include instructions for prescribed doses, drug interactions, and general usage.[156] Even then, despite rigorous pre-market trials for new medicine, safety is not always guaranteed, as exemplified by the Thalidomide fiasco[157] and the

ancestors, are believed to have used various technologies for more than a million years prior to the advent of modern humans).

151 *Id.*

152 *Id.* at 53.

153 *See* Chakrabarty, *supra* note 59, at 305 (noting the significant value of this genetically engineered bacterium because of its capability of breaking down components of crude oil).

154 *See* KLOPPENBURG, *supra* note 15, at 193-94 (providing a brief overview on biotechnology and how genetic engineers routinely transfer genes from one organism into another organism).

155 *See id.* It is important to note that "science" and "knowledge" are used synonymously and interchangeably in this context.

156 *See* SALLY ROBINSON, ET AL., EMERGING SAFETY MEASURES: WORKSHOP SUMMARY 1 (2008) (exploring the application of innovative technologies to the assessment of drug safety), *available at* http://www.nap.edu/openbook.php?record_id=11975.

157 In the early 1960s, pregnant women who took the Thalidomide drug to combat

post-market withdrawal of ten new pharmaceutical drug products between 2000 and 2006 by the FDA on safety concerns.[158]

Thus, as with pharmaceuticals, transgenic plant agricultural technology products also have inbuilt safety science systems and accompanying operational manuals on its manufacturing process, cultivation, handling, and transportation in order to safeguard public health and obviate in situ adventitious commingling with non-transgenic crops in the wild.[159] With regards to safety science, for example, transgenic food crops are deemed to be substantially equivalent to, and no different from, non-transgenic food crops.[160] According to the FDA policy statement on the substantial equivalence doctrine, the methods of genetic engineering technique in plant agriculture are "extensions at the molecular level" of traditional plant breeding and should therefore be regulated in an equivalent manner.[161] The hotly contested substantial equivalence doctrine[162] is ostensibly premised on the assumption that the science underpinning the transfer of rDNA between plant and non-plant species, and the production process of transgenic crops, is no different from traditional or conventional

morning sickness gave birth to physically deformed children. Frederick Dove, *What's happened to the Thalidomide babies?* BBC WORLD SERVICE (Nov. 3, 2011), http://www.bbc.co.uk/news/magazine-15536544 (reporting on the physically deformed children that were born to pregnant women in the early 1960's as a result of taking the Thalidomide drug to combat morning sickness).

158 ROBINSON ET. AL., *supra* note 156, at 1.

159 *See* Field Testing of Plants Engineered to Produce Pharmaceutical and Industrial Compounds, 68 Fed. Reg. 11337, 11337-40 (proposed Mar. 10, 2003) (to be codified at 7 C.F.R. pt. 340).

160 In the United States, the federal government regulates "biotechnology products," including transgenic crops and foods, through a policy guidance known as the Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23302 (June 26, 1986). The policy was announced by the President's Office of Science and Technology in 1986, and was subsequently amended in 1992. Michael Baram, *Governance of GM Crop and Food Safety in the United States, in* GOVERNING RISK IN GM AGRICULTURE 15, 26 (Michael Baram & Mathilde Bourrier eds, 2011). Crucially, one of the policy assumptions in the Coordinated Framework is the principle of substantial equivalence, which posits that transgenic crops and products "should be subject to no greater degree of oversight than was a comparable organism or product previously used in a past safe introduction in a comparable target environment." *Id.* at 28.

161 Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22987 (May 29, 1992).

162 *See infra* Part III.

plant breeding techniques.[163] Thus, arguably, the "substantial equivalence" doctrine seeks to give safety assurances regarding the science underpinning transgenic crops cultivation and consumption respectively for the environment and public health.[164] This again raises the question: How reliable, objective, or certain is this science, which largely informs regulatory and policy framework for transgenic plant technology? The following section will assay an answer by exploring the contentious scientific opinions on the safety science of transgenic plant technology with respect to public health and the environment. It will also consider how the underlying contested science has informed and continues to shape the differing regulatory and policy regimes in the United States and the European Union.

C. Transgenic Plant Agriculture: Contested Science, Contested Technology

Transgenic plant agricultural technology is one of the most hotly contested of contemporary technologies. Disagreements amongst scientists are rife, typically polemical, and often acrimonious, with opposing sides entrenched in their views.[165]

163 *See* Paul R. Billings & Peter Shorett, *Coping with Uncertainty: The Human Health Implications of GE Foods*, *in* GENETICALLY ENGINEERED CROPS: INTERIM POLICIES, UNCERTAIN LEGISLATION 75, 75-79 (Iain E. P. Taylor ed., 2007) (noting how the "substantial equivalence" doctrine was used to justify the launching of transgenic foods into the market without long-term nutritional and toxicological testing on animals).

164 With regards to pre-empting adventitious commingling of transgenic and non-transgenic crops for example, regulators had to draw on the science underpinning plant pollination and reproduction processes. For example, the United States Department of Agriculture policy guidelines on on-farm separation distances between transgenic crops fields and non-transgenic crops and plants, is ostensibly premised on scientific knowledge on plants' sexual reproduction systems and the behaviour of the pollinating agencies of natural reproduction systems such as butterflies, birds, winds, etc. Field Testing of Plants Engineered to Produce Pharmaceutical and Industrial Compounds, *supra* note 159, at 11337-40. For example, the amended United States Department of Agriculture's guidelines on experimental field testing for transgenic pharmaceutical corn crop, inter alia requires that the size of the perimeter fallow zone around a trial field must be fifty feet and that no corn should be grown within one mile (5,280 feet) of the trial field throughout the duration of any field test, which involves open-pollinated corn. *See id.*

165 *See* Herring, *supra* note 23, at 2 (noting that some scientists are deeply troubled by transgenic plant agriculture, due to "specifiable 'known unknowns' – horizontal gene flow, allegenicity from novel proteins – and almost certainly unknown unknowns' as well").

Indeed, a cursory look at the literature since the 1996 commercial debut of transgenic crops[166] reveals a dramatic and eclectic mix of titles that are symptomatic of the charged and polemical discourse on environmental and public health risks posed by transgenic plant crops: *Seeds of Destruction: The Hidden Agenda of Genetic Manipulation*;[167] *Genetic Roulette: The Documented Health Risks of Genetically Engineered Foods*;[168] *Seeds of Contention: World Hunger and the Global Controversy over GM Crops*;[169] *Seeds of Deception: Exposing Corporate and Government Lies about the Safety of Genetically Engineered Food*;[170] *Genetically Modified Food: A Short Guide for the Confused*;[171] *GMO Free: Exposing the Hazards of Biotechnology to Ensure the Integrity of Our Food Supply*;[172] and *Genes, Trade, and Regulation: The Seeds of Conflict in Food Biotechnology*.[173] Notably, the palpable polemics, contestations, tensions, and dissents inherent in the literature, are generally reflective of the opinions in wider society.[174]

Even academic researchers and scientists, who are routinely caught up in the transgenic plant agriculture polemics, are neither above the fray nor immune from the typically partisan and stifling

166 *See* PAARLBERG, *supra* note 31, at 10-11 (noting that genetically engineered crops was first accomplished in a laboratory in 1973 and soon thereafter found "commercial applications in medicine"); *see also* KLOPPENBURG, *supra* note 15, at 296.

167 *See* ENGDAHL, *supra* note 79, at 341.

168 *See* JEFFREY M. SMITH, GENETIC ROULETTE: THE DOCUMENTED HEALTH RISKS OF GENETICALLY ENGINEERED FOODS 319 (2007).

169 *See* PINSTRUP-ANDERSEN & SCHIØLER, *supra* note 10, at 164.

170 *See* JEFFREY M. SMITH, SEEDS OF DECEPTION: EXPOSING CORPORATE AND GOVERNMENT LIES ABOUT THE SAFETY OF GENETICALLY ENGINEERED FOOD 254 (2004).

171 *See* ANDY REES, GENETICALLY MODIFIED FOOD: A SHORT GUIDE FOR THE CONFUSED 248 (2006).

172 *See* HO, *supra* note 35, at 133.

173 *See* THOMAS BERNAUER, GENES, TRADE, AND REGULATION: THE SEEDS OF CONFLICT IN FOOD BIOTECHNOLOGY 229 (Princeton Univ. Press ed., 2003).

174 Quite apart from the open hostility and resistance to transgenic plant agriculture and foods in Europe, there are pockets of resistance even in the United States as exemplified by the aborted transgenic plant food labelling law in the State of Oregon in 2003, and the failed judicial challenge to the governance systems for transgenic plant agriculture and foods. Alliance for Bio-Integrity v. Donna Shalala, 116 F. Supp. 2d 166 (D. D.C. 2000); *see also* PAARLBERG, *supra* note 31, at 17-23 (discussing how ninety-four percent of Americans polled in a 2003 survey showed preference for labelling of transgenic plant food products).

discourse. This is because unfavourable research outputs perceived as "bad science" could effectively truncate a burgeoning or promising academic career,[175] or be retracted dramatically by editors or publishers,[176] or be rebutted vigorously by opponents.[177] Also, there are abiding suspicions that research results are routinely skewed in favor of the funding industry or agency;[178] research institutes have had their experimental transgenic plant fields picketed, threatened and trashed,[179] and transgenic crops scientists have succumbed to pressure to terminate open field

175 For example, Dr. Arpad Pusztai controversially lost his job due to an alleged "premature release of flawed research data on the toxicity of GM potatoes," while Ignacio Chapela of the University of California, Berkeley, allegedly forfeited his tenure for "publishing a faulty paper on Bt maize." S. Shantharam, S. B. Sullia & G. Shivakumara Swamy, *Peer Review Contestations in the Era of Transgenic Crops*, 95 CURRENT SCIENCE 167, 168 (2008).

176 *Id.*

177 In 1999, for example, a report demonstrated that nearly half of the monarch butterfly caterpillars that ate leaves dusted with transgenic Bt Maize pollen died within 4 days. John E. Losey, Linda S. Rayor, & Maureen E. Carter, *Transgenic Pollen Harms Monarch Larvae*, 399 NATURE 214 (1999). The highly controversial report prompted further research funded by industry and government, and by 2001, six papers were published, which effectively neutered the 1999 report 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. *See id.; see also* "Bt or not Bt: Is that the question?" 98 PROC. NAT'L ACAD. SCI. 12328, 12328-30 (2001).

178 For example, the strong pro-transgenic crops stance of The Royal Society of the United Kingdom (founded in 1660 and thus the world's oldest scientific organisation) has been attributed to the alleged millions of pounds in funding from major agricultural biotechnology companies. The organisation's strong support for transgenic agriculture is reputedly exemplified by numerous pro-transgenic crops publications, and particularly the attacks on the unfavourable research outputs of Dr. Arpad Pusztai on the deleterious effects of transgenic potatoes on rats. *See* REES, *supr*a note 171, at 43-44. 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. *See* BILLINGS & SHORETT, *Coping with Uncertainty: The Human Health Implications of GE Foods*, in GENETICALLY ENGINEERED CROPS: INTERIM POLICIES, UNCERTAIN LEGISLATION, *supra* note 163, at 75.

179 *See* Clive Cookson, *Food Battle Looms on Hertfordshire Fields*, FINANCIAL TIMES (May 25, 2012), http://www.ft.com/intl/cms/s/0/e69684d2-9cf1-11e1-9327-00144feabdc0.html#axzz2gH6MTrjF (describing how anti-transgenic crops activists planned "mass action against genetically modified wheat" at Hertfordshire, where scientists were experimenting genetically engineered wheat plants that could resist aphid pests).

trials of promising transgenic crops.[180]

Indeed, contemporary scientific research into transgenic plant agriculture is so perilous that no active participant could be guaranteed "a quiet life."[181] 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*,[182] which opined that the potential unintended molecular effects and implications of inserting novel genes into plant cells were not given sufficient attention.[183] David Schubert later reflected that "[p]eople who look into safety issues and pollination and contamination issues get seriously harassed."[184] In a related development, an attempt was made to suppress the publication of Bruce Tabashnik's 2008 paper, which addressed how the evolution of insect resistance threatened the success of transgenic crops producing Bacillus thuringiensis toxins designed to combat traditional pests, such as the European corn borer.[185] Prior to the publication of the paper, Bruce Tabashnik had received an email from William Moar, an entomologist at Auburn University, warning that the paper would give anti-transgenic crops brigade the ammunition to attack the technology.[186] However, following the publication of Tabashnik's paper in *Nature Biotechnology Journal* in February 2008, William Moar, criticized the paper at conferences[187] and in a swift rejoinder in *Nature Biotechnology*

180 *See* Quirin Schiermeier, *German Universities Bow to Public Pressure Over GM Crops*, 453 NATURE 263, 263 (2008) (discussing how two German universities pulled the plug on field trials of transgenic maize crops due to aggressive picketing and threats from anti-transgenic agriculture activists, who had the full support of the local population).

181 Emily Waltz, *GM Crops: Battlefield: Papers Suggesting that Biotech Crops Might Harm the Environment Attract a Hail of Abuse From Other Scientists*, 461 NATURE 27, 27 (Sept. 3, 2009).

182 *See* David Schubert, *A Different Perspective on GM Food*, 20 NATURE BIOTECHNOLOGY 969, 969 (2002).

183 *Id.*

184 Waltz, *supra* note 181, at 28.

185 *See* Bruce E. Tabashnik, Aaron G. Gasmann, David W. Crowder & Yves Carriere, *Insect Resistance to Bt Crops: Evidence Versus Theory*, 26 NATURE BIOTECHNOLOGY 199 (2008).

186 *See* Waltz, *supra* note 181, at 30.

187 *Id.* William Moar has since swapped academia for the laboratory of Monsanto, a transgenic Bacillus thuringiensis crops manufacturer based in St. Louis, Missouri,

Journal,[188] challenged the methodology, validity, accuracy, and reliability of Tabashnik's paper. Moar claimed 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.[189] However, in his response to Moar's rejoinder, Tabashnik contended that the "rigorous analysis in our paper was based on systematic, objective analysis of all of the relevant data."[190]

Whilst constructive criticisms of scientific research are an integral and validating feature of the peer-review system, the scathing criticisms against research perceived as unfavourable, often bordered on personal attacks, as exemplified by the hostile reception and subsequent rebuttals to Rosi-Marshall's paper on the negative effects of transgenic Bacillus thuringiensis maize on caddis-fly larvae and the ecosystems.[191] The Rosi-Marshall's paper was critically panned by fellow scientists who branded her two-year research as "bad science,"[192] with accompanying, albeit unfounded, insinuations of scientific misconduct.[193] 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 maize designed to express insecticidal toxins from Bacillus thuringiensis, was extensively cultivated.[194] Rosi-Marshall et al. then discovered that the twelve streams under study were strewn with leaves, pollen, stalks, and cobs from transgenic Bacillus thuringiensis maize.[195] In subsequent laboratory studies, the researchers found that caddis-fly larvae (herbivorous stream insects), which "fed only on Bt maize debris[,] grew half as fast as those that ate debris

USA.

188 William Moar et al., *Field-evolved Resistance to Bt Toxins*, 26 NATURE BIOTECHNOLOGY, 1072, 1072-74 (2008).

189 *Id*. at 1072.

190 *See* Waltz, *supra* note 181, at 30.

191 *See* E.J. Rosi-Marshall et al., *Toxins in Transgenic Crop By-products May Affect Headwater Stream Ecosystems*, 104 PROC. NAT'L ACAD. SCI. 16204, 16204-08 (2007).

192 *See* Waltz, *supra* note 181, at 28.

193 *Id*. at 28-29.

194 *See id.* at 27.

195 *See id.*

from conventional maize."[196] Furthermore, caddis flies that were "fed high concentrations of Bt maize pollen died at more than twice the rate of caddis flies fed non-Bt pollen."[197] Rosi-Marshall et al. then concluded 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."[198]

Even though the Rosi-Marshall et al. paper was not the first to study the possible deleterious effects of transgenic Bt. crops on the environment and the ecosystems,[199] the ensuing negative rejoinders and hostile rebuttals in six 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 agriculture academics and researchers, was simultaneously predictable, hostile, and ad hominem.[200] 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 job."[201] Also, the piece was branded as "an idiotic experiment,"[202] whilst its conclusions were described as "dubious" and "arguably amount[ing] to investigator misconduct."[203] In the *Journal of Current Science*, the Rosi-Marshall paper was described as "offen[sive]" and liable to be used by anti-transgenic plant agriculture activists to "hamper the progress of science."[204]

But then, these hostile responses were predictable and

196 *Id.*

197 *Id.; see also* E.J. Rosi-Marshall et al., *supra* note 191, at 16204-08.

198 *See* E.J. Rosi-Marshall, et al., *supra* note 191, at 16204.

199 There are numerous previous studies on the possible negative effects of transgenic crops on the environment, which include the 1999 German publication, 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. *See* Frank Gebhard & Kornelia Smalla, *Monitoring Field Releases of Genetically Modified Sugar Beets for Persistence of Transgenic Plant DNA and Horizontal Gene Transfer*, 28 FEMS MICROBIOLOGY ECOLOGY 261, 261- 72 (1999).

200 *See* Waltz, *supra* note 181, at 27.

201 *Id*. at 28.

202 *Id.* at 32.

203 *Id.* at 28-29.

204 *See* Shantharam et al., *supra* note 175, at 168.

characteristic of the increasingly negative tactics by pro-transgenic plant agriculture scientists and researchers, self-proclaiming experts who would "forcefully present themselves as the ultimate arbiters of truth."[205] The modus operandi of the characteristically hostile rebuttals against research perceived as unfavourable to transgenic plant agriculture is aptly summed up by Emily Waltz as follows:

> No one gets into research on genetically modified (GM) crops looking for a quiet life . . . . But those who, like Rosi-Marshal 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.[206]

Further, the increasingly acrimonious attacks by pro-transgenic plant scientists and researchers elicited the following reflection and response from an editor of Entomological Society of America:

> I personally am in favour of GMOs in general, and think that they are very beneficial for the environment. But I do have problems with the tactics of the large block of scientists who denigrate research by other legitimate scientists in a knee-jerk, partisan, emotional way that is not helpful in advancing knowledge and is outside the ideals of scientific inquiry.[207]

However, it has been noted that pre-emptive attacks against unfavorable transgenic plant scientific research outputs with perceived flaws are designed to neuter any possible influence on policy makers.[208] The motive and ultimate goal underlying the strategic attacks is succinctly framed by Emily Waltz as follows: "[w]hen a paper comes out in which they see problems, they react quickly, criticize the work in public forums, write rebuttals letters, and send them to policy-makers, funding agencies and journal editors."[209] The strategy was however justified by Brian Federici,

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205 *See* Waltz, *supra* note 181, at 31 (citing an "editor for the Entomological Society of America who asked to remain anonymous").

206 *Id.* at 27.

207 *Id*. at 31.

208 *See id.* at 27-28.

209 *Id.* at 27.

an insect pathologist at the University of California, Riverside, on grounds that "bad science deserves more criticism than your typical peer-reviewed paper."[210] But then this raises a pertinent question: whose prerogative is it to adjudge a peer-reviewed paper "as bad science"? The Rosi-Marshall paper and similar others certainly show a tendency for scientists to characterise unfavourable research outputs as "bad science." However, this is a needless attack, because a patently bad transgenic plant research paper would become apparent in due course to the entire scientific community, whether or not the research favours transgenic plant agriculture. After all, numerous biomedical and life-science research articles have been retracted over the past decades on grounds such as error, plagiarism, fraud, and suspected fraud.[211] This seemingly would imply that a patently bad transgenic plant research paper, irrespective of its take on transgenic plant technology, could hardly survive long-term scrutiny of the entire scientific community. Therefore, the characteristically partisan and hostile rebuttals of unfavourable transgenic plant research papers is hardly warranted, and would only serve to aggravate the deepening divide between scientists and stifle beneficial scholarship on transgenic plant agriculture.

However, despite the efforts by pro-transgenic plant agriculture scholars to discredit the Rosi-Marshall paper in the eyes of regulatory authorities, it nevertheless gained traction and influenced policy makers in Europe. This was especially the case 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 used as justification for banning the cultivation of Monsanto's Bt. maize (MON810) in France in January 2008.[212] Within the context of the significance of regulatory science, the French government's reliance on the Rosi-Marshall paper arguably underscores the visceral hold of "science" over the policy framework for transgenic plant agricultural technology governance, and the dramatic transformation of

210 *Id.* at 27.

211 Fang et al., *supra* note 42, at 1702 (discussing how a comprehensive search in May 2012 of the PubMed database revealed a total of 2,047 biomedical and life-science research articles retracted on grounds that ranged from error to misconduct).

212 Waltz, *supra* note 181, at 32.

"science" into an unwitting battleground for the attention of regulatory authorities across the world. Most significantly, the differing scientific opinions on the proprieties of transgenic plant agriculture and food respectively for the environment and public health inevitably translate into differing regulatory and policy frameworks for countries around the world.[213] Further, the Rosi-Marshall paper underscores the uncertainties that underpin the safety science of transgenic plant agriculture. Thus, the foregoing discourse aims to demonstrate how highly contentious and uncertain the "science" is behind the regulation and policy of transgenic plant agriculture, and how acrimonious the debates are about the proprieties of transgenic plant agriculture and food. Certainly, there is no denying the palpable sense of discord, and the emotional cacophonies that continue to characterize and define the scholarship and social discourse on the propriety of transgenic plant agricultural technology. The following section will further demonstrate how the uncertainty of the underlying "science" of transgenic plant agriculture continues to shape different regulatory regimes amongst countries.

III. The Limits of Regulatory Science in Transgenic Plant Agriculture Governance

This section will explore the uncertainties and divisions that have hindered the science of transgenic plant agriculture and fueled the debates on the proprieties of the technology, as well as the legitimacy of the current science-centric regulatory and policy framework. In particular, this section examines the propriety of the substantial equivalence doctrine, which is a science-based regulatory tool for transgenic plant agriculture governance, by using selected case studies that indicate scientific uncertainties and conflicting results. The primary aim is to demonstrate the limits of regulatory science in transgenic plant agriculture governance by highlighting the dynamics of the uncertainties inherent in its underlying science.

213 *See id.* (noting, for example, that despite the wide backlash against Rosi-Marshall's paper, the French government announced a ban on cultivated maize after France's watchdog on GM foods announced that "one of Monsanto's types of Bt maize, known as MON810, may have an impact on wildlife" and citing the Rosi-Marshall's paper as evidence for this assertion).

A. The Propriety of the Substantial Equivalence Doctrine for Transgenic Plant Agriculture Governance

The first bone of contention in the current regulatory and policy framework for transgenic plant agriculture governance is the substantial equivalence doctrine, which equates the science of transgenic plant agriculture and its resultant technology with that of conventional plant agriculture.[214] As previously noted,[215] the substantial equivalence doctrine, which is rooted in the 1992 U.S. FDA policy, posits that transgenic plant foods are similar in their chemical composition to conventional plant foods and are therefore "generally recognized as safe," as they "do not introduce unique health risks to consumers."[216] Thus, there is a tacit assumption that the genetic materials found 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."[217] The doctrine also posits that similarity between a transgenic food and its conventional counterpart could be demonstrated by testing their chemical composition,[218] and if this comparative study could not resolve safety concerns, then "feeding studies or other toxicological tests may be warranted."[219] The FDA has 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."[220]

The 1992 policy on substantial equivalence sprang from the 1986 policy of the Office of Science and Technology Policy on "coordinated framework for regulation of biotechnology,"[221] which resolved that no new legislation would be necessary for the

214 *See* Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22984, Part I (May 29, 1992).

215 *See* BILLINGS & SHORETT, *supra* note 163, at 75-79.

216 *See id.* at 78-79.

217 Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. at 22984-85.

218 *See id.* at 22987.

219 *Id.* at 23004.

220 *Id.; see also* Levidow, Murphy, & Carr, *supra* note 32, at 35.

221 Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23302, 23302-93 (June 26, 1986).

governance of transgenic plant agriculture and foods.[222] Thus, by extrapolation, in regulatory and governance terms, transgenic plant agriculture and resultant crops would not be treated any differently from conventional plant agriculture and crops, because the methods of genetic engineering technique in plant agriculture are deemed to be extensions at the molecular level of traditional plant breeding.[223] As noted earlier in this article, this is arguably the basis for the FDA's rejection of a labeling regime for transgenic plant foods in the United States,[224] even though some states, such as Oregon, and most Americans polled in a 2005 survey expressed their preference for the labeling of transgenic plant foods.[225] But, the United States government's official aversion for the labeling of transgenic plant foods is understandable, given that a labeling regime would tend to highlight the differences, if any, between transgenic and conventional plant agriculture and foods. This would inevitably undermine or negate the very essence of the substantial equivalence doctrine.[226]

Also, and most significantly, the substantial equivalence doctrine was given a fillip by its tacit international recognition and

222 *See id.* Part I, Sec. A.; *see also* Levidow, Murphy, & Carr, *supra* note 32, at 34.

223 *See* Coordinated Framework for Regulation of Biotechnology, 51 Fed. 23302-93 (June 26, 1996).

224 Obviously, labeling transgenic plant food products would run counter to, and possibly undermine the doctrine of substantial equivalence. For what would be the essence of labeling transgenic plant foods with a view to distinguishing them from conventional plant foods if transgenic plant foods were really the same as conventional plant foods? *See* Alliance for Bio-Integrity v. Donna Shalala, 116 F. Supp. 2d 166 (D. D.C. 2000) (upholding the non-labeling rule of the Food and Drug Administration as predicated upon on the substantial equivalence doctrine).

225 *See* PAARLBERG, *supra* note 31, at 22 ("In response to a Pew Initiative survey in 2005, half of a representative sample of Americans even said they would oppose the introduction of genetically modified foods into the U.S. food supply, with 33% saying they would oppose GM foods strongly (Pew Initiative 2005)."); *see also* Oriola, *supra* note 123, at 570-71 (discussing the use of a referendum to assess the majority's view on a labeling versus non-labeling policy by using the example of Oregon's aborted transgenic food labeling rule in 2002).

226 *See Alliance for Bio-integrity*, 116 F. Supp. at 166. The United States District Court for the District of Columbia observed the implications of labeling for transgenic plant foods, as follows: "Plaintiffs fail to understand the limitation on the FDA's power to consider consumer demand when making labeling decisions because they fail to recognize that the determination that a product differs materially from the type of product it purports to be is a factual predicate to the requirement of labeling." *Id.* at 179.

endorsement in a 1991 joint report by the Food and Agriculture Organization and the World Health Organization (FAO/WHO), 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.[227] Similarly in 1993, the Organization for Economic Co-operation 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."[228] The 1993 OECD report explicitly endorsed the substantial equivalence doctrine as follows:

> [I]f 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.[229]

Furthermore, in 1996, the FAO/WHO in a joint statement explicitly and unconditionally endorsed the substantial equivalence doctrine, and ostensibly drew on the doctrine to allay any concerns on possible negative effects of transgenic plant agriculture on the environment.[230] This support by cognate and

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227 WORLD HEALTH ORGANIZATION, STRATEGIES FOR ASSESSING THE SAFETY OF FOODS PRODUCED BY BIOTECHNOLOGY: REPORT OF A JOINT FAO/WHO CONSULTATION Sec. 6.3.1(2) (1991), *available at* http://www.who.int/foodsafety/publications/biotech/en/1990.pdf [hereinafter STRATEGIES]. 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." *Id.* at Sec. 7.1(6). The report also noted that such data were not widely available at the time of consultation and writing. *Id.*

228 ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT, SAFETY EVALUATION OF FOODS DERIVED BY MODERN BIOTECHNOLOGY: CONCEPTS AND PRINCIPLES 10 (1993).

229 *Id.* at 13.

230 Food and Agriculture Organization of the United Nations (FAO) & World Health Organization (WHO), *Joint FAO/WHO Expert Consulation on Biotechnology and Food Safety* (Sept. 30 to Oct. 4, 1996), ftp://ftp.fao.org/es/esn/food/biotechnology.pdf (last visited Oct. 7, 2013). This 1996 joint statement issued by FAO/WHO declared *inter alia* that "the environmental issues related to biotechnology have been well defined." *Id.* at 2. It is important to note this statement in comparison to the first

reputable international organizations facilitated international harmonization of mutually accepted "safety judgments" for transgenic plant agriculture and foods, and it paved the way for the liberalization of international trade in transgenic plant products and food.[231]

In light of international approval of the substantial equivalence doctrine, it was inevitable that regulatory authorities in the European Union[232] and other countries around the world[233] would draw upon this doctrine to assure the mass publics of the safety of transgenic plant foods for public health, and the compatibility of transgenic plant agriculture with the environment and biodiversity.[234] Moreover, the official international consensus amongst policy makers on the viability of the substantial equivalence doctrine (which has been "variously called a concept, a principle, a risk assessment tool, or all three at once"[235]) for the

FAO/WHO endorsement in 1991, which had cautiously noted that comparative data for the assessment of transgenic and non-transgenic plant foods was not widely available at the time. *See* STRATEGIES, *supra* note 227, at 7.1(6).

231 *See* Levidow, Murphy, & Carr, *supra* note 32, at 36.

232 *Id.* (noting that the European legislation's alignment with the substantial equivalence doctrine in 1997 helped "harmonize product approval across the Atlantic"). In 1997, the European Union introduced Regulation 258/97 on Novel Rood, which imposed a legal duty to seek approval before any novel food, such as GM food, is introduced into the market. *Id.* This new law provided a simplified procedure that essentially allowed companies to avoid a risk assessment if they could show that a transgenic food was substantially equivalent to an existing safe food. *Id.* However, in 1998, EU Regulatory Committee adopted United Kingdom's more stringent criteria for the simplified procedure and in June 1999, the EU Environment Council imposed an "unofficial de facto moratorium on approval of any additional GM products". *Id.* at 41.

233 *See* Levidow, Murphy, & Carr, *supra* note 32, at 28 (noting that while in 1997, the United Kingdom implemented EU Novel Food Regulation 258/97 on the substantial equivalence doctrine, the United Kingdom Advisory Committee on Novel Foods (ACNFP) then conditionally accepted the substantial equivalence doctrine for simplified procedure "only in cases in which no intact transgenic DNA or protein remains after processing).

234 *See* Billings & Shorett, *supra* note 163, at 79 (explaining that the substantial equivalence doctrine has been used by regulatory authorities in Canada and the United Kingdom to justify the introduction of transgenic plant agriculture and food products); *see also* THE ROYAL SOCIETY, GENETICALLY MODIFIED PLANTS FOR FOOD USE AND HUMAN HEALTH—AN UPDATE 5, (2002), *available at* http://royalsociety.org/uploaded Files/Royal_Society_Content/policy/publications/2002/9960.pdf (discussing the "use of substantial equivalence in the safety assessment of GM food).

235 Levidow, Murphy, & Carr, *supra* note 32, at 27.

regulation of transgenic plant agriculture and foods is indicative of the transnational reach of the doctrine as a putative regulatory tool.

However, whilst the substantial equivalence doctrine enjoys transnational supports, critics are quick to question its allegedly dubious ideological basis by challenging its scientific propriety and validity.[236] For example, critics have characterised the substantial equivalence doctrine as an ideologically driven policy contrived by the U.S. federal government, primarily aimed at promoting and expediting the adoption of biotechnology products by "minimizing federal constraints on the advance of commercially advantageous technology and preventing growth of the federal bureaucracy."[237] Indeed, securing a regime of minimal regulation for transgenic plant agriculture would necessitate circumventing the regulatory reach of the U.S. Congress. This was precisely what the 1992 policy framework for biotechnology products accomplished,[238] when it vested oversight role of transgenic plant agriculture and food in three Federal agencies: the U.S. Department of Agriculture, the Environmental Protection Agency, and the FDA–each was directly accountable to the Office of the President of the United States, rather than to Congress.[239]

If the substantial equivalence doctrine succeeded in expediting the approval of transgenic plant agriculture and food, it would be at the expense of the Congress' total exclusion from transgenic plant agriculture governance, a scheme that arguably could be tantamount to denying transgenic plant technology governance systems a comparably rigorous regulatory and concomitant safety regime, which is the norm for new pharmaceuticals, as demonstrated by legislatively-mandated rigorous clinical trials on

236 *See generally* Baram, *supra* note 160, at 53 (recognizing the limitations of a relaxed regulatory system in the United States that currently govern the safety of GM agriculture and food and the dangers of relying on the common law liability system alone).

237 *Id.* at 27 (explaining that the substantial equivalence doctrine was in conformity with the President Ronald Regan's political theme of light federal regulation of businesses).

238 *See id.* at 26 (noting that the 1992 policy framework was an expanded version of the 1986 United States policy framework for federal regulation of "biotechnology products"); *see also* Coordinated Framework for Regulation of Biotechnology, *supra* note 221, at 23302.

239 *See* Baram, *supra* note 160, at 26-27.

animals and humans at both pre and post market debut phases.[240] Inevitably, the palpable disparity in regulatory rigor for new pharmaceuticals and transgenic plant products highlights the inherent weakness of the substantial equivalence doctrine, given that, like transgenic seed companies, drug companies now routinely use rDNA in new pharmaceutical production, as exemplified by transgenic human insulin, which was the first commercial transgenic product produced in 1982, using genetically modified bacterium.[241] The pertinent question therefore follows: why should pharmaceuticals undergo rigorous safety checks via mandatory clinical trials,[242] whilst transgenic plant products literally breeze through safety checkpoints, ostensibly piggybacking on the substantial equivalence doctrine. In other words, why are transgenic plant products subject to a relatively weaker safety oversight regime in the substantial equivalence doctrine, vis-a-vis the stricter mandatory regulatory clinical trials regime that is the norm for new pharmaceutical products, given that rDNA technology is increasingly becoming an integral feature of the production process for new pharmaceuticals?[243]

The above question, is particularly tangent, because pro-transgenic plant agriculture scientists and scholars like Ronald J. Herring and Robert Paarlberg are wont to bemoan the inherent irony in the unquestioning acceptance by the general public, of the

240 Oriola, *supra* note 20, 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).

241 *See* PAARLBERG, *supra* note 31, at 11 (noting how transgenic human insulin was the first commercial product of transgenic technology to be approved by the Food and Drug Administration in the United States).

242 *See* Oriola, *supra* note 240, at 33 (noting that mandatory pre-clinical and clinical trials for new pharmaceuticals can average 12 years prior to approval by the Food and Drug Administration). Typically, clinical trials contain three phases: phase one studies compare pharmacological effects in animal experimentation and those expressed in human subjects; phase two studies seeks the amount of dosage required to achieve anticipated therapeutic effects; and phase three studies seek to confirm therapeutic efficacy and safety for the wider patient population at the dosage proposed for marketing. *Id.* at 31-32.

243 It has been estimated that recombinant DNA technique now constitutes twenty-five percent of all newly approved pharmaceutical products. *See* PAARLBERG, *supra* note 31, at 18.

use of rDNA technology in medicine,[244] and the paradoxical disdain and scepticism of the general public for the use of rDNA in plant agriculture and products, especially in Europe.[245] Perhaps, the general public's ready embrace and acceptance of transgenic medicine, in contradistinction to their relative scepticism and disdain for transgenic plant agriculture and foods, partly could be explained by the perceived inadequacy of the regulatory framework in 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,[246] the continuing vulnerability of non-transgenic plant farmers to intellectual property lawsuits,[247] and possible economic damage from in situ

244 This is exemplified by transgenic human insulin. *See* Pandey Shivanand & Suba Noopur, *Recombinant DNA Technology: Applications in the Field of Biotechnology and Crime Sciences*, 1 INT'L J. OF PHARMACEUTICAL SCI. REV. & RES 43, 44 (2010), *available at* http://www.globalresearchonline.net/volume1issue1/Article%20009.pdf (noting how transgenic human insulin, albeit from animal protein, is structurally identical to naturally produced insulin in humans).

245 Herring, *supra* note 107, at 614-15 (noting how rDNA techniques were widely accepted in pharmaceuticals, medicine, and industry); s*ee also* PAARLBERG, *supra* note 31, at 18 (discussing 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).

246 *See* David Winickoff et al., *Adjudicating the GM Food Wars: Science, Risk, and Democracy in World Trade Law*, 30 YALE J. INT'L L. 81, 102-03 (2005) (discussing the StarLink case as an example of a regulatory reversal which resulted from "human behaviors that the initial risk assessments had failed to anticipate"). StarLink was a maize hybrid that was labeled as "a crop, a food, and a pesticide, [thereby] requiring risk assessments by three separate agencies" under U.S. law. *Id.* at 102. Due to StarLink's "potential allergenicity in humans . . . all three agencies determined that a 'split registration' would be granted: the maize was to be used in animal feed but not in human food." *Id.* at 103. Nonetheless, StarLink DNA was found in food products in September 2000 and caused a "massive and costly recall." *Id.*

247 *See, e.g.*, Monsanto Co. v. McFarling, 302 F.3d 1291, 1291 (Fed. Cir. 2002) (affirming a preliminary injunction against farmer McFarling's saving of transgenic seeds because there was a reasonable likelihood of success on the intellectual property infringement claim against McFarling); Schmeiser v. Monsanto Canada Inc., 2002 FCA 309, *available at* http://www.ariplex.com/percyschmeiser/Appeal%20Decision.pdf

gene flow and adventitious commingling of transgenic and non-transgenic plant materials.[248]

Most significantly, the general public disaffection with the minimal federal regulatory system overseeing transgenic plant agriculture in the United States ostensibly precipitated numerous abortive legislative initiatives by county and state authorities.[249] These abortive initiatives include labeling rules by the State of Oregon in the fall of 2002,[250] California's 2008 transgenic plant liability law designed for the protection of non-transgenic plant farmers from intellectual property infringement lawsuits, concomitant economic loss or damage arising from adventitious commingling of transgenic and non-transgenic crops.[251] Thus,

(granting Monsanto an injunction after finding that some claims of Monsanto's Canadian patent for the invention of a genetic insert was infringed upon); *see also* Maria Lee & Robert Burrell, *Liability for the Escape of GM Seeds: Pursuing the 'Victim'?* 65 MOD. L. REV. 517, 519-27 (2002) (discussing the implications of the enforcement of intellectual property rights in transgenic seeds against farmers in circumstances of adventitious commingling).

248 *See* Yarui Li, Eric J. Wailes, Andrew McKenzie, & Michael Thomsen, *LL601 Contamination and Its Impact on U.S. Rice Prices*, 42 J. OF AGRIC. & APPLIED ECON. 1, 31 (2010) (exploring the impact of LL601, a genetically modified rice variety that was unapproved for commercial use, and its effect on the prices and volume in the U.S. and Thailand market); *see also* Sample v. Monsanto, 283 F. Supp. 2d 1088, 1090 (E.D. Mo. 2003) (involving farmer's class action lawsuit against Monsanto for alleged economic loss stemming from the sale of genetically modified soybeans and corn in the market).

249 Attempts by numerous county authorities, including four California counties and numerous New England towns, to restrict the cultivation of transgenic crops locally were stifled by state legislatures via pre-emption laws which curbed the ability of local authorities to regulate seeds and plants. *See* Britt Bailey, *States Introduce Numerous Bills to Regulate Genetically Modified Foods*, ENVIRONMENTAL COMMONS, http://environmentalcommons.org/gmo-regulation-2007.html (last visited Feb. 28, 2013). Between 2004 and 2006, nearly twenty state legislatures attempted to suppress legislative measures by county authorities to restrict cultivation of transgenic crops. *Id.*

250 Oriola, *supra* note 123, at 519-20 (discussing Oregon's aborted transgenic foods labeling rule when in the fall of 2002, a coalition of consumer advocates and environmental activists initiated a proposal for the labeling of transgenic food sold in the state); *see also* Patricia Callahan, *Oregon May Require Labels on Genetic Food*, WALL ST. J., Sept. 30, 2002, at B.1.

251 AB 541 (Cal. 2007), http://www.leginfo.ca.gov/pub/07-08/bill/asm/ab_0501-0550/ab_541_bill_20080927_chaptered.html (adding to the Food and Agricultural Code in California with regards to liability when concerning genetically engineered plants); *see also California's First Law Protecting Farmers From Threats of Genetic Engineering Signed by Governor*, GENETIC ENGINEERING POLICY ALLIANCE http://www.gepolicyalliance.org/action_alert_support_ab541.htm (last visited on Feb.

arguably, the substantial equivalence doctrine is no more than a fait accompli for shoehorning transgenic plant agricultural products into the global food systems. This point is aptly summed-up by Michael Baram as follows:

> 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 regulation that would treat these products differently than 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 petitions for more stringent safety reviews and precautionary policies, and rejected proposals for labeling GM products that would enable informed choice by consumers.[252]

Most significantly, the voluntary consultation process for the implementation of the substantial equivalence doctrine by the FDA would appear to give a short shrift to the safety and risks inherent in transgenic plant agriculture.[253] According to Sheldon Krimksy et al., rather than new regulations, the FDA introduced a discretionary and voluntary consultation process for companies planning to introduce transgenic foods into the market.[254] Under the voluntary consultation regime, transgenic seed developers "are provided a flow chart indicating when consultation with the agency is desirable."[255] According to the 1996 FDA guidance document for industry on the procedures for consultation:

> Under the process a developer who intends to commercialize a bioengineered food meets with the agency to identify and discuss relevant safety, nutritional, and other regulatory issues

28, 2013) (noting that on Sept. 27, 2008, Governor Schwarzenegger signed AB 541, the "landmark piece of legislation protecting California's farmers from liability").

252 Baram, *supra* note 160, at 16.

253 *See* Krimsky & Murphy, *supra* note 53, at 80 (2002) (examining the "FDA's policies on genetically modified foods including its voluntary consultation program and its proposed rule on market notification and data submission").

254 *Id.* at 82.

255 *Id.*

> regarding the bioengineered food prior to marketing it . . . . A developer may initiate such a consultation early or late in the development of the food.[256]

However, the consultation process appears largely voluntary or discretionary, as there is no legal obligation for a transgenic plant foods developer to initiate a consultation with the FDA prior to its products market debut.[257] Thus, it would be logical to infer from the FDA consultation procedures for introducing new transgenic plant foods, that there could be occasions when the FDA would not deem consultation procedures desirable at all. This is in stark contrast to the production process for new pharmaceuticals, for which the U.S. Congress has mandated rigorous clinical trials on animals and humans prior to market debut.[258] Even when consultation might be deemed desirable by the FDA, Sheldon Krimksy et al., noted that the FDA 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."[259] Instead, 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."[260] 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 FDA was 155 days and 175 days respectively.[261] Again, this is in stark contrast to the FDA's approval process for new pharmaceuticals, which could take up to

256 *Id.*

257 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 leeway not to initiate any consultation process: "A developer *may* initiate a consultation early or late in the development of the food." *See id.* It should be noted, however, that there was a formal agency proposal in January 2001 to require premarket notifications of bioengineered foods and that the proposal was expected to be finalized in 2002. *Id.* at 83.

258 *See* Oriola, *supra* note 240, at 31 ("In the United States as in Europe, pre-clinical and clinical trials are legally mandated by law, and are often drawn out over a period of years, adding considerably to the costs of drug development.").

259 *See* Krimsky & Murphy, *supra* note 53, at 82.

260 *Id.*

261 *See id.* at 83.

12 years prior to the product's commercial debut.[262]

Unsurprisingly, the FDA's voluntary and discretionary consultation procedures for new transgenic plant foods approval was criticized by stakeholders for its apparently inadequate safeguards for public health protection.[263] This led to recommendations by an FDA Advisory Committee that transgenic foods producers should submit safety and nutritional assessments to the agency, prior to new transgenic plant products market debut.[264] The FDA published a proposal on January 18, 2001, which mandated premarket notifications of new transgenic plant foods by developers.[265] Amongst other things, the proposed rule required transgenic plant foods manufacturers to submit a scientific and regulatory assessment of transgenic foods to the FDA 120 days prior to transgenic plant foods market debut.[266] 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.[267] 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."[268] Second, the method of development of the transgenic plant in question, detailing "the construction of the vector used in the transformation of the parent plant and a thorough characterization of the introduced genetic material, [etc.]"[269] Third, analysis of newly inserted genes with antibiotic properties.[270] Fourth, "substances introduced into or modified (present at an increased level relative to comparative food)."[271] And fifth, a comparison of the composition and

262 *See* Oriola, *supra* note 240, at 33.

263 *See* Krimsky & Murphy, *supra* note 53, at 83.

264 *See id.*

265 Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. 4706, 4713 (Jan. 18, 2001) (to be codified at 21 C.F.R. pts. 192 and 592).

266 *Id.*

267 *Id.*; *see also* Krimsky & Murphy, *supra* note 53, at 84.

268 Krimsky & Murphy, *supra* note 53, at 84.

269 *Id.*

270 *Id.*

271 *Id.*

characteristics of the transgenic food to comparable conventional foods, as well as an analysis of how the transgenic food is as safe as comparable non-transgenic food.[272] Sheldon Krimsky et al., succinctly summarized the consultation procedure as follows:

> 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.[273]

However, whilst the requirement of the submission of mandatory scientific data on the nature and safety of transgenic plant foods to the FDA prior to market debut is a welcome improvement on the hitherto voluntary consultation process, the research is entirely industry-led and generated, and it is doubtful whether the FDA, which suffers from dwindling personnel, funding, and "deficient scientific base," would have the necessary wherewithal to vet or verify the accuracy and validity of every piece of self-generated scientific data submitted by applicants.[274] Yet, verifying the accuracy of industry-generated scientific data by regulatory agencies is crucial to an effective science-based regulatory regime, as the industry is historically notorious for suppressing unfavourable scientific data.[275]

Even in the unlikely event that an unfavourable scientific data was submitted by a transgenic plant developer to the FDA,[276] the

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272 *Id.*

273 *Id.*

274 LEBOVITZ ET AL., *supra* note 33, at 25.

275 *See* Gerald Markowitz & David Rosner, *Corporate Responsibility for Toxins*, 284 ANNALS AM. ACAD. POL. & SOC. SCI. 1, 159-74 (2002) (discussing how corporations deliberately suppressed the knowledge of dangerous industrial toxins that were a threat to public health in furtherance of corporate benefits and interests).

276 *See* Press Release, Friends of the Earth, GM Safety Tests Flawed: New Research (Nov. 16, 2004) (on file with author), *available at* http://www.foe.co.uk/resource/press_releases/gm_safety_tests_flawed_new_24112004 (noting that companies

transgenic plant in question might still pass the FDA's regulatory muster, if risk analysis of potential danger to the environment and public health was deemed reasonable, minimal, or too costly to manage.[277] 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."[278] In that circumstance, 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."[279] A fortiori, a potential food risk might still pass the FDA'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 commercialization, and use flexible performance-based standards rather than rigid prescriptive or design standards to deal with end products risks."[280]

Thus, it is theoretically possible for the FDA to countenance unfavourable scientific data on an outstanding or unresolved risk, if the 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 a zero tolerance approach to eliminating every conceivable risk that new toxins and allergens might pose to the consuming public, could arguably smack of regulatory recklessness. Moreover, since risk is relative, it is unclear what might constitute reasonable or minimal risk in the transgenic plant foods context, and whether the general public, who would ultimately consume transgenic plant foods, would have the same level of tolerance to the permissible reasonable or

routinely ignored the Food and Drug Administration requests for additional information and that the Food and Drug Administration would often review summaries of industry-generated data, rather than the full contents of the studies on which industry data were predicated).

277 BARAM, *supra* note 160, at 27.

278 *Id.*

279 *Id.*

280 *Id.*

minimal risk that some cost-benefit analysts have deemed too costly to regulate. Moreover, unlike new pharmaceuticals,[281] the FDA has no post-market oversight over transgenic plant foods, and therefore cannot check industry records for evidence of harm or recall unsafe transgenic plant foods.[282]

It is therefore unsurprising that critics like Paul R. Billings et al., have characterized 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."[283] 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."[284] However, as previously noted, the FDA has 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."[285] In the same vein, David Schubert expressed concerns on the lack of sufficient study on the potential unintended molecular effects and implications of inserting novel genes into plant cell,[286] thus underscoring the limits of the substantial equivalence doctrine as a regulatory tool for transgenic plant foods. Even Consumers International, an independent and authoritative global voice for consumers, did voice their reservations and concerns on the 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

281 *See* ROBINSON ET AL., *supra* note 156, at 1 (noting that the United States Food and Drug Administration withdrew ten pharmaceutical drug products between 2000 and 2006 following their market debut because of safety concerns).

282 BARAM, *supra* note 160, at 42 (noting that the FDA 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).

283 *See* Billings & Shorett, *supra* note 163, at 79.

284 *Id.*

285 Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg 22988, Part VII, sec. G (May 29, 1992).

286 *See* Schubert, *supra* note 182, at 969.

> 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 the mechanisms are still a mystery, great caution is needed.[287]

Moreover, the United States District Court for the District of Columbia in its ruling on the essence of substantial equivalence doctrine noted inter alia that "ultimately, it is the food producer who is responsible for assuring safety."[288] This underscores the limits of the FDA's oversight regime for assuring transgenic foods safety via the substantial equivalence doctrine. It is a limitation that even the FDA has tacitly acknowledged, by noting that transgenic plant foods "are likely in some cases to present more complex safety and regulatory issues than seen to date."[289]

It was perhaps the perceived inadequacy of the manner in which the United States implemented the substantial equivalence doctrine that influenced a relatively stricter variant of the concept in the United Kingdom and the European Union.[290] In the United Kingdom, for example, the United States' variant of the substantial equivalence doctrine was perceived by experts as a "simplified procedure" for transgenic plant foods regulation, which was suitable only for fully processed foods that no longer contained "intact DNA or protein."[291] According to the United Kingdom Advisory Committee on Novel Foods Processes, there should be additional mandatory tests on the stability of the novel or foreign nucleic acid proteins inserted into plant genome:

> If we must use that criterion alone, [substantial equivalence] 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 the DNA has been denatured. Moreover, we will specify what tests are

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287 Les Levidow et al., *supra* note 32, at 37.

288 *See* Alliance for Bio-Integrity v. Donna Shalala, 116 F. Supp. 2d 166, 177 (D. D.C. 2000).

289 Premarket Notice Concerning Bio-engineered Foods, 66 Fed. Reg. at 4709.

290 Les Levidow et al., *supra* note 32, at 38-39.

291 *See* MINISTRY OF AGRICULTURE FISHERIES & FOOD, ADVISORY COMMITTEE ON NOVEL FOODS AND PROCESSES (ACNFP) 1998 ANNUAL REPORT 1, *available at* http://www.food.gov.uk/multimedia/pdfs/acnfp1998.pdf.

required; the company must monitor generations of the crop over two years at six sites.[292]

The European Union subsequently adopted and incorporated the United Kingdom's more stringent variant interpretation,[293] by noting that "whilst 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."[294] However, the pertinent question is whether the United Kingdom and member countries of the European Union could use their stringent and variant interpretation of the substantial equivalence doctrine to bar the import of approved transgenic plant foods and products from the United States, Canada, or Argentina? Arguably, the answer is no, in light of the World Trade Organization Dispute Settlement Board's Panel decision in the European Communities *Biotech Products* case,[295] 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 (SPS Agreement).[296] The European Union was held to have breached, amongst others, 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.[297] Thus, unless the European Union could prove the scientific merit of their stringent interpretation or variant of the substantial equivalence doctrine, they could hardly use it to bar the importation of transgenic plant foods and products from the United States, Canada, Argentina, or other countries who utilize a looser interpretation of the substantial equivalence doctrine. Against the background of the European Communities *Biotech Products* case, it is certainly a probable scenario that the European Union could again deadlock with the United States and countries

292 Les Levidow et al., *supra* note 32, at 39.

293 *Id.*

294 European Parliament & Council on Genetically Modified Food and Feed, (EC) NO.1829/2003 of 22 Sept. 2003, art. 2(12) at 2-3.

295 *See* Panel Report, *European Communities— Measures Affecting the Approval and Marketing of Biotech Products*, WT/DS291R, WT/DS292R, WT/DS293R (Sept. 29, 2006), *available at* http://www.worldtradelaw.net/reports/wtopanels/ec-biotech(panel).pdf.

296 *See id.*

297 *See id.*

with varied interpretation of the substantial equivalence doctrine, thus reinforcing the disparate, differing, and divergent approaches to the interpretation of the "science" that underpins the regulatory and policy framework for transgenic plant agriculture and foods.

B. Science on Trial: Alliance for Bio-integrity *and the Legal Challenge to the Substantial Equivalence Doctrine*

The validity and legality of the substantial equivalence doctrine was challenged before the United States District Court for the District of Columbia in *Alliance for Bio-integrity v. Donna Shalala*,[298] by plaintiffs comprising a coalition of groups, individuals, scientists, and religious leaders. The plaintiffs contended inter alia that transgenic plant foods should be labeled, and that the FDA's substantial equivalence policy presumption that transgenic plant foods, as a class, were generally recognized as safe (GRAS), and therefore not subject to regulation as food additives, should be discountenanced. The plaintiffs further contended that FDA non-labeling policy violated the GRAS requirements of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321(s), and therefore arbitrary and capricious.[299] According to the provisions of § 321(s), a producer of food additive must submit food additive petition to the FDA for approval, unless the FDA 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."[300]

The plaintiffs' claim did raise a pertinent question before the

298 *See* Alliance for Bio-Integrity v. Donna Shalala, 116 F. Supp. 2d 166, 166-81 (D. D.C. 2000).

299 *Id.* at 175.

300 *See* Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 387(1) (2010) (defining "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 tobacco product (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding)"). Additives may 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, among other things. *Id.* For a comparable law in the European Union, see Council Directive on Approximation of the Laws of the Member States Concerning Food Additives Authorised for Use in Foodstuffs Intended for Human Consumption, 89/107/EEC, art. 1.2, 1988-1989 O.J. (L40) 32. .

court: why did the FDA not characterize nucleic acid proteins used in the genetic modifications of transgenic plant foods as "food additives," in order to allow for automatic submission of transgenic plant foods to the FDA approval process prior to market debut? The court reasoned that it was because "nucleic acid proteins," were not only generally recognized as safe, but also deemed crucial for the survival of plant and animal organisms.[301] According to the court:

> 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 FDA concluded that rDNA engineered foods should be presumed to be GRAS unless evidence arises to the contrary.[302]

The court further noted that whilst the plaintiffs did not dispute the FDA's claim that nucleic acid proteins were generally recognized as safe per se, the plaintiffs did argue that there were significant disagreements among scientific experts as to whether or not nucleic acid proteins were generally recognized as safe when used to alter organisms genetically.[303] In other words, while nucleic acid proteins might be safe in their natural environment as such, scientists do disagree on the safety implications of using nucleic acid proteins to genetically alter or modify a plant's genome. Nevertheless, the court went on to hold 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.[304] The court rationalized the premise for deferring to the FDA's judgment in awarding GRAS status to transgenic plants foods as follows:

> 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

301 *See Alliance for Bio-Integrity*, 116 F. Supp. at 176.

302 *Id.* at 176-77.

303 *Id.* at 177.

304 *Id.*

a choice between rational alternatives.[305]

However, the court's reluctance to pick and choose between conflicting scientific opinions or "rational alternatives" on whether or not nucleic acid proteins are generally recognized as safe when used in the alteration of the genome of transgenic plant foods is understandable in the context of the court's lack of relevant scientific expertise. This is especially so as the court did acknowledge that the area was "characterized by scientific and technological uncertainty,"[306] and picking between alternative scientific opinions is almost always a judicial dilemma for judges who often rely on expert witnesses due to a general lack relevant scientific expertise.[307] But then, it is arguably an avoidable dilemma that perhaps could have been (partly) pre-empted had the FDA subjected transgenic plant foods to rigorous nutritional, toxicological, and allergenic tests on animals and humans, prior to market debut, instead of blindly drawing on industry-generated data and studies to affirm the rebuttable presumption that nucleic acid proteins are generally recognized as safe when used in the modifications of transgenic plant foods and should therefore be exempt from food additive petitions.[308] Moreover, the FDA's excuse that rigorous toxicological tests could be hamstrung by the relative difficulty of administering "exaggerated doses" in "feeding studies"[309] is no justification for not making it an integral

305 *See id*. The Court drew on the decisions in Int'l Fabricare Inst. v. EPA, 972 F.2d 384, 389 (D.C. Cir. 1992) and Envtl. Def. Fund, Inc. v. Costle, 578 F.2d 337, 339 (D.C. Cir. 1978).

306 *See Alliance for Bio-Integrity*, 116 F. Supp. at 177.

307 *See* Daubert v. Merrell Dow Pharm., 509 U.S. 579 (1993) (discussing the nature of expert testimony and the criteria for picking and choosing between conflicting scientific evidence by judges); *see also* Taiwo A. Oriola, *The Propriety of Expert Ethics Testimony in the Courtroom: A Discourse*, 6 J. PHIL. SCI. & L. 1, 1-25 (2006).

308 *Alliance for Bio-Integrity*, 116 F. Supp. at 175-76 (noting that the Food and Drug Administration's presumption that the nucleic acid proteins used in genetic engineering of plants genome was generally recognised as safe, was rebuttable). Moreover, despite the FDA presumption of GRAS for transgenic plant foods, "certain genetically modified substances might trigger application of the food additives petitioning process." *Id.* The FDA recognised that "the intended expression product in a food could be a protein, carbohydrate, fat, or oil, or other substance that differs significantly in structure, function, or composition from substances found currently in food" and that "such substances may not be GRAS and may require regulation as a food additive." *Id.* at 176.

309 *See* Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg.

feature of the approval process for transgenic plant foods. For it is only by mandating rigorous nutritional, toxicological, and allergenic tests on transgenic plant foods that novel nucleic acid proteins used in the alteration of plant genome could automatically be subjected to food additive petition processes under § 321(s).[310]

Furthermore, the plaintiffs in *Alliance for Bio-integrity* claimed that transgenic plant food ought to be labeled and that failure to do so by the FDA was tantamount to denying consumers with genuine religious concerns and transgenic food allergens a means of exercising their food preferences.[311] The FDA had rejected labeling on grounds that transgenic plant foods were substantially equivalent to conventional plant foods, and that they were not legally obliged to label transgenic plant foods under § 321(n).[312] The court agreed with the FDA, and held that the agency had limited authority to require labelling of foods under § 321(n),[313] and that they could only do so where non-labelling would lead to food misbranding, which would occur where there was a failure to reveal facts that were material to the consequences associated with consuming the foods.[314]

The court further noted that since Congress had not "squarely addressed whether materiality pertains only to safety concerns or whether it also includes consumer interest,"[315] then the FDA must be allowed to interpret the provisions of § 321(n).[316] The court then went on to defer to the FDA's interpretation of the provisions of § 321(n) to the effect that "no material change" under § 321(n)

at 24.

310 *See* Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321(s) (2010) (discussing what would constitute "food additive" and the circumstances under which a food additive could be subject to the FDA's approval process).

311 *See Alliance for Bio-Integrity*, 116 F. Supp. at 177.

312 21 U.S.C. § 321(n) (granting the Food and Drug Administration limited authority to require food labelling if non-labelling would lead to mis-branding of foods, which would occur if food labelling "fails to reveal facts . . . material with respect to consequences which may result from the use of the article to which the labelling . . . relates under conditions of use prescribed in the labelling . . . or under such conditions of use as are customary or usual"); *see also Alliance for Bio-Integrity*, 116 F. Supp. at 178.

313 *See* 21 U.S.C. § 321(n).

314 *Alliance for Bio-Integrity*, 116 F. Supp. at 178 (emphasis added).

315 *Id.*

316 *Id.*

had occurred "in the rDNA derived foods at issue," and that the FDA's "exclusion of consumer interest from factors which determine whether a change is 'material' constitutes a reasonable interpretation of the statute."[317] The court further noted that it was doubtful whether the FDA had the power under § 321(n) to require labelling in circumstances where the sole basis was consumer demands.[318] The court finally emphasized the virtual implausibility of labelling under § 321(n) as follows:

> Plaintiffs fail to understand the limitation on the FDA's power to consider consumer demand when making labeling decisions because they fail to recognize that the determination that a product differs materially from the type of product it purports to be is a factual predicate to the requirement of labeling. Only once materiality has been established may the FDA consider consumer opinion to determine whether a label is required to disclose a material fact. Thus if there is a material difference, and consumers would likely want to know about the difference then labelling is appropriate. If however, the product does not differ in any significant way from what it purports to be, then it would be misbranding to label the product as different . . . . The FDA has already determined that, in general, rDNA modification does not "materially" alter foods, and . . . this determination is entitled to deference . . . the FDA lacks a basis upon which it can legally mandate labelling, regardless of consumer demand.[319]

It is thus clear that the substantial equivalence doctrine was the basis for the court's rejection of plaintiffs' claims for the labelling of transgenic plant foods and refusal to automatically subject transgenic plant foods to "food additive" scrutiny.[320]

However, it is submitted that the court 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

317 *Id.* at 179.

318 *Id.; see also* Stauber v. Shalala, 895 F. Supp. 1178, 1193 (W.D. Wis. 1995) (holding that "in the absence of evidence of a material difference between [milk cows treated with a synthetic hormone] and ordinary milk, the use of consumer demand as the rationale for labelling would violate the Food, Drug, and Cosmetic Act").

319 *Alliance for Bio-Integrity*, 116 F. Supp. at 179.

320 *See* 21 U.S.C. § 321(s) (defining "food additive").

misbranding" had occurred to warrant labelling of transgenic plant foods under § 321(n).[321] 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 labeling of transgenic plant foods under § 321(n).[322] But then, by narrowly conceptualising "material facts" solely in safety terms for the purposes of labelling of transgenic plant foods, the court was able to focus entirely on scientific considerations, which were easily explained by the doctrine of substantial equivalence that posits that transgenic plant foods were substantially equivalent to conventional plant foods.[323] However, whilst this interpretation of § 321(n) rendered the labeling 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 foods, as exemplified by the ninety-four percent support for labeling of transgenic plant foods in a 2003 survey in the United States.[324]

However, even the use of substantial equivalence doctrine would not quell safety concerns, as it is no magic wand that would automatically assuage concerns or resolve conflicting science on the possible risks posed by new transgenic plant foods toxins and allergens for humans. For instance, as previously noted, the European Union holds the view that "whilst 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."[325] This view was re-echoed 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

321 *Alliance for Bio-Integrity*, 116 F. Supp. at 178.

322 *See id.* (recognizing that Congress did not expressly define what would constitute "material facts" for the purposes of determining whether food misbranding had occurred to warrant labelling of transgenic plant foods under the Federal Food, Drug, and Cosmetic Act).

323 *See* Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22984, 24 (May 29, 1992).

324 *See* PAARLBERG, *supra* note 31, at 17-23.

325 *See* European Parliament & Council on Genetically Modified Food and Feed, (EC) NO.1829/2003 of 22 Sept. 2003, art. 2(12) ¶ 6.

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.[326] The authors then suggested rephrasing of the substantial equivalence principle as the "Comparative Safety Assessment" approach, which "better outlines the comparative nature of the assessment, while avoiding the idea that it is a safety assessment in itself."[327] Indeed, both the FDA and the court in *Alliance for Bio-integrity* seemed cognizant of the limits of the substantial equivalence doctrine. The former noted that transgenic plant foods "are likely in some cases to present more complex safety and regulatory issues than seen to date,"[328] and the latter reasoned that the subject "is characterized by scientific and technological uncertainty,"[329] and that "ultimately, it is the food producer who is responsible for assuring safety."[330] Arguably, these assertions by the FDA and the court are no more than tacit disclaimers on the presumed viability or reliability of the substantial equivalence doctrine and, by extrapolation, a tacit acknowledgement of the uncertainty of its underlying science, inevitably raising questions on its propriety for transgenic plant foods governance.

In the following section, the article will examine the conflicting scientific studies and opinions on transgenic plant foods allergens and toxins, and further aims to demonstrate the weakness of the substantial equivalence doctrine, as well as underscore the limits of the "science" that underpins the regulatory science systems for the governance of transgenic plant agriculture and foods.

326 *See* Esther J. Kok & Harry A. Kuiper, *Comparative Safety Assessment for Biotech Crops*, 21 TRENDS BIOTECHNOLOGY 439, 440 (2003).

327 *Id.* at 443.

328 *See* Premarket Notice Concerning Bio-engineered Foods, 66 Fed. Reg. 4706, 4709.

329 *See* Alliance for Bio-Integrity v. Donna Shalala, 116 F. Supp. 2d 166, 177 (D. D.C. 2000).

330 *Id.*

C. Conflicting and Conflicted Science on New Allergens and Toxins in Transgenic Plant Foods

The transfer of desirable nucleic acid proteins (DNA) from one organism into another, irrespective of speciation, is the critical mass of genetic engineering techniques.[331] DNA is found in all living things. DNA transmits, encodes, and expresses genetic information.[332] In the context of plant genetic engineering techniques, desirable DNA from Bt 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.[333]

However, there are proven possible and numerous side-effects to the alteration of plant genome via the insertion of novel or foreign DNA. For example, it has been established that genetic alteration or modification of plant crops via novel DNA could affect the expression of non-target genes in the plant's genome.[334] Indeed, the FDA acknowledged that the insertions of rDNA into a 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.[335] The FDA also acknowledged that transgenic plant developers using rDNA technology could not control with precision the ultimate location at which the inserted nucleic acid proteins would settle in the plant genome.[336] Furthermore, the FDA 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,[337] and dramatically alter the

331 *See* KLOPPENBURG JR., *supra* note 15, at 2-4; *see also* REISS & STRAUGHAM, *supra* note 14, at 1-2.

332 *See Alliance for Bio-Integrity*, 116 F. Supp. at 176-77 (expressing views worthy of note).

333 *See* Madhuri Kota et al., *supra* note 105, at 1840-45 (discussing Bacillus thuringiensis).

334 *See* Krimsky & Murphy, *supra* note 53, at 84.

335 *See* Premarket Notice Concerning Bio-engineered Foods, 66 Fed. Reg. 4706, 4706-38 (Jan. 18, 2001).

336 *Id.* at 4710.

337 *Id.* at 4709.

composition of transgenic plant crops significantly, with concomitant nutritional, toxicity, and safety issues.[338]

Yet, while the full ramifications of the numerous possible side-effects of the alteration of plant genome on food toxicity and nutrition quality are currently unknown,[339] and despite the reservations of some scientists,[340] and that of the FDA on the nutritional, toxicity, and allergenic implications of the introduction of novel or foreign genes into a food crop, transgenic plant foods and products are not automatically treated as additive by the FDA due largely to the substantial equivalence doctrine, unless there is evidence of health risk for humans stemming from the expression of novel proteins in transgenic plant foods.[341] For example, due to the possible presence of antibiotic resistance properties in its delayed-ripening Flavr Savr tomato, Calgene filed for a food additive petition with the FDA during the consultation procedure for the approval of the transgenic tomato.[342] The food additive petition was necessary because the company had "introduced genes into the cells of the tomato that made them resistant to kanamycin and neomycin, two clinically used antibiotics."[343]

338 *Id.* at 4710; *see also* Mathilde Bourrier, *Applying Safety Science to Genetically Modified Agriculture*, *in* GOVERNING RISK IN GM AGRICULTURE 236, 236 (discussing how transgenic agriculture has added new safety issues that ranged from adventitious commingling of transgenic and non-transgenic crops, environmental safety concerns to "new food safety issues").

339 *See* Schubert, *supra* note 182, at 969.

340 *See* Kok & Kuiper, *supra* note 326, at 441 (noting concerns expressed by scientific and public groups on the "unintended and unexpected side effects" of transgenic plant food consumption on human and animal health); *see also* Billings & Shorett, *supra* note 163, at 79-80 (discussing 1999 studies conducted by Marc Lappe and colleagues and published in the *Journal of Medicinal Food*, which indicated that soybeans "genetically modified for herbicide tolerance contained significantly lower levels of phyto-estrogens than their conventional counterparts"). Authors also cited industry studies of soybeans showing "heightened Trypsin inhibitor levels in defatted non-toasted soybean meal," and limited experiments on transgenic herbicide-resistant maize, which showed "unexpected changes in fat and carbohydrate content." *Id.*

341 *See* Krimsky & Murphy, *supra* note 53, at 83 (describing the principle of the substantial equivalence doctrine); *see also* Alliance for Bio-Integrity v. Donna Shalala, 116 F. Supp. 2d 166, 176 (D. D.C. 2000) (dismissing plaintiffs' request that transgenic foods be regarded as containing additives due to the presence of novel or foreign nucleic acid proteins, on grounds that nucleic acid proteins were generally recognised as safe given its integral part of all living organisms).

342 *See* Krimsky & Murphy, *supra* note 53, at 86-87.

343 *Id.*

Even where food additive petitions are not filed by transgenic plant crop developers, on the assumption that their transgenic crops are comparably similar to conventional crops, scientists are still divided on the nutritional, toxicity, and allergenic implications of transgenic plant foods for human consumption.[344]

In the following paragraphs, the article will consider in seriatim, the conflicting scientific literature on the degree to which transgenic plant foods for human consumption are susceptible or prone to new allergens and toxins. The primary aim is again to underscore the frailty of the science underlying the regulatory and policy framework for transgenic plant agriculture and foods and, by extrapolation, to concomitantly challenge the basis for science's exclusive prerogative on the governance systems for transgenic plant agriculture and foods.

i. Conflicting Scientific Views on Transgenic Plant Food Allergens

According to Samuel B. Lehrer et al., food allergens are mostly proteins or glycol-proteins.[345] Food allergies are said to occur from "adverse immunology reactions to proteins" and other components in food.[346] The most common 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 anaphylactic shock."[347] However, scientists believe that the percentage of allergenic proteins is small, and that only approximately two hundred of the thousands of proteins that are

344 *See* Trish Malarkey, Human Health Concerns with GM Crops, 544 MUTATION RESEARCH 217, 221 (2003) (discussing the potential allergenicity and toxicity of transgenic plant foods and noting how the safeguard measures in place are sufficient to ensure that transgenic plant foods "are as safe and nutritious as conventional counterparts" and that "the changes in the composition of existing foods produced through biotechnology are limited and have no adverse nutritional or safety consequence"). This conclusion is sharply contradicted by a 1996 publication that demonstrated that a major Brazil nut allergen had been transferred into Pioneer Hi-Bred transgenic soybeans; *see also* Billings & Shorett, *supra* note 163, at 83.

345 *See* Samuel B. Lehrer et al., *Why Are Some Proteins Allergenic? Implications for Biotechnology*, 36 CRITICAL REV. FOOD SCI. & NUTRITION 553, 553-564 (discussing allergenic proteins).

346 *See* Billings & Shorett, *supra* note 163, at 82.

347 *Id.*

consumed in foods are allergens.[348] It is also estimated that two percent of adults and eight percent of children in industrialized countries suffer from food allergies, and that ninety percent of food allergies ranging from moderate to severe are due to "a narrow range of nuts, cereal grains, seafood, soybeans, and dairy products,"[349] demonstrating that food allergies are common to both transgenic and conventional plant foods.[350] However, unlike transgenic plant foods, conventionally cultivated crops have "a well-established history of safe use,"[351] while categories of allergenic foods such as Brazil nuts, are relatively well defined and fairly established, albeit "difficult to detect."[352]

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 crop allergenicity.[353] The authors suggested that it would be relatively easy to evaluate and minimize allergens in transgenic plant foods, if the sources of the genes responsible for the allergens were known.[354] The authors further observed that the greatest challenge posed by allergens in transgenic plant foods was in determining whether or not a particular protein was allergenic, and then discovering the source of that protein.[355] The authors also noted that whilst there was no generally, established procedure for defining or predicting a protein's allergenicity, methods ranging

348 Malarkey, *supra* note 344, at 219.

349 *See* Billings & Shorett, *supra* note 163, at 82.

350 *See* Kok & Kuiper, *supra* note 326, at 443 (noting that "traditional plant breeding practices such as chemical mutagenesis might lead to higher rate of mutations compared with genetic changes induced by recombinant DNA technology").

351 European Parliament & Council on Genetically Modified Food and Feed, (EC) No.1829/2003 of 22 Sept. 2003, art. 2(12) (defining conventional plant crops as "food or feed produced without the help of genetic modification and for which there is a well-established history of safe use").

352 *See* PINSTRUP-ANDERSEN & SCHIØLER, *supra* note 10, at 42-43 (citing Samuel B. Lehrer's view on how complex and extensive allergy tests were and how most foodstuffs would never pass the tests); *see also* Billings & Shorett, *supra* note 163, at 82 (noting that "food allergies are difficult to detect, measure objectively and assess in terms of their impact on human health generally").

353 Lehrer et al., *supra* note 345, at 554.

354 *Id.* at 554 (discussing how scientists used traditional *in vitro* inhibition assays to reduce allergen contents in transgenic rice).

355 *Id.*

from the comparison of the structures of the novel protein with known allergens, to Th-2 cell simulation, to IgE antibody induction in animal models, could be useful in identifying and reducing allergenic proteins in transgenic plant foods.[356] In the same vein, a joint consultation policy statement by the FAO/WHO formulated a "decision-tree" methodology for assessing potential allergens in transgenic plant foods.[357] According to the FAO/WHO report, the "decision-tree" approach:

> 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.[358]

Significantly, whilst Samuel B. Lehrer et al. conceded that transgenic plant foods could be allergenic, they concluded that there was no evidence that rDNA in transgenic plant foods were more allergenic than traditional proteins in conventionally grown plant foods.[359] 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 be subjected to comparative safety, allergenic, and toxicity tests that were the norms for transgenic plant foods.[360] However, albeit ingenious, it is doubtful that justifying transgenic plant foods on grounds that they are no more allergenic than conventionally cultivated plant foods would persuade skeptics to renounce their entrenched bias against transgenic plant foods. Furthermore, the hypothesis that

356 *Id.* at 558.

357 *See* Food and Agriculture Organization & World Health Organization, Jan. 22-Jan. 25, 2001, *Evaluation of Allergenicity of Genetically Modified Foods, available at* http://www.who.int/foodsafety/publications/biotech/en/ec_jan2001.pdf.

358 *Id.* at 5.

359 *See* Lehrer et al., *supra* note 345, at 563-64 (discussing allergenic proteins).

360 *See* E.J. Kok et al., *Comparative Safety Assessment of Plant-Derived Foods*, 50 REG. TOXICOLOGY & PHARMACOLOGY 98, 98-113 (2008); *see also* Kok & Kuiper, *supra* note 326, at 439-44; Malarkey, *supra* note 344, at 217-21; A König et al., *Assessment of the Safety of Foods Derived from Genetically Modified (GM) Crops*, 42 FOOD & CHEMICAL TOXICOLOGY 1047, 1047-88 (2004).

transgenic plant foods are no more allergenic than conventional plant foods arguably smacks of classic "mudslinging" no-food-types-are-allergens-free retort, which fails to offer any evidence of superior or comparative advantages of transgenic plant foods over conventionally grown foods in allergens reduction terms, and thereby dispels safety concerns on transgenic plant foods allergens, especially in Europe.[361]

Also, and most significantly, the hypothesis that transgenic plant foods are no less allergenic than conventional plant foods could further alienate the generally skeptical public, and reinforce their preference for conventionally grown plant foods, which are familiar, have been around for ages, and do enjoy a long history of safe usage relative to novel or transgenic plant foods.[362] Thus, given the reality that both transgenic and conventional plant foods are susceptible to allergens, the choice between transgenic and conventional plant foods for the skeptical public could ultimately be framed in terms of "better the devil you know than the devil you do not know." Therefore, for the informed consumers who are enabled by labeling law to choose between transgenic and conventional plant foods,[363] nothing short of proven evidence of superior safety records for transgenic plant foods in allergens reduction terms, could likely detract from their preference for the familiar conventionally grown plant foods with concomitant advantage of a long history of safe use.[364]

However, the pertinent question, which is central to the theme of this article, is: if transgenic plant foods were no less safe and no

361 *See* Lee, *GM Resistant: Europe and the WTO Panel Dispute on Biotech, in* ETHICS, LAW, AND SOCIETY, *supra* note 29, at 131-39 (discussing safety concerns for transgenic plant foods in Europe).

362 *See, e.g.*, European Parliament & Council on Genetically Modified Food and Feed, (EC) No. 1829/2003 of 22 Sept. 2003, art. 2(12) (noting that conventional crops are defined by the European Union as "food or feed produced without the help of genetic modification and for which there is a well-established history of safe use").

363 Oriola, *supra* note 123, at 535 (discussing the legal and ethical imperatives for transgenic plant food labeling, and discussing inter alia the State of Oregon's abortive transgenic plant food labeling initiatives). It goes without saying that the choice between transgenic and conventional foods is only plausible under a labeling regime, which is the norm in Europe, but shunned in the United States. *Id.*

364 *See* European Parliament & Council on Genetically Modified Food and Feed, (EC) No. 1829/2003 of 22 Sept. 2003, art. 2(12) (describing conventional plant crops as having "a well-established history of safe use").

more allergenic than conventionally grown plant foods, why the abiding concerns about transgenic plant foods allergens amongst certain scientists?[365] For there are scientists who passionately disagree with the scientific stance espoused by Samuel B. Lehrer et al., that transgenic plant foods are no less allergenic or no less prone to allergens than conventional plant foods.[366] For example, Mae-Wan Ho and Lim Li Ching colleague argued that studies such as that of Samuel B. Lehrer et al., are unreliable due to "paucity of published data."[367] According to Ho and Ching: "There is a distinct scarcity of published data relevant to the safety of GM foods. Not only that, the scientific quality of what has been published is, in most instances, not up to the usually expected standards of good science."[368]

Moreover, Ho and Ching further buttressed their criticisms of the safety science of transgenic plant foods by drawing on the evidence of cancer expert, Stanley Ewen, regarding the safety of transgenic plant crops before the Scottish Parliament as follows: "It is unfortunate that very few animal trials of GM human food are available in the public domain in scientific literature. It follows that GM foods have not been shown to be without risk and, indeed, the available scientific experimental results demonstrate cause for concern."[369]

However, it is certainly not sufficient to disprove the validity or reliability of the scientific literature on the safety science of transgenic plant foods merely on grounds of paucity of published scientific data. Surely, concrete scientific data should be proffered to counter the hypothesis that transgenic plant foods are no more allergenic and therefore no less safe than conventional plant foods?[370] Notably, those scientists, who believe that transgenic

365 *See* SMITH, *supra* note 168, at 51 (citing medical personnel and scientists who claimed that transgenic soybeans could be highly susceptible to allergens, and a physician allergy specialist, John Boyle, who claimed that transgenic soybeans "is so dangerous that I tell people never to eat it").

366 *See* HO & CHING, *supra* note 101, at 21-23.

367 *Id.* at 21. Mae-Wan Ho is a prominent opponent of transgenic plant agriculture and foods.

368 *Id.*

369 *Id.*

370 *See* PAPINEAU, *supra* note 71, at 98 (noting that scientific knowledge and theories are grounded on deductions or data derived from observations and controlled

plant foods are prone to food allergens, often tend to seek evidence in the weakness of the safety science that underpins the production process of transgenic plant foods. For instance, some scientists contend that not only are transgenic plant foods more prone to allergens than conventional plant foods, but that such allergens could be more difficult to tackle because they: "[i]nclude 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."[371]

In other words, while the categories of conventional plant foods with allergens, such as Brazil nuts,[372] are fairly and relatively known, transgenic plant foods potentially could create unknown or novel allergens. This is exemplified by the acknowledgement of the FDA 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.[373] Furthermore, transgenic plant foods are said to be more susceptible to allergens because they not only incorporate proteins into the food systems "from known source[s] of common allergens," but many transgenic plants in development also embody allergenic proteins from "organisms never previously consumed as food."[374]

Scientists have also argued that whilst it was difficult enough to predict and tackle transgenic crops allergens using the FAO\WHO criteria,[375] the task has been further exacerbated by

experiments conducted on the physical and natural world, and not mere assumptions or wild speculations); *see also* PIELKE, JR., *supra* note 74, at 43-44 (discussing how the grounding of scientific knowledge on observable facts led to the ascription of high value to scientific information by the society, vis-a-vis non-scientific information, which the society tended to perceive negatively).

371 Billings & Shorett, *supra* note 163, at 83.

372 *See* Marion Nestle, *Allergies to Transgenic Foods: Questions of Policy*, 334 NEW ENG. J. MED. 722, 726 (1996) (noting that nuts are among the most common food allergies).

373 *See* Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. 4706, 4710 (Jan. 18, 2001).

374 Billings & Shorett, *supra* note 163, at 84.

375 *Id.* at 83 (noting that even the FAO\WHO reports acknowledged that current criteria for predicting the allergenicity of crops were unreliable).

biotechnology companies' increasing use of microorganisms rather than food plants as gene donors.[376] Furthermore, critics have noted how biotechnology companies routinely design and customize proteins "even though the allergenic potential of these newly introduced microbial proteins is uncertain, unpredictable[,] and untestable."[377] Even studies conducted by Monsanto scientists revealed that Monsanto's "glycophosate-tolerant soybeans showed a 28 percent increase in Kunitz trypsin inhibitor, a known anti-nutrient and allergen."[378]

Scientists who believe that transgenic plant foods are more susceptible to allergens often reference a 1996 study published in *New England Journal of Medicine*,[379] which found a major Brazil-nut allergen in Pioneer Hi-Bred transgenic soybeans.[380] The Brazil-nut allergen had found its way into the Pioneer Hi-Bred transgenic soybeans when Pioneer Hi-Bred scientists inserted Brazil-nut gene, 2S albumin, into soybeans genome in order to increase the amount of sulphur-containing amino acids methionine and cysteine in soy-based animal feed.[381] The Brazil-nut's 2S albumin is especially rich in methionine and cysteine, and "its gene was a logical choice as a donor."[382] Whilst the primary aim of the experiment was to enrich the constituent protein of the Pioneer Hi-Bred's transgenic soybeans with beneficial amino acid (methionine),[383] IGE immunoreactivity tests on the blood samples of volunteers revealed that those who were allergic to Brazil-nut were also allergic to the Pioneer Hi-Bred transgenic soybeans.[384] According to Julie A. Nordlee et al, the study firmly established

376 *See* Nestle, *supra* note 372, at 726.

377 *Id.*

378 Billings & Shorett, *supra* note 163, at 84.

379 *See* Julie A. Nordlee et al., *Identification of a Brazil-nut Allergen in Transgenic Soybeans*, 334 NEW ENG. J. MED. 688, 688-93 (1996).

380 *Id*.

381 *Id*. at 688.

382 Nestle, *supra* note 372, at 726.

383 *See* Nordlee et al., *supra* note 379, at 688 (discussing the nutritional quality of legumes). Legumes, such as soybeans, for humans and animals, are compromised by the deficiency of methionine in the "protein faction of the seeds." *Id.* Consequently, domestic animals fed on soybeans must have their feed fortified "with methionine or protein sources of this essential amino acid." *Id.*

384 *Id.*

that "an allergen from a food known to be allergenic can be transferred into another food by genetic engineering."[385]

However, whilst it would appear relatively easy to determine that a natural or known allergenic food crop could retain its allergenic properties when genetically transferred into another food crop, such a determination is not always as easy to make from experimental studies. This is exemplified by an experimental animal study, in which the Brazil-nut transgenic soybeans failed to induce an immunoglobulin response. This led the authors of the study to conclude that the Pioneer Hi-Bred transgenic soybeans infused with Brazil-nut genes were non-allergenic.[386] Thus, without the subsequent human study, the transgenic soybeans in question could have slipped through scientific and regulatory net virtually undetected.[387] Therefore, the discrepancies in the results between the prior animal study and the subsequent human study led scientists to conclude that the subsequent positive allergenic results of Brazil-nut transgenic soybeans on humans had been fortuitous, as responses in animals could not reasonably predict responses in humans.[388] However, since Pioneer Hi-Bred transgenic soybeans were designed primarily for animal feeds and not human consumption, it should not have mattered much that it was allergenic. But then, given the increasing incidences of adventitious commingling of unapproved transgenic crops with food crops, as exemplified by the StarLink corn fiasco,[389] there

385 *Id.*

386 *See* Mitchell Berger, Public Health and Agricultural Biotechnology: A Review of the Legal, Ethical, and Scientific Controversies Presented by Genetically Altered Foods (Mar. 22, 2000) (unpublished dissertation, Emory University) (on file with Rollins School of Public Health, Emory University).

387 *Id.* at 126.

388 *See* Nestle, *supra* note 372, at 727 (discussing how the general public was fortunate in that the donor species (Brazil-nut) was known to be allergenic, serum samples from persons allergic to Brazil-nut were available for testing, and the product was subsequently withdrawn). He noted that the public might be less fortunate in the future, and emphasized "the pressing need to expand basic and clinical research on food allergies" and the need for more information on the "incidence, prevalence, dietary exposure, antigenicity, immune responses, diagnosis, and treatment that would help researchers, regulators, and biotechnology company predict whether transgenic proteins are likely to cause harm." *Id.*

389 *See infra* Part II, sec. A (discussing the StarLink corn as an experimental transgenic corn that was infused with Trypsin, an insulin precursor, especially designed to combat diarrheal in piglets by Prodigene Corporation). Although the transgenic corn

was no sure way of keeping Pioneer Hi-Bred transgenic soybeans out of the food chain,[390] underscoring the imperatives for basic and clinical testing of all transgenic plant food crops on humans for possible allergens, whether or not they were designed for animal feeds or human consumption.[391]

It has been established that food allergens such as those from Brazil-nut could cause health problems that range from mild-itching to death.[392] However, food allergies are common to both transgenic and conventional plant foods and are relatively difficult to detect.[393] On the other hand, conventionally grown plant foods enjoy a long history of safe usage,[394] and the categories of allergenic foods that are conventionally grown are clearly known and relatively established.[395] However, as shown under this section, scientists are clearly divided on whether transgenic plant foods are no less safe and allergenic than conventional plant foods.[396]

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was never approved for human consumption, its adventitious entry into the global food chain caused national and international furor, and underscored the challenges of segregating transgenic plant crops from non-transgenic crops. Winickoff et al., *supra* note 389, at 103.

390 *See* Berger, *supra* note 386, at 126.

391 *See* Nestle, *supra* note 372, at 728 (recommending the "pressing need for basic and clinical research on food allergies"). Note however the challenges and limitations of conducting human feeding studies, which the United States Food and Drug Administration acknowledged as follows: "feeding studies on whole foods have limited sensitivity" since it would be relatively difficult "to administer exaggerated doses." Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 23004 (May 29, 1992).

392 *See* Nestle, *supra* note 372 at 726.

393 *See also* Billings & Shorett, *supra* note 163, at 82 (noting that "food allergies are difficult to detect, measure objectively and assess in terms of their impact on human health generally").

394 *See* European Parliament & Council on Genetically Modified Food and Feed, (EC) No. 1829/2003 of 22 Sept. 2003, art. 2(12).

395 *See* Nordlee, *supra* note 372, at 688 (noting that allergies to nuts are said to be the most common food allergies, while allergies to Brazil-nut are well documented).

396 *See* Lehrer et al., *supra* note 345, at 563-64 (noting that while transgenic plant foods are allergies prone, they are no more susceptible to allergies than conventional plant foods). Contrast this argument with that in Billings & Shorett, *supra* note 163, at 83 (noting how transgenic plant foods were more susceptible to allergies via "unanticipated creation of novel allergens through gene inactivation or over expression of genes that code for a minor allergen"); *see also* HO & CHING, *supra* note 101, at 21 (contending that the published data on the safety of transgenic plant foods were

The conflicting and conflicted nature of the scientific evidence on the allergenicity of transgenic plant foods inevitably feeds into the central theme of this article on the propriety of science's exclusive prerogative on the governance systems for transgenic plant agricultural technology and foods. Implicit in this thesis is the following recurring question: in light of the apparent lack of unanimity of scientific literature and views as exemplified by the discourse on transgenic plant foods allergens, should science or scientific knowledge, which underpins the regulatory and policy framework for transgenic plant technology, continue to exclude alternative governance systems such as ethics, religious beliefs, and conscience, as canvassed by the plaintiffs in *Alliance for Bi-integrity*?[397] The following paragraph will review the literature on the scientific views on the toxicity of transgenic plant foods and its relevance to the policy and regulatory framework for transgenic plant agriculture and foods.

ii. Conflicting Scientific Views on the Toxicity of Transgenic Plant Foods

Food toxicity is an enduring part of human dietary experience.[398] 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.[399] For example, spinach and rhubarb, common vegetables 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.[400] Furthermore, onions are known to harbour sulphuric acid, which could corrode "the upper gastrointestinal tract of humans" if eaten in excess.[401] Moreover, many mushrooms species are poisonous and could be "lethal in small doses," and are often "difficult to

unreliable because the scientific quality were short of "the usual standards of good science").

397 *See* Alliance for Bio-Integrity v. Donna Shalala, 116 F. Supp. 2d 166 (D. D.C. 2000); *see also infra* Part II, sec. B (detailing the facts of the case).

398 *See* Billings & Shorett, *supra* note 163, at 84.

399 *Id.*

400 *Id.*

401 *Id.*

distinguish from their edible counterparts."[402]

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 than naturally occurring toxins? If not, then why do some scientists readily dismiss such concerns?

The following paragraphs will briefly review the conflicting scientific literature on the nature of transgenic plant foods toxins, with a view to contextualising the discourse on the uncertainty that underpins the science on which transgenic plant policy is predicated, and the propriety of transgenic policy's continual deference to science at the expense of ethics, culture, and religion-based policy systems, as canvassed unsuccessfully by plaintiffs in *Alliance for Bio-integrity*.[403]

According to Paul R. Billings and Peter Shorett, genetic modifications of plant genome could "alter both existing and unanticipated toxicological characteristics of foods."[404] Indeed, scientific literature is indicative that gene insertion could generate unexpected and unintended increases in the levels of naturally occurring toxins.[405] As noted previously, even the FDA, one of the three regulatory bodies for transgenic plant agriculture and foods, 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 plant crops significantly with concomitant nutritional, toxicity, and safety implications.[406]

Furthermore, the uncertainties surrounding the implications of transgenic plant foods for public health was alluded to by John Godfrey, who noted in his letter to *The Lancet* that while there was

402 *Id.*

403 *See* Alliance for Bio-Integrity v. Donna Shalala, 116 F. Supp. 2d 166, 166 (D. D.C. 2000).

404 *See* Billings and Shorett, *supra* note 163, at 84.

405 *Id.*

406 Premarket Notice Concerning Bioengineered Foods, 66 Fed. Reg. 4710 (Jan. 18, 2001) (to be codified at 21 C.F.R. pts 192 and 592).

no current evidence that transgenic plant foods were inherently harmful, one could not conclude that all applications would be harmless due to the possibility of the evolution of new allergens and toxins.[407] 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 food crops, such as soybeans and maize that have been engineered to produce the inherently toxic insecticide from the DNA of Bt bacterium.[408]

Moreover, as evidence of the prevailing uncertainties beclouding the safety science of transgenic plant foods, 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 undigested DNA could "reach peripheral leucocytes, spleen, and liver via the intestinal-wall."[409] Whilst it could be premature to speculate on what could be the public health implications of undigested toxic transgenic DNA permanently lodged in the human gut, 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 glysophate 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.[410]

If the prognosis of Susan Bardocz was correct, then the digestive systems of half the world's population could potentially morph "into pesticide factories" overtime, given that transgenic plant feed and food products, from soybeans and maize, that are

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407 *See* John Godfrey, *Do Genetically Modified Foods Affect Human Health?* THE LANCET, Jan. 29, 2000, at 414.

408 *Id.*

409 *Id. See also* Rainer Schubert, Doris Renz, Birgit Schmitz, and Walter Doerfler, *Foreign (M13) DNA Ingested by Mice Reaches Peripheral Leukocytes, Spleen, and Liver via the Intestinal Wall Mucosa and can be Covalently Linked to Mouse DNA*, PROCEEDINGS OF THE NAT'L ACAD. OF SCIENCES OF THE UNITED STATES OF AMERICA, Feb. 4, 1997, at 961-966.

410 JEFFREY M. SMITH, GENETIC ROULETTE: THE DOCUMENTED HEALTH RISKS OF GENETICALLY ENGINEERED FOODS, *supra* note 168, at 136.

genetically modified to embody and express the inherently toxic DNA of Bt bacterium have been commercially available globally since 1996 for livestock and human consumption. Therefore, any consequential health problems from indigestible Bt toxins in human and animal guts would have global public health ramifications and resonance.[411]

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* two months following the publication of John Godfrey's letter.[412] In his robust defence of transgenic Bt plant foods, Anthony Trewavas argued that transgenic Bt plant foods had been subjected to:

> [T]housands 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.[413]

Anthony Trewavas noted further 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

411 As noted previously, food and feed crops that incorporated Bt toxins, a naturally occurring toxic chemical used in pesticide products, have been commercially available world-wide since 1996. For discussion on the nature of Bt toxins, see Carrie Swadener, *supra* note 104, at 13-20. For discussion on the advent of commercial transgenic Bt. crops in 1996, see ROBERT PAARLBERG, STARVED FOR SCIENCE: HOW BIOTECHNOLOGY IS BEING KEPT OUT OF AFRICA, *supra*, note 31, at 10-11.

412 *See* Anthony Trewavas, *Toxins and Genetically Modified Food*, THE LANCET, Mar. 11, 2000, at 931.

413 *Id.*

foods by the general public.[414] However, the problem with this analysis is that while millions of "qualitatively different genes" may be ingested daily via plant foods by the general public, DNA from Bt bacterium toxins is a natural pesticide with toxic properties that potentially could cause harm to the human body if permanently lodged in the human gut.[415] Besides, Bt toxin is not the sort of toxin commonly found in edible plant foods such as spinach and rhubarb, which could be managed by moderate consumption.[416] Rather, transgenic plant Bt toxin is from Bt bacterium that is often used to manufacture industrial pesticide[417] and was never a natural component of plant foods commonly consumed by humans, until it was genetically incorporated into commercial food crops globally in 1996.[418]

The uncertainties underlying the public health implications of human consumption of Bt toxins in approved transgenic food crops is further exemplified by a 2011 study by Canadian scientists,[419] which would appear to undermine Anthony Trewavas' claim that "[Bt] toxin is simply digested in the gut."[420] Scientists at the Department of Obstetrics and Gynaecology, the University of Sherbrook Hospital Centre in Quebec, Canada, tested blood samples of pregnant women and found traces of Bt toxins in ninety-three percent of the pregnant mothers tested, as

414 *Id.*

415 Bacillus thuringiensis is a bacterium that is naturally imbued with insecticide properties. As a microorganism, the bacterium is not part of our natural diets. However, the incorporation of the bacterium's DNA into plant foods via genetic engineering techniques has brought the bacterium into the food chain with as yet unknown consequences. For discussion on Bacillus thuringiensis bacterium, see Carrie Swadener, *supra* note 104, at 13-20; *see also* Madhuri Kota, Henry Daniell, Sam Varma, Stephen F. Garczynski, Fred Gould, and William J. Major, *supra* note 105, at 1840-45.

416 *See* Billings & Shorett, *supra* note 163, at 84 (noting that spinach and rhubarb contain "oxalic acid, an anti-nutritional compound that inhibits calcium and iron absorption," which could be potentially poisonous if eaten in excess).

417 *See* Carrie Swadener, *supra* note 104, at 13-20.

418 Examples of food crops that have been genetically modified to incorporate the DNA of Bacillus thuringiensis bacterium are transgenic maize and soybeans. *See* ROBERT PAARLBERG, STARVED FOR SCIENCE: HOW BIOTECHNOLOGY IS BEING KEPT OUT OF AFRICA, *supra* note 31, at 10-11.

419 *See* Aziz Aris and Samuel Leblanc, *Maternal and Foetal Exposure to Pesticides Associated to Genetically Modified Foods in Eastern Townships of Quebec,* REPRODUCTIVE TOXICOLOGY, May 2011, at 534-39.

420 Anthony Trewavas, *supra* note 412, at 931.

well as in eighty percent of the umbilical cords studied.[421] 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.[422] If this were so, 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, as exemplified by the study on Canadian pregnant women and their umbilical cords.[423] Also, 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 toxins merely by eating meat from livestock fed on transgenic Bt corn feed, so could men. Also, contrary to Anthony Trewavas' claim that "Bt toxin is simply digested in the gut,"[424] 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 by John Godfrey in his letter to *The Lancet* in January 2000,[425] and Susan Bardocz.[426]

However, unsurprisingly, the findings by Canadian scientists Avis and Leblanc were characteristically and swiftly challenged and disputed in a rejoinder by Bayer CropScience, the primary registrant of glufosinate-ammonium, the active ingredient in transgenic Bt. corn and soybeans that was the subject of Avis and Leblanc's study.[427] Bayer CropScience, who had a commercial interest in the transgenic Bt corn feed in question, wrote a

421 *See* Aziz Aris and Samuel Leblanc, *supra* note 419, at 534-39.

422 *See id.*

423 *See id.*

424 Anthony Trewavas, *supra* note 412, at 931.

425 *See* John Godfrey, *supra* note 407, at 414.

426 *See* JEFFREY M. SMITH, GENETIC ROULETTE: THE DOCUMENTED HEALTH RISKS OF GENETICALLY ENGINEERED FOODS, *supra*, note 168, at 136.

427 *See* Ann Blacker, Richard Breum, Stephen Dacus, Pat Kwiatkowski, Frank Laporte, Bryan Mallyon, Kent Rupprecht, and Klaus Stumpf, *Bayer CropScience's Position on the Findings of Glufosinate and its Metabolite*, REPRODUCTIVE TOXICOLOGY, Dec. 2011, at 494-95.

rejoinder in which they disputed and questioned "the accuracy and credibility of the authors' findings and conclusions related to glufosinate and metabolite 3-MPPA."[428] However, in his response to Bayer CropScience's rejoinder, Aziz Aris, the lead researcher of the Canadian study countered as follows:

> [T]he comments of the authors of BCS remain speculation derived from studies on animals. Our study is the first to demonstrate in humans traces of pesticides, used especially in crops genetically modified to tolerate them. Our study has the merit to provide an order of magnitude of actual concentrations in human serum. What is reassuring is that the concentrations found are far below those in used in animal toxicology. However, as pesticides are bioaccumulative, endocrine disruptors at low doses and acting in the long-term, other human studies must be conducted to develop guidelines. These studies should involve all players, both private and public.[429]

But then, scientists are not only divided on whether or not DNA from the Bt bacterium toxins consumed in transgenic Bt plant foods could accumulate overtime and be permanently lodged in the guts of animals and humans.[430] There is also a lack of unanimity of views amongst scientists on the possible health effects of transgenic Bt plant toxins in 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.[431] 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.[432] Prior to the two-year feeding study on mice, there had been several biotechnology

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428 *Id.* at 494.

429 Aziz Aris, *Response to Bayer CropScience's Position on the Findings of Glufosinate and its Metabolite*, REPRODUCTIVE TOXICOLOGY, Dec. 2011, at 497.

430 *See* JEFFREY M. SMITH, GENETIC ROULETTE: THE DOCUMENTED HEALTH RISKS OF GENETICALLY ENGINEERED FOODS, *supra* note, 168, at 136 (citing Susan Bardocz, a biochemist and nutritionist).

431 *See* Gilles-Eric Séralini et al., *Long Term Toxicity of a Roundup Herbicide and a Roundup-tolerant Genetically Modified Maize*, FOOD AND CHEMICAL TOXICOLOGY, Nov. 2012, at 4224-25.

432 *See id*. at 4221.

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.[433] Moreover, although there had been prior "long-term and multi-generational animal feeding trials" with contrasting safety results,[434] 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 [eleven] blood and urine samples over [two] years."[435] Whilst the mice in the study suffered debilitating ailments including cancerous mammary tumours, liver damage, and kidney damage, approximately fifty percent of males and seventy percent of females in the groups on the diet containing transgenic NK603 glysophate maize died prematurely.[436]

Although the French study was not the first to link the consumption of transgenic crops to debilitating diseases in mice,[437] characteristically, the study was swiftly rebutted and condemned by the European Food Safety Authority (EFSA), Monsanto Corporation, and scientists from the academia. For example, in its October 2012 Press Release, the EFSA concluded that the French study was "of insufficient scientific quality to be considered as

433 *See id*.

434 *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.").

435 *See id*.

436 *See* Gilles-Eric Séralini, *supra* note 431, at 4223.

437 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. For discussion, see HO & CHING, *supra* note 101, at 21-22. 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 dies in the first week of life. The mortality rate was six times that 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. For discussion, see F. WILLIAM ENGDAHL, SEEDS OF DESTRUCTION: THE HIDDEN AGENDA OF GENETIC MANIPULATION, *supra* note 79, at 245-46.

valid for risk assessment."[438] 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.[439]

However, while the EFSA sought further clarifications and scientific data from the authors, other criticisms were withering and less circumspect. For example, by the first week of November 2012, there had been at least seventeen rejoinders to the editors of the *Journal of Food and Chemical Toxicology*, sixteen of which were extremely critical of the study.[440] The rejoinder written by scientists at Monsanto Corporation concluded as follows:

> As a result of methodological failures, incomplete data presentation, and lack of proper statistical analysis, Séralini et al.'s conclusions regarding NK603 and or Roundup cannot be supported by the present data. Indeed, the fundamental flaw in regards to the number of animals employed makes it highly unlikely that any of the purported findings can be statistically supported using standard approaches to analysis even if more data were to be provided by the authors.[441]

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438 *See* Press Release, European Food Safety Authority, EFSA Publishes Initial Review on GM Maize and Herbicide Study, (Oct. 4, 2012), http://www.efsa.europa.eu/en/press/news/121004.htm (last visited Oct. 7, 2013).

439 *Id.*

440 As of November 12, 2012, a cursory look at the journal's website showed that there were at least seventeen letters and rejoinders on the French study to the editors of *Food and Chemical Toxicology*. *See* Science Direct in SC, http://www.sciencedirect.com/science/article/pii/S0278691512005637 (last visited Oct. 7, 2013).

441 *See* Bruce Hammond, Daniel A. Goldstein, and David Saltmiras, *Letter to the Editor*, FOOD AND CHEMICAL TOXICOLOGY, (Nov. 7, 2012), http://dx.doi.org/10.1016/j.fct.2012.10.044, (last visited Oct. 7, 2013).

Some of the rejoinders wondered how the research conducted by the French scientists managed to pass the peer review process "in its current form and [taking into account] the impact of this for the normally high standards adopted by your journal."[442] In the same vein, Mark Tester criticized the French paper for being "misleading and fundamentally flawed" and wondered how the *Journal of Food and Chemical Toxicology* could reconcile its reputation for quality research with the publication of "such poor work".[443] Mark Tester then proceeded systematically to debunk the findings in the French paper as follows:

> Séralini's allegation of negative impacts on rat health as a result of eating biotech corn and glyphosate have been refuted by numerous studies, including long-term feeding studies, in the peer-reviewed scientific literature . . . . A 2008 two-year rat feeding study by Sakomoto et al. found that biotech soybeans pose no health risks. A 2012 assessment by Snell et al., reviewed 12 long-term feeding studies of biotech maize, potato, soybean, rice, and triticale and found that biotech crops are nutritionally equivalent to their conventional counterparts and can safely be used in food and feed. Previous peer-reviewed rat feeding studies using the same products (NK603 and Roundup) have not found any negative food safety impacts.[444]

Also, some of the rejoinders demanded for an immediate withdrawal of the French article in the *Journal of Food and Chemical Toxicology*.[445] For instance, in his criticism of the ethical propriety of the conditions of the mice used in the French study, Anthony Trewavas noted that the accompanying pictures depicting mice inflamed with tumours and diseases "was frankly nothing more than propaganda."[446] He noted further that because

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442 *See* Andrew Cockburn, *Letter to the Editor*, FOOD AND CHEMICAL TOXICOLOGY, (Article in Press, Nov. 7, 2012), at http://dx.doi.org/10.1016/j.fct.2012.10.040 (last visited Oct. 7, 2013).

443 Mark Tester, *Letter to the Editor*, FOOD AND CHEMICAL TOXICOLOGY, (Nov. 7, 2012), at http://dx.doi.org/10.1016/j.fct.2012.10.046 (last visited Oct. 7, 2013).

444 *Id.; see also* Wim Grunewald and Jo Bury, *Comment on "Long term toxicity of a Roundup Herbicide and Roundup-tolerant Genetically Modified Maize" by Séralini et al.*, FOOD AND CHEMICAL TOXICOLOGY, (Nov. 2012), http://dx.doi.org/10.1016/j.fct.2012.10.051 (last visited Oct. 7, 2013).

445 *See* Anthony Trewavas, *Letter to the Editor*, FOOD AND CHEMICAL TOXICOLOGY, (Nov. 2012), http://dx.doi.org/10.1016/j.fct.2012.10.050 (last visited Oct. 7, 2013).

446 *Id.*

"[s]cience requires the dispassionate presentation of information- this paper and this journal have dealt the value of evidence-based knowledge a serious blow and it can only be rectified if the paper is withdrawn by the authors with an apology for misleading the public and the scientific community alike."[447]

Unsurprisingly, the French study that linked Monsanto's transgenic Bt maize to cancerous tumours and liver failure in mice 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.[448] For example, as noted earlier, the EFSA issued a Press Release in which it demanded comprehensive data from the authors, without which they could not rely on the study for risk assessment purposes.[449] 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 maize from the United States.[450]

Arguably, the political and regulatory responses to the French study that links Monsanto's transgenic maize to cancerous tumours and liver failures in mice validates the central hypothesis in this article that the policy and governance systems for transgenic plant agriculture and foods are largely underpinned by "science."[451] By extrapolation, the disputed French study also highlights the state of uncertainty of the "science" that underpins the regulatory and policy framework for the governance of

447 *Id.*

448 Approved transgenic plant food products are generally available in Europe subject to labeling regulation. Ditto approved transgenic plant feed, which is indispensable to the livestock industry. *See* Margret Rosso Grossman, *European Community Legislation for Traceability and Labeling of Genetically Modified Crops in* LABELING GENETICALLY MODIFIED FOOD: THE PHILOSOPHICAL AND LEGAL DEBATE, (Paul Weirich, ed. 2007) at 32-62.

449 *See* Press Release, European Food Safety Authority, EFSA Publishes Initial Review on GM Maize and Herbicide Study, supra note 438.

450 *See* Sean Poulter, *Russia Suspends Import and use of American GM Corn after Study Revealed Cancer Risk*, MAILONLINE, (Sept. 26, 2012), http://www.dailymail.co.uk/news/article-2208452/Russia-suspends-import-use-American-GM-corn-study-revealed-cancer-risk.html (last visited Oct. 7, 2013).

451 The word "science" is defined as "an organised body of knowledge on any subject." *See* OXFORD DICTIONARY AND THESAURUS, *supra* note 34, at 802.

transgenic plant agriculture and foods, and arguably legitimizes one of the central questions in this Article, on the propriety of excluding possible parallel governance systems for transgenic plant agriculture and foods that are rooted in ethics, culture, and religious beliefs, as canvassed by plaintiffs in *Alliance for Bio-integrity*.[452] Although ethical, cultural, and religious beliefs might lack the agnosticism, coherence, homogeneity, and certainty required of credible governance systems for transgenic plant technology, it is submitted that the current science-centric governance system for transgenic plant agriculture and foods is not as agnostic, coherent, or certain as it could possibly be, in light of conflicting scientific knowledge that underpins current policy and regulations for transgenic plant technology.

D. The Challenge of Adventitious Gene Flow and Implications for the Environment and Biodiversity

Scientists are divided on the merits of transgenic plant agriculture for the environment and biodiversity.[453] This section will revisit this debate with a view to highlighting the contrasting and conflicting scientific evidence on the effects of transgenic plant agriculture on the environment. It also will address how these uncertainties continue to reinforce differing regulatory and policy frameworks for transgenic plant agriculture around the world.[454] Indeed, it is this conflicted science fueling disparate regulatory policies that prompts one of the key questions in this article regarding the propriety of sidelining possible parallel governance systems such as ethical and cultural imperatives.[455] The question is especially pertinent since the science on which the current regulatory framework is predicated is not as coherent,

452 *See* Alliance for Bio-Integrity v. Donna Shalala, 116 F. Supp. 2d 166, 166 (D. D.C. 2000).

453 *See* REECE WALTERS, ECO CRIME AND GENETICALLY MODIFIED FOOD, (Oxford: Routledge, 2011) at 38 (discussing "the weight of evidence that points to greater environmental risks and concerns through GM crops and ecological contamination").

454 This is exemplified by the differences in regulatory approaches between the United States and countries of the European Union. *See* Armin Spök, *Biotechnology Policy in the European Union, in*, GENETICALLY ENGINEERED CROPS: INTERIM POLICIES, UNCERTAIN LEGISLATION, (Iain E.P. Taylor ed.) *supra*, note 163, at 229-63.

455 *See Alliance for Bio-Integrity*, 116 F. Supp. 2d at 166.

certain, stable, objective, or agnostic as it should, or could, be.[456] However, it is clear that as the science of transgenic plant agriculture continues to evolve, so would the yet unknown implications of the advent of the technology.[457] After all, commercial transgenic plant agriculture is still less than two decades old,[458] and whilst scientists might disagree on specific findings, there appears to be a general consensus that there could "be no proof that all risks are known or that current knowledge will not be determined by new findings."[459]

The world population is in a spiral climb with concomitant concerns about food security, as well as the capability and sustainability of the agrochemical-dependent conventional plant agriculture to meet the world's growing food needs.[460] "Agrochemical" is a generic term for a range of 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.[461] Moreover, in the 1960s, American

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456 This hypothesis is predicated on the evidence of contested and conflicting science on the full ramifications of transgenic plant agriculture and food respectively for the environment and public health, as amply demonstrated in part III of this essay. Thus, the image of an unsettled and highly contested science arguably detracts from science's perceived agnosticism, neutrality, objectivity, and relative certitude that intrinsically set science apart from culture, religion, and ethics. *See* Hans Radder, *Science and Technology: Positivism and Critique*, *in* A COMPANION TO THE PHILOSOPHY OF TECHNOLOGY (Jan Kyrre Berg Olsen, Stig Andur Pedersen, and Vincent F. Hendricks, eds.), *supra* note 73, at 61-62.

457 This is exemplified by a 2012 study, which showed for the first time 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 that are crucial for soil enrichments. *See* Tanya E. Cheeke, Todd N. Rosentiel, and Mitchell B. Cruzan, *supra* note 95, at 700-07.

458 Transgenic plant crops were first commercially grown in 1996. *See* Jack Ralph Kloppenburg Jr., *supra* note 15, at 296.

459 Ronald J. Herring, *supra* note 107, at 4.

460 *See* PER PINSTRUP-ANDERSEN AND EBBE SCHØLER, SEEDS OF CONTENTION: WORLD HUNGER AND THE GLOBAL CONTROVERSY OVER GM CROPS, *supra* note 169, at 1-6 (discussing how plant genetic engineering techniques could be used to ameliorate food security problems especially in Africa).

461 *See* VANDANA SHIVA, THE VIOLENCE OF THE GREEN REVOLUTION, 114-19

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*.[462] 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.[463] Therefore, given the adverse effects that agro-chemical dependency in conventional agriculture has on the environment, any technology that could ameliorate the problems posed by synthetic chemicals for the environment should 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 Bt engineered insect-resistance crops, which they believed could benefit the environment by significantly reducing the use of agrochemicals in plant agriculture.[464] 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 percent of world farmers who plough "arid and semi-arid regions marked by long dry seasons and scant rainfall even in the wet season."[465] 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.[466]

(London & New York: Zed Books Limited, 2002).

462 *See* RACHEL CARSON, SILENT SPRING, (London & New York: Penguin Classics, 2000).

463 *See* Pamela Ronald, *Plant Genetics, Sustainable Agriculture and Global Food Security*, 188 GENETICS 11, 11-12 (May 2011).

464 *See* Miguel A. Altieri, *Transgenic Crops: Agro-biodiversity and Agro-ecosystem Function*, *in* GENETICALLY ENGINEERED CROPS: INTERIM POLICIES, UNCERTAIN LEGISLATION, (Iain E. P. Taylor, ed.) *supra* note 163, at 37-38. *See also* REECE WALTERS, ECO CRIME AND GENETICALLY MODIFIED FOOD, *supra*, note 453, at 38.

465 *See* ROBERT PAARLBERG, STARVED FOR SCIENCE: HOW BIOTECHNOLOGY IS BEING KEPT OUT OF AFRICA, *supra* note 31, at 149.

466 *See id*. at 149-77.

However, despite the promising 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.[467] But gene flow is not unique to transgenic plant agriculture. Rather it is a natural phenomenon through which genes from plant species could be disseminated to other plant species in the wild via pollen, seeds, and in some cases, "vegetative propagules."[468] However, most transgenic plants, such as those encoded with genes from Bt bacteria, 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 plants,[469] which enable farmers to kill weeds without harming their crops, could pass on their gene to non-transgenic conventional or organic soybeans or maize as well as weeds in the wild.[470] Indeed, a 2004 study conducted by the Union of Concerned Scientists in the United States showed evidence of an adventitious presence of glyphosate resistant genes in samples of six conventional, non-transgenic soybeans cultivars at the levels of 0.0.5 and 1% in 50%.[471] Whilst this could have significant economic and intellectual property rights implications for non-transgenic plant farmers,[472] it is the

467 *See* Mary A. Rieger et al., *Pollen-Mediated Movement of Herbicide Resistance Between Commercial Canola Fields*, SCI., (June 28, 2002), at 2386-88.

468 *See* Carol Mallory-Smith & Maria Zapiola, *Gene Flow from Glyphosate-resistant Crops*, PEST MANAGEMENT SCIENCE, (Apr. 2008), at 428, 430.

469 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 & Stephen B. Powles, *Glyphosate: A Once-in-a-century Herbicide: Mini Review*, PEST MANAGEMENT SCI., (Apr. 2008), at 319-25.

470 *See* Carol Mallory-Smith & Maria Zapiola, *supra* note 468, at 428-40.

471 *See id.* at 431 (citing Mellon M. & Rissler J., *Gone to Seed: Transgenic Contaminants in the Traditional Seed Supply* 28, 40-42, UCS Publications, 2004).

472 Notably, organic and conventional farmers who trade in non-transgenic markets could lose their markets if their crops tested positive for transgenes. For example, a Western Australian organic farmer, Steven Marsh, sued his neighbouring farmer, Michael Baxter for economic damaged arising from the loss of his organic certification. Mr Marsh attributed the loss of his organic certification to the transgenic canola materials, which escaped from his neighbour's farm into his farm. *See Organic Farmer to Sue Over GM Contamination*, ABC NEWS, (Jan. 13, 2011), http://www.abc.net.au/news/2011-01-13/organic-farmer-to-sue-over-gm-contamination/1904328, (last visited

prospect that gene flow could create stubborn "super-weeds" that most scientists and farmers find troublesome.[473]

Evidence of weeds' resistance to Monsanto's glyphosate herbicide was first discovered in Australia,[474] whilst herbicide-resistant volunteer canola is now a major weed problem in Canada.[475] In the United States, farmers are said to be coping with resurgence in glyphosate Roundup resistant weeds that, as of 2010, have plagued approximately seven to ten million acres of arable farmland.[476] In order to combat super weed 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."[477] For instance, Mr. Anderson, a Tennessee farmer, had to wrestle with a notoriously tenacious species of glyphosate resistant weed known as "Palmer amaranth" or "Pigweed."[478] According to William Newman and Andrew Pollack, Pigweed could grow up to three inches daily and reach seven-feet or more,

Oct. 8, 2013). Moreover, seed companies such as Monsanto have filed numerous lawsuits for intellectual property infringement against non-transgenic farmers, who allegedly saved and cultivated their proprietary seeds without prior consent. *See* MONSANTO, *Saved Seed and Farmer Lawsuits*, at http://www.monsanto.com/newsviews/Pages/saved-seed-farmer-lawsuits.aspx, (last visited Oct. 8, 2013). For discussion on the economic and intellectual property right implications of adventitious presence of transgenic plant gene in conventional agriculture, see Schmeiser v. Monsanto Canada Inc., 2002 FCA 309, *available at* http://www.ariplex.com/percyschmeiser/Appeal%20Decision.pdf; *Maria Lee & Burrell*, *supra* note 247, at 517-37.

473 For example, the first documented case of weed resistance to glyphosate involved rigid ryegrass (*Lolium rigidum*) and was found near Orange in New South Wales, Australia. *See* Stephen B. Powles et al., *Evolved Resistance to Glyphosate in Rigid Ryegrass (Lolium rigidum) in Australia*, 46 WEED SCI. 604, 604-07, (Sept.-Oct. 1998).

474 *See id*.

475 *See* Miguel A. Altieri, *Transgenic Crops, Agro-biodiversity, and Agro-ecosystem Function, in* GENETICALLY ENGINEERED CROPS: INTERIM POLICIES, UNCERTAIN LEGISLATION, (Iain E.P. Taylor, ed.) *supra* note 163, at 43.

476 *See* William Newman and Andrew Pollack, *U.S. Farmers Cope with Roundup-Resistant Weeds*, N. Y. TIMES, May 4, 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.*

477 *See id.*

478 *Id.*

with ability to choke out crops and damage harvesting equipment.[479] Thus, it is ironic that farmers had to resort to herbicide in order to combat the emergence of super-weeds. This is especially true since the herbicide resistant transgenic plant was designed in part to reduce the use of toxic herbicide on arable farmland.

The increased use of toxic herbicide would appear to belie the claim by biotechnology companies that herbicide-resistant transgenic plants were beneficial to the environment,[480] a sentiment shared by Bill Freese, a science policy analyst for the Center for Food Safety in Washington, who stated: "The biotech industry is taking us into a more pesticide-dependent agriculture when they've always promised, and we need to be going in, the opposite direction."[481] Even Monsanto Corporation, who is the proprietary owner of glyphosate herbicide, has acknowledged that weeds' resistance to the herbicide is "a serious issue."[482] In fact, the company is so worried about the problem of weed-resistant herbicide that they agreed to subsidize 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.[483] 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.[484] 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.[485] Furthermore, Monsanto is said to be developing transgenic crops that are resistant to dicamba herbicide, whilst Syngenta is developing

479 *See id.*

480 *See* Miguel A. Altieri, *Transgenic Crops: Agro-biodiversity and Agro-ecosystem Function*, *in* GENETICALLY ENGINEERED CROPS: INTERIM POLICIES, UNCERTAIN LEGISLATION, (Iain E. P. Taylored.) *supra* note 163, at 37-38.

481 *See* William Newman & Andrew Pollack, *supra* note 476, at B1.

482 *See id.* (citing one Rick Cole, who managed weeds resistance issues for Monsanto in the United States).

483 *See id.*

484 *See id.*

485 *See id.*

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 [W]ar."[486] It is however doubtful whether the development of new herbicides would solve the challenge posed by super weeds. If weeds could develop resistance to the current variants of commercial herbicides, they could overtime develop resistance to new varieties of herbicides, until there is no known herbicide left with which to fight weeds. It is also clear that the environment and biodiversity would be the worse for it, as weeds continually evolve resistance to all known herbicides.

Apart from the weeds' resistance problem, scientists have argued that targeted pests could, overtime, also become resistant to the Bt toxins in transgenic Bt Maize or soybeans.[487] 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.[488] Indeed, bioengineers regard insects' resistance to Bt toxins as inevitable, 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.[489]

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 biodiversity.[490] This is exemplified by the Rosi-Marshall paper, which was based on the study of twelve streams in northern Indiana.[491] The paper found that caddis-fly

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486 *See* William Newman & Andrew Pollack, *supra* note 476, at B1.

487 *See* Miguel A. Altieri, *Transgenic Crops, Agro-biodiversity, and Agro-ecosystem Function*, *in* GENETICALLY ENGINEERED CROPS: INTERIM POLICIES, UNCERTAIN LEGISLATION, (Iain E.P. Taylor ed.), *supra* note 163, at 46-48.

488 *See id.*

489 *See id.*

490 *See* Rosi-Marshall, et al., *supra* note 191, at 16204-08.

491 *See id.*

larvae that were "fed only on Bt maize debris grew half as fast as those that ate debris from conventional maize."[492] As previously discussed, the Rosi-Marshall paper was criticized by fellow scientists in numerous rejoinders and rebuttals that bordered on ad hominem and insinuations of academic and scientific fraud.[493]

But then the Rosi-Marshall paper was neither the first nor the last to link transgenic Bt crops to negative environmental impacts.[494] For example, as previously noted, 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.[495] However, the main problem is that arbuscular mycorrhizal fungi are no ordinary fungi. Rather, they exist in a mutually beneficial and symbiotic relationship with land plants species, through which arbuscular mycorrhizal fungi depend on land plants for carbon nutrition, and land plants depend on arbuscular mycorrhizal for phosphorous intake from the soil.[496] 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 appear that the full ramifications of the advent of transgenic plant agriculture for the environment and biodiversity are at best ambivalent. 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,

492 Emily Waltz, *supra* note 181, at 27.

493 *See generally supra* Part IIC of the essay (discussing Rosi-Marshall paper). *See also* Emily Waltz, *supra* note 181, at 27-30.

494 *See* Tanya E. Cheeke et al., *Evidence of Reduced Arbuscular Mycorrhizal Fungal Colonization in Multiple Lines of Bt Maize*, AM. J. OF BOTANY, *supra* note 95, at 700-07.

495 *See id.*

496 *See* N.S. Bolan, *A Critical Review on the Role of Mycorrhizal Fungi in the Uptake of Phosphorous by Plants*, 134 PLANT AND SOIL 2, 189-207 (July, 1991)*; see also* Berta Bago, *Putative Sites for Nutrient Uptake in Mycorrhizal Fungi*, 226 PLANT AND SOIL 2, 263-74 (Nov. 2000).

as more arable farmlands are cultivated with transgenic plant crops around the world, and more research studies are conducted on the long term environmental impacts of transgenic agriculture. Thus, to the extent that the full ramifications of the environmental impacts of transgenic plant agriculture are yet unknown, the hypothesis earlier posited in this article that the current science that underpins the regulatory and policy framework for transgenic plant agriculture is at best evolving or evolutionary in nature, has arguably been validated.[497] Furthermore, to the extent that the current science on the full environmental impacts of transgenic plant agriculture is ambivalent, ambiguous, and highly contested, any regulatory and policy framework predicated on it would, of necessity, reflect the differing scientific findings on the full ramifications of transgenic plant agriculture for the environment. This is exemplified by the fact that Austria is still opposed to transgenic plant agriculture on grounds of its possible negative impacts on public health and the environment.[498] However, the governments of the United States and Canada, where commercial plant agriculture has flourished since 1996, did not share the concerns of the Austrian government that commercial transgenic plant agriculture might be incompatible to a sustainable agricultural environment.[499] On the other hand, the government of

497 *See supra* Part I (analysis); *see also* notes 94, 95, 97, and accompanying text.

498 Under Regulation No. 45 of the Federal Ministry for Consumer Health Protection of 13 February 1997, Austria prohibited the sale of Bt-176 maize in the country on the basis of the safeguard clause contained in Article 16 of Directive 90/220/EC on Deliberate Release of Genetically Modified Organisms, which was repealed by Directive 2001/18/EC on Deliberate Release of Genetically Modified Organisms. Article 16 of the repealed Deliberate Release Directive 90/220/EC, which is now Article 23 of Deliberate Release Directive 2001/18/EC, allowed national governments to provisionally prohibit the use or sale of approved transgenic plant products if human health and the environment were put at risk. When Austria's decision was challenged by the United States, Canada, and Argentina in *European Communities – Measures Affecting the Approval and Marketing of Biotech Products* (WT/DS291/R, WT/DS292/R, and WT/293/R, Sept. 29, 2006), *supra* note 295, Austria argued *inter alia* that "new scientific results have questioned the present scientific possibility of a conclusive evaluation of the mechanism of gene transfer, as well as the development of resistance to Bt toxin." The Panel concluded that Austria's safeguard measure on BT-176 maize fell within the scope of Annex A (1) (b) and (c) of the Sanitary and Phytosanitary (SPS) Agreement, an international treaty of the World Trade Organization. *See id*. at 885-93.

499 Indeed, Canada and the United States successfully challenged the European Union moratorium on the approval and sale of new transgenic plant organisms in

the United Kingdom, where there is as of yet no locally managed commercial transgenic plant agriculture,[500] was recently urged by members of Parliament to exercise caution and conduct independent reports "on the potential impacts on the environment of GM crops, and their impacts on farming and on the global food system."[501] This thus begs the recurring question: if the science that underpins the differing national and transnational regulatory and policy frameworks for transgenic plant agriculture is not sacrosanct, what is the justification for the exclusion of possible alternative governance systems premised on ethical, religious, and cultural imperatives?

Therefore, within the context of relevant case law, Part IV of the article will analyze the imperatives for the inclusion of ethical, conscientious, religious, and cultural values in the governance of transgenic plant agriculture, as unsuccessfully canvassed for by plaintiffs in *Alliance for Bio-integrity*.[502]

IV. The Tyranny of Science: What Role for Ethical, Conscientious, Religious, and Cultural Values in the Governance of Transgenic Plant Agriculture and Food?

The national and transnational regulatory and policy frameworks for transgenic plant agriculture and food range from approval systems for new transgenic plant seeds,[503] transgenic

European Communities–Measures Affecting the Approval and Marketing of Biotech Products. *Id.* at 1. Moreover, commercial transgenic plant agriculture has flourished in Canada and the United States since 1996, with millions of arable farmland under cultivation, and millions of transgenic soybeans and corn sold annually on the domestic and export markets. In the United States for example, it is estimated that approximately 170 million acres are planted with transgenic soybeans, corn and cotton crops. *See* Newman & Pollack, *supra* note 476, at B1.

500 Despite numerous field trials, which often face intense local opposition and picketing, there is as yet no commercial transgenic plant agriculture in the United Kingdom. For a report on local opposition to field trials for new transgenic crops, see Telegraph View, *Witless GM Vandalism*, (May 21, 2012), http://www.telegraph.co.uk/earth/agriculture/geneticmodification/9278916/Witless-GM-vandalism.html (last visited Oct. 8, 2013).

501 *See* Alistair Driver, *MPs Urge Government Caution on GM Crops*, FARMERS GUARDIAN, (May 14, 2012), http://www.farmersguardian.com/home/arable/mps-urge-government-caution-on-gm-crops/46916.article, (last visited Oct. 8, 2013).

502 *See* Alliance for Bio-Integrity v. Donna Shalala, 116 F. Supp. 2d 166, 166 (D. D.C. 2000).

503 *See* Directive 2001/18/EC, of the European Parliament and of the Council of 12

plant seed cultivation rules,[504] to marketing and labeling rules for new transgenic plant seeds and food products.[505] The role of science as the fulcrum anchoring the regulatory and governance systems for transgenic plant agriculture and food has been demonstrated in previous sections of this article.[506] For example, it was noted how the guidance document of the EFSA on the environmental risk assessment for transgenic plant is predicated on "available scientific and technical data and on common methodology for identification, gathering and interpretation of the relevant data."[507] Ditto the rules governing field testing or trials of plants genetically engineered to produce pharmaceuticals and industrial compounds by the U.S. Department of Agriculture, which mandated on-farm separation distances between transgenic pharmaceutical plant and non-transgenic plant, and the creation of plants "refuges" or buffer zones between transgenic and non-transgenic plants, as a bulwark against in situ gene flow and the concomitant adventitious commingling of genes between transgenic and non-transgenic plants.[508]

The regulatory and governance systems for transgenic plant agriculture and food are science-dependent or science-centric. However, whilst there is nothing wrong with a science-centric regulatory and policy framework, the apparent exclusion of possible parallel governance systems that range from ethics, to religion, to culture, as exemplified by *Alliance for Bio-integrity*,[509]

Mar. 2001 on the Deliberate Release into the Environment of Genetically Modified Organisms 90/220/EEC, 2001 O.J. (L 106) 1 (stipulating the conditions for approval for the release into the environment of genetically modified organisms).

504 *See id.*

505 *See, e.g.*, Regulation (EC) No. 1830/2003 of the European Parliament and of the Council of 22 Sept. 2003, L268/24, O.J. (concerning the traceability and labeling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms).

506 *See generally supra* Parts I, II, & III (discussing the role of science in transgenic food governance).

507 *See* EFSA Panel on Genetically Modified Organisms, *supra*, note 54, at 3.

508 *See* Department of Agriculture, Animal and Plant Health Inspection Service, *Field Testing of Plants Engineered to Produce Pharmaceutical and Industrial Compounds*, 68 Fed. Reg. 11337-40 (Mar. 10, 2003).

509 *See* Alliance for Bio-Integrity v. Donna Shalala, 116 F. Supp. 2d 166, 166 (D. D.C. 2000). *See also*, Jeffrey L. Fox, *FDA, Activists Seeks Judgments in Food Policy Lawsuit*, 17 NATURE BIOTECHNOLOGY at 746-47 (Aug. 1999).

smacks of science determinism and tyranny. This is especially so, since the science that anchors the current regulatory and policy framework for transgenic plant agriculture and food is at best evolutionary, conflicted, and not as reliable, certain, or agnostic as it should or could be. It is therefore undeserving of its ostensible monopoly over the governance systems for transgenic plant agriculture.[510]

The following paragraphs will review and analyze selected case law in relative detail, with a view to ascertaining the significance and extent to which non-scientific considerations are excluded from the regulatory and policy framework for transgenic plant agriculture and food. It will also examine the propriety of the exclusion and how the current governance systems for transgenic plant agriculture and food could benefit from a more comprehensive, holistic, and inclusive regime that take cognizance of ethical, religious, and cultural imperatives.

A. Alliance for Bio-integrity v. Donna Shalala*: Religious Belief Suppression Challenge to the Substantial Equivalence Doctrine*

As noted previously in this article,[511] the plaintiffs in *Alliance for Bio-integrity*[512] were a coalition of scientists, chefs, civil activists, and religious leaders who were opposed to transgenic plant agriculture and food on grounds that it posed unacceptable risks to public health and the environment.[513] They contended that the FDA's non-labeling regime for transgenic plant food unfairly burdened their religious beliefs and violated their rights to free exercise of religion as guaranteed by the First Amendment to the United States Constitution and the provisions of the Religious Freedom Restoration Act.[514] This section of the article will focus on the propriety of the plaintiffs' religious challenge to the FDA policy statement on substantial equivalence doctrine and its concomitant non-labeling regime for transgenic plant food, and the

510 *See generally supra* Part III C & D (discussing improvements in scientific process).

511 *See generally supra* Part III B (addressing *Alliance for Bio-Integrity*).

512 *See Alliance for Bio-integrity*, 116 F. Supp. 2d at 166.

513 *See id.* at 170.

514 *See id.* at 180.

legal imperatives for accommodating religious and cultural beliefs alongside science in the regulatory and policy framework for transgenic plant agriculture and food systems.

The plaintiffs in *Alliance for Bio-integrity* argued inter alia that the FDA policy statement on substantial equivalence doctrine, which endorsed and validated a non-labeling regime for transgenic plant food, unconstitutionally violated their right to free exercise of religion under the First Amendment to the Constitution of the United States,[515] which provides inter alia that "Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof."[516] However, whilst drawing on the United States Supreme Court decision in *Employment Division v. Smith*,[517] the Federal District Court in *Alliance for Bio-integrity* rejected plaintiffs' argument on grounds that the FDA statement of policy on the substantial equivalence doctrine, on which the non-labeling rule for transgenic plant food was predicated, was a neutral law of general application. The court concluded that neutral laws of general application would not violate the Free Exercise Clause of the First Amendment, "even if the laws incidentally burden religion."[518]

The pertinent questions follow. First, what is a neutral law of general application, and to what extent is the FDA statement of policy on substantial equivalence doctrine, and its concomitant non-labeling regime for transgenic plant food, a neutral law of general application?[519] Second, are all neutral laws of general application automatically exempted from the Free Exercise Clause of the First Amendment as opined by the *Alliance for Bio-integrity* court?[520] Third, was the court correct in holding that the statement of policy on the substantial equivalence doctrine, on which the non-labeling rule for transgenic plant food was premised, did not violate plaintiffs' free exercise right of religion as guaranteed by

515 *See id.* at 179.

516 *See* U.S. CONST. Amend. I (regarding freedom of speech, freedom of the press, religious freedom, freedom of assembly, and the right to petition).

517 *See* Employment Division v. Smith, 494 U.S. 872 (1990).

518 *See* Alliance for Bio-Integrity v. Donna Shalala, 116 F. Supp. 2d 166, 179-80 (D. D.C. 2000).

519 *See id.* at 180 (it is instructive to note that the parties never disputed that the Statement of Policy was a neutral law of general applicability).

520 *See id.* at 179-80.

the First Amendment to the United States Constitution on grounds that it was a neutral law of general application?[521]

Answering these questions is paramount to a proper analysis of the free exercise clause decision of the court in *Alliance for Bio-integrity*,[522] especially because the court appeared to gloss over these questions when it presumptively found that the FDA statement of policy on the substantial equivalence doctrine and its non-labeling policy for transgenic plant food, was a neutral law of general application that was automatically exempted from the Free Exercise Clause of the First Amendment, notwithstanding its apparent derogation from plaintiffs' religious beliefs.[523] However, answering the above questions would necessitate a brief but thorough review of the decision of the Supreme Court of the United States in *Employment Division v. Smith*.[524]

In *Smith*,[525] the central issue for determination before the Court was whether the Free Exercise Clause permitted Oregon to penalize the religious use of peyote as a class B drug.[526] Oregon law prohibits the knowing or intentional possession of a "controlled substance" unless the substance had been prescribed by a medical practitioner.[527] The respondents, Alfred Smith and Galen Black, were dismissed from their jobs with a private drug rehabilitation organization because they ingested peyote, a hallucinogen class B drug for sacramental purposes at a religious ceremony in a Native American Church, of which they were members.[528] The respondents subsequently applied to the petitioner, the Employment Division of the State of Oregon, for

521 *See id.*

522 *See Alliance for Bio-integrity*, 116 F. Supp. 2d, at 166.

523 The Federal District Court drew on *Employment Division v. Smith*, 494 U.S. 872 (1990), in support of the finding that the FDA statement of policy on substantial equivalence and its non-labeling regime for transgenic plant food, was a neutral law of generally applicability that was exempted from the free exercise clause of the First Amendment to the Constitution of the United States. *See Alliance for Bio-integrity*, 116 F. Supp. 2d at 180.

524 *See* Employment Division v. Smith, 494 U.S. 872, 872 (1990).

525 *See Smith*, 494 U.S. at 872.

526 *See id.* at 874.

527 *See id.* at 874. *See also* Oregon Rev. Stat. § 475.992(4) (1987).

528 *See Smith*, 494 U.S. at 874.

unemployment benefits.[529] However, the petitioner determined that the respondents were ineligible for unemployment benefits because they had been dismissed for a work-related "misconduct."[530] Nevertheless, the Oregon Court of Appeals reversed the determination, on grounds that denial of unemployment benefits to the respondents violated their "free exercise rights under the First Amendment."[531] In an appeal to the Supreme Court of Oregon, the petitioner argued that the denial of underlying benefits was permissible because respondents' consumption of peyote a Class B drug, was a crime under the law of the State of Oregon.[532] However, the Supreme Court of Oregon reasoned that the respondents' criminal use of peyote was inadequate to justify the burden that the denial of unemployment benefits "imposed on respondents' religious practice."[533] The Supreme Court of Oregon then concluded that the respondents were entitled to payment of unemployment benefits.[534]

The petitioner further appealed to the U.S. Supreme Court, where the main question for determination was whether the prohibition of religious use of peyote, a Class B drug, under the State of Oregon's narcotics law was permissible under the Free Exercise Clause of the First Amendment to the United States Constitution.[535] In their judgment, the Supreme Court of the United States noted that the Free Exercise Clause not only guaranteed the personal right to believe and profess whatever religious doctrine one desired,[536] but also preserved and protected:

529 *See id.*

530 *Id.*

531 *Id.* at 874.

532 *Id.* at 875.

533 *Id.*

534 *Smith*, 494 U.S. at 875. For the Oregon Supreme Court decision, *see Smith v. Emp't Div. Dep't of Human Res.*, 301 Or. 209, 217-219 (1986). For a remanded decision by the Oregon Supreme Court, see *Smith v. Emp't Div. Dep't of Human Res.*, 308 Or. 68, 72-73 (1988). The U.S. Supreme Court had remanded the case to the Supreme Court of Oregon to determine whether or not the Respondents' religious use of peyote was prohibited by Oregon law. The Oregon Supreme Court held that there was no religious use exemption for the use of peyote drug under Oregon law, but nevertheless went on to affirm its previous ruling that the State of Oregon could not deny unemployment benefits to the Respondents for their religious use of peyote drug. *Id.*

535 *Smith*, 494 U.S. at 876.

536 *Id.* at 877.

"[t]he performance of (or abstention from) physical acts: assembling with others for a worship service, participating in sacramental use of bread and wine, proselytizing, abstaining from certain foods or certain modes of transportation."[537]

However, the Court discountenanced the respondents' claim that their religious use of peyote placed them beyond the reach of the narcotics law of the State of Oregon that was not specifically directed at their religious practice,[538] on grounds inter alia that the claim was tantamount to taking the meaning of "'prohibiting the free exercise [of religion]' one large step further."[539] The U.S. Supreme Court further noted that the Court had "never held that an individual's religious beliefs excuse him from compliance with an otherwise valid law prohibiting conduct that the State is free to regulate."[540] In support of its reasoning, the Supreme Court of the United States then drew on its earlier decision in *Minersville School District Board of Education v. Gobitis*[541] as follows:

> Conscientious scruples have not, in the course of the long struggle for religious toleration, relieved the individual from obedience to a general law not aimed at the promotion or restriction of religious beliefs. The mere possession of religious convictions which contradict the relevant concerns of a political society does not relieve the citizen from the discharge of political responsibilities.[542]

The Court further noted that in its previous decisions, it had been consistent in the application of the principle that the right to free exercise of religion did not relieve an individual of the obligation to comply with a "valid and neutral law of general applicability on the ground that the law proscribes (or prescribes) conduct that his religion prescribes (or proscribes)."[543] One of

537 *Id.*

538 This argument was solely geared towards enabling the respondents to claim unemployment benefits, which was rejected by the petitioner on grounds that the respondents' religious use of peyote, a class B drug, was a felony under the State of Oregon's law. *Id.* at 877-878.

539 *Smith*, 494 U.S. at 878.

540 *Id.* at 878-879.

541 *See* Minersville School Dist. Bd. of Ed. v. Gobitis, 310 U.S. 586, 594-95 (1940).

542 *Smith*, 494 U.S. at 879.

543 *Id.* at 879.

such decisions was *Prince v. Massachusetts*,[544] in which the Supreme Court of the United States held that a mother could be prosecuted under the child labor laws for using her children to disseminate religious literature on the street, notwithstanding her own religious motivations.[545] Yet another decision was *Braunfeld v. Brown*,[546] in which Sunday-closing laws were upheld against the claim that the laws burdened the religious practices of persons whose religions compelled them to refrain from work on other days.[547]

However, the U.S. Supreme Court noted that there could be exceptional circumstances under which the free exercise right of religion could bar a valid and neutral law of general application.[548] These would include a circumstance in which the free exercise right was coupled with other constitutional rights such as the freedom of speech and the freedom of the press.[549] According to the Supreme Court of the United States:

> The only decisions in which we have held that the First Amendment bars application of a neutral, generally applicable law to religiously motivated action have involved not the Free Exercise Clause alone, but the Free Exercise Clause in conjunction with other constitutional protections, such as freedom of speech and of the press.[550]

As an example of exceptions to the general rule, the U.S. Supreme Court referenced its previous judgment in *Wisconsin v. Yoder*,[551] in which a valid and neutral law of general application, which mandated compulsory school attendance for pupils, was invalidated for Amish parents who refused to send their children to school on religious grounds.[552] Notably, the exemption to the universal reach of neutral laws of general application by the Free

544 Prince v. Massachusetts, 321 U.S. 158, 171 (1944) (stating the United States Supreme Court found no constitutional infirmity in "excluding [these children] from doing there what no other children may do").

545 *Id.* (cited in Employment Div. v. Smith, 494 U.S. at 879-80).

546 Braunfeld v. Brown, 366 U.S. 599 (1961).

547 *Id.* at 599; *see also Smith*, 494 U.S. at 880.

548 *See id.* at 881.

549 *Id.*

550 *Id.*

551 Wisconsin v. Yoder, 406 U.S. 205 (1972).

552 *Smith*, 494 U.S. at 881 (citing Wisconsin v. Yoder, 406 U.S. at 205-06 (1972)).

Exercise Clause in conjunction with other constitutional rights, as exemplified by *Wisconsin v. Yoder*,[553] and *Murdock v. Pennsylvania*,[554] was described by the U.S. Supreme Court in *Smith*,[555] as a hybrid situation, which the Court found inapplicable to the respondents, whose claim to free exercise right of religious use of peyote, a class B drug, was not coupled with any other known constitutional rights.[556]

Yet another exemption to the general rule that the Free Exercise Clause would not bar a neutral and valid law of general application is the "compelling governmental interest" test espoused by the U.S. Supreme Court in *Sherbert v. Verner*.[557] The test, which is otherwise known as the *Sherbert* test, posits that any governmental actions that substantially burden a religious practice must be justified by a compelling governmental interest.[558] Significantly, the respondents in *Smith*[559] had additionally sought refuge under the *Sherbert* test by arguing that their claim to religious exemption from Oregon's narcotics law should be evaluated under the *Sherbert* "compelling governmental interest" test set forth by the U.S. Supreme Court in *Sherbert*.[560] In *Smith*, the respondents invoked the *Sherbert* test and called on the Court to balance their alleged right to religious use of peyote against Oregon's narcotics law, and then determine whether the State of Oregon had a compelling interest that could justify the general enforcement of its narcotics law, notwithstanding that such enforcement would be prejudicial to respondents' religious use of peyote.[561] However, the Court noted that it rarely applied the *Sherbert* test beyond the realm of unemployment compensation claims,[562] and then declined plaintiffs' request to apply the

553 *Yoder*, 406 U.S. at 205.

554 In *Murdock v. Pennsylvania*, 319 U.S. 105 (1943), the United States Supreme Court invalidated a law that imposed a flat tax on solicitation for the dissemination of religious ideas.

555 *Smith*, 494 U.S. at 881-82.

556 *Id.* at 882.

557 Sherbert v. Verner, 374 U.S. 398 (1963).

558 *Id.* at 402-03.

559 *Smith*, 494 U.S. at 882-83.

560 *Id.* at 883 (citing *Sherbert v. Verner*, 374 U.S. at 402-03).

561 *See Smith*, 494 U.S. at 882-83.

562 *Id.* at 883.

Sherbert test "to require exemptions from a generally applicable criminal law."[563] Although the U.S. Supreme Court did countenance the possibility of applying the *Sherbert* test beyond the realm of unemployment compensation,[564] it categorically refused to apply the *Sherbert* test in *Smith*[565] to exempt compliance with a generally applicable criminal law:

> Even if we were inclined to breathe into *Sherbert* some life beyond the unemployment compensation field, we would not apply it to require exemptions from a generally applicable criminal law. The *Sherbert* test, it must be recalled, was developed in a context that lent itself to individualized governmental assessment of the reasons for the relevant conduct . . . our decisions in the unemployment cases stand for the proposition that where the State has in place a system of individual exemptions, it may not refuse to extend that system to cases of "religious hardship" without compelling reasons.[566]

Significantly, the impracticality of applying the "compelling governmental interest" test in *Sherbert* to all religiously motivated actions, and the imperative for a restrictive or narrow application of the "compelling governmental interest" test was aptly summed up by the Court as follows:

> [P]recisely because we value and protect that religious divergence, we cannot afford the luxury of deeming presumptively invalid, as applied to the religious objector, every regulation of conduct that does not protect an interest of the highest order. The rule respondents favor would open the prospect of constitutionally required religious exemptions from civic obligations of almost every conceivable kind–ranging from compulsory military service . . . to payment of taxes . . . and child neglect laws.[567]

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563 *Id.* at 884.

564 *Id.* at 884. Although it rarely did so, the United States Supreme Court had indeed applied the *Sherbert* test beyond the realm of unemployment compensation in the following cases: *United States v. Lee*, 445 U.S. 252 (1982), *Gillette v. United States*, 401 U.S. 437 (1971), and *Sable v. Communications of California v. FCC*, 492 U.S. 115, 126 (1989), where compelling governmental interest was invoked in the context of governmental regulation of the content of speech.

565 *See Smith*, 494 U.S. at 884.

566 *Id.* at 884.

567 *Id.* at 888-89.

The Supreme Court of the United States then concluded that because respondents' ingestion of peyote was prohibited under Oregon law, which was a generally applicable neutral law, and because that prohibition was constitutional, Oregon could, consistent with the Free Exercise Clause of the First Amendment, deny respondents' unemployment compensation, primarily because their dismissal from work was triggered by the criminal use of peyote, a class B drug.[568]

The pertinent question is whether the district court in *Alliance for Bio-Integrity*[569] correctly applied the Supreme Court decision in *Smith*[570] with regards to when neutral laws of general application would be invalidated by the Free Exercise Clause. To begin with, the court in *Alliance for Bio-Integrity*[571] was certainly correct in its determination that the FDA's statement of policy, and its concomitant non-labeling rule for transgenic plant food was a neutral law of general application,[572] not least because it was policy of the U.S. Government that was generally applicable to all citizens and residents irrespective of religious affiliations.[573] Most importantly, it was in evidence that the parties in *Alliance for Bio-Integrity* never disputed that the statement of policy of the FDA that ground the non-labeling policy for transgenic plant food, was a neutral law of general application.[574] A fortiori, the determination of the district court in this respect was no more than an affirmation of a trite and undisputed point of law.

Moreover, the court in *Alliance for Bio-Integrity* was arguably wrong in its sweeping generalization that "neutral laws of general applicability do not violate the Free Exercise Clause, even if the laws incidentally burden religion."[575] This reasoning patently glossed over the determination by the Court in *Smith* that not all

568 *Id.* at 890.

569 *See* Alliance for Bio-Integrity v. Donna Shalala, 116 F. Supp. 2d 166, 179-81 (D. D.C. 2000).

570 *Smith*, 494 U.S. at 872.

571 *Alliance for Bio-Integrity*, 116 F. Supp. 2d at 166.

572 *Id.* at 179-80.

573 *Id.* at 179-81.

574 *Id.* at 180 (containing the observation of the Federal District Court that the parties never disputed that the statement of policy was neutral and generally applicable).

575 *Id.* at 179.

neutral laws of general application would be automatically exempted from the constitutional reach of the Free Exercise Clause.[576] Thus, the court in *Alliance for Bio-Integrity* failed to consider plaintiffs' claim to Free Exercise of Clause in the context of exceptions to the general rule adumbrated in *Smith*.[577]

As noted previously, the first exception to the general rule on the inviolability of neutral laws of general application by the Free Exercise Clause, as espoused in *Smith*, is when the Free Exercise Clause is coupled with other constitutional rights.[578] This circumstance is exemplified by *Yoder*, in which a valid and neutral law of general application, which mandated compulsory school attendance for pupils, was invalidated for Amish parents who refused to send their children to school on religious grounds.[579] Thus, in *Alliance for Bio-Integrity* the court ought to have considered whether or not plaintiffs' claim to free exercise of religion was coupled with other constitutional rights such as freedom of speech. For it is arguable that the FDA's rejection of a labeling regime for transgenic plant food is tantamount to suppression or abridgement of freedom of speech, which also is guaranteed by the First Amendment.[580] This proposition is legally plausible because labeling of transgenic plant food essentially pertains to the communication of information relating to food contents or properties by farmers, the food industry and grocers to the general public, and its suppression by the FDA's statement of policy on substantial equivalence doctrine, could arguably be tantamount to an infraction of the freedom of speech of a

576 *See Employment Div. v. Smith*, 494 U.S. 872, 881-90 (1990) (discussing the two exemptions to the general rule on neutral laws of general application and the free exercise of religion clause under the First Amendment: the first being where the free exercise clause right is coupled with other constitutional rights; and the second being the "compelling governmental interests" test in the *Sherbert* case).

577 *Id.*

578 *Id.* at 881-82.

579 *See* Wisconsin v. Yoder, 406 U.S. 205, 205 (1972).

580 The First Amendment prohibits Congress and state legislatures from passing legislation that could abridge the freedom of speech, which is codified as a constitutional right by the First Amendment to the Constitution of the United States. See the text of the First Amendment, which provides "Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof; or abridging the freedom of speech, or of the press; or the right of the people peaceably to assemble, and to petition the Government for a redress of grievances." U.S. CONST. amend. I.

commercial or economic strand that is guaranteed by the First Amendment.[581]

Although under the circumstances plaintiffs or the general public would be no more than mere recipients of information conveyed by labeling of transgenic plant food, this should by no means derogate from its qualification for constitutional protection as commercial speech, because, according to the Supreme Court of the United States in *Virginia State Pharmacy Board v. Virginia Citizens Consumer Council*, "freedom of speech 'necessarily protects the right to receive.'"[582] A fortiori, failure in *Alliance for Bio-Integrity* to adopt the Supreme Court's approach in *Smith*,[583] and consider whether or not plaintiffs' claim to free exercise of religion was coupled with other constitutional rights (the obvious right being freedom of speech), arguably deprived the judgment of the necessary depth and quality it might otherwise have had, and by extrapolation, deprived plaintiffs of the benefits of a material point of law that could have swayed the decision of the district court in their favor.

The second exception to the general rule on the inviolability of neutral laws of general application by free exercise of religion is the principle enunciated in *Sherbert*, which holds that any governmental actions that substantially burden a religious practice must be justified by a compelling governmental interest.[584] The "compelling governmental interest" test in *Sherbert* was again revisited in *Smith*,[585] and was subsequently enacted into law by the U.S. Congress in the form of the Religious Freedom Restoration Act.[586] According to this Act, "[g]overnment shall not

581 Being commercial or economic in nature, the information in question is tantamount to "commercial speech" and is in principle protectable by the First Amendment to the United States Constitution. *See* Va. State Pharmacy Bd. v. Va. Citizens Consumer Council, 425 U.S. 748 (1976).

582 *Id.* at 757 (quoting Kleindienst v. Manel, 408 U.S. 753, 726-63 (1972); *see also* Taiwo A. Oriola, *Regulating Unsolicited Commercial Electronic Mail in the United States and the European Union: Challenges and Prospects*, 7 TULANE J. TECH. & INTELL. PROP 113, 140-51 (2005).

583 *See* Employment Division v. Smith, 494 U.S. 872, 881-90 (1990).

584 *See* Sherbert v. Verner, 374 U.S. 398 402-03 (holding that any governmental actions that substantially burden a religious practice must be justified by a compelling governmental interest).

585 *See Smith*, 494 U.S. at 883-90.

586 Religious Freedom Restoration Act, 42 U.S.C. §2000bb-2000bb-4 (2003).

substantially burden a person's exercise of religion even if the burden results from a rule of general applicability."[587] However, government may burden a person's exercise of religion if it can be demonstrated that the burden would further a compelling governmental interest, and that the burden is the least restrictive means of furthering that compelling governmental interest.[588] Moreover, the Religious Freedom Restoration Act further stipulates that a person whose religious exercise has been substantially burdened in violation of the provisions of the Act could assert the violation as a claim or defense in a judicial proceeding and obtain appropriate relief against a government.[589]

The plaintiffs in *Alliance for Bio-Integrity* had urged the court to hold that the FDA's non-labeling policy for transgenic plant food constituted a substantial burden on their religion, and thereby violated the provisions of the Religious Freedom Restoration Act.[590] However, the court rejected plaintiffs' argument in the following terms:

> Assuming arguendo that Plaintiffs meet the RFRA requirement that their beliefs are sincerely held and can demonstrate an "honest conviction" desiring to avoid genetically engineered foods, Plaintiffs still must establish that Defendants have substantially burdened Plaintiffs' religion. A substantial burden does not arise merely because "the government refuses to conduct its own affairs in ways that comport with the religious beliefs of particular citizens." The Free Exercise Clause (as interpreted before Smith and incorporated into RFRA) does not require the government to take action to further the practice of individuals' religion. Indeed, were the government to take such action, it might bring itself precariously close to violating the First Amendment's Establishment Clause.[591]

It could thus be inferred that the district court was not satisfied that plaintiffs had discharged their burden of proof, a civil procedural obligation, which required plaintiffs to establish on

587 *Id.* §2000bb (1) (a).

588 *Id.* §2000bb (1) (b) (1)-(2).

589 *Id.* §2000bb (1) (c).

590 Alliance for Bio-Integrity v. Donna Shalala, 116 F. Supp. 2d 166, 180 (D. D.C. 2000).

591 *Id.* at 180.

balance of probability and preponderance of credible evidence that defendants' refusal to label transgenic plant food had substantially burdened plaintiffs' religion. If this inference were correct, then the district court ought not to have granted defendants' prayer for summary judgment,[592] which invariably denied plaintiffs the benefits of a full trial that would have afforded plaintiffs a better forum to prove their case than in summary judgment proceedings. For, according to the Federal Rules of Civil Procedure, a summary judgment could only be granted if the applicant litigant could show that "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law."[593] However, judging by the quality and diversity of the supporting sworn affidavit evidence from Rabbis, a member of the Christian Clergy, a Buddhist, and a Hindu religious organization,[594] contrary to the reasoning in *Alliance for Bio-Integrity*, plaintiffs did show that they had a "genuine dispute" and concerns regarding the suppression of their religious practice by the defendants' policy prohibiting the labeling of transgenic plant food.[595] A fortiori, the district court ought to have refused defendants' prayer for summary judgment and allowed plaintiffs' case to proceed to a full trial.

However, assuming arguendo that the district court was correct in granting defendants' order for summary judgment, arguably the court was wrong in holding that plaintiffs had not established that their religious belief had been substantially burdened by defendants' non-labeling policy for transgenic plant food.[596] This proposition is supported by the relative cogency and strength of plaintiffs' affidavit evidence in support of their religious belief suppression claim, which was sworn to by an Orthodox Rabbi, a

592 The Federal District Court granted defendants' prayer for a summary judgment on grounds that there was no genuine issue as to any material fact, and that defendants were entitled to judgment as a matter of law. *See id.* at 170-71.

593 *See* FED. R. CIV. P. 56(a).

594 For a full list of plaintiffs with religious objections to transgenic plant food in the *Alliance for Bio-Integrity* case, see the webpage of Alliance for Bio-Integrity at http://www.biointegrity.org/ReligiousPlaintiffs.htm, (accessed on Feb. 28, 2013). *See also Alliance for Bio-Integrity*, 116 F. Supp. 2d at 179-81.

595 *See Alliance for Bio-Integrity*, 116 F. Supp. 2d at 179-81.

596 The court in *Alliance for Bio-Integrity* reasoned that plaintiffs failed to establish that defendants had substantially burdened their religion. *Id.* at 180-81

Christian Clergy member, a Buddhist, and a Hindu practitioner.[597] Arguably, the sworn affidavit evidence was, *ex facie*, sufficiently cogent and weighty enough to establish plaintiffs' claim that their religion had been substantially burdened; the court was wrong to have held to the contrary.[598]

This proposition is buttressed by the sworn affidavit evidence of the Reverend Samuel Kedala of the Orthodox Christian Laity[599] and Rabbi Alan Green, a United States citizen of Beth Israel Synagogue in Winnipeg, Canada.[600] For example, Rabbi Green's sworn affidavit evidence in support of plaintiffs' claim in *Alliance for Bio-Integrity* reveals a practitioner of Conservative Judaism, who was worried that transgenic plant food was inimical to "kosher dietary laws, which are grounded in the Torah" that was "a basic aspect" of his "religious life" to which he strictly adhered.[601] The importance of kosher dietary laws to Rabbi Alan Green's food choices is aptly put in paragraph 5 of his sworn affidavit evidence as follows:

> These laws govern my choice, preparation[,] and consumption of food. They specifically prohibit certain types of foods, food additives and ingredients, including those containing substances from insects and certain types of animals. I believe that substances produced by genes from these prohibited species are unacceptable. I further believe that when such genes are inserted within the DNA of an otherwise permissible organism, that organism and all products derived from it are made unkosher and thus spiritually unacceptable.[602]

Similarly, paragraphs sixteen and eighteen of plaintiffs' supporting affidavit evidence in *Alliance for Bio-integrity*, which

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597 See *id.* at 179-81.

598 *See id.* at 180.

599 *See* Reverend Samuel Kedala, *Father Samuel Kedala: Bioengineering of Food is an Expression of the Spiritual Dark Forces at Work in the World*, ORTHODOX CHRISTIAN LAITY (May 27, 1999), http://archive.ocl.org/?id=8175.

600 *See* plaintiffs' supporting affidavit evidence sworn to by Rabbi Alan Green, in Court document filed in the United States District for the District of Columbia. *See* Declaration of Rabbi Alan Green at ¶ 1, Alliance for Bio-Integrity v. Donna Shalala, 116 F. Supp. 2d 166 (D. D.C. 2000) (No. 98-1300), http://www.ogmdangers.org/enjeu/philosophique/religion/greendeclaration.html.

601 *See id.* ¶ 4.

602 *See id*. ¶ 5.

was sworn to by Reverend Samuel Kedala of the Orthodox Christian Laity in Wantage, New Jersey, aptly captured the alleged burden imposed on members of Eastern Christian Orthodox Religion in New Jersey by the FDA's non-labeling policy for transgenic plant food as follows:

> I believe that organisms that have been engineered to express foreign genes by the use of viral vectors have in some significant way been infected with a negative spiritual energy, which adheres to any substances derived from them. Accordingly, I feel strongly motivated on the basis of spiritual principle to avoid all foods containing ingredients from such organisms. However, it is currently extremely difficult for me to act on my beliefs and avoid genetically engineered foods, because the FDA permits them to be marketed without identifying labels. Therefore, although there have been fundamental structural changes made to these foods that have major spiritual implications from a standpoint of the Eastern Orthodox Christian religion, I and other members of this Church who feel a strong religious reason to avoid the engineered foods are being unduly inhibited in the free exercise of our religion. I find this highly objectionable, and I demand a prompt change of policy.[603]

In light of the foregoing excerpts from plaintiffs' affidavit evidence, which denote genuine disputes of material facts relating to plaintiffs' alleged religious belief suppression claim, the district court ought to have rejected defendants' order for summary judgment and allowed plaintiffs the benefits of a full trial.[604] Moreover, given the strength of plaintiffs' supporting affidavit evidence, the district court ought not to have held that plaintiffs failed to establish that their religious belief had been substantially burdened by defendants' non-labeling policy for transgenic plant food.[605]

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603 *See* Kedala, *supra* note 599, ¶¶ 16, 18.

604 *See Alliance for Bio-Integrity*, 116 F. Supp. 2d at 170-171 (In which the Federal District Court granted defendants' prayer for a summary judgment on grounds that there was no genuine issue as to any material fact, and that defendants were entitled to judgment as a matter of law. However, according to Rule 56(a) of the Federal Rules of Civil Procedure, a summary judgment could only be granted in the absence of genuine disputes on material fact, which, going by the strength of the supporting affidavit evidence, was not the case in *Alliance for Bio-Integrity*).

605 *See id.* at 180.

Furthermore, the court failed to address the central question on whether or not government had a compelling interest for rejecting plaintiffs' demand for labeling of transgenic plant food, in line with the "compelling governmental interest" requirement of the Religious Freedom Restoration Act, which forbids government to burden religious beliefs of citizens absent "compelling governmental interests."[606] It is submitted that the federal government had no compelling governmental interest to suppress labeling of transgenic plant foods, since plaintiffs' claim for labeling was not tantamount to an outright ban on transgenic plant foods.[607] Moreover, food labeling is ubiquitous and generally legally mandated to establish nutritional and dietary contents. There was no evidence from the FDA that labeling of transgenic plant foods would denigrate the interest of the federal government. For whilst the federal government might have compelling economic or security interest for opposing an outright ban on transgenic agriculture and food, it is hard to fathom any "compelling governmental interest" justifications for refusing plaintiffs' request for labeling of transgenic plant food.

Nevertheless, the district court chose to ignore plaintiffs' affidavit evidence and indulge in a hypothetical reasoning that a substantial burden would not arise merely because "the government refuses to conduct its own affairs in ways that comport with the religious beliefs of particular citizens."[608] For had the district court specifically addressed plaintiffs' affidavit evidence in the context of the provisions of the Religious Freedom Restoration Act,[609] the district court would have realized that the only effective legal rebuttal to such weighty and cogent affidavit evidence was a compelling governmental interest for refusing labeling of transgenic plant food, a legal rebuttal that the defendants patently failed to demonstrate in *Alliance for Bio-Integrity*,[610] even though the summary judgment proceeding was

606 Religious Freedom Restoration Act, 42 U.S.C. §2000bb (1) (a)-(b) (1993).

607 *See Alliance for Bio-Integrity*, 116 F. Supp. 2d at 180.

608 *Id.* at 180.

609 *See* Religious Freedom Restoration Act, 42 U.S.C. §2000bb-2000bb-4 (1993), especially §2000bb (1) (a), which provides that "Government shall not substantially burden a person's exercise of religion even if the burden results from a rule of general applicability."

610 *Alliance for Bio-Integrity*, 116 F. Supp. 2d at 166.

decided entirely on points of law.[611]

After all, the Religious Freedom Restoration Act was enacted by the U.S. Congress to safeguard the Free Exercise Clause from undue judicial limitations and constraints imposed by the Supreme Court of the United States in *Smith*,[612] and arguably, the district court decision in *Alliance for Bio-Integrity* was nothing short of a judicial limitation on the Free Exercise of Clause. Even the Supreme Court in *Smith* opined that it could apply the compelling governmental interest test outside of unemployment compensation cases to exempt compliance with a generally applicable law,[613] and *Alliance for Bio-Integrity* exemplifies such a case.

But then the district court decision in *Alliance for Bio-Integrity* is consistent with, and symptomatic of, undue judicial deference to scientific imperatives at the expense of religious, cultural, or ethical considerations.[614] This is especially so since the substantial equivalence doctrine is a scientific tool that posits that transgenic and non-transgenic plant foods are equivalent, and by extrapolation, labeling of transgenic plant foods is superfluous. Indeed, the scientific nature of the substantial equivalence doctrine was tacitly acknowledged by the district court in its decision regarding the validity of substantial equivalence policy of the FDA, when it held that the Court would defer to the expert judgment of the Food and Drug Administration because the subject in question was "characterised by scientific and technological uncertainty."[615] However, as previously noted, such judicial decisions and the concomitant legislation constitute regulatory science, which is extremely limited and constrained by the uncertainties that continue to characterize the science of transgenic plant agriculture and food.[616] The following paragraphs

611 Whilst granting defendants' prayer for summary judgment, the Federal District Court referenced the provision of Rule 56(a) of the Federal Rules of Civil Procedure that a litigant was entitled to summary judgment when "there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law." *Id.* at 170-71.

612 *Id.* at 180.

613 *See* Employment Div. v. Smith, 494 U.S. 872, 884 (2011).

614 *See Diamond v. Chakrabarty*, 447 U.S. 303, 303; *see also Onco-mouse/Harvard*, OJ EPO 1990, 476 at 1-4.

615 *See Alliance for Bio-Integrity*, 116 F. Supp. 2d. at 177.

616 For discussion on the concept of regulatory science and its inherent limitations

will discuss the primacy of regulatory science in the context of cases showing similar judicial deference to scientific imperatives at the expense of religious and cultural objections to transgenic plant agriculture and food.

B. The European Communities Biotech Products Case: The Triumph of Science Over Non-Scientific Objections to Transgenic Plant Agriculture and Foods

Whilst the *Alliance for Bio-Integrity* case exemplifies the primacy of regulatory science and its underlying "science" over religious, cultural, and non-scientific considerations in the governance of transgenic plant agriculture and food at the national level, the European Communities Biotech Products case[617] exemplifies the supremacy of science over non-scientific considerations on a transnational scale amongst the 157 members and twenty-seven observer governments of the World Trade Organization (WTO),[618] which was established by the 1994 signing of the Uruguay Round negotiations in Marrakesh, Morocco.[619]

In the European Communities *Biotech Products* case, the

induced by the "science" on which regulatory science is premised, see *infra* Parts I, II, and III of the essay. *See also* Gareth Davies, *Morality Clauses and Decision-Making in Situations of Scientific Uncertainties* 6-7 (The Hebrew University of Jerusalem Int'l Law Forum's SSRN Research Paper Series, Research Paper No. 10-06, 2006), *available at* www.ssrn.com/abstractid=920754 (discussing the uncertainties and inconclusiveness of science in addressing environmental and public health issues posed by transgenic plant agriculture and food).

617 See *European Communities – Measures Affecting the Approval and Marketing of Biotech Products*, *supra* note 295.

618 As of 24 August 2012, the World Trade Organization has 157 members and 27 observer governments. For a list of membership, see Members and Observers, WORLD TRADE ORGANIZATION, http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm.

619 *See* TIM JOSLING ET AL., FOOD REGULATION AND TRADE: TOWARDS A SAFE AND OPEN GLOBAL SYSTEM 35-36 (2004). The World Trade Organization now administers the 1994 General Agreement on Tariffs and Trade (GATT), which is a progeny of the 1947 General Agreement on Tariffs and Trade (GATT). *See id.* WTO also administers the following trade agreements: the Agreement on Trade-Related Aspects of Intellectual Property Rights, located in Annex 1C, Article 8.1 of the Marrakesh Agreement Establishing the World Trade Organization, Apr. 15, 1994, 1867 U.N.T.S. 154, 33 I.L.M. 1125, 1201; the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), Apr. 15, 1994, 1867 U.N.T.S. 493; and the Uruguay Agreement on Technical Barriers to Trade, Apr. 15, 1994, 1868 U.N.T.S. 120.

United States, Canada, and Argentina filed a complaint before the WTO'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 both the General Agreement on Tariffs and Trade (GATT) and the Marrakesh Agreement on the Application of Sanitary and Phytosanitary Measures (MAASPM).[620] The European Commission had justified the moratorium on approval of new transgenic plant materials on grounds of precautionary principle, which authorized safeguard measures in the face of scientific uncertainties.[621] The Communication from the Commission on the Precautionary Principle sums up the essence of the precautionary principle of the European Union as follows:

> 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 in several fields.[622]

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 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

620 *See European Communities – Measures Affecting the Approval and Marketing of Biotech Products*, *supra* note 295, at 1-3.

621 *See id.* at 3.

622 *See Communication from the Commission on the Precautionary Principle*, at 9, COM (2001) 1 final (Feb. 2, 2000).

measures under Article XX of GATT, which recognizes governments' sovereign right to adopt restrictive trade measures for public health, public moral, and environmental safeguards.[623]

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 V(1) and II(2) of the MAASPM, which requires that all food safety measures must be based on 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.[624] Again, this argument was dismissed by the Dispute Settlement Panel as unscientific and illegal under the combined provisions of the GATT and the MAASPM.[625] Thus, the decision of the WTO Dispute Settlement Panel in the European Communities Biotech Products case, like that of the Federal District Court in *Alliance for Bio-Integrity*,[626] is indicative of the triumph of science over non-scientific oppositional grounds to transgenic plant organisms.

However, the question of morality or ethics is not as foreign to the jurisprudence of the WTO as it might seem, in light of the provision of Article XX (a) of the GATT, which allows for public morality protection as a basis for derogation from compliance with its non-discriminatory provisions.[627] Moreover, albeit a non-science-related case, the WTO case of U.S. measures affecting the

623 *See European Communities–Measures Affecting the Approval and Marketing of Biotech Products*, *supra* note 295, at 1067-87.

624 *See id.* at 1067-1087.

625 *See id.* at 1067-87.

626 *See* Alliance for Bio-Integrity v. Donna Shalala, 116 F. Supp. 2d 166, 166 (D. D.C. 2000).

627 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." General Agreement on Tariffs and Trade art. XX (a), Oct. 30, 1947, 55 U.N.T.S. 194.

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 GATT.[628] Interestingly, the WTO Appellate Body Report held that the provisions of Article XIV(a) of the GATT[629] were analogous to the provision of Article XX(a) of the GATT on public morality preservation derogation from general compliance with the non-discriminatory provisions of the GATT.[630]

However, in the context of the regulation of new technologies, the propensities for judicial inclinations to defer to science are high and rife, as exemplified by the Supreme Court in *Diomond v. Chakrabarty*, in which the Court refused to invalidate a patent on a genetically modified bacterium invention that had been designed to consume oil.[631] The Supreme Court dismissed the arguments that the "invented" bacterium and similar genetic research could "spread pollution and disease" or "result in a loss of genetic diversity," or "depreciate the value of human life."[632] Rather, the Court held that only the United States Congress had the legislative oversight to determine the conditions under which inventions could be patented.[633] Similarly, in Onco-mouse/Harvard, European patents examiners drew on the benefits inherent in the advancement of cancer research to hold that the Harvard Onco-mouse invention did not contravene the provisions of Article 53(a) of the European Patent Convention, which excluded from patentability inventions that were contrary to public policy, public order, or morality.[634] However, as noted earlier in this article,

628 *See* Appellate Body Report, *US- Measures Affecting the Cross-Border Supply of Gambling and Betting Services*, ¶ 299, WT/DS285/AB/R (Apr. 7, 2005).

629 Article XX on "General Exceptions," provides in Article XX (a) that members may adopt discriminatory measures that are "necessary to protect public morals" or maintain public order. *See* General Agreement on Tariffs and Trade, *supra* note 627, at art. XX (a).

630 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." *See* Appellate Body Report, *supra* note 628, ¶ 296.

631 *See* Diamond v. Chakrabarty, 447 U.S. 303, 316-18 (1980).

632 *Id.* at 316.

633 *Id.* at 317-18.

634 *See Onco-mouse/Harvard*, at 1, 4; *see also*, Oriola, *supra* note 58, at 497-29

scientific knowledge is not as agnostic, certain, or sacrosanct as it could be, and in the context of transgenic plant agriculture governance systems, even scientists have acknowledged that there are 'known unknowns,' and scientific uncertainties on new allergens, toxins, and environmental impacts that are yet to be resolved by the current science of transgenic plant agriculture.[635]

C. The European Commission v. The Republic of Poland*: Science Trumps Cultural Objections to the Marketing and Registration of Transgenic Plant Seeds*

The case of the *European Commission v. The Republic of Poland* again demonstrates the supremacy of science over religious and cultural bases for the governance of transgenic plant agriculture and food.[636] 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.[637] The Polish authorities had justified their anti-transgenic plant legislation on ethical and religious grounds.[638] However, the European Court of Justice held inter alia that the Polish law contravened the provisions of Articles 22 and 23 of the Deliberate Release Directive 2001/18/EC.[639]

Article 22 of the Deliberate Release Directive enjoins member states of the European Union not to prohibit, restrict, or impede the placing on the market of transgenic plant organisms, which had complied with the requirements of the Deliberate Release Directive.[640] In the same vein, Article 23(1) provides that a

(discussing deliberative and public policy-induced legislative and juridical examples of pro-biotechnology research policies).

635 *See, e.g.*, Ronald J. Herring, *supra* note 23, at 2 (explaining the author acknowledged, "there are scientists deeply troubled by genetically engineered organisms. There are specifiable 'known unknowns'; - horizontal gene flow, allergenicity from novel proteins – and almost certainly 'unknown unknowns' as well.")

636 Case C-165/08, Comm'n of the European Cmtys. v. Republic of Poland, OJ C 220 (2009).

637 *Id.* at 66.

638 *Id.* at 35.

639 *Id.* at 66.

640 *See* Deliberate Release Directive, *supra* note 72, art. 22.

member state may only prohibit or restrict the use or sale of transgenic plant organisms that had been 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.[641] 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 European Union Court of Justice (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.[642]

However, it is instructive to note that the European Court of Justice did not take into consideration the provision of paragraph 9 of the recitals to the Deliberate Release Directive, which provides for an ethical basis 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."[643]

Therefore, the failure of the European Court of Justice to take into consideration the provision of paragraph 9 of the recitals to the Deliberate Release Directive on ethical bases for the governance of transgenic plant organisms 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 furthered 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.[644] Recitals are no more than preliminary

641 *See id.* art. 23(1).

642 Case C-165/08, Comm'n of the European Cmtys. v. Republic of Poland, OJ C 220, at 66 (2009).

643 *See* Deliberate Release Directive, *supra* note 72, recital ¶ 9.

644 Recitals are preliminary parts 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.

explanations of the purpose, factual background, and essence of legislative texts, and are not construed as part of the substantive texts of legislative instruments.[645] 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 Directive, it is indicative that it is inferior or secondary to the provisions of Articles 22 and 23 of the Deliberate Release Directive.[646]

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 skepticism and disdain for transgenic plant agriculture, especially when science, as the fulcrum on which the regulatory and policy regime for transgenic plant agriculture is premised, is not as agnostic or certain as it could or should be. Moreover, skepticism 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 fail 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.[647] In the United States for example, dissatisfaction with the status quo is exemplified by the 2008 transgenic agriculture liability law of the State of California, which primarily protects non-transgenic plant farmers from intellectual property rights and associated liabilities surrounding

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*, EUR-LEX (last visited Feb. 28, 2013), http://eur-lex.europa.eu/en/techleg/10.htm.

645 *See id.*

646 *See* Deliberate Release Directive, *supra* note 72, art 22, 23 and recital ¶ 9.

647 For discussion on possible remedies for property and economic damage caused by adventitious commingling of transgenic and non-transgenic plant materials see Lee, *supra* note 247, at 517-37.

transgenic plant agriculture.[648] Similarly, the State of Oregon was involved in an abortive initiative in 2002 to label transgenic plant foods, whilst numerous county authorities across the United States have been involved in abortive attempts to legislate against the perceived threats posed by transgenic plant agriculture that Federal authorities had sufficiently failed to address through the current science-centric regulatory framework.[649]

V. Conclusion: The Imperatives for Reconciling Science and Social Values in the Governance of Transgenic Plant Agriculture and Food Systems

It is imperative to reconcile science and social values in the governance of transgenic plant agriculture and food in order to inspire public confidence in the technology. Indeed, rather than being the prerogative of religious fundamentalists on the societal margins, religious opposition to transgenic plant agriculture and food could be mainstream and transcendental of religious faiths and denominations, as exemplified by plaintiffs' claim in *Alliance for Bio-Integrity*, whose affidavit evidence straddled Hindu, Jewish, and Christian religions.[650] However, there is nothing to suggest that all religious groups are unanimously opposed to transgenic plant agriculture and food, as exemplified by the budding literature on religion and transgenic plant agriculture, which depicts variations in religious oppositional views that range from subtle to critical.[651] Thus, religious, ethical, and cultural perspectives on transgenic plant agriculture and food are inherently fractious and far from unanimous, even for people of similar faith. For example, while Rabbi Green, a plaintiff in *Alliance for Bio-Integrity* was totally opposed to transgenic plant

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648 *See* Cal. Civ. Code, B. No. 541 §7200 (2007) or Food; Agric. Code, Chapter 3 Part 1 Div. 1, .Art. 6 § 510 (2007).

649 *See* Bailey, *supra* note 250; Callahan, *supra* note 250, at B1; Oriola, *supra* note 123, at 535 n.92.

650 *See* Alliance for Bio-Integrity v. Donna Shalala, 116 F. Supp. 2d, 166, 166 (D. D.C. 2000).

651 *See* Carl Feit, *Genetically Modified Food and Jewish Law (Halakhah)*, in GENETICALLY MODIFIED FOODS: DEBATING BIOTECHNOLOGY 123, 123-29 (Michael Ruse and David Castle eds., 2002) (discussing the flexibility of Talmudic thought on transgenic plant foods).

agriculture and food as an adherent of Conservative Judaism,[652] a rational interpretation of the Torah according to rabbinic thought that dated "back to Talmudic discussions on the questions of mixtures of permitted and forbidden food," demonstrated an ambivalent Jewish law that neither condemns or embraces transgenic plant agriculture and food.[653] Furthermore, whilst not expressly condemning transgenic plant agriculture and food, there was an unmistakable caution in the address of the late Pope John Paul II to the agricultural community in November 2000, in which he noted that "the Earth belongs to God" and that it "must therefore be treated according to his law."[654] The late Pope also cautioned against "irresponsible culture of "dominion" over the earth that was being fuelled by frenetic scramble for natural resources "with devastating ecological consequences" that were contrary to "God's plan."[655] He further observed that the divine strictures in Genesis chapter 1, verse 28 that men should "fill the earth and subdue it; and have dominion over the fish of the sea and over the birds of the air" merely entrusted "the earth to man's use, not abuse." He noted further that the strictures in Genesis chapter 1, verse 28 did "not make man the absolute arbiter of the earth's governance, but the Creator's "co-worker", and that man's mission is "marked by precise boundaries that can never be transgressed with impunity."[656] He urged biotechnology companies to remember this principle in agricultural production, whenever there was a question that could not "be evaluated solely on the basis of immediate economic interests," and that such question must be subjected "to rigorous scientific and ethical examination to prevent them from becoming disastrous for human health and the future of the earth."[657]

Thus, there are inherent challenges in relying on disparate religious, ethical, and cultural values for transgenic plant

652 *See* Declaration of Rabbi Alan Green, *supra* note 600, at ¶¶ 4, 5.

653 *See* Carl Feit, *supra* note 651, at 123-29 (discussing the flexibility of Talmudic thought on transgenic plant foods).

654 *See* Pope John Paul II, *Jubilee of the Agricultural World*, in GENETICALLY MODIFIED FOODS: DEBATING BIOTECHNOLOGY 112 (Michael Ruse and David Castle eds., 2002).

655 *Id.*

656 *Id.*

657 *Id.*

agriculture governance, given the lack of unanimity of religious, ethical, and cultural views on transgenic plant agriculture and food. But then, it is arguable that religious, ethical, and cultural views on transgenic plant agriculture and food are no less disparate, uncertain, and contradictory than scientific opinions and knowledge on the propriety of transgenic plant agriculture and food.[658] Indeed, as this article has amply demonstrated, there are plant scientists, food nutritionists, geneticists, and toxicologists who are genuinely worried about the continuing scientific uncertainty on the long term implications of transgenic plant agriculture and food respectively for the environment and public health. Such genuine concerns could never be simply wished away by the presumed agnosticism and certainty of science, when the reality is indeed very different.[659]

Most significantly, there are legal and ethical imperatives for holistic governance systems that are sensitive to and cognizant of deep-rooted socio-cultural and religious norms. For example, it was argued in this article that religious belief was wrongly excluded as a basis for labeling of transgenic plant foods in the United States by the court in *Alliance for Bio-Integrity*.[660] This proposition is predicated on the argument that labelling is a protected informational commercial speech under the First Amendment to the Constitution of the United States.[661] Moreover, consumers do have a fundamental right and prerogative to choose whether or not to eat transgenic plant foods, and it should not matter whether consumer preference is predicated on cultural or religious beliefs.[662] Moreover, it is arguably unethical to deprive consumers of the fundamental right to food preferences, or to foist

658 *See supra* Part II.C, on the contested nature of the science that underpins transgenic plant technology, *supra* Part III.C, on the conflicting and conflicted science on the potential for new allergens and toxins in transgenic plant food.

659 For discussion on the contested safety science of transgenic plant agriculture and food, *see supra* Part II.C.

660 *See generally* Part IV.A of the Article on the religious belief suppression challenge in *Alliance for Bio-Integrity v. Donna Shalala*, 116 F. Supp. 2d. 166, 166 (D. D.C. 2000).

661 *See supra* Part IV.A, particularly with regards to the analysis on labelling as a form of commercial speech protectable by the First Amendment, which lead up to footnotes 584, 585, and 586.

662 For discussion on consumers' fundamental right to food preferences, *see* Oriola, *supra* note 123, at 530.

on entire populations the inevitability of transgenic plant agriculture and food.[663] Thus, addressing religious, cultural, and ethical concerns of the public through holistic governance systems that are sensitive to and cognizant of socio-cultural and religious values could help in disarming the continuing resistance to transgenic plant technology, especially in Europe.[664]

663 *See id.*

664 For discussion *see* Lee, *supra* note 29 at 131-39.