

LEVELING THE PLAYING FIELD IN GMO RISK ASSESSMENT: IMPORTERS, EXPORTERS AND THE LIMITS OF SCIENCE

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ABSTRACT

The WTO system requires that trade restrictions meant to protect health and safety be based on a risk assessment supported by “sufficient scientific evidence.” Scholars and international standards organizations have pointed out, however, that science is incapable of providing answers to questions of health and safety without incorporating the risk assessors’ value judgments and assumptions. Before GMO-importing countries conduct risk assessments, GMO-producing and -exporting countries have already conducted their own risk assessments, which led to their decision to produce and market the products in the first place. Both the exporting and importing countries’ risk assessments employ science informed by the risk assessors’ value judgments and assumptions. Scrutinizing the exporting and importing countries’ risk assessments, and making their value judgments explicit would level the playing field between GMO-producing and GMO-importing nations in the WTO. Instead of tacitly adopting the GMO-producing country’s value judgments, GMO-importing countries might highlight their distinct, but situationally appropriate, judgments, and defend their risk assessments as supported by scientific evidence informed by those context-appropriate judgments.

I. INTRODUCTION

Risk assessment of biotechnology products (“GMOs”¹) occurs on two fronts. First, countries conduct risk assessments to determine whether to permit the development, planting, harvesting and marketing of GMOs. Second, countries conduct risk assessments to determine whether to block or restrict the import of GMOs based on potential harm to human health or the environment. While these trade-restricting risk assessments have been the subject of considerable scrutiny in the WTO and of debate in legal scholarship,² the first-order risk

¹ “GMO,” an acronym for “genetically modified organism,” technically describes products that have been genetically modified by any method, including traditional breeding methods as well as modern biotechnology. According to conventional practice, however, this article uses the term “GMO” to refer to products modified by means of biotechnology.

² See, e.g., Appellate Body Report, *United States—Continued Suspension of Obligations in the EC-Hormones Dispute* WT/DS320/AB/R (Oct. 16, 2008) [hereinafter *US-Continued Suspension*], available at <http://tiny.cc/mhqdt>; Appellate Body Report, *Japan—Measures Affecting the Importation of Apples*, WT/DS245/AB/R (Nov. 26, 2003) [hereinafter *Japan-Apples*], available at <http://tiny.cc/9n8f0>; Appellate Body Report, *European Communities—Measures Concerning Meat and Meat Products (Hormones)*, WT/DS26/AB/R, WT/DS48/AB/R (Jan. 16, 1998) [hereinafter *EC-Hormones*]; Panel Report, *European Communities—Measures Affecting the Approval and Marketing of Biotech Products*, WT/DS291/R, WT/DS292/R, WT/DS293/R (Sept. 9, 2006) [hereinafter *EC-Biotech*], available at <http://tiny.cc/p5g8p>; Ilona Cheyne, *Precaution in International Trade in Food and Other Agricultural Products*, 4 EUR. FOOD & FEED L. REV.

assessments – those that result in products being developed and introduced into international trade in the first place – have been largely overlooked in the debate over international trade of GMOs.

Social science and legal scholars have argued that risk assessments are not the neutral exercise of “sound science,” as often characterized by the WTO; rather, they are inherently shaped by the risk assessors’ value judgments.³ These scholars have called for the WTO to protect its legitimacy by using a “sliding scale” to allow countries to take a more precautionary (i.e., trade restrictive) approach where, as in the case of GMOs, there is low certainty about the relevant information and analytical methods, and low consensus about the framing of the scientific issues and the values to be protected.⁴

While this proposal is sensible, it does not strike at the root of the legitimacy crisis in the international treatment of GMOs. The problem begins at the domestic level, when a country decides – based on its own risk assessment – to develop and market GMOs domestically and internationally. Once these products are in the stream of international commerce, countries that wish to reject or restrict them are on the defensive. At best, they may attempt to control these products’ entry through trade barriers, but such trade barriers may be (and have been) subject to WTO dispute proceedings.⁵ In a WTO proceeding, the trade-restricting party must introduce and defend its risk assessment – but the exporting party’s own risk assessment (which adjudged the products safe enough to produce and market) is not similarly scrutinized or compared.⁶ The deck is stacked against the more precautionary party by the time the issue even reaches the WTO.

Moreover, a WTO panel declined to adopt the sliding-scale approach in the *EC-Biotech* case,⁷ and a country may lose the battle to reject or restrict GMOs

47 (2009); Robert Howse, *Democracy, Science, and Free Trade: Risk Regulation on Trial at the World Trade Organization*, 98 MICH. L. REV. 2329 (2000); Alan O. Sykes, *Domestic Regulation, Sovereignty, and Scientific Evidence Requirements: A Pessimistic View*, 3 CHI. J. INT’L L. 353 (2002).

³ See, e.g., Conrad Brunk et al., *VALUE ASSUMPTIONS IN RISK ASSESSMENT: A CASE STUDY OF THE ALACHLOR CONTROVERSY* (Wilfrid Laurier Univ. Press 1991); Vern R. Walker, *The Myth of Science as a “Neutral Arbiter” for Triggering Precautions*, 26 B.C. INT’L & COMP. L. REV. 197 (2003) [hereinafter Walker, *The Myth of Science*]; Vern R. Walker, *Keeping the WTO from Becoming the “World Trans-Sciencescience Organization”: Scientific Uncertainty, Science Policy, and Factfinding in the Growth Hormones Dispute*, 31 CORNELL INT’L L.J. 251 (1998); David Winickoff et al., *Adjudicating the GM Food Wars: Science, Risk, and Democracy in World Trade Law*, 30 YALE J. INT’L L. 81 (2005).

⁴ See, e.g., Winickoff et al, *supra* note 3, at 107-22.

⁵ See, e.g., *EC-Biotech*, *supra* note 2.

⁶ *Id.*

⁷ *EC-Biotech*, *supra* note 2. Scholars, as *amicus curiae*, submitted this argument to the Panel in *EC-Biotech*. Amicus Curiae Submission from Lawrence Busch et al., *European Communities—Measures Affecting the Approval and Marketing of Biotech*

while the international legal squabbles continue. GMOs are difficult or impossible to distinguish from non-GMO counterparts without laboratory testing and have a tendency to contaminate non-GMO seeds, fields and harvests with which they come into contact.⁸ Dozens of cases exist in which GMOs were discovered in countries and in streams of commerce for which they were not approved by law.⁹ In short, by the time one country has made the decision that GMOs are safe for production and consumption, that decision carries a *de facto* presumption of legitimacy in international trade, due to both the realities of trade dispute resolution and the uncontrollability of plant pollen and seed in the wild.

The United States is the world's largest producer and exporter of GMOs.¹⁰ The decision to approve the development, planting and marketing of these products was made by the executive branch in the late 1980s and early 1990s.

Products, WT/DS291/R, WT/DS292/R, WT/DS293/R (Apr. 30, 2004), available at <http://tiny.cc/6668g>. The Panel declined to follow the analysis suggested by the Amicus.

⁸ See generally MARGARET MELLON & JANE RISSLER, GONE TO SEED: TRANSGENIC CONTAMINANTS IN THE TRADITIONAL SEEDS SUPPLY 7 (Union of Concerned Scientists 2004) (reporting results of tests indicating that commercial crop DNA was found in corn, soybean, and canola seeds), available at <http://tiny.cc/m02x7>; Biotechnology Industry Organization (BIO), Adventitious Presence, <http://tiny.cc/25zvr> (discussing adventitious presence, or the accidental "commingling of trace amounts of one type of seed . . . with another" and its inevitability).

⁹ See, e.g., GREENPEACE INT'L, GM CONTAMINATION REGISTER REPORT (2007) [hereinafter *Greenpeace*].

¹⁰ In 2009, 134 million hectares of biotechnology crops were planted, nearly half (64 million) in the United States. See Global Status of Commercialized GMO/Biotech Crops: 2009, available at <http://tiny.cc/tirhv>. The United States planted more than twice as many hectares to biotech crops as the next largest adopting countries, Brazil and Argentina, which planted 21.4 and 21.3 million hectares, respectively. *Id.*

Large scale commercial planting of biotech crops began in 1996, with 1.66 million hectares of biotech crops. Graham Brookes & Peter Barfoot, International Service for the Acquisition of Agri-Biotech Applications, GM Crops: The First 10 Years – Global Socio-Economic and Environmental Impacts at 2 (2006), available at <http://tiny.cc/a3tfj>. The period between 1996 and 1999 saw a twentyfold increase in hectares planted to biotech products, or nearly 40 hectares. Simonetta Zarrilli, United Nations Conference on Trade and Development, *International Trade in Genetically Modified Organisms and Multilateral Negotiations*, 5, U.N.Doc. UNCTAD/DITC/TNCD/1 (Jul. 5, 2000) [hereinafter Zarrilli], available at <http://tiny.cc/dniri>. Nearly all of those hectares planted were in the United States, Argentina, or Canada; 72% of them were in the United States. *Id.* at 6. By 2005, Brazil and China had joined the list of countries planting significant shares of biotech crops. Brookes & Barfoot, *supra* note 10, at 2. More than 87 million hectares of crops with biotech traits were planted in 2005. *Id.* By 2007, the global market value of biotech crops was estimated at \$6.9 billion USD, or 16 percent of the global crop protection market and 20 percent of the global commercial seed market. *Id.*

This risk assessment was presented in public documents as a product of objective scientific observation. As other scholars have argued, however, all risk assessments are shaped by values and culturally-specific framing of the scientific issues. This applies equally to the U.S.'s initial risk assessment to develop and market the products as to the E.U.'s decision to restrict their import.

Within the U.S. itself, the failure to acknowledge the cultural and situational particularity of any risk assessment has begun to meet with challenges. In *Geertson Seed Farms v. Johanns*,¹¹ a federal district court held that the USDA could not deregulate GMO alfalfa without consideration of biodiversity impacts, even though the USDA had determined that GMO alfalfa was not toxic to humans or animals.¹² In other words, a risk assessment is particular to its context, not a "yay" or "nay" question that may simply be answered once and applied by rote to all policy goals.

While GMO trade and contamination are already the reality, the recognition of the specificity of the U.S.'s risk assessment, and its *de facto* presumption of legitimacy in international GMO trade, is more than mere spilt milk. For advocates working toward protection of national choice to reject or restrict GMOs, addressing the root of the problem may offer strategic advantages not posed by focusing entirely on the WTO. Because of the political and biological realities of GMO trade, the greatest hope for protecting a precautionary approach toward GMOs in importing countries is to create pressure toward a more precautionary approach in the GMOs' countries of origin. Products that are carefully regulated at home can be more easily regulated in trade. The *Geertson* case illustrates that there is already political pressure from within the U.S. to take a closer look at GMOs.¹³ If advocates focus on revealing the values inherent in the U.S.'s own initial risk assessment, the political process within the U.S. may result in a clearer acknowledgment of those values and a more candid framing of the scientific issues in various contexts for which risks of GMOs are assessed domestically.

Second, these arguments may also be employed within WTO proceedings as a means of highlighting the *de facto* preference given to the risk assessment of the U.S. (or other exporting country) as opposed to that of the importing party, regardless of any standard of review employed by the WTO itself. Countries defending GMO trade restrictions on these grounds might frame their argument based on harm to sovereignty rather than to health or the

¹¹ *Geertson Seed Farms v. Johanns*, No. C 06-01075 CRB, 2007 WL 518624, at *12 (N.D. Cal. Feb. 13, 2007).

¹² *Id.*

¹³ The court's reasoning in *Geertson* has been followed in a subsequent case involving deregulation of genetically modified sugar beets. See *Center for Food Safety v. Vilsack*, No. C 08-00484 JSW, 2009 WL 3047227 (N. D. Calif. Sep. 21, 2009).

environment.¹⁴ Even a sympathetic review of this argument by a WTO body might become a political tool to hasten the ongoing domestic political process in the U.S. of reconsidering the executive's initial risk assessment on GMOs.

Section II of this Article considers the limits of scientific neutrality in GMO risk assessments and the inherent role of nation-specific value judgments and assumptions in framing any risk assessment. Applying these concepts to a case study of GMO risk assessment in the U.S., Section III considers a 1992 policy statement by the Food and Drug Administration ("FDA") that stated that new GMO products were presumed to be "generally recognized as safe," ("GRAS"), and therefore not subject to premarket review (i.e., product-by-product risk assessment). This section takes a closer look at the scientific basis for the policy statement and concludes that, for reasons both factual and logical, scientific principles alone could not account for the policy arrived at by FDA. Something else – the value judgments and assumptions involved in framing – informed the outcome of the risk assessment.

Section IV compares the process of framing in the U.S. and in other countries. Since framing decisions are dependent on economic, legal, cultural, social and political, as well as scientific context, it follows that those framing decisions will not be, and should not be, identical for each country. This situational particularity of framing gives rise to legitimacy concerns for an international trade system that scrutinizes the risk assessments of import-restricting countries without expressly considering the role of nation-specific value judgments and assumptions, and without considering whether the producing and exporting country's framing decisions can be appropriately applied to the importing country.

Section V examines the *Geertson* decision's holding that risk assessments are dependent upon the specific context in which they occur and the specific harm sought to be prevented. Finally, Section VI returns to the role of scientific evidence in risk assessments before the WTO, concluding that science may still play a viable role in harmonizing trade laws and preventing the use of health and safety measures as a pretext for protectionism. At the same time, the WTO may achieve greater legitimacy by scrutinizing importing and exporting countries' scientific evidence in light of the value judgments and assumptions, appropriate to each country, that framed each country's risk assessment.

II. FRAMING AND VALUES IN U.S. RISK ASSESSMENTS: THE LIMITS OF SCIENTIFIC NEUTRALITY

In the WTO framework, the Agreement on the Application of Sanitary and

¹⁴ This argument was developed in Alison Peck, *The New Imperialism: Toward an Advocacy Strategy for GMO Accountability*, 21 GEO. INT'L ENV'T L. REV. 37 (2008).

Phytosanitary Measures¹⁵ requires that any trade-restricting measures designed to protect human, animal or plant life or health must be based on “scientific principles” and may not be maintained “without sufficient scientific evidence.”¹⁶ The agreement also requires that the measures be based on “an assessment of the risks” to human, animal or plant life or health, and that such risk assessments accord with “risk assessment techniques developed by the relevant international organizations.”¹⁷ This focus on scientific evidence has motivated much of the WTO’s analysis of risk assessments used to support trade-restricting health and safety laws (“SPS measures”),¹⁸ including a WTO Panel’s rejection of GMO import restrictions set by the European Community and some of its member states in *EC-Biotech*.¹⁹

Despite this focus on objective scientific evidence as a basis for SPS measures, international food safety organizations and social science scholars have sought to make clear that science cannot provide a value-neutral, one-size-fits-all source of decisional principles on which to uphold or strike down SPS measures.²⁰ Instead, the process of risk assessment, even if based on

¹⁵ Agreement on the Application of Sanitary and Phytosanitary Measures, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 59 (2007) (1999), 1867 U.N.T.S. 493 [hereinafter *SPS Agreement*], available at http://www.wto.org/english/docs_e/legal_e/15-sps.pdf.

¹⁶ “Members shall ensure that any [SPS] measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in [Art. 5.7].” *SPS Agreement*, *supra* note 15, art. 2.2. The exception in Art. 5.7 also emphasizes the role of scientific evidence:

In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt [SPS] measures on the basis of available pertinent information, including that from the relevant international organizations as well as from [SPS] measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the [SPS] measure accordingly within a reasonable period of time.”

SPS Agreement, *supra* note 15, art. 5.7.

¹⁷ Art. 5.1 of the SPS Agreement provides, “Members shall ensure that their [SPS] measures are based on an assessment, as appropriate to the circumstances, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations.” *SPS Agreement*, *supra* note 15, art. 5.1.

¹⁸ See *US-Continued Suspension*, *supra* note 2; *Japan-Apples*, *supra* note 2; *EC-Hormones*, *supra* note 2; *EC-Biotech*, *supra* note 2.

¹⁹ *EC-Biotech*, *supra* note 2.

²⁰ See, e.g., Food & Agriculture Organization of the United Nations (FAO), FAO Expert Consultation on Food Safety: Science and Ethics (Sept. 2002) [hereinafter FAO], available at <ftp://ftp.fao.org/docrep/fao/006/j0776e/j0776e00.pdf>; Walker, *The Myth*

sound science, requires risk assessors to make value judgments.²¹ Those judgments may be influenced by economic, legal, cultural, social or environmental values as well as scientific principles.²²

In an effort to guide decision making and bring greater transparency to these necessary value judgments in the field of food safety, the Food and Agriculture Organization of the United Nations, together with the World Health Organization, convened an "Expert Consultation on Food Safety: Science and Ethics."²³ In its report, the FAO addressed the misperception that science might provide an entirely value-neutral framework for risk assessments:

Codex [Alimentarius Commission] policies emphasize that risk analysis should be based upon risk assessment as a scientific enterprise. Since the relationship between science and ethics is a crucial element of risk analysis, we need to clarify what is meant by "scientific." If scientific is taken to mean rigorous, impartial and with interpersonal objectivity, then this is a good description of the standard for which risk assessment should strive. If scientific is meant to imply "value free" and providing the only "right" answers in the identification, assessment and management of risks, then this is plainly wrong. Implicit in risk analysis are some – mostly uncontroversial – value judgements, which merit further analysis.²⁴

The FAO delineated a range of value judgments and policy choices that must be made by scientific risk assessors in selecting data samples, methodologies and assumptions to be used in the risk assessment.²⁵ For example:

- Risk assessors must choose whether to confine the hazards identified to mortality and morbidity (illness) due to known toxicity or disease, or to include less well-characterized or even unknown and unforeseen outcomes. The FAO emphasized that

of Science, supra note 3; Vern R. Walker, *The Siren Songs of Science: Toward a Taxonomy of Scientific Uncertainty for Decisionmakers*, 23 CONN. L. REV. 567 (1991) [hereinafter Walker, *Siren Songs*]; Winickoff et al., *supra* note 3; *see also* Codex Alimentarius Commission, Report of the Twenty-Sixth Session, Rome, Italy, June 30-July 7, 2003, Appendix IV: Working Principles for Risk Analysis for Application in the Framework of the Codex Alimentarius, ¶ 25, *available at* <http://www.fao.org/DOCREP/006/Y4800E/y4800e0o.htm#bm24> ("The report of the risk assessment should indicate any constraints, uncertainties, assumptions and their impact on the risk assessment. Minority opinions should also be recorded.").

²¹ *See* FAO, *supra* note 20, at v; Winickoff et al., *supra* note 3, at 94.

²² FAO, *supra* note 20, at vi.

²³ *Id.* at v.

²⁴ *Id.* at 6.

²⁵ *Id.* at 17-20.

people who see little benefit from the technology or product at issue may favor a broader definition of hazards;²⁶

- Risk assessors must make the assumption that hazards to the population studied can be extrapolated to the population actually exposed (such as extrapolating from animal studies to human populations or from studies based on human populations in wealthy countries to those in less developed countries);²⁷
- Risk assessors must estimate exposure based on assumptions about whether best practice and the intended use of the product realistically reflect actual exposure. The FAO cited the example of whether to assess risk relative to all genetically modified foods, though many are never developed, or only those intended for food and not animal feed, although food contamination may occur, or some other assumption.²⁸

Social scientists use the term “framing” to define this process of making value judgments and assumptions that influence the outcome of a risk assessment.²⁹ Frames are “principles of selection, emphasis, and presentation composed of little tacit theories about what exists, what happens, and what matters.”³⁰ The value judgments and policy decisions used to establish the frame for a risk assessment “are, by definition, non-scientific,”³¹ and critical to the outcome of the risk assessment. According to the FAO, “[t]he reliability of a risk assessment is influenced by many factors, not the least of which are the appropriate framing of the questions being asked and the relative completeness of the knowledge of the risk assessors.”³²

III. FRAMING IN U.S. BIOTECH RISK ASSESSMENT

The United States, as the largest producer and exporter of GMOs, is responsible for the first-order risk assessments of the majority of GM products on the international market.³³ Because those first-order risk assessments are not subject to scrutiny in WTO controversies over GMO trade restrictions,

²⁶ *Id.* at 17-18.

²⁷ *Id.* at 18.

²⁸ *Id.*

²⁹ See Winickoff et al., *supra* note 3, at 94; see generally DONALD A. SCHÖN & MARTIN REIN, *FRAME/REFLECTION: TOWARD THE RESOLUTION OF INTRACTABLE POLICY CONTROVERSIES* (BasicBooks 1994).

³⁰ TODD GITLIN, *THE WHOLE WORLD IS WATCHING: MASS MEDIA IN THE MAKING & UNMAKING OF THE NEW LEFT* 6 (Univ. of California Press 1980).

³¹ Winickoff et al., *supra* note 3, at 95.

³² FAO, *supra* note 20, at 6.

³³ See *infra* notes 105-113 and accompanying text.

however, they have not been subject to the same rigorous analysis applied to risk assessments employed by nations instituting SPS measures restricting GMOs.

This lack of scrutiny of first-order risk assessments is especially problematic in light of the recognition that all risk assessments are influenced by the frames – that is, the value judgments, assumptions and policy decisions – made by the risk assessors. Those judgments are necessarily linked to the risk assessors' economic, legal, social, cultural and environmental values³⁴ – values that other countries may not share.

A. *1984-1992: Establishing The Frame for GMO Risk Assessments in the United States*

In the United States, risk assessments on individual GMO products are divided among three agencies: the FDA (food, feed, food additives, and veterinary drugs), USDA (plant pests, plants, and veterinary biologic), and the EPA (microbial/plant-pesticides, new uses of existing pesticides, novel microorganisms).³⁵ As discussed below, those individual product risk assessments – or, in some cases, decisions not to conduct risk assessments³⁶ – are “framed” by evolving agency policies, and by executive branch policy statements produced during the early period of biotechnology commercialization in the 1980s and early 1990s.

Initially, the Reagan Administration charged the White House Office of Science and Technology Policy (“OSTP”) with drafting a federal framework for food biotechnology.³⁷ The OSTP’s 1984 Coordinated Framework for Regulation of Biotechnology announced the policy that products created by biotechnology were no different than other products, and that existing statutes were sufficient to regulate biotechnology.³⁸ After publication of the Coordinated Framework, the White House convened the Biotechnology Science Coordinating Committee (“BSCC”), an inter-agency committee

³⁴ See FAO, *supra* note 20, at vi.

³⁵ Coordinated Framework for the Regulation of Biotechnology Notice, 51 Fed. Reg. 23,302, 23,304 (June 26, 1986) [hereinafter *Coordinated Framework*].

³⁶ See, e.g., *infra* notes 46-56 and accompanying text (foods derived from biotechnology presumed to be “generally recognized as safe” and not normally required to undergo pre-market review); Geertson, 2007 WL 518624 (reviewing APHIS’ determination of non-regulated status to biotech alfalfa without preparation of Environmental Impact Statement).

³⁷ Proposal for a Coordinated Framework for Regulation of Biotechnology, 49 Fed. Reg. 50,856-58,057 (Dec. 31, 1984).

³⁸ *Id.* (“the U.S. Department of Agriculture, the Environmental Protection Agency and the Food and Drug Administration intend to apply their existing regulatory authorities to biotechnology products”).

responsible for coordination for science policy.³⁹ When the BSCC was unable to come to agreement, its working materials were forwarded to the President's Council on Competitiveness, a pro-industry council formed by President Bush and led by Vice President Dan Quayle.⁴⁰ The Council on Competitiveness established an Ad Hoc Committee on Scope, which, together with the OSTP, established the scope of agency jurisdiction over biotechnology.⁴¹

During its deliberation process, the OSTP proposed draft policy statements that indicated a goal to "minimize regulatory burden while assuring protection of public health and welfare," and to "accommodate the rapid advances in biotechnology."⁴² These goals were facilitated by the OSTP's perspective on risk: "Products developed through biotechnology processes do not per se pose risks to human health and the environment; risk depends instead on the characteristics of use of the individual products."⁴³

The OSTP published its Final Statement of Scope in 1992. The Final Statement includes five policy principles underlying the Administration's tenets regarding GM foods:

1. The same physical and biological laws govern the response of organisms modified by modern molecular and cellular methods and those produced by classical methods;
2. Information about the process used to produce a [GM] organism is . . . not a useful criterion for determining whether the product requires less or more oversight;
3. No conceptual distinction exists between genetic modification of plants and microorganisms by classical methods or by molecular techniques . . .
4. Crops modified by molecular and cellular methods should pose risks no different from those modified by classical methods for similar traits . . . ; [and]

³⁹ SHELDON KRIMSKY, *BIOTECHNICS AND SOCIETY: THE RISE OF INDUSTRIAL GENETICS* 197, 204 (Praeger Publishers 1991).

⁴⁰ *Id.*; see also Emily Marden, *Risk and Regulation: U.S. Regulatory Policy on Genetically Modified Food and Agriculture*, 44 B.C. L. REV. 733, 739-41 (2003).

⁴¹ See Principles for Federal Oversight of Biotechnology: Planned Introduction into the Environment of Organisms with Modified Hereditary Traits, 55 Fed. Reg. 31,118, 31,119 (proposed Jul. 31, 1990) (describing participation of BSCC) [hereinafter *Proposed Statement of Scope*]; see also KRIMSKY, *supra* note 39, at 197, 204; Marden, *supra* note 40, at 739-41.

⁴² Notice of Exercise of Federal Oversight Within Scope of Statutory Authority: Planned Introductions of Biotechnology Products into the Environment, 57 Fed. Reg. 6753, 6760 (Feb. 27, 1992) [hereinafter, *Final Statement of Scope*].

⁴³ *Id.*

5. In many respects, molecular methods resemble the classical methods for modifying particular strains of microorganisms, but [are even more useful than the classical methods]⁴⁴

B. The Effect of U.S. Risk Assessment Framing on Agency Oversight of Biotech Products

These early statements of policy guide federal agencies' determinations of whether a new biotech product should be subject to agency oversight and risk assessment, and set the basic scope of any such risk assessment. As such, they are the first step in the framing of U.S. agencies' decisions whether to perform risk assessments on new biotech products. To look more closely at the role of framing in U.S. risk assessments, this section considers a particular case: the FDA's 1992 policy that new foods derived from biotech plants are presumed to be GRAS under the Federal Food, Drug and Cosmetics Act ("FFDCA").⁴⁵

1. FDA 1992 GRAS Presumption for New Biotech Foods: Are Biotech and Unmodified Plant Varieties Fungible?

In 1992, the FDA announced a policy that most new foods created using biotechnology would not be subject to safety testing under the FFDCA.⁴⁶ The FFDCA requires that ingredients added to foods must be approved by the FDA as food additives, unless they are GRAS.⁴⁷ In the case of "traditional" foods, the burden is on the producer to establish that novel food products are eligible to be treated as GRAS, or to go through the process for approval of any new trait as a food additive.⁴⁸ In the case of GM products, however, the FDA in 1992 announced a policy that most GM products were presumed or likely to be GRAS, and therefore not subject to food additive review.⁴⁹ The FDA stated that biotechnology traits did not present safety concerns different from traditional plants and thus could be presumed GRAS:

With respect to transferred genetic material (nucleic acids), generally FDA does not anticipate that transferred genetic material would itself be subject to food additive regulation. Nucleic acids are present in the cells

⁴⁴ *Id.* at 6755. For additional statements of the first Bush Administration's view of risk and tenets of oversight, see PRESIDENT'S COUNCIL ON COMPETITIVENESS, REPORT ON NATIONAL BIOTECHNOLOGY POLICY (1991).

⁴⁵ Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301-399a (s) (2006) (requiring FDA approval for any substance used in food if it is not "generally recognized" by experts as safe).

⁴⁶ Notice of Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22,984 (May 29, 1992) [hereinafter, 1992 FDA Policy].

⁴⁷ 21 U.S.C. § 321(s).

⁴⁸ *Id.* § 348(b).

⁴⁹ 1992 FDA Policy, 57 Fed. Reg. at 22,990.

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. In regulatory terms, such material is presumed to be GRAS.

...

... When the substance present in the food is one that is already present at generally comparable or greater levels in currently consumed foods, there is unlikely to be a safety question sufficient to call into question the presumed GRAS status of such naturally occurring substances and thus warrant formal premarket review and approval by FDA.⁵⁰

With its 1992 policy, the FDA expressly sought to articulate a policy consistent with the goals articulated in the Administration's Final Statement of Scope. Those principles guided agency oversight by directing that "[i]nformation about the process used to produce a [GM] organism is ... not a useful criterion for determining whether the product requires less or more oversight," and that "[c]rops modified by molecular and cellular methods should pose risks no different from those modified by classical methods for similar traits."⁵¹ In a memorandum describing the policy, then-FDA Commissioner David Kessler stated, "[t]he approach and provisions of the [FDA policy] are consistent with the general biotechnology policy established by the Office of the President in the recently published 'scope' document."⁵² The policy referred to the Final Statement of Scope's product-based focus by equating biotech and non-biotech forms of genetic modification: "[m]odification" is used in a broad context to mean the alteration in the composition of food that results from adding, deleting or changing hereditary traits, irrespective of the method."⁵³ The policy emphasized its conformity with the product-based Scope principle, stating that its focus in evaluating safety was on the "characteristics of the food product, rather than the fact that the new methods are used."⁵⁴

The 1992 FDA Policy is curious in that it departs from the FDA's longstanding policy with regard to novel food products. For new foods not developed using biotechnology, the FDA has warned that food companies should not assume that an ingredient is GRAS simply because it is present in food in other forms or in other countries.⁵⁵ The FDA has never issued a

⁵⁰ *Id.*

⁵¹ Final Statement of Scope, 57 Fed. Reg. at 6755.

⁵² Memorandum from David Kessler, Commissioner of FDA, to the Secretary for Health and Human Services (Mar. 20, 1992), <http://www.biointegrity.org/FDAdocs/23/kesslerp.pdf> [hereinafter Kessler Memorandum].

⁵³ 1992 FDA Policy, 57 Fed. Reg. 22,984 n.3 (May 29, 1992).

⁵⁴ *Id.* at 22, 984-85.

⁵⁵ Marden, *supra* note 40, at 749. For example, even components of foods, such as

presumption of GRAS status for new hybrids or other novel food products created using traditional breeding methods, and 1992 FDA policy expressly applies that presumption only to products created using biotechnology.⁵⁶

The FDA justified its policy on the grounds, articulated in the Final Statement of Scope, that genetic modification through biotechnology posed risks no different from genetic modification through traditional methods, such as hybridization. Whatever its scientific merits, this Scope principle provides support for regulating foods that have been altered, whether through biotechnology or other methods, the same way. But by treating biotech products *more* favorably than other types of new modified foods (for which the burden of proving they are GRAS remains on the producer), the FDA's GRAS presumption for novel biotech products actually does something different than the Scope principle suggests. Instead of treating novel biotech products the same as novel foods modified by traditional methods, the FDA policy treats novel biotech products the same as their *unmodified* counterparts. Only biotech products are presumed, as a matter of policy, to be the same as their unmodified relatives. Rather than creating a level playing field for products altered through biotechnology and products altered through traditional methods, the FDA policy instead favors biotech products, treating them as fungible with traditional (non-altered) varieties.

2. Did Scientific Knowledge Require Treating New Biotech Foods as GRAS?

The concept of "framing" arises from the notion that science cannot provide purely objective answers on policy issues like food safety, because the scope and methods of scientific inquiry are always informed by value judgments. In the case of the 1992 FDA Policy, the presumption of GRAS status for new foods modified through biotechnology was presented by the FDA as a conclusion of scientific fact that biotech foods do not pose new risks, at least where the new traits already exist in other foods.⁵⁷ Any value judgments made by the FDA in establishing this policy, or by the Administration committees that developed the Final Statement of Scope, are at best implicit.

But are the proponents of express articulation of framing overstating the case? Can the 1992 FDA Policy be justified purely on the basis of objective scientific principles, without reference to value judgments? Or are the value judgments involved in the scientific inquiry so obvious that they need not be stated, let alone debated? If it can be established as an irrefutable scientific fact that foods modified through biotechnology *are* identical to their non-

phytosterols derived from vegetable oil, must be demonstrated by the manufacturer to be GRAS in the level and form existing in the new product. *Id.*

⁵⁶ 1992 FDA Policy, 57 Fed. Reg. at 22,990.

⁵⁷ 1992 FDA Policy, 57 Fed. Reg. at 22,990.

modified counterparts, then the 1992 FDA Policy of treating them the same for oversight purposes is sensible.

Unfortunately for the credibility of the FDA's policy, this line of reasoning runs into difficulty at both the factual and logical levels. First, at the factual level, scientists within the FDA itself, in commenting on drafts of the policy, disputed whether plants modified through biotechnology modification were identical to non-modified varieties for purposes of food safety. For example, in an October 28, 1991, memorandum to the Toxicology Section of the Biotechnology Working Group entitled "Analysis of Major Plant Toxicants," a scientist for the Department of Health and Human Services wrote, "[a] genetically engineered plant may contain an identical profile of expected plant toxicant levels . . . as is normally found in a closely related, natural plant. However, genetically modified plants could also contain unexpected[ly] high concentrations of plant toxicants."⁵⁸ The memorandum describes two possible methods by which existing levels of plant toxins might be enhanced as a result of biotech modifications, or normally inactive toxicants might be expressed because of the presence of the new traits.⁵⁹ The report cautions that "the task of analysis of all major toxins in genetically engineered plant food includes the assessment of both expected toxicants and unexpected toxicants that could occur in the modified plant food."⁶⁰ Another FDA scientist, commenting on the draft FDA policy, wrote:

The unintended effects [of biotech modification] cannot be written off so easily by just implying that they too occur in traditional [plant] breeding. There is a profound difference between the types of unexpected effects from traditional breeding and genetic engineering which is just glanced over in this document. This is not to say that they are more dangerous, just quite different, and this difference should be and is not addressed.⁶¹

In a memorandum commenting on the draft 1992 FDA Policy, the director of the FDA Division of Toxicological Review and Evaluation recommended that the draft be changed to indicate concerns within FDA about the toxicity of plants modified through biotechnology.⁶² In his summary of "recommended changes" to the policy, he wrote:

⁵⁸ Memorandum from Edwin J. Matthews, Department of Health and Human Services, to Toxicology Section of the Biotechnology Working Group (Oct. 28, 1991), <http://www.biointegrity.org/FDAdocs/02/02.pdf>.

⁵⁹ *Id.*

⁶⁰ *Id.*

⁶¹ Memorandum from Dr. Louis J. Pribyl on Biotechnology Draft Document 1 (Mar. 6, 1992), <http://www.biointegrity.org/FDAdocs/04/04.pdf> [hereinafter, Pribyl Memorandum].

⁶² Memorandum from Samuel L. Shibko to James Maryanski (Jan. 31, 1992), <http://www.biointegrity.org/FDAdocs/03/03.pdf>.

At this time it is unlikely that molecular and compositional analysis can reasonably detect or predict all possible changes in toxicant levels or the development of new toxic metabolites as a result of genetic modifications introduced by the new methods of biotechnology. FDA believes that, until sufficient data and experience with the new techniques of gene transfer have accumulated, the possibility of unexpected, accidental changes in genetically engineered plants justifies a limited traditional toxicological study with the edible part of the plant.⁶³

The recommended change was not incorporated into the policy.

The fact that neither the 1992 FDA Policy, nor the Final Statement of Scope or the background documents cited by the OSTP in support of the Scope principles, attempt any detailed description of the scientific understanding of the safety effects of biotechnology, strongly suggests that objective scientific principles do not strictly mandate the 1992 FDA Policy. Those documents state conclusions about the safety of biotechnology without articulating the scientific methods, research, areas of debate or uncertainty, or means of arriving at a consensus opinion that biotechnology poses no distinct risks from other methods of modification (or, going further as the 1992 FDA Policy does, that plants altered through biotechnology pose no distinct risks from non-modified varieties).

Internal FDA documents take the draft policy to task for failure to include any scientific background sufficient to justify the FDA's policy decision to limit oversight of new biotech plants. One scientist wrote:

What has happened to the scientific elements of this document? . . . The examples do not supply the scientific rational[e] that is needed. . . If the FDA wants to have a document based on scientific principles these principles must be included, otherwise it will look like and probably be just a political document.⁶⁴

⁶³ *Id.*

⁶⁴ Pribyl Memorandum, *supra* note 61, at 1. These and other internal agency documents were relied on in a challenge to the 1992 FDA Policy in *Alliance for Bio-Integrity v. Shalala*, 116 F. Supp. 2d 166 (D.D.C. 2001). Among other claims, the plaintiffs argued that the FDA's determination that GMOs are subject to GRAS treatment was arbitrary and capricious under the FFDCA definition of "food additive." The plaintiffs argued that, while nucleic acid proteins were generally recognized as safe by themselves, scientists within the FDA itself were in disagreement as to whether they were safe when used to alter other foods genetically. The court held that "critical comments of lower-level FDA officials" on the 1992 FDA Policy "do[] not invalidate the agency's subsequent application and interpretation of its own regulation." *Id.* at 177-78 (internal citation omitted). While the court may have felt constrained to defer to agency expertise, the internal disagreement among the agency's own scientists, including the director of the Division of Toxicology Review and Evaluation, however,

The Final Statement of Scope similarly articulates policy without a detailed discussion of the state of scientific knowledge. The Final Statement of Scope quotes a report of the National Research Council ("NRC")⁶⁵ for the five concepts underlying its policy conclusion that "organisms that have been genetically modified are not *per se* of inherently greater risk than unmodified organisms."⁶⁶ In its Preface, the NRC report acknowledges that its goal was not "to write a primer on new technology, such as recombinant-DNA techniques, nor to provide a detailed background on the biological information that has led to our present level of knowledge."⁶⁷ Instead, the NRC was asked to consider the prospective *regulatory* environment for field testing of biotechnology, then in its infancy, which posed obvious risks that previous laboratory testing had not.⁶⁸ The NRC committees concluded that their "most important task was to reach a consensus about the science surrounding the issues of environmental introductions."⁶⁹ The resulting report offers recommendations on risk assessment procedures with little discussion of the state of scientific knowledge, how its authors arrived at their "consensus," or what the major areas of discussion or doubt might have been.

The NRC report cites a 1987 report of the National Academy of Sciences ("NAS")⁷⁰ as the source of the "fundamental principle" that ultimately found its way into the Final Statement of Scope: "that safety assessment of a recombinant DNA-modified organism 'should be based on the nature of the organism and the environment into which it will be introduced, not on the method by which it was modified.'"⁷¹ The NAS report offered even less scientific support for its conclusion that product, not process, was material for oversight. The NAS's twenty-four-page pamphlet has been described as "noteworthy for its brevity, simple language, and forthright conclusions about the scientific basis for releasing genetically modified organisms in the environment."⁷²

seems to cast considerable doubt on the FDA's determination that biotechnology is "*generally recognized as safe*." Other internal FDA documents introduced by plaintiffs are available at <http://www.biointegrity.org/list.html>.

⁶⁵ NATIONAL RESEARCH COUNCIL, FIELD TESTING GENETICALLY MODIFIED ORGANISMS: FRAMEWORK FOR DECISIONS (National Academy Press 1989) [hereinafter NRC].

⁶⁶ Final Statement of Scope, 57 Fed. Reg. 6755 (Feb. 27, 1992).

⁶⁷ NRC, *supra* note 65, at viii.

⁶⁸ *Id.* at vii-viii.

⁶⁹ *Id.* at viii.

⁷⁰ NATIONAL ACADEMY OF SCIENCES, INTRODUCTION OF RECOMBINANT DNA-ENGINEERED ORGANISMS INTO THE ENVIRONMENT: KEY ISSUES (1987) [hereinafter NAS].

⁷¹ NRC, *supra* note 65, at 2 (citing NAS, *supra* note 70).

⁷² KRIMSKY, *supra* note 39, at 141. For instance, the NAS pamphlet concludes, "Adequate scientific knowledge exists to guide the safe and prudent use of R-DNA-engineered organisms in the environment and to identify the most problematic introductions." NAS, *supra* note 70, at 9. According to one observer of the developing

In fact, the principles articulated in the NRC report, and adopted by the Final Statement of Scope, are essentially inconsistent with the FDA's creation of a blanket presumption of GRAS status for all new biotech foods. According to one of those principles, "[i]nformation about the process used to produce a [GM] organism is important in understanding the characteristics of the product. However, the nature of the process is not a useful criterion for determining whether the product requires less or more oversight."⁷³ The FDA (and indeed, the Final Statement of Scope) focused on the second sentence of the principle, emphasizing that biotechnology would be treated as posing no new risks.⁷⁴ While the Scope principle creates a product-based rather than a process-based standard, the first sentence of the principle makes clear that the proper level of oversight cannot be determined without studying the product's characteristics – implicitly mandating a case-by-case evaluation of all new products, including those created using biotechnology. This case-by-case evaluation of a new food product's final characteristics may be particularly important in the case of new foods created through biotechnology, since the biotechnology's potential arises from the fact that it creates a new product with distinct and often heralded characteristics not achievable through traditional breeding methods.⁷⁵ The FDA's blanket presumption that all

scientific and regulatory environment at the time, this conclusion "runs counter to the belief of leading ecologists that predictive knowledge about safe releases is still in its infancy and current methods of evaluating risks are unreliable." KRIMSKY, *supra* note 39, at 141.

⁷³ Final Statement of Scope, 57 Fed. Reg. 6755 (Feb. 27, 1992).

⁷⁴ The 1992 FDA Policy provides,

[t]he method by which food is produced or developed may in some cases help to understand the safety or nutritional characteristics of the finished food. However, the key factors in reviewing safety concerns should be the characteristics of the food product, rather than the fact that the new methods are used.

57 Fed. Reg. 22,984-85 (May 29, 1992).

⁷⁵ In a 1984 report, the United States Office of Technology Assessment stated, Biotechnology has the technical breadth and depth to change the industrial community of the 21st century because of its potential to produce substantially unlimited quantities of:

- products never before available,
- products that are currently in short supply,
- products that cost substantially less than products made by existing methods of production,
- products that are safer than those that are now available, and
- products made with raw materials that may be more plentiful and less expensive than those now used.

By virtue of its wide-reaching potential applications, biotechnology lies close to

biotech products are GRAS flies in the face of the NRC's recommendation that oversight be tailored to the characteristics of the product.

3. Could More Conclusive Scientific Knowledge Provide an Objective Basis for the GRAS Presumption?

The state of scientific knowledge as advised by the NRC and scientists within the FDA, then, did not by itself mandate FDA's decision to not require risk assessments for most new biotech food products. But was that failure merely a matter of the novelty of biotech products at the time the policy was established in 1992? Could more conclusive scientific knowledge provide unequivocal proof of safety, obviating product-specific risk assessments for new biotech foods – and undercutting the notion that culturally-contingent framing decisions shape scientific opinion about risk?

The notion that objective scientific inquiry could provide the basis for biotechnology policy and risk assessment standards runs into an obstacle at the logical level as well as at the factual level. The Final Statement of Scope turns on the notion that plants modified through biotechnology are equivalent to plants modified through traditional breeding methods: they are governed by “the same physical and biological laws”;⁷⁶ there is “no conceptual distinction” between the new technology and traditional breeding techniques;⁷⁷ biotech plants “pose risks no different” than plants modified by traditional methods;⁷⁸ biotech methods “resemble the classical methods” (and, if anything, are even more useful).⁷⁹

Articulating this fundamental notion of equality between biotech and traditional breeding methods and products, federal regulatory policy

the center of many of the world's major problems—malnutrition, disease, energy availability and cost, and pollution.

OFFICE OF TECHNOLOGY ASSESSMENT, COMMERCIAL BIOTECHNOLOGY: AN INTERNATIONAL ANALYSIS 65 (1984).

As Krinsky notes, one reason for the public anxiety concerning biotechnology is because the technology has been trumpeted by science and industry as having transformative power, on par with synthetic organic chemistry and nuclear physics, both of which have proven to be potentially powerful forces for destruction as well as innovation. KRINSKY, *supra* note 39, at 97. Krinsky notes further:

This is not simply another discovery in the slow, incremental growth of science. This discovery has given birth to a new industrial process for radically reconfiguring biological matter. . . . The simultaneous pronouncements about power and safety seem incongruous to a popular culture that has been sensitized to technological failure. *Id.*

⁷⁶ Final Statement of Scope, 57 Fed. Reg. 6755.

⁷⁷ *Id.*

⁷⁸ *Id.*

⁷⁹ *Id.*

documents have cited the “substantial equivalence” doctrine developed by the Organization for Economic Cooperation and Development (OECD) in 1992.⁸⁰ That doctrine provides that if a biotech product is substantially equivalent to a traditional food, then no further safety regulation is necessary.⁸¹ “The concept of substantial equivalence embodies the idea that existing organisms used as food, or as a source of food, can be used as the basis for comparison when assessing the safety of human consumption of a food or food component that has been modified or is new.”⁸² The FDA also cited the OECD substantial equivalence doctrine in establishing its rules for review of biotech plants, including the GRAS presumption.⁸³

The Final Statement of Scope purports to define plants modified by biotechnology and plants modified by traditional breeding methods as “likes.” The 1992 FDA Policy, with its GRAS presumption for biotech products, goes a step further, defining biotech plants and their unmodified relatives as “likes.” The corollary to this definition of biotech and non-biotech products as “likes,” according to the equality principle, is that they should be treated alike – and hence not subject to new or additional regulation or oversight.

The trouble with basing federal biotech regulatory policy on a general presumption of substantial equivalence is that equality between two distinct objects cannot, by definition, be decided in the abstract. The principle that objects that are alike should have justice administered to them in a like manner was elaborated by Aristotle⁸⁴ and remains an accepted principle in philosophy.⁸⁵ Scholars of both philosophy and law have argued, however, that the enduring acceptance of the equality principle is due to the fact that it

⁸⁰ See ORGANIZATION FOR ECONOMIC COOPERATION AND DEVELOPMENT, *SAFETY EVALUATION OF FOODS DERIVED BY MODERN BIOTECHNOLOGY: CONCEPTS AND PRINCIPLES* 14 (1992).

⁸¹ *Id.* at 15.

⁸² *Id.* at 14.

⁸³ The 1992 FDA Policy states,

[t]he scientific concepts described in this guidance section are consistent with the concepts of substantial equivalence of new foods discussed in a document under development by the Group of National Experts on Safety in Biotechnology of the Organization for Economic Cooperation and Development (OECD).

1992 FDA Policy, 57 Fed. Reg. 22,984, 22,992 (May 29, 1992).

⁸⁴ See ARISTOTLE, *ETHICA NICOMACHEA* V.3.1131a-1131b (W.D. Ross trans., Oxford University Press 1925) (“The just, then, is a species of the proportionate (proportion being not a property only of the kind of number which consists of abstract units, but of number in general.”); see also *Metaphysica*, in *THE WORKS OF ARISTOTLE* I.5.1055b-1056b (W.D. Ross trans., Clarendon Press 2d ed. 1928).

⁸⁵ “To everyone the idea of justice inevitably suggests the notion of a certain equality. From Plato and Aristotle, through St. Thomas Aquinas, down to the jurists, moralists and philosophers of our own day runs a thread of universal agreement on this point.” CHAIM PERELMAN, *THE IDEA OF JUSTICE AND THE PROBLEM OF ARGUMENT* 12 (John Petrie trans., Humanities Press 1963).

expresses nothing but a tautology.⁸⁶ “Objects that are alike,” for purposes of the equality principle, may mean one of three things. First, it may mean objects that are alike in every respect. But this, of course, is a null set. If this were its meaning, the equality principle would have nothing whatsoever to say about how things should be treated. Second, “objects that are alike” may mean objects that are alike in some respects. This definition, however, is as standardless as the first, but for over-inclusiveness rather than under-inclusiveness. In other words, no two things are alike in every respect, but all are alike in some respect.⁸⁷ Third, the equality principle may refer to objects that are alike in some *normatively relevant* respect. Of course, “[normatively] alike objects do not exist in nature; [normative] alikeness is established only when people define categories.”⁸⁸ To determine whether two objects should be treated alike, one must refer to the norms underlying the treatment for which the objects are being compared. If both objects possess the normatively relevant quality, then they are, of course, “alike” in that respect. If one possesses the quality and the other does not, then they are “unlike” – but only for purposes of the underlying norm and the quality that justifies treatment according to that norm.

Biotech and non-biotech products – like any two separate objects – are alike in some ways, and not alike in other ways. In order to define them as “like” or “unlike” for purposes of determining how to regulate biotech products, one must determine which of their features is normatively relevant for affording regulatory treatment. For instance, biotech alfalfa and conventional alfalfa are alike in the sense that bees can pollinate both crops. If this is the relevant characteristic for determining how we should regulate biotech alfalfa, then we would call biotech and conventional alfalfa “alike.” But biotech (Roundup Ready) alfalfa and conventional alfalfa are different in the sense that the first is tolerant to the herbicide glyphosate, while the second is not. If this is the relevant characteristic for determining how we should regulate biotech alfalfa, then we would call the two “unlike.”

Defining biotech products and their non-biotech counterparts as “like” or “unlike,” without more, is conclusory. The real work in deciding what regulatory treatment to afford biotech alfalfa occurs at the prior stage – deciding which characteristic of alfalfa is normatively relevant for affording

⁸⁶ See, e.g., Bernard Williams, *The Idea of Equality*, in *PHILOSOPHY, POLITICS AND SOCIETY* 110, 111 (Peter Laslett & W. G. Runciman eds., 1962); Don Locke, *The Trivializability of Universalizability*, 77 *PHIL. REV.* 25, 25 (1968); Peter Westen, *The Empty Idea of Equality*, 95 *HARV. L. REV.* 537, 547-48 (1982).

⁸⁷ Westen, *supra* note 86, at 544.

⁸⁸ *Id.* at 545. I use the word “normative” in place of Westen’s “moral” to avoid confusion. While any definition of the criteria of alikeness inherently involves judgment, that judgment may derive just as easily from pragmatic as from metaphysical principles.

regulatory controls. “Equivalence” is merely the tautology that follows once we have determined that the relevant characteristic is one that both biotech and non-biotech alfalfa share.

Because the determination of “likeness” or “unlikeness” requires a reference – whether explicit or hidden – to the underlying norm triggering regulation, the question of equivalence between two distinct objects cannot be decided in the abstract. It is meaningless to say two distinct products are “like” or “unlike” without knowing the normative purpose for which they are being compared – Is the relative norm human mortality risk? Human morbidity? Adult or child morbidity? Animal morbidity? Biodiversity? But this is exactly what the Final Statement of Scope and the 1992 FDA Policy purport to do – to define biotech products and non-biotech products as “alike,” absent any explicit reference to the underlying norms that might lead society to consider regulation.

The kinds of value judgments that underlie any application of the “equality principle” (or “substantial equivalence”) are precisely the kinds of issues that scholars and international organizations have cited in describing the “framing” of risk assessments.⁸⁹ International organizations like the FAO have challenged regulators to make those value judgments transparent and open to public debate in food safety risk assessments.⁹⁰ As FDA Compliance Officer Linda Kahl commented in reviewing the 1992 FDA Policy, the statement tries to “fit a square peg into a round hole” by asking scientists, without specific data, to form hypotheses on which to base a risk assessment.⁹¹ Kahl continued:

It’s no wonder there are so many different opinions – it is an exercise in hypotheses forced on individuals whose jobs and training ordinarily deal with facts. . . . I wonder if part of the problems associated with this approach – using scientific issues to set the stage for the policy statement – are due to the fact that the scope of technical experts assigned to the project did not include anyone whose usual job is risk analysis.⁹²

The NRC Report on which the Final Statement of Scope is based explicitly recognizes that biotech products are not “like” non-biotech products in all respects. For example, the report discusses instances in which introduction of a new, genetically-modified product into the wild could pose environmental risks. In particular, in a chapter entitled “Enhanced Weediness: A Major Environmental Issue,” the report discusses two potential problems with new biotech products: first, that the new strain may become dominant (weedy) in

⁸⁹ See *supra* notes 20-32 and accompanying text.

⁹⁰ See FAO, *supra* note 20, at vi, 3.

⁹¹ Memorandum from Linda Kahl, FDA Compliance Officer, to James Maryanski, FDA Biotechnology Coordinator 1 (Jan. 8, 1992), <http://tiny.cc/69cyq>.

⁹² *Id.* at 2-3.

its environment, and second, that the biotech product may transfer its genetically-modified traits to wild relatives in the environment, causing those wild plants to become weedy.⁹³ As the report explains, “weediness” may result when a plant either escapes to a new environment that lacks ecological factors that controlled the plant in its original habitat (such as a particular plant pest), or when a plant in its original environment gains a trait that permits it to overcome previous control factors.⁹⁴ “Any added trait that enhances performance (such as frost resistance or drought tolerance) would also be analogous to providing the plant with an advantage sometimes gained by plants in a new environmental range.”⁹⁵

The report concludes that genetically-modified organisms are unlikely to themselves revert to a wild or weedy state because highly domesticated crops, such as most agricultural crops that are the subject of genetic modification, have lost their ability to compete effectively in the environment with wild plants.⁹⁶ The report does, however, acknowledge that plants may acquire traits through genetic modification that may contribute to weediness, and recommends field trials to identify such possibilities.⁹⁷ The report also notes that the likelihood of weediness is higher with some forage crops⁹⁸ – such as the alfalfa at issue in *Geertson*, discussed below.

With regard to hybridization between biotech crops and their wild relatives, the report advises that precautions be taken where the genetically modified strain has wild relatives in the environment.⁹⁹ The report notes that this concern is less pronounced in North America because “[t]he paucity of crops derived from North American sources means there will be relatively few opportunities for hybridization between crops and wild relatives in the United States.”¹⁰⁰ The report notes, however, that “greater care may be needed” in the introduction of genetically modified crops in other areas, such as Asia Minor, southeast Asia, the Indian subcontinent, and South America, which are the source of many cultivated food crops.¹⁰¹

⁹³ NRC, *supra* note 65, at 37-53.

⁹⁴ *Id.* at 38.

⁹⁵ *Id.*

⁹⁶ *Id.* at 42. “Domesticity arises because many characteristics that would enhance weediness (seed shattering, thorns, seed dormancy, and bitterness) have been deliberately eliminated from the crop plant through intensive breeding efforts.” *Id.*

⁹⁷ *Id.*

⁹⁸ *Id.* at 52.

⁹⁹ *Id.* at 43.

¹⁰⁰ *Id.*

¹⁰¹ *Id.* at 47.

IV. CASTING LIGHT ON FIRST-ORDER FRAMING: COST-BENEFIT ANALYSIS AND BIOTECH RISK ASSESSMENT POLICY IN THE U.S. AND ELSEWHERE

The Final Statement of Scope implicitly recognizes that the proper scope of oversight will vary depending upon circumstances and attendant risks. The Final Statement of Scope states the principle that “oversight will be exercised only where the risk posed by the introduction is unreasonable, that is, when the value of the reduction in risk obtained by additional oversight is greater than the cost thereby imposed.”¹⁰² After articulating the scope principles focusing on product rather than process, the Final Statement of Scope returns to this point to justify its approach:

[A]gency resources are scarce, and cannot be applied to every possible problem; *responsible officials must choose carefully the risks of highest concern* and find the best way to combat them. In order to protect the public and the environment, the scope of oversight should help focus agency efforts at reduction of the *most important risks* (and at least cost, so that society’s resources are kept available to combat the next highest risks).¹⁰³

But the *relative costs* of risk and oversight necessarily depend upon circumstances, which vary from country to country. In countries where the occurrence of a particular risk would be catastrophic for human health and welfare, the cost of the risk outweighs the cost of regulation. In countries where the occurrence of the risk would have less extreme consequences, the cost of regulation may be higher than the cost of the risk.

Incorporating an abstract presumption of equivalence into particular policy contexts, involving particular products in particular circumstances, prevents the legal system and the polity from engaging in an open and informed discussion of the underlying circumstances, attendant risks, and value judgments that prompted the polity to consider regulation, and the costs and benefits of biotechnology in that particular instance. Instead, the public is largely excluded from the conversation, and equivalence is presumed and applied in very different contexts. At the domestic level, failure to acknowledge the framing of risk assessment decisions is an infringement of the democratic process.

Obscuring the underlying issues in biotech regulation becomes even more troubling when products authorized by one country’s framing of the risk assessment (or lack thereof) become introduced into international trade. The producing/exporting country’s value judgments carry a presumption of validity by virtue of the fact that they lead to the production and export of biotech products, which other countries must now contend with through

¹⁰² *Final Statement of Scope*, *supra* note 42, at 6753.

¹⁰³ *Id.* at 6756 (emphases added).

regulation, sometimes in the face of WTO challenges (and costs). As the FAO has pointed out, a technology's risks and benefits may vary considerably depending on a country's cultural, political, economic, and environmental context.¹⁰⁴ The "weediness" example cited by the NRC Report is a case in point: while hybridization between biotech plants and wild relatives is of relatively low concern in North America (and thus may not outweigh the costs of regulation), it is of considerably higher concern in areas such as Asia Minor, whose ecosystems include more wild relatives of cultivated crops. Assumption of a value judgment that framed a risk assessment by a sovereign in North America by exporting biotech products to Asia Minor, without making that framing decision explicit and subject to inquiry and challenge in the new circumstances, invokes a question of infringement of the sovereignty of the importing country.

A. *Cost-Benefit Analysis of Biotechnology Regulation in the U.S.*

The United States is in a unique position globally with regard to biotechnology, and its value judgments and framing decisions might reasonably be expected to reflect its unique circumstances. At the inception of the development of biotechnology, the United States led the world in commercial development of biotechnology, primarily because of the combination of a strong research base in biomedical sciences, federal government support, and existence of venture capital to fund ideas.¹⁰⁵ Its government and government-supported university laboratories were the birthplace of many of the scientific advances in biotechnology.¹⁰⁶ In addition to the federal and state governments, U.S. industry provided early capital and promotion of new biotechnology products.¹⁰⁷ In 1991, half of new biotechnology companies were located in five states (California, Massachusetts, New Jersey, New York, and Maryland), in proximity to major bioscience research universities.¹⁰⁸ In 1991, the U.S. Office of Technology Assessment reported that "[d]edicated biotechnology companies are almost exclusively a U.S. phenomenon."¹⁰⁹ As of 1992, the biotechnology industry in the United States included 400 start-up firms, 200 established firms that had diversified into biotechnology, and more than 200 supply firms,¹¹⁰ and

¹⁰⁴ FAO, *supra* note 20, at vi.

¹⁰⁵ See OFFICE OF TECHNOLOGY ASSESSMENT, OTA-BA-494, BIOTECHNOLOGY IN A GLOBAL ECONOMY 3 (Oct. 1991) [hereinafter OTA].

¹⁰⁶ See PRESIDENT'S COUNCIL OF ADVISORS ON SCIENCE AND TECHNOLOGY, ACHIEVING THE PROMISE OF THE BIOSCIENCE REVOLUTION: THE ROLE OF THE FEDERAL GOVERNMENT 1 (Dec. 1992).

¹⁰⁷ See KRIMSKY, *supra* note 39, at 25-42.

¹⁰⁸ *Id.* at 35-36.

¹⁰⁹ OTA, *supra* note 105, at 3.

¹¹⁰ PRESIDENT'S COUNCIL ON COMPETITIVENESS, *supra* note 44, at 4.

produced \$2 billion worth of pharmaceuticals, diagnostic tests, and agricultural products.¹¹¹

Currently, farmers in the United States grow approximately half of all planted acreage of biotech crops. In 2008, the United States had 62.5 million acres planted to biotech crops; Argentina, the second-largest biotech crop producer, planted twenty-one million.¹¹² As of 2000, United States firms, nonprofits, universities, and the federal government owned sixty-two percent of all United States patents on agricultural biotechnology products.¹¹³

Not surprisingly, with this substantial nascent industry for developing and promoting biotechnology products, the United States government showed a strong interest in fostering the biotechnology industry in its oversight and funding policies. The President's Council on Competitiveness described the "proper role for the U.S. government" as "(1) provid[ing] needed support to activities that are undersupported by the market; and] (2) reduc[ing] artificial barriers to proper market functioning."¹¹⁴ The President's Council of Advisors on Science and Technology in 1992 recommended that the federal government's biotechnology policy work toward two goals: "[p]romoting the health of the American people and all mankind through research in the biosciences; and [f]ostering a vigorous American biotechnology industry."¹¹⁵ In a memorandum commenting on the 1992 FDA Policy, FDA Commissioner David Kessler cited the United States' unique economic context as a factor motivating the policy on biotech oversight: "The approach and provisions of [the 1992 FDA Policy] are consistent with the general biotechnology policy established by the Office of the President in the recently published 'scope' document. It also responds to White House interest in ensuring the safe, speedy development of the U.S. biotechnology industry."¹¹⁶

The Kessler Memorandum suggests another unique nation-specific situation - the political culture of the 1980s and 1990s - that framed the Administration and FDA's values and decisions to not conduct pre-market risk assessments of new biotech products. When the Office of Science and Technology Policy and the FDA were considering regulation of new biotech products, the U.S. political pendulum had swung in favor of less government regulation and greater

¹¹¹ *Id.* at 4-5.

¹¹² CLIVE JAMES, ISAAA, EXECUTIVE SUMMARY: BRIEF 39 GLOBAL STATUS OF COMMERCIALIZED BIOTECH/GM CROPS: 2008 4, 6 (2008), <http://tiny.cc/t8cxo> [hereinafter ISAAA, *Commercialized Biotech Crops 2008*].

¹¹³ See United States Dept. of Agriculture Economic Research Service, Agricultural Biotechnology Intellectual Property: Overview Chart 3 (Aug. 26, 2004), <http://www.ers.usda.gov/data/AgBiotechIP/Gallery/Graphic3.htm> (backup data provided in Excel format linked to web address).

¹¹⁴ PRESIDENT'S COUNCIL ON COMPETITIVENESS, *supra* note 44, at 5.

¹¹⁵ PRESIDENT'S COUNCIL OF ADVISORS ON SCIENCE AND TECHNOLOGY, *supra* note 106, at 1.

¹¹⁶ Kessler Memorandum, *supra* note 52, at 2.

support for free markets and business. In this political context, regulators and risk assessors would likely be guided by the values of promoting the biotech industry's growth and limiting regulation. These values logically led to decisions to regulate biotech products under existing laws and regulations enacted before biotech products were contemplated, and to make detailed risk assessments presumptively unnecessary for most new biotech products.

In comparison with this strong incentive to support the burgeoning U.S. biotech industry, other risks for the U.S., might reasonably be viewed as relatively minor. With regard to risks to the environment, the NRC study pointed out that a "major environmental issue" was the potential for enhanced weediness, particularly the potential of biotech plants to pass the new traits to wild relatives, which then gain a competitive advantage in natural ecosystems and harm biodiversity.¹¹⁷ The NRC report pointed out that "[t]emperate North America, especially the United States, includes the home ranges for very few crops, as U.S. agriculture is based largely on crops of foreign origin,"¹¹⁸ resulting in relatively few opportunities for hybridization between genetically engineered crops and wild relatives in the U.S.¹¹⁹

Other potential risks of biotechnology also have relatively low associated costs in the U.S., at least when all benefits are considered. U.S. farmers may face substantial disadvantage under contracts to plant biotech seed, such as the prohibition against saving seed for next year's planting.¹²⁰ But even U.S. farmers who may face substantial economic losses due to negligent seed saving or inadvertent contamination of neighboring fields will not ordinarily face starvation as a result, as may be the case for subsistence farmers in developing countries who lack resources other than the saved seed. As a matter of federal policy, these costs to U.S. farmers may be offset by the benefits that flow to agricultural biotechnology patent holders who can protect their intellectual property rights, receiving remuneration for violations of those rights by seed-saving farmers, and to farmers themselves who may be able to produce higher yields using fewer chemical inputs. Moreover, the legal

¹¹⁷ NRC, *supra* note 65, at 37-53.

¹¹⁸ *Id.* at 43.

¹¹⁹ *Id.*

¹²⁰ See FARMERS' LEGAL ACTION GROUP, FARMERS' GUIDE TO GMOs 27 (2d ed. Feb. 2009), available at <http://www.flaginc.org/topics/pubs/arts/FGtoGMOs2009.pdf>. The FLAG study reports that Monsanto alone investigates approximately 500 farmers per year for seed saving and has collected \$21,500,000 in court judgments and \$85 million annually in out-of-court settlements with farmers, many but not all of which involve seed saving. *Id.* at 29. Farmers may face other disadvantages resulting from their inferior bargaining power with biotech companies, such as lack of opportunity to negotiate contract terms; remedies for damages limited to replacement of seed or reimbursement of the price of the seed; legal obligations to conduct certain farming practices and to keep GMO products out of unauthorized marketing channels; and potential liability for contamination of neighboring farms. *Id.* at 8-42.

protection of intellectual property rights provides incentives for biotechnology companies to invest substantial capital in research and development of new biotech products that may substantially benefit society. Finally, while human health risks such as allergenicity, toxicity, antibiotic resistance, and unforeseeable health effects cannot be disproven at this stage in the development and use of biotech foods, no such effects have so far been documented for biotechnology products generally.¹²¹ While there is some concern among scientists that particular products might pose health risks,¹²² the United States may feel that those risks are sufficiently addressed by its risk assessment policy.

B. Cost-Benefit Analysis of Biotechnology Regulation Outside the U.S.

For other countries, the calculation of benefits and risks of biotechnology adoption – and hence the value judgments that frame risk assessments – may come out considerable differently than in the U.S. To begin with, few countries have a biotechnology industry as robust as that of the U.S.,¹²³ and thus do not have the potential benefits of industry growth to offset any environmental, sociological, or health costs. Second, those costs may be considerably higher for other countries than for the U.S., depending on that country's circumstances.

In developing countries, for example, the benefits of biotechnology are sometimes viewed with skepticism for a number of reasons. First, because biotechnology research and development has primarily been conducted by entities in temperate regions, most research has been devoted to making incremental improvements (generally herbicide and pesticide resistance) to major temperate agricultural crops.¹²⁴ For tropical regions such as sub-Saharan Africa, these advances offer little benefit.¹²⁵ If more biotechnological improvements were made to increase the shelf life or disease resistance of tropical food crops such as cassava, yams, millet and sorghum, developing countries in tropical regions would benefit significantly more from their adoption.¹²⁶ Biotechnological development of these crops has been slow,

¹²¹ Union of Concerned Scientists, Risks of Genetic Engineering, <http://tiny.cc/ucsusa> (last revised Oct. 30, 2002).

¹²² See *id.*; see also *supra* notes 58-64 and accompanying text.

¹²³ Japan has made biotechnology development a national priority. See OTA, *supra* note 105, at 19-21.

¹²⁴ See *Review of Artificial Barriers to U.S. Agricultural Trade and Foreign Food Assistance: Before the H. Comm. on Agriculture*, 108th Cong. 80-82 (2003) (testimony of Calestous Juma, Director, Program for Science Technology and Innovation, John F. Kennedy School of Government, Harvard University) [hereinafter Juma], available at <http://agriculture.house.gov/hearings/108/1081.pdf>.

¹²⁵ *Id.*

¹²⁶ *Id.* at 82.

however, because biotechnology research has been largely funded by the private sector, which has little incentive to develop products for poor regions and farmers.¹²⁷ Developing country participation in biotechnology research is limited.¹²⁸

Developing countries also face high socio-economic risks associated with dependence upon foreign intellectual property holders. Because technology agreements between biotech patent holders and farmers usually prohibit farmers from saving seed for replanting the following year, farmers in developing countries who begin to grow biotech crops may face the new expense each year of paying for seed. For small and subsistence farmers operating on very tight margins, this input cost may become prohibitive. Poor farmers may invest in converting their operations for growing biotech crops and then, in lean years, find themselves unable to afford the seed.¹²⁹

Moreover, subsistence farming may be less suited to biotechnology than large monocrop farms. One of the recognized risks of biotech plants is the potential for hybridization with wild relatives, creating a weedy strain that outcompetes other plants and threatens biodiversity.¹³⁰ The potential for biodiversity loss, while significant for all agricultural ecosystems, may be devastating for subsistence farmers. Subsistence farming depends on a diversity of crops – if one or more crops fails during a season, the household may be able to subsist on other crops or wild plants that fared better. If biodiversity is lost due to biotech plants in an ecosystem, subsistence farmers risk losing food security alternatives – and falling into increased dependency on patented foreign technology. Finally, reluctance to adopt biotechnology subject to foreign patents may be exacerbated where the source material for the invention was taken from developing countries themselves with little or no compensation, and the subsequent patented products sold to those countries at high prices.¹³¹

¹²⁷ *Id.*; see also Zarrilli, *supra* note 10, at 4-5.

¹²⁸ See Prabhu Pingali & Terry Raney, *From Green Revolution to Gene Revolution: How Will the Poor Fare?* (U.N. Food & Agric. Org., ESA Working Paper No. 05-09, 2005), available at <http://tiny.cc/l9rf2>. Pingali & Raney estimated that the private sector in developing countries invested, at best, only one-third the amount invested by the private sector in developed countries. *Id.* at 5-6. As of 2005, only three developing countries – China, India, and Brazil – had extensive research programs in all areas of biotechnology. *Id.* at 6.

¹²⁹ In an attempt to mitigate this risk, biotechnology companies have, in some cases, entered into agreements with developing country governments to share agricultural biotechnology on a preferential basis, such as by offering royalty-free licenses for production by low-income farmers for local consumption. See Juma, *supra* note 124, at 8.

¹³⁰ NRC, *supra* note 65, at 43-53.

¹³¹ See Zarrilli, *supra* note 10, at 5. Although the Convention on Biological Diversity does require “benefit sharing” with countries providing source material for plant-based

In developed countries outside the United States, the cost-benefit analysis may be rather simple, and may militate against widespread acceptance of GMOs. Developed countries are generally not concerned with food security; agricultural policy in Europe tends to be preoccupied with overproduction, rather than the underproduction issues that might be remedied by biotechnology products.¹³² With a smaller and more fragmented industry¹³³ and no society-wide advantage to be gained by increasing yields, these countries may reasonably see few benefits to outweigh the costs of the known environmental risks and unforeseeable health risks associated with biotechnology.

V. *GEERTSON SEED FARMS V. JOHANNIS*: THE CONTEXTUAL PARTICULARITY OF RISK ASSESSMENT

Countries that assess risk of biotech products differently from the U.S. find themselves behind the eight-ball in international trade proceedings: While their risk assessments must stand up to inquiry into their methodology and scientific objectivity, the first-order risk assessments (or lack thereof) by the U.S. (or other biotech producing countries) are not similarly scrutinized. Those first-order risk assessments, no less than the risk assessments conducted by importing countries, are framed by value judgments and assumptions that are specific to that nation's economic, legal, cultural, social and environmental values.¹³⁴ If the framing decisions of the producing/exporting country are not made explicit in international trade disputes, those decisions will carry a tacit presumption of legitimacy, by virtue of the fact that they put biotech products on the international market. In WTO challenges, the distinct - but appropriate - framing decisions of importing countries must then somehow disprove or negate the risk assessment arising from the producing/exporting country's value judgments, without the opportunity to show that the first-order risk assessment was contingent upon value judgments and framing decisions that do not, and should not, apply to the importing country.

Is it too late? With U.S. biotech policy now being guided for nearly two decades by the presumption of substantial equivalence in the Final Statement

inventions, the United States is not a party to the CBD, and the WTO and the TRIPS agreement do not address these situations. *See id.* at 5.

¹³² Juma, *supra* note 124, at 5. While some biotechnology advancements have been devoted to improved taste, texture or nutritional value that might appeal to consumers in affluent countries, most biotechnology advantages derive from increased yields, decreased pesticide use, and better weed control (potentially accompanied by higher use of herbicides), rather than discernible taste or nutritional advantages. *See* Zarrilli, *supra* note 10, at 3.

¹³³ *See* OTA, *supra* note 105, at 19.

¹³⁴ FAO, *supra* note 20, at vi.

of Scope, and by federal regulations and guidance implementing that policy and its presumption, can the framing decisions of the U.S. and other exporting countries be meaningfully incorporated into the international trade dialogue? Can the unique value judgments and resulting risk assessments of importing countries be placed on an equal footing with the value judgments made by producing/exporting countries? Or will the reality of biotech products in international trade effectively undermine any attempt at a more explicit understanding of the role of framing in all risk assessments?

There are signs that the U.S. government is beginning to recognize, as a matter of federal regulatory policy, the logical problems and undesired consequences of failing to make framing decisions transparent, and the problem with defining “substantial equivalence” in the abstract. In two recent federal court cases, *Geertson Seed Farms v. Johanns*¹³⁵ and *Center for Food Safety v. Vilsack*,¹³⁶ non-biotech farmers and consumer groups challenged USDA’s decision to end all regulatory oversight of glyphosate-tolerant (“Roundup Ready”) alfalfa and sugar beets, respectively. USDA had made the decision without preparing an Environmental Impact Statement (“EIS”), i.e., without a complete risk assessment. The courts in both cases held that USDA violated the National Environmental Policy Act (“NEPA”)¹³⁷ by failing to conduct an EIS - a requirement for all “major Federal actions significantly affecting the quality of the human environment.”¹³⁸

The Plaintiffs in *Geertson* were alfalfa growers, the Sierra Club, and other farmer and consumer associations.¹³⁹ The parties’ cross-motions for summary judgment raised

a close question of first impression: whether the introduction of a genetically engineered crop that might significantly decrease the availability or even eliminate all non-genetically engineered varieties is a ‘significant environmental impact’ requiring the preparation of an environmental impact statement, at least where it involves the fourth largest crop in the United States.¹⁴⁰

Because the biotech product in *Geertson*, Roundup Ready alfalfa, was engineered to resist an herbicide (glyphosate, used in the Monsanto herbicide Roundup), it was initially subject to regulation under the Plant Protection Act

¹³⁵ *Geertson Farms Inc. v. Johanns*, No. C 06-01075 CRB, 2007 WL 518624 (N.D. Calif. Feb. 13, 2007).

¹³⁶ *Center for Food Safety v. Vilsack*, No. C 08-00484 JSW, 2009 WL 3047227 (N. D. Calif. Sep. 21, 2009).

¹³⁷ National Environmental Policy Act, 42 U.S.C. §§ 4321-70a (2006).

¹³⁸ 42 U.S.C. § 4332(2)(C) (2006); see *Geertson*, 2007 WL 518624, at *9.

¹³⁹ *Geertson*, 2007 WL 518624, at *1.

¹⁴⁰ *Id.*

("PPA").¹⁴¹ The PPA gives USDA's Animal and Plant Health Inspection Service ("APHIS") jurisdiction over "organisms and products altered or produced through genetic engineering that are plant pests or believed to be plant pests."¹⁴² Monsanto, the manufacturer of Roundup (the herbicide that the biotech alfalfa was modified to tolerate), submitted a petition seeking a determination that the Roundup Ready alfalfa was not a plant pest risk and therefore should not be regulated.¹⁴³ APHIS granted the petition, withdrawing all oversight of the genetically engineered alfalfa strain.¹⁴⁴

Before granting the petition, APHIS conducted an Environmental Assessment ("EA") pursuant to NEPA.¹⁴⁵ Of the 663 comments APHIS received in response to the EA, 520 opposed complete deregulation.¹⁴⁶ On June 14, 2005, APHIS issued a Finding of No Significant Impact ("FONSI") and granted the petition for deregulation in its entirety.¹⁴⁷ Based on its finding that the deregulation of Roundup Ready alfalfa did not have a significant impact on the environment, APHIS did not prepare an EIS.

Plaintiffs argued that alfalfa was different from other deregulated biotech products because bees could pollinate alfalfa over long distances, making it extremely difficult for farmers to isolate biotech and non-biotech alfalfa to prevent contamination in the field.¹⁴⁸ The court noted APHIS's own finding of fact in the EA that insects pollinate alfalfa up to two miles from the pollen source.¹⁴⁹

APHIS, much like the FDA, defended its decision on the basis of the equivalence between biotech alfalfa and its non-modified counterpart. APHIS argued that its action was justified even if contamination was inevitable, because it had found that the glyphosate-resistant gene was not toxic or pathogenic to humans and livestock – that the genetically-engineered enzyme for glyphosate resistance was "equivalent in all biological respects" to natural

¹⁴¹ 7 U.S.C. § 7711(a) (2006).

¹⁴² 7 C.F.R. § 340.0(a)(2) n. 1 (2009).

¹⁴³ *Geertson*, 2007 WL 518624, at *1; see 7 C.F.R. § 340.6 (2009) (outlining process for submitting petitions for deregulated status).

¹⁴⁴ *Geertson*, 2007 WL 518624, at *1.

¹⁴⁵ An EA is "a concise public document that briefly provide[s] sufficient evidence and analysis for determining whether to prepare an EIS or a finding of no significant impact." *Blue Mountains Biodiversity Project v. Blackwood*, 161 F.3d 1208, 1212 (9th Cir. 1998).

¹⁴⁶ *Geertson*, 2007 WL 518624, at *2.

¹⁴⁷ *Id.* at *2; see Availability Determination of Nonregulated Status for Alfalfa Genetically Engineered for Tolerance to the Herbicide Glyphosate, 70 Fed. Reg. 36,917 (Jun. 27, 2005). The original EA and FONSI are available at <http://tiny.cc/3o2lr> [hereinafter *Alfalfa FONSI/EA*].

¹⁴⁸ *Geertson*, 2007 WL 518624, at *4-5.

¹⁴⁹ *Id.* at *2, *5.

enzymes found in nature.¹⁵⁰ The EA states that the protein used in Roundup Ready alfalfa has been encoded in other plants without indication of toxicity.¹⁵¹ The EA also emphasized that the protein is taken from a naturally occurring organism, a soil-inhabiting bacterial plant pathogen, and is similar to naturally occurring alfalfa genes.¹⁵²

In its brief opposing the plaintiffs' motion for summary judgment, APHIS dismissed the argument that loss of non-biotech alfalfa might be a significant environmental effect under NEPA, arguing:

[A]ny reproduction [of biotech genes in non-biotech alfalfa] would lack "biological significance" because the gene for the challenged alfalfa's engineered enzyme is (1) "similar to the gene that is normally present in alfalfa and is not known to have any toxic property" and (2) also equivalent to a natural enzyme present in both green plants and microorganisms inhabiting "common soil."¹⁵³

At the hearing, the court pressed counsel on the argument:

¹⁵⁰ *Id.* at *8. APHIS also advanced several other arguments in support of its decision to deregulate glyphosate-tolerant alfalfa. First, APHIS concluded, based on the "buffer zones" required by the National Organic Program, that it was the responsibility of organic farmers, not the growers of biotech varieties, to protect their crops and seed supplies from contamination – in effect, that organic and conventional farmers had a duty to "fence out" contamination. *Id.* at *5-6; see Thomas P. Redick & A. Bryan Endres, *Litigating the Economic Impacts of Biotech Crops*, NAT. RESOURCES & ENV'T 24, 27 (2008) (discussing potential development of "fence in/fence out" rule, borrowed from livestock context, to apply to biotech contamination). APHIS also argued that the National Organic Program did not "necessarily" prohibit the unintentional presence of biotech traits. *Geertson*, 2007 WL 518624, at *5. Second, APHIS argued that NEPA only requires consideration of physical environmental impacts, not the "economic impacts" alleged by the plaintiffs. *Id.* at *7.

¹⁵¹ See, e.g., APHIS, USDA, RETURN TO REGULATED STATUS OF ALFALFA GENETICALLY ENGINEERED FOR TOLERANCE TO THE HERBICIDE GLYPHOSPHATE 1 (2005), available at <http://tiny.cc/i1wl0>; *Alfalfa FONSI/EA*, *supra* note 147, at 9 ("It does not cause disease and has a history of safe use in a number of deregulated genetically engineered plants (e.g., corn, cotton and soybean varieties)."); *Id.* at 10 ("Expression of [the gene] in [alfalfa] is not expected to cause plant disease or influence susceptibility of [the encoded alfalfa] or their progeny to diseases or other pests."; "No qualitative or quantitative observations indicated any biologically meaningful differences from control populations or differences outside the range of conventional alfalfa norms.").

¹⁵² *Id.* at 12 ("The gene that codes for the enzyme EPSPS that confers glyphosate tolerance is from the bacterium *Agrobacterium* sp. strain CP4. This gene is similar to the gene that is normally present in alfalfa and is not known to have any toxic property.").

¹⁵³ Federal Defendants' Opposition to Plaintiffs' Motion for Summary Judgment at 11, *Geertsen Seed Farms Inc. v. Johanns*, 439 F.Supp.2d 1012 (N.D. Calif. Nov. 17, 2006) (No. C-06-1075 CRB).

THE COURT: . . . [I]t's your view that even if it eliminates all organic alfalfa, no – a FONSI would be appropriate, even if it wipes it out?

MR. PAGE: Yes, Your Honor. The view is, is that unless wiping it out would precipitate a significant environmental effect on water, air, soils or species, it's not cognizable under NEPA—

...

Because, quite frankly, APHIS's scientific knowledge . . . and the analysis underlying its conclusion and determination that the gene that has been engineered here is identical in all relevant biological respects to a gene that has been common in nature since time [im]memorial, deserves to –

THE COURT: . . . Okay. So they are positing a case in which they believe that the introduction of the . . . genetically-engineered alfalfa will actually eliminate organic alfalfa. And you're coming back and saying . . . if it did happen, that would not qualify. So what. . . . Because that still doesn't result in . . . a significant environmental impact, the elimination of all organic alfalfa.

MR. PAGE: Yes, Your Honor.¹⁵⁴

When further pressed by the court, counsel for the government asserted that, by making alfalfa resistant to glyphosate, the genetically-engineered strain merely restored a natural ecosystem balance before the widespread use of herbicides and pesticides, when alfalfa was not threatened by chemical inputs:

THE COURT: Let's say it disappears. Say it disappears.

MR. PAGE: Under the theory that it would have disappeared, what would have disappeared, Your Honor? . . .

What has been lost is the resist—the vulnerability of this crop to a manmade [herbicide]. . . .

THE COURT: So it's sort of like a super race of alfalfa. You're saying we got rid of all those weaklings out there, and now we have got a super race, sort of a wunderkind of produce, of grasses. . . .

But are you really saying – I hear when you are saying that we have developed a better product. . . . And they come in and say, well, that's your view that it's a better product. We think, actually, it's not; and we'd sure like you to study it, because you are getting rid of the, quote, inferior

¹⁵⁴ Reporter's Transcript of Proceedings, at 51-53, *Geertsen Seed Farms Inc. v. Johanns*, 439 F.Supp.2d 1012 (N.D. Calif. Nov. 17, 2006) (No. C-06-1075 CRB) (on file with author).

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product. . . .

. . .

You're saying you wouldn't even support that?

. . .

MR. PAGE: Well, Your Honor, no, because what we would have to assume, to assume that the hypothetical you described is true, is that the vulnerability and susceptibility of alfalfa domestically grown to a manmade pesticide is part of the balance of nature. Because by taking the enzyme that's located elsewhere in the natural environment and designing it to also be present in alfalfa, what's undisputed is you simply brought back a natural metabolic process that used to exist before all of these herbicides were used.¹⁵⁵

As applied by the government in *Geertson*, the Final Statement of Scope principles result in several extraordinary positions: (1) alfalfa that is altered by biotechnology to resist an herbicide is entirely fungible, both environmentally and commercially, with non-biotech alfalfa; (2) inserting into alfalfa a gene from bacteria that occurs in nature – but never in alfalfa – does not create a distinct product; and (3) genetically-engineered alfalfa is more “natural” than conventional alfalfa because the genetically-engineered variety is resistant to new, man-made chemical inputs.

After expressing deep skepticism about the government's treatment of GMO alfalfa and conventional alfalfa as interchangeable, the district court held that the potential elimination of conventional alfalfa was a “significant environmental impact” under NEPA and required preparation of an EIS.¹⁵⁶ The court rejected the government's assertion that GMO and conventional alfalfa were interchangeable:

For those farmers who choose to grow non-genetically-engineered alfalfa, the possibility that their crops will be infected with the engineered gene is tantamount to the elimination of all alfalfa; they cannot grow their chosen crop. The government's apparent belief that the farmers' and consumers' choice is irrational because the engineered gene is *similar in all biological respects to a gene found in nature (although never in alfalfa)* is beside the point. An action which potentially eliminates or at least greatly reduces the availability of a particular plan – here, non-engineered alfalfa – has a significant effect on the human environment.¹⁵⁷

¹⁵⁵ *Id.* at 57-59.

¹⁵⁶ *Geertson Farms Inc. v. Johanns*, No. C 06-01075 CRB, 2007 WL 518624, at *8-9 (N.D. Calif. Feb. 13, 2007).

¹⁵⁷ *Id.* at *9 (emphasis added).

In rejecting the government's argument, the court in *Geertson* alluded to the flaw in the substantial equivalence doctrine – that substantial equivalence tends to obscure the normative choice among policy options that must occur to decide if two distinct objects are “alike” and “should be treated alike” for purposes of regulation. The government in *Geertson* contented that it was not required to prepare an EIS because it found that genetically-engineered alfalfa does not have harmful health effects on humans or livestock – a determination of “likeness” with regard to human and animal mortality and morbidity.¹⁵⁸ While accepting this finding as a matter of deference to agency expertise, the court noted that “[p]ublic health and safety . . . is only *one* of [the] factors that an agency should consider when determining whether a major federal action may have a significant environmental impact.”¹⁵⁹ While APHIS may have determined that engineered and non-engineered alfalfa are “alike” for purposes of health risks to humans and livestock, Congress in NEPA made the normative choice to require preparation of an EIS in circumstances that go beyond health risks: “One of Congress’s express goals in adopting NEPA was to ‘attain the widest range of beneficial uses of the environment without degradation, risk to health and safety, or other undesirable and unintended consequences.’”¹⁶⁰ With regard to the potential to impact biodiversity by eliminating non-engineered alfalfa, the court held that engineered and non-engineered alfalfa were “unlike” and should be so treated. In both the government’s and the court’s analysis, the determining factor is the choice of the relevant underlying norm, not the tautological conclusion that two products should be treated alike when they are alike.¹⁶¹

While the scope of *Geertson*’s impact on federal policy remains to be seen, another judge on the same court has already followed *Geertson*’s reasoning. In *Center for Food Safety*, plaintiffs challenged APHIS’s decision to deregulate Roundup Ready sugar beets without conducting an EIS. The court noted APHIS’s own findings that sugar beet pollen can frequently disperse up to 800 meters,¹⁶² and that gene transfer from genetically modified sugar beets to non-modified sugar beets, and to related species of red table beets and Swiss

¹⁵⁸ *Id.* at *8.

¹⁵⁹ *Id.*

¹⁶⁰ *Id.* (citing 42 U.S.C. § 4331(b)(3) (2006) (emphasis added by court)).

¹⁶¹ On March 12, 2007, the district court enjoined further sale and planting of Roundup Ready alfalfa. *Geertson*, 2007 WL 776146, at *2 (granting preliminary injunction); *id.* at *9 (N.D.Cal. May 3, 2007) (entering permanent injunction); *id.* at *4 (granting motion to correct or amend judgment). The Ninth Circuit upheld the injunction on appeal, and on June 24, 2009, denied a petition for rehearing. *Geertson Seed Farms v. Johanns*, 570 F.3d 1130, 1141 (9th Cir. 2009).

¹⁶² *Center for Food Safety v. Vilsack*, No. C 08-00484 JSW, 2009 WL 3047227, at *7 (N. D. Calif. Sep. 21, 2009).

chard, was possible.¹⁶³

APHIS declined to consider the effect of gene transmission to other plants on the grounds that any loss of non-genetically-modified sugar beet markets was a socio-economic effect that NEPA did not reach.¹⁶⁴ As in the alfalfa case, APHIS's view that the effects of biotech gene transmission are purely socio-economic, not physical or biological, is possible only if the two crops are considered fungible. The court, following *Geertson*, rejected APHIS's argument that biotech gene transmission was not a "significant environmental effect" under NEPA. "As the court concluded in *Geertson Seed Farms v. Johanns*, this Court finds that the potential elimination of farmer's choice to grow non-genetically engineered crops, or a consumer's choice to eat non-genetically engineered food, and an action that potentially eliminates or reduces the availability of a particular plant has a significant effect on the human environment."¹⁶⁵

VI. NAMING THE FRAMING: PRESERVING SOVEREIGNTY AND LEGITIMACY IN THE WTO

Science informed by value judgments and assumptions is an indispensable part of any risk assessment. And assessment of risks is an indispensable part of any determination of how to expend limited government resources. That process is as indispensable for nations with industries proposing to develop and market new technologies as it is for countries considering whether or how to regulate the import of those technologies.

This reality need not be fatal to the legitimacy of international technology trade. It also need not give way to wholly subjective health and safety standards unsupported by science, or mere pretexts for protection of domestic industry. Making the framing decisions underlying a risk assessment transparent can aid the democratic legitimacy of any domestic risk assessment by giving the public a voice in those value judgments and assumptions. Transparency can also aid the legitimacy of the international trade regime and the WTO by providing an opportunity for an importing country to openly compare its own framing decisions with those of the producing/exporting nation. With both nations' context-specific value judgments brought into the WTO debate, the importing (and trade restricting) nation may more easily make the argument that affording respect its value judgments is more appropriate than importing the producing/exporting nation's value judgments, which assessed the risks in very different circumstances.

Moreover, sound science can and should still function to place boundaries on the use of SPS measures to limit imports, either out of irrational fear or as a

¹⁶³ *Id.* ("Even APHIS acknowledged that '[g]ene introgression from [event H7-1] into wild or cultivated sexually compatible plants is possible.'").

¹⁶⁴ *Id.* at *8. APHIS also concluded, puzzlingly, that it need not consider gene transmission because there was no evidence of an organic sugar beet market. *Id.*

¹⁶⁵ *Id.* at *9.

pretext for protection of domestic industry. A recent decision of the WTO Appellate Body outside the biotech context offers a model of this type of protection of nation-specific risk assessment (and thus sovereignty) while still requiring that decisions taken be *consistent with* sound science. In *United States—Continued Suspension of Obligations in the EC-Hormones Dispute*, (“*US-Continued Suspension*”),¹⁶⁶ the Appellate Body considered an attempt by the EC to implement and support an SPS measure. The EC appealed a decision of the Panel that favored a strict approach to scientific evidence and risk assessment. The Panel had relied heavily on standards set in risk assessments by international bodies, which would likely result in greater uniformity of SPS measures among WTO member states. The Appellate Body rejected this approach as too rigid, announcing instead a standard that permits greater individuality of SPS measures among WTO members, while balancing that freedom with standards that seek to ensure rigorous scientific review of even the most nation-specific solutions.

In reviewing the EC’s risk assessment, the Panel had conducted its own inquiry of several scientific experts with regard to the scientific conclusions upon which the EC’s risk assessment was based. The Panel explained that it relied on the majority scientific opinion where one existed; and, where scientific views were divergent, it relied on the view that “appeared, in our view, to be the most specific in relation to the question at issue and to be best supported by arguments and evidence.”¹⁶⁷ The EC argued that the Panel applied an improper standard of review under Art. 5.1 of the SPS Agreement, seeking to determine “what the correct scientific conclusions are” rather than simply assessing whether there was a sufficient scientific basis for the EC’s conclusions in its risk assessment.¹⁶⁸ The Appellate Body stated, “the review power of a panel is not to determine whether the risk assessment undertaken by a WTO member is correct, but rather to determine whether that risk assessment is supported by coherent reasoning and respectable scientific evidence and is, in this sense, objectively justifiable.”¹⁶⁹ The Appellate Body noted that a WTO member is entitled to rely on divergent or minority views, as long as those views come from a “respected and qualified source.”¹⁷⁰

Following the ruling in *US-Continued Suspension*, making framing decisions transparent in WTO challenges could further enhance consideration of the sovereign prerogatives of Member nations, while still being subject to review to determine whether there is a “sufficient scientific basis” for the SPS measure *considering the unique costs and benefits for that nation, and the*

¹⁶⁶ *US-Continued Suspension*, *supra* note 2.

¹⁶⁷ *Id.* ¶ 596.

¹⁶⁸ *Id.* ¶ 585.

¹⁶⁹ *Id.* ¶ 590.

¹⁷⁰ *Id.* ¶ 591 (citing Appellate Body Report, *EC-Hormones*, *supra* note 2, ¶ 194).

framing decisions made in light of those challenges. This standard offers equal respect to the sovereignty of both exporting and importing nations, while still requiring that any trade-restricting SPS measures be consistent with scientific evidence. In fact, greater transparency of first-order framing decisions might enhance the scientific soundness of technology import regulations. If importing nations can demonstrate that the framing decisions of the exporting nation are inconsistent with sound science, those first-order risk assessments would lose the presumption of soundness they carry by virtue of their role in placing the products in the stream of international commerce in the first place.

VII. CONCLUSION

Making the value judgments and assumptions employed in first-order risk assessments explicit would help to bolster the WTO's legitimacy as an institution that harmonizes trade without abridging its member nations' sovereignty. In the context of regulation of biotech products, greater transparency would lend legitimacy on two levels. First, if framing decisions of first-order risk assessments were subject to WTO scrutiny, biotech-producing and -exporting nations like the U.S. would likely begin to examine those decisions with more transparency when setting biotech regulatory policy and conducting risk assessments. This increased transparency would increase opportunity for democratic decision making in the producing/exporting country, lending greater democratic credibility to the first-order risk assessments that may ultimately be examined in a WTO dispute.

The democratic legitimacy of first-order risk assessments is neither given nor moot: even within the producing/exporting nation, the particular context and attendant value judgments may change over time. For example, the political culture that influenced the development of the Final Statement of Scope favored limited government regulations and robust trust of industry and the free market. Recently, the collapse of the financial services industry has altered the U.S. political climate, leading to calls for greater government regulation of business and to the election of Democrats to the White House and majorities of both branches of Congress. This altered political climate, skeptical of the limited-regulation view prevalent at the time of the Final Statement of Scope, calls into question whether the framing decisions made in and before 1992 are still those that U.S. society would choose to frame decisions about risk assessment. Indeed, this shift has already begun to show in the context of biotech regulation: in October 2008, the USDA, without publication of an EIS, issued a proposed regulation that would further reduce APHIS oversight of biotech plants.¹⁷¹ After President Obama's election, the USDA extended the comment period and, in April 2009, held a public hearing

¹⁷¹ Importation, Interstate Movement, and Release into the Environment of Certain Genetically Engineered Organisms, 73 Fed. Reg. 60,008 (Oct. 9, 2008) (to be codified at 7 C.F.R. §340).

on the proposed regulation.¹⁷² As framing decisions for risk assessment change based on changing economic, legal, cultural, social, and environmental values, the legitimacy of the risk assessment in both domestic politics and international trade disputes may be enhanced if those framing decisions are transparent and open to public debate.

The *Geertson* and *Center for Food Safety* cases, and APHIS' reconsideration of the proposed biotech regulations, suggest that the U.S. may be moving toward greater transparency in biotech policy and risk assessment. This is good news for advocates of SPS restrictions on biotech imports from the U.S. While the WTO provides a forum for adjudicating disputes over trade in biotech products, the reality of biotech contamination means that it is much more practical to regulate biotechnology at the production/export end of the chain than at the import end, after the products are already in the stream of international commerce. The U.S. may have begun to move away from the one-size-fits-all presumption of "substantial equivalence" between biotech products and their unmodified counterparts and instead to focus on the characteristics of the particular biotech product (e.g., alfalfa that bees can pollinate up to two miles from the pollen source), the particular use in question (e.g., complete deregulation of field planting), and the particular risk prompting potential regulation (e.g., the loss of non-biotech alfalfa through contamination in the field). If U.S. policy begins to move toward more case-specific risk assessment, with express consideration and debate of the characteristics, uses and risks, it is likely that U.S. biotech policy will move toward a more precautionary approach toward biotech regulation, at least in the case of some of the more predictable risks of biotech products (such as contamination of non-biotech counterparts). For importing countries, greater precaution on the exporting end may alleviate the need for stringent SPS measures on the importing end: it is easier to track and control products that are already tracked and controlled at their source.

The second legitimacy advantage of "naming the framing" in first-order risk assessments occurs when a trade dispute occurs. Importing countries may argue to the WTO that both risk assessments – its own and that of the producing/exporting country – are influenced not only by scientific evidence but by the value judgments and assumptions made by the risk assessors. Instead of looking for "sufficient scientific evidence" supporting the importing country's risk assessment in the abstract, this argument urges the WTO to consider whether the existing state of scientific knowledge, *framed by country-specific economic, legal, cultural, social,*

¹⁷² Importation, Interstate Movement, and Release into the Environment of Certain Genetically Engineered Organisms, 74 Fed. Reg. 2907 (Jan. 16, 2009) (extending comment period to Mar. 17, 2009); Importation, Interstate Movement, and Release into the Environment of Certain Genetically Engineered Organisms, 74 Fed. Reg. 10,517 (Mar. 11, 2009) (announcing Apr. 2009 hearing and extending comment period to June 2009). As of August 2009, the agency has not yet taken any final action on the proposed regulation.

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and environmental factors, supports the importing country's (trade-restricting) risk assessment at least to the same degree as the exporting-country's (production-generating) risk assessment. This standard still requires importing countries to justify SPS measures based on sound scientific evidence, but it unseats the presumption favoring the exporting country's situation-specific values and assumptions that occur when framing decisions are not transparent.