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ESSAY

Harmony with Nature and Genetically Modified Seeds: A Contradictory Concept in the United States and Brazil?

HEATHER LEIBOWITZ*

“If the biota, in the course of aeons, has built something we like but do not understand, then who but a fool would discard seemingly useless parts? To keep every cog and wheel is the first precaution of intelligent tinkering.”

- Aldo Leopold¹

I. INTRODUCTION

Trade and economics have customarily driven policy and regulatory decisions. More recently, various national approaches controlling genetically modified organisms (GMOs), specifically in the context of seeds, seem to prioritize environmental safety. However, the implementation of the policy yields results no different than if they were motivated by traditional economics. Growing social movements are voicing dismay at the inconsistency between the regulatory policies’ aspirational goals and outcomes, but are facing great difficulties at achieving tangible reforms.² Policy reforms are being enacted under the

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1. ALDO LEOPOLD, ROUND RIVER: FROM THE JOURNALS OF ALDO LEOPOLD 146-47 (1953).

2. *Thematic Debate on the Green Economy*, LA VIA CAMPENSINA (June 14, 2011), http://viacampesina.org/en/index.php?option=com_content&view=article&id=1057:peasant-seeds-dignity-culture-and-life-farmers-in-resistance-to-defend-their-right-to-peasant-seeds&catid=22:biodiversity-and-geneticresources

guise of sustainable development, but the influences of economic concerns are frustrating progress. While economic success and sustainable development are not diametrically opposed goals, without an objective framework that guides and ensures the accountability of those that enact reforms, consistent change that strives for a more sustainable future seems unlikely.

In a time when excessive price volatility of the food market has been a pressing concern, biotechnology's innovative ability to improve the quality of food cannot be ignored. In the wake of the United Nations Conference of Sustainable Development (UNCS D)³ this past June, and the closing of 2012, which was declared by the United Nations as the International Year of Sustainable Energy for All,⁴ the importance of sustainable development cannot be forgotten. To assure that GMO policy promotes this environmental initiative, scientific evaluation needs to guide regulations. Looking at the differing regulatory frameworks for GMOs in the United States and Brazil, this Article will help demonstrate how a lack of scientifically objective standards has allowed regulatory agencies to circumvent environmentally protective and sustainable policies. Additionally, this analysis will help illuminate what corrective steps can be taken.

II. BENEFITS OF AGRICULTURAL BIOTECHNOLOGY

Advancements in agricultural biotechnology holds "the promise of leading to increased food security and sustainable forestry practices, as well as improving health in developing countries by enhancing food nutrition."⁵ The genetically modified

&Itemid=37; João Pedro Stedile, *The Dilemma of Agrarian Reform in Brazil's Agribusiness*, FRIENDS OF THE MST (Jan. 7, 2013), <http://www.mstbrazil.org/news/dilemma-agrarian-reform-brazils-agribusiness>.

3. U.N. CONF. OF SUSTAINABLE DEV., www.uncsd2012.org (last visited Dec. 21, 2012).

4. U.N. SUSTAINABLE ENERGY FOR ALL, www.sustainableenergyforall.org (last visited Dec. 21, 2012).

5. *Hearing to Review the Opportunities and Benefits of Agricultural Biotechnology: Hearing Before the H. Subcomm. on Rural Dev., Research, Biotechnology & Foreign Agric.*, 112th Cong. 19 (2011) (statement of Calestous Juma, Professor, Harvard Kennedy School, Harvard University), available at <http://agriculture.house.gov/sites/republicans.agriculture.house.gov/files/>

(GM) “crops currently on the market are mainly aimed at an increased level of crop protection through either the introduction of resistance against plant diseases caused by insects or viruses, or through increased tolerance to herbicides.”⁶ Biotechnology can thus increase the human food supply through a more efficient use of land and a more productive harvest, improve the quality of food, and may reduce the use of agrochemicals.⁷

III. POTENTIAL RISKS AND NEGATIVE EFFECTS OF AGRICULTURAL BIOTECHNOLOGY ON SUSTAINABLE DEVELOPMENT

On the other hand, agricultural biotechnology can have negative effects as well, and has the potential to hinder the goals of sustainability. Sustainable development meets “the needs of the present without compromising the ability of future generations to meet their own needs.”⁸ Seen as the guiding principle for long-term global progress, sustainable development is founded on the three pillars of economic development, social development, and environmental protection.⁹ Accordingly, the risks associated with biotechnological activity can be divided and summarized into three categories: (1) risks to the economy, (2) risks to the environment, and (3) risks to health.

The main threat of agricultural biotechnology to the economy is to farmers. As stated by Deutsche Bank, “[i]ncreasingly, GMOs are, or in our opinion, becoming a liability to farmers.”¹⁰ There are concerns that the initial acquisition price of genetically modified seeds will not be made up for in increased crop yields, thereby increasing prices rather than decreasing the costs for

transcripts/112/112-19.pdf.

6. *20 Questions on Genetically Modified Foods*, WORLD HEALTH ORG., <http://www.who.int/foodsafety/publications/biotech/20questions/en/> (last visited Feb. 11, 2013).

7. *Hearing to Review the Opportunities and Benefits of Agricultural Biotechnology*, *supra* note 5.

8. Report of the World Commission on Environment and Development, G.A. Res. 42/187, ¶ 2, U.N. Doc. A/RES/42/187 (Dec. 11, 1987).

9. *About Rio +20*, U.N. CONF. ON SUSTAINABLE DEV., <http://www.uncsd2012.org/rio20/about.html> (last visited Feb. 11, 2013).

10. Alexander G. Haslberger, *Monitoring and Labeling for Genetically Modified Products*, 287 SCI. 431 (2000).

farmers and consumers.¹¹ Small farmers fear large agribusinesses will corner the market, depriving the small family farms of their livelihood.¹²

There are four main risks of agricultural biotechnology to the environment. First, there is a chance that there will be a loss of biodiversity provoked by the widespread use of few species of crops leading to a monoculture. Second, the United Nations Food and Agricultural Organization's (FAO's) report expressed the possibility that the inclusion of new herbicide resistant genes into plants could lead to the proliferation of herbicide resistant weeds.¹³ They caution that the inclusion of pest resistance in plants should be carefully evaluated for potential development of resistance in pests and possible side effects on beneficial organisms.¹⁴ It is unknown how animals and insects will react to crops engineered to contain natural pesticides. However, one must consider the case of mosquitoes that became resistant to DDT.¹⁵ Third, there is a possibility that the planting of crops containing herbicide-resistant genes may, ironically, result in increased herbicide use, as farmers would be free to use herbicides to control weeds without fear of harming the crop plants themselves. Further, the crop plants may transfer these resistance genes to wild plants, potentially creating herbicide-resistant weeds that are a threat to the environment. Last, introduction of any new organism into an ecosystem might affect its dynamics or the gene pool of wild relatives. These effects can

11. CLIVE JAMES, INT'L SERV. FOR THE ACQUISITION OF AGRI-BIOTECH APPLICATION, GLOBAL STATUS OF COMMERCIALIZED BIOTECH/GM CROPS: 2011 (2011), available at <http://www.isaaa.org/resources/publications/briefs/43/executivesummary/pdf/Brief%2043%20-%20Executive%20Summary%20-%20English.pdf>; James Hanson et al., *Risk and Risk Management in Organic Agriculture: Views of Organic Farmers*, 19 RENEWABLE AGRIC. & FOOD SYS. 218 (June 14, 2004), available at <http://ddr.nal.usda.gov/bitstream/10113/38313/1/IND43693099.pdf>.

12. *Global Agribusiness: Two Decades of Plunder*, GRAIN (July 13, 2010), <http://www.grain.org/article/entries/4055-global-agribusiness-two-decades-of-plunder>.

13. Bernal E. Valverde, *Herbicide-Resistance Management in Developing Countries*, in WEED MANAGEMENT FOR DEVELOPING COUNTRIES: ADDENDUM 1 (Ricardo Labrada ed., 2004).

14. *Id.*

15. *Should We Grow GM Crops?*, PBS, <http://www.pbs.org/wgbh/harvest/exist/arguments.html> (last visited Dec. 21, 2012).

be exacerbated when considering the ability of seeds to cross-pollinate.¹⁶

The main risk to health is allergy. An example of this is seen in the allergic side effects provoked in humans by the addition of Brazil nut protein to soybeans.¹⁷

IV. PROBLEMS WITH GM SEEDS IN BRAZIL

Rural communities have sustained traditional agriculture in Brazil for generations helping farmers maintain local culture and dignity for their communities.¹⁸ A process involving identification, selection, and enhancement of wild seeds has allowed these farmers to stabilize food production, secure an adequate standard of living, and ensure a sustainable environment.¹⁹

Brazil is presently the world's second largest producer of GM crops.²⁰ The Brazilian government only first approved the use of GM seeds in 2005, but since that time, the production of some GM crops has even overtaken traditionally grown yields.²¹ This transformation is demonstrated by Brazil's soybean sector, where GM crops account for two-thirds of Brazil's overall production—a ratio among the highest in the world.²²

16. *Id.*

17. *Id.*

18. *Struggle for Survival in Brazil in Focus*, BUS. & HUMAN RIGHTS DOCUMENTATION PROJECT, <http://www.bhrd.org/fe/subinfocus/php?id=11> (last visited Mar. 5, 2013); Miguel A. Altieri et al., *Agroecologically Efficient Agricultural Systems for Smallholder Farmers: Contributions to Food Sovereignty*, 32 *AGRONOMY FOR SUSTAINABLE DEV.* 1, 3 (2012).

19. *Struggle for Survival in Brazil in Focus*, *supra* note 18; ANTONIO C. GUEDES & MARIA JOSE SAMPAIO, BRAZ. AGRIC. RESEARCH CORP., GENETIC RESOURCES AND TRADITIONAL KNOWLEDGE IN BRAZIL 4 (2000), *available at* http://r0.unctad.org/trade_env/docs/brazil.pdf.

20. *Struggle for Survival in Brazil in Focus*, *supra* note 18; *Global Status of Commercialized Biotech/GM Crops: 2009*, INT'L SERV. FOR THE ACQUISITION OF AGRI-BIOTECH APPLICATION, http://www.isaaa.org/resources/publications/briefs/41/pptslides/Global_Status_Map-2009.pdf (last visited Feb. 11, 2013).

21. *Struggle for Survival in Brazil in Focus*, *supra* note 18; Laura Nelson, *Biosafety Law Brings Stem-Cell Research to Brazil*, 434 *NATURE* 10 (2005), *available at* <http://www.nature.com/nature/journal/v434/n7030/pdf/434128b.pdf>.

22. *Struggle for Survival in Brazil in Focus*, *supra* note 18; *Plants: Global Cultivation Area, Soybean*, GMO COMPASS, <http://www.gmo->

Despite certain benefits of large-scale, industrialized farming techniques used by agribusiness, rural farm workers argue that sustainability provided by traditional methods make it a preferable choice. This belief that traditional methods can better ensure their livelihood, food, and water security has been proven true in some regions.²³ Ultimately, the expansion of large-scale industrial agriculture may affect the environment to such an extent that rural Brazilians' rights to sufficient amounts of safe food, uncontaminated drinking water, and general health will be jeopardized.²⁴

These issues are particularly surprising considering the emphasis placed on environmental protection in Brazil's Constitution. Among other environmental provisions, Brazil's Constitution provides that "[t]he Union, the states, the Federal District, and the municipalities, in common, have the power . . . to protect the environment and to fight pollution in any of its forms; to preserve the forests, fauna and flora . . . [and] to legislate concurrently on . . . [the] preservation of nature . . . protection of the environment."²⁵ Additionally,

it is incumbent upon the Government to . . . preserve the diversity and integrity of the genetic patrimony of the country and to control entities engaged in research and manipulation of genetic material; . . . demand, in the manner prescribed by law, for the installation of works and activities which may potentially cause significant degradation of the environment, a prior environmental impact study, which shall be made public; control the production, sale and use of techniques, methods or substances which represent a risk to life, the quality of life and the environment; . . . [and] protect the fauna and the flora, with

compass.org/eng/agri_biotechnology/gmo_planting/342.genetically_modified_soy_bean_global_area_under_cultivation.html (last visited Feb. 11, 2013).

23. *Struggle for Survival in Brazil in Focus*, supra note 18; see Inae Riveras, *Biggest Brazil Soy State Loses Taste for GMO Seed*, REUTERS (Mar. 13, 2009, 3:34 PM), <http://www.reuters.com/article/idUSTRE52C5AB20090313>.

24. *UN Special Rapporteur on The Right Of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health*, U.N. HUMAN RIGHTS: OFFICE OF THE HIGH COMM'R FOR HUMAN RIGHTS (2012), <http://www.ohchr.org/EN/Issues/Health/Pages/InternationalStandards.aspx>.

25. CONSTITUIÇÃO FEDERAL [C.F.] [CONSTITUTION] art. 23, § IV, VII, art. 24 (Braz.).

prohibition, in the manner prescribed by law, of all practices which represent a risk to their ecological functions, cause the extinction of species or subject animals to cruelty.²⁶

Despite these constitutional provisions, regulations fail to provide concrete standards that agencies must follow. Subjective standards in biotechnological regulations illustrate how agencies are able to defeat the statutes objective of environmental assessment, leaving small farmers in a difficult position. This demonstrates the effect of economic motivation and trade-related pressure on a country's domestic policy.

A. History and Regulatory System Overview

Initially, the basic framework of regulations concerning GMOs in Brazil was established by Law 6938²⁷ and Law 8974.²⁸ Through Law 6938, the National Environmental Policy Act (NEPA) was established. The policy's objective was to allow for sustainable development—ensuring social and economic development was compatible with preservation of the ecological equilibrium. CONAMA²⁹ was the elected Council responsible for passing rules and defining standards on environmental quality.³⁰ The Council therefore passed two administrative acts, Resolution 001 and Resolution 237.³¹ Resolution 001, Article 2 provided that activities that will alter the environment will be subject to a prior environmental impact study, including an environmental impact

26. *Id.* art. 255, § II, IV, V (Braz.).

27. Lei da Política Nacional do Meio Ambiente (National Environmental Policy Act), Lei No. 6.938, de 31 de Agosto de 1981 (Braz.), *available at* http://www.planalto.gov.br/ccivil_03/Leis/L6938.htm.

28. Lei No. 8.974, de 5 de Janeiro de 1995 (Braz.), *available at* http://www.planalto.gov.br/ccivil_03/Leis/L8974.htm.

29. Conselho Nacional de Meio Ambiente [National Council of Environment].

30. *O que é o CONAMA?* [What is CONAMA?], MINISTÉRIO DO MEIO AMBIENTE, <http://www.mma.gov.br/port/conama/index.cfm> (last visited Mar. 4, 2013).

31. Resolução Conama No. 1A, de 23 de Janeiro de 1986, DIÁRIO OFICIAL DA UNIÃO [D.O.U.] de 8.4.1986 (Braz.), *available at* <http://www.mma.gov.br/port/conama/legiabre.cfm?codlegi=24>; Resolução Conama No. 237, de 19 de Dezembro de 1997, DIÁRIO OFICIAL DA UNIÃO [D.O.U.] de 22.12.1997 (Braz.), *available at* <http://www.mma.gov.br/port/conama/legiabre.cfm?codlegi=237>.

report.³² Moreover, it establishes in Article 6, section II, how the environmental impact study should be prepared.³³ Resolution 237 complemented and modified Resolution 001 by establishing a mandatory licensing procedure before the genetically modified species was released into the environment.³⁴ Additionally, it was specified that the license was contingent on both the environmental impact study and an environmental impact report.

Law 8974, later repealed by Law 11,105 in 2005, regulated Article 225, sections I, II and V, of the Brazilian Constitution, and established rules to be observed when using genetic engineering in creating, manipulating, transporting, commercializing, consuming, liberating, and disposing of genetically modified organisms in the environment.³⁵ In sum, this law regulated the environmental impact study and the environmental impact report. This law further allowed the executive branch to create a special commission, the National Technical Commission of Biosafety (CTNBio, in Portuguese), to be responsible for, among other things, establishing norms concerning the safe use of these techniques in Brazil, and determining if any specific use would be considered safe.³⁶ Although this law established the competence of several federal agencies in dealing with this matter, it specified that all these agencies would observe the opinion of the CTNBio. Initially, the President of CTNBio had the power to decide when a prior environmental impact study or an environmental impact report would be necessary. The consequence of this innovation was to transform the constitutional requirement of a prior environmental impact study (regulated by Article 225, section I, and IV of the Brazilian Constitution, and discussed earlier) into

32. Resolução Conama No. 1A, *supra* note 31, art. 2.

33. *Id.* art. 6, § 2.

34. Resolução Conama No. 237, *supra* note 31, art. 2, § 1, annex 1, art. 3.

35. Lei No. 8.974, de 5 de Janeiro de 1995 (Braz.), available at http://www.planalto.gov.br/ccivil_03/Leis/L8974.htm.

36. Lesley K. McAllister, *Judging GMOs: Judicial Application of the Precautionary Principle in Brazil*, *ECOLOGY L. Q.*, 149, 172 (2005), available at http://www.nationalaglawcenter.org/assets/bibarticles/mcallister_judging.pdf.

an unconstitutional discretionary requirement, leading to the 1998 Brazilian Institute of Consumer Defense (IDEC) case.³⁷

B. Case Study

On June 15, 1998, Monsanto initiated the process for the commercial exploitation in Brazil of the soy “Roundup Ready” (soy modified genetically for being tolerant to the pesticide glyphosate), applying for authorization from CTNBio. Later that same year, CTNBio authorized the commercial exploitation of the soy through an internal act without the proper environmental impact study.³⁸ On November 5, 1998, the IDEC brought a preparatory action to the Federal Union in the Eleventh Federal District Court in Sao Paulo.³⁹ IDEC intending to obtain an injunction in order to bar any exploitation of the soy “Roundup Ready” until a proper regulation governing the matter was enacted, and until a proper environmental impact study was prepared. A provisory injunction was granted and later, on August 10, 1999, the Sixth Federal District Court decided the case in favor of IDEC, confirming the provisory injunction granted, and transforming this provisory injunction into a definitive order.⁴⁰ The court held that commercial exploitation of the genetically modified soy “Roundup Ready” in Brazil by Monsanto must be subject to prior enactment of a proper and specific regulation concerning biosafety and the presentation of a prior environmental impact study.⁴¹

The ambiguity of the legislation concerning GM products, the power granted to the CTNBio, and the CTNBio’s tendency to disregard the need for prior environmental impact studies, fostered a policy that failed to enforce regulations. Although the

37. *See, e.g.*, Instrução Normativa CTNBio No. 18, de 15 de Dezembro de 1998, DIARIO OFICIAL DA UNIÃO [D.O.U.] de 30.12.1998 (Braz.), *available at* <http://www.ctnbio.gov.br/index.php/content/view/11980.html>.

38. *Id.*

39. Ação Cautelar, Processo No. 1998.34.00.027681-8, 6 Vara Federal da Seção Judiciária do Distrito Federal, Juiz Antônio Souza Prudente (decided on Aug. 10, 1999), *available at* http://www.greenpeace.org.br/transgenicos/pdf/judicial_19990810.pdf; McAllister, *supra* note 36, at 160-62.

40. McAllister, *supra* note 36, at 162.

41. *Id.*

court in IDEC recognized that CTNBio was neglecting their duty to the environment, this failed to substantially change how CTNBio operates.

C. Brazil GMO Regulation Today

Since the 2005 government approval of GMOs, alteration in the regulatory policy suggests significant, tangible reformations have been made.⁴² Although some progress must be acknowledged, apparent inconsistencies in these agencies seem to allow, once again, for the promotion of economic gains at the expense of scientific environmental studies. Now, the regulatory framework for agricultural biotechnology in Brazil is delineated in Law 11,105 of 2005, altered by Law 11,460 of 2007 and Decree Number 5,591 of 2006.⁴³

There are two main governing bodies that regulate agricultural biotech in Brazil today. One body is the National Biosafety Council (CNBS, in Portuguese).

This council falls under the Office of the President and is responsible for the formulation and implementation of the national biosafety policy (PNB, in Portuguese) in Brazil. It establishes the principles and directives of administrative actions for the federal agencies involved in biotechnology. It evaluates socioeconomic implications and national interests regarding approval for commercial use of biotech products. No safety considerations are evaluated by CNBS. Under the presidency of the Chief of Staff of the Office of the President, CNBS is comprised of 11 cabinet ministers and needs a minimum quorum of 6 ministers to approve any relevant issue.⁴⁴

42. See Lei No. 11.105, de 24 de Março de 2005, DIARIO OFICIAL DA UNIÃO [D.O.U.] de 28.3.2005 (Braz.), available at http://www.planalto.gov.br/ccivil_03/_Ato2004-2006/2005/Lei/L11105.htm.

43. See Lei No. 11.460, de 21 de Março de 2007, DIARIO OFICIAL DA UNIÃO [D.O.U.] de 22.3.2007 (Braz.), available at http://www.planalto.gov.br/ccivil_03/_Ato2007-2010/2007/Lei/L11460.htm; JOAO F. SILVA, USDA FOREIGN AGRIC. SERV., ANNUAL AGRICULTURAL BIOTECHNOLOGY REPORT 5 (2007), available at www.fas.usda.gov/gainfiles/200707/146291792.doc [hereinafter BIOTECH ANNUAL 2007].

44. JOAO F. SILVA, USDA FOREIGN AGRIC. SERV., AGRICULTURAL BIOTECH ANNUAL (2012), available at <http://gain.fas.usda.gov/Recent%20GAIN%20>

The previously discussed CTNBio, the same agency established in 1995 under the first Brazilian Biosafety Law (Law 8,974), is the second regulatory body.⁴⁵ In an attempt at corrective measures,

[u]nder the current law, CTNBio was expanded from 18 to 27 members to include official representatives from 9 ministries of the federal government, 12 specialists with scientific and technical knowledge from 4 different areas including animal, plant, environment, and health (3 specialists from each area), and 6 other specialists from other areas such as consumer defense and family farming. Members of CTNBio are elected for two years with a possibility of being re-elected for an additional two years. CTNBio is now under the Ministry of Science and Technology. All technical related issues are debated and approved under CTNBio. Imports of any agricultural commodity for animal feed or for further processing, or any ready-to-consume food products, and pet food containing biotech events must be pre-approved by CTNBio. Approvals are on a case-by-case basis and they are indefinite.⁴⁶

Although it seems that Law 8,974, enacted after the IDEC case, was intended to rectify the inordinate amount of power given to CTNBio, Law 11,460 takes a step in the opposite direction. Law 11,460 of March 21, 2007, changed Article 11 of Law 11,105 of March 24, 2005, which required unanimity in voting by CTNBio members, “and established that a simple majority of votes is needed out of the 27 total voters on CTNBio’s board to approve new biotech products.”⁴⁷ This law was enacted

Publications/Agricultural%20Biotechnology%20Annual_Brasilia_Brazil_7-13-2012.pdf [hereinafter BIOTECH ANNUAL 2012].

45. JOAO F. SILVA, USDA FOREIGN AGRIC. SERV., AGRICULTURAL BIOTECHNOLOGY ANNUAL: AGRICULTURAL TECHNOLOGIES REPORT 4 (2009), available at http://gain.fas.usda.gov/Recent%20GAIN%20Publications/AGRICULTURAL%20BIOTECHNOLOGY%20ANNUAL_Brasilia_Brazil_7-15-2009.pdf [hereinafter AGRICULTURAL TECHNOLOGIES REPORT].

46. JOAO F. SILVA, USDA FOREIGN AGRIC. SERV., BIOTECHNOLOGY-GE PLANTS AND ANIMALS: BRAZILIAN ANNUAL BIOTECHNOLOGY PRODUCTION & OUTLOOK 5 (2010), available at http://gain.fas.usda.gov/Recent%20GAIN%20Publications/Biotechnology%20-%20GE%20Plants%20and%20Animals_Brasilia_Brazil_7-23-2010.pdf.

47. AGRICULTURAL TECHNOLOGIES REPORT, *supra* note 45, at 4.

to counteract anti-biotech groups, who had been slowing the approval procedures of new biotech events since 2006, by requiring fewer votes to accelerate the process.⁴⁸

On June 18, 2008 the National Biosafety Council (CNBS) decided that it will only review administrative appeals that are of national interest, involving social or economic issues, as per the Brazilian Biotech Law. CNBS will not evaluate technical decisions on biotech events that are approved by the National Technical Commission of Biosafety (CTNBio). The Council considers all approvals of biotech events by CTNBio as conclusive. This important decision, along with the change in majority voting, eliminates a major barrier for approval of biotech events in Brazil.⁴⁹

Initially after the IDEC case, changes made to CTNBio, which included increasing and diversifying its membership, were reformations seemingly intended to provide the agency with a more holistic view of biotechnological issues. However, further regulation enacted out of fear that environmental assessment may inhibit trade, weaken the effect of earlier remedial measures made by CTNBio.

V. PROBLEMS WITH GM SEEDS IN THE UNITED STATES

The United States is the largest commercial grower of GM crops in the world.⁵⁰ Statistics show the proliferation of GM crops in the United States has dramatically increased in the past two decades.⁵¹ “Ninety-seven percent of commercial varieties once sold in the United States in 1900 are no longer commercially

48. BIOTECH ANNUAL 2007, *supra* note 43, at 3.

49. AGRICULTURAL TECHNOLOGIES REPORT, *supra* note 45, at 4.

50. *Executive Summary: Global Status of Commercialized Biotech*, INT’L SERV. FOR THE ACQUISITION OF AGRI-BIOTECH APPLICATION, <http://www.isaaa.org/resources/publications/briefs/43/executivesummary/default.asp> (last visited Feb. 5, 2013).

51. See CLIVE JAMES, INT’L SERV. FOR THE ACQUISITION OF AGRI-BIOTECH APPLICATIONS, BRIEF 39: GLOBAL STATUS OF COMMERCIALIZED BIOTECH/GM CROPS: 2008 15 (2008), *available at* <http://www.isaaa.org/resources/publications/briefs/39/default.html>.

available to the public, replaced by a handful of staple crops.”⁵² The increase in GM crops has “led to fears of dwindling biodiversity in the country’s staple crops,” where a majority of the two largest staple crops being planted are genetically modified.⁵³ The rise of a monoculture in United States’ farming, similar to events previously discussed regarding Brazil, coincides with the rise of agribusiness and the mass adoption of fertilizers, pesticides, and herbicides.⁵⁴

Given the prevalence of GM crops, the fear of crosspollination of GM and non-GM varieties is an increasing concern, only heightened by deregulation. Although the National Environmental Policy Act⁵⁵ (NEPA) is a procedural measure intended to “ensure that the agency will not act on incomplete information, only to regret its decision after it is too late to correct,” a lack of objective standards allows agencies to circumvent meaningful scientific assessments.⁵⁶ NEPA requires all federal agencies to “conduct an environmental analysis and fully disclose its results prior to carrying out any major actions with the potential to significantly impact the environment.”⁵⁷ The NEPA process consists of an evaluation of the environmental effects of a federal undertaking including its alternatives.

There are three levels of analysis: categorical exclusion determination, preparation of an environmental assessment/finding of no significant impact (EA/FONSI), and preparation of an environmental impact statement (EIS). At the first level, an undertaking may be categorically excluded from a detailed environmental analysis if it meets certain criteria which a federal agency has previously determined as having no

52. Christian B. Miller, Comment, *Honey Get My Gun, The Transgenic Seeds Are in the Field Again*, 11 J. MARSHALL REV. INTELL. PROP. L. 439, 440 (2011), available at <http://www.jmripl.com.php5-10.dfw1-2.websitetestlink.com/articles/Miller1.pdf>.

53. *Id.* at 438.

54. *Id.* at 440.

55. National Environmental Policy Act of 1969, 42 U.S.C. §§ 4331-4375 (2006).

56. *Blue Mountains Biodiversity Project v. Blackwood*, 161 F.3d 1208, 1216 (9th Cir. 1998).

57. Marc J. Stern et al., *The Meaning of the National Environmental Policy Act Within the U.S. Forest Service*, 91 J. ENVTL. MGMT. 1371 (2010).

significant environmental impact. At the second level of analysis, a federal agency prepares a written environmental assessment (EA) to determine whether or not a federal undertaking would significantly affect the environment. If the answer is no, the agency issues a finding of no significant impact (FONSI). If the EA determines that the environmental consequences of a proposed federal undertaking may be significant, an EIS is prepared. An EIS is a more detailed evaluation of the proposed action and alternatives. The public, other federal agencies and outside parties may provide input into the preparation of an EIS and then comment on the draft EIS when it is completed.⁵⁸

Although an EA is supposed to contain “sufficient evidence and analysis for determining whether to prepare an environmental impact statement or a finding of no significant impact”⁵⁹ to promote informed decision making, various cases show this is not always done. Additionally, after the Final Environmental Impact Statement is completed, NEPA does not prohibit the agency from completing the proposed action even if adverse environmental effects were determined in the report, as the Act is purely a procedural requirement.⁶⁰ This leaves consumer health and environmental advocates attempting to slow the deregulation of GM crops through administrative challenges.

A. History and Regulatory System Overview

With the emergence of biotechnology in the 1980s, the federal administration publicly expressed the need for regulation to protect both human health and the environment.⁶¹ President Reagan assigned the White House Office of Science and Technology Policy (OSTP) with the challenge of assessing and

58. *National Environmental Policy Act: The NEPA Process*, U.S. EPA, <http://www.epa.gov/compliance/basics/nepa.html> (last visited Feb. 5, 2013).

59. 40 C.F.R. § 1508.9 (2012); *National Environmental Policy Act*, U.S. EPA, <http://www.epa.gov/compliance/nepa/> (last visited Dec. 21, 2012).

60. *Id.*

61. *Compliance and Assessment*, USDA, http://www.aphis.usda.gov/regulations/compliance/environmental_nepa_act.shtml (last modified Jan. 22, 2009).

deliberating what regulatory practices should govern GMOs.⁶² The first policy released was the 1986 Coordinated Framework for Regulation of Biotechnology (Coordinated Framework)⁶³ including the stated intent to “achieve a balance between regulation adequate to ensure health and environmental safety while maintaining sufficient regulatory flexibility to avoid impeding the growth of an infant industry.”⁶⁴ After deliberating on how to accomplish this task, the OSTP determined that GMOs were “not fundamentally different from conventional products” and that regulation should govern the product, rather than the process, based on the manner of its use.⁶⁵

The Coordinated Framework chose to fit the regulation of GMOs within the already-existing federal laws through the coordination of the United States Department of Agriculture (USDA), the Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA). Each agency is charged with a role: the USDA ensures GMOs are safe to grow⁶⁶ and its department of Animal and Plant Health Inspection Services (APHIS) regulates risk to plant or animal health;⁶⁷ the EPA is responsible for ensuring that GMOs are safe for the environment; and the FDA ensures that food developed from GMOs are safe for consumption.⁶⁸

After several years of this regulatory approach, the OSTP recognized the problem with cross-contamination from GM crops in the environment. In 2002, the Coordinated Framework, along with the USDA, the EPA, and the FDA, outlined additional testing requirements for both plants and food developed through biotechnology.⁶⁹ The purpose of the 2002 update included three

62. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302, 23,306 (June 26, 1986).

63. *See id.*

64. *Id.* at 23,302-03.

65. Margaret Rosso Grossman, *Genetically Modified Crops and Food in the United States: The Federal Regulatory Frame, State Measures, and Liability in Tort*, in *THE REGULATION OF GENETICALLY MODIFIED ORGANISMS: COMPARATIVE APPROACHES* 299, 300 (Luc Bodiguel & Michael Cardwell eds., 2010).

66. *Id.*

67. *Id.* at 301.

68. *Id.* at 300.

69. *Id.* at 301.

specific objectives: (1) field tests should consist of confinement based on the level of risk to health and the environment; (2) in the case of unknown or unacceptable risks, strict confinement should ensue with GM materials prohibited from seeds, and products; and (3) cross-contamination should remain minimal, although some low levels of biotechnology-produced gene presence could prove acceptable.⁷⁰

B. Case Study

Geertson Seed Farms v. Johanns illustrates how the lack of clarity and cohesion in United States' regulatory policy has led to contamination of fields by GM seeds.⁷¹ Geertson Seed Farms challenged the APHIS' assessments in preparing EAs without an EIS for potentially serious environmental risks and in 2010 went up to the Supreme Court. The Supreme Court decision in declining to enjoin planters of GM alfalfa before the completion of an in-depth environmental study is indicative of the Court's confidence in the federal government's ability to manage scientific uncertainty.⁷²

After APHIS had classified Monsanto's Roundup Ready alfalfa as regulated, Monsanto sought to have the status of the product changed.⁷³ In response, APHIS concluded in its EA that Roundup Ready alfalfa would have no significant impact on the environment and, therefore, deregulated Roundup Ready alfalfa unconditionally.⁷⁴ Since the EA resulted in a finding of no significant impact, APHIS was not required by NEPA to prepare an EIS.⁷⁵ The agency went on to authorize 300 field trials of Roundup Ready alfalfa over eight years.⁷⁶ In response to the non-regulated status of Roundup Ready alfalfa, conventional

70. *Id.*

71. See *Geertson Farms, Inc. v. Johanns*, No. C 06-01075, 2007 WL 776146, at *2 (N.D. Cal. Mar. 12, 2007).

72. *Monsanto Co. v. Geertson Seed Farms*, 130 S. Ct. 2743, 2771 (2010).

73. *Id.* at 2750.

74. *Geertson Farms, Inc.*, 2007 WL 776146 at *1.

75. *Geertson Seed Farms*, 130 S. Ct. at 2750.

76. *Id.*

alfalfa farmers and environmental groups filed an action against the Secretary of Agriculture for violating NEPA.⁷⁷

The district court in *Geertson*, held that APHIS violated NEPA because its EIS was not complete.⁷⁸ APHIS made several unsupported statements in its EA with regard to the risks of deregulating roundup-ready alfalfa.⁷⁹ APHIS based its conclusion that there was no risk to organic populations of alfalfa by assuming that organic farmers could prevent contamination.⁸⁰

APHIS reached this determination despite admitting: (1) pollinators and wind could transmit GM pollen up to two miles; and, (2) APHIS would have no control over the proximity of the GM crop to non-transgenic crops once GM alfalfa was deregulated. APHIS also argued that the complete loss of all non-transgenic alfalfa would not be considered a significant environmental impact per NEPA. The court found APHIS's deregulation decision capricious and unfounded because the agency's conclusions: (1) ignored whether organic farmers could prevent contamination; and (2) did not fully appreciate the significance of contamination upon deregulation. Additionally, the court noted one of NEPA's statutory aims was to preserve biodiversity.⁸¹

The court granted a permanent injunction over planting more of this GM alfalfa, which vacated the APHIS's deregulation decision, and the district court ordered the agency to complete an EIS.⁸²

Justice Alito, writing for the Supreme Court's majority, acknowledged that they had not complied with NEPA, but criticized both the grant of injunction⁸³ and the district court's decision to remand the matter back to the agency.⁸⁴ The Court found the *Geertson* respondent was not harmed in a manner

77. *Id.*

78. *Geertson Farms, Inc.*, 2007 WL 776146 at *1.

79. *See Geertson Seed Farms*, 130 S. Ct. at 2763.

80. *Id.* at 2763.

81. Miller, *supra* note 52, at 447.

82. *Geertson Farms, Inc. v. Johanns*, No. C 06-01075, 2007 WL 1302981, at *9 (N.D. Cal. May 3, 2007).

83. *Geertson Seed Farms*, 130 S. Ct. at 2758.

84. *Id.* at 2754.

consistent with obtaining a permanent injunction.⁸⁵ While the Court admitted that enjoining APHIS from fully deregulating GM alfalfa until it completed an EIS was within judicial power, the injunction interfered with the power Congress vested in APHIS to partially-deregulate.⁸⁶

C. United States' GMO Regulation Today

OSTP's decision to divide GMO regulatory policy between three agencies has led to inconsistent regulatory control, which is only exacerbated by NEPA's subjective standard.⁸⁷ Despite OSTP's intentions that the agencies coordinate, concern has been raised that the regulatory structure promotes narrow views, leading to increased GMO risk.⁸⁸ In *Monsanto Co. v. Geertson Seed Farms*, Justice Stevens expressed this fear as the sole dissenter, and took issue with APHIS for failing to consider the implications of deregulation holistically.⁸⁹ He echoes the apprehension of the district court regarding the unconsidered consequences caused by cross-pollination, and decontamination of organic crops by the GM gene.⁹⁰

VI. CONCLUSION: UNCSO, THE ROLE OF SCIENCE, AND THE FUTURE

The above cases from Brazil and the United States illustrate the various ways in which GMO regulations can fail to implement protective measures. In Brazil, the IDEC case shows that although some policies like NEPA are designed to ensure effective environmental assessment, agencies like CTNBio do not always

85. *Id.* at 2759-60.

86. *Id.*

87. DIAHANNA LYNCH & DAVID VOGEL, COUNCIL ON FOREIGN RELATIONS, THE REGULATION OF GMOS IN EUROPE AND THE UNITED STATES: A CASE STUDY OF CONTEMPORARY EUROPEAN REGULATORY POLITICS (2001), available at <http://www.cfr.org/genetically-modified-organisms/regulation-gmos-europe-united-states-case-study-contemporary-european-regulatory-politics/p8688>.

88. *See id.*

89. *Geertson Seed Farms*, 130 S. Ct. at 2743, 2762 (Stevens, J., dissenting); see also *Johanns*, 2007 WL 776146 at *2.

90. *Geertson Seed Farms*, 130 S. Ct. at 2762; see also *Geertson Farms, Inc.*, 2007 WL 776146 at *1.

follow procedure.⁹¹ Additionally, other laws have created agencies that supposedly have the primary objective of guaranteeing safety, but are diluted in implementation by competing motivations.⁹² In the United States, the GMO regulatory framework intends to foster complementarity among agencies, but fails to promote a holistic assessment of risk regarding agricultural biotechnology.⁹³ Additionally, NEPA's use of the "significant impact" standard allows for a high degree of subjective analysis, and inconsistently triggers further investigation.⁹⁴ The fact that NEPA is only a procedural requirement further weakens its ability to stimulate in-depth scientific assessments. Therefore, science and empirical data need to be the driving forces behind policy, implementation, and the overall framework of GMO regulations. This begins to address the overarching issue relating to the prevalence of economic incentives and suggests that taking corrective measures at an international level would be the most effective solution to rectify all aspects of this problem.

Current international events are creating an atmosphere that may be particularly receptive to addressing these GMO regulatory weaknesses. At the UNCSO this past June, world leaders, along with thousands of participants from governments, the private sector, NGOs, and other groups, came together in Brazil to discuss how reduction of poverty, advancement of social equity, and environmental protection can best be achieved.⁹⁵ The UNCSO resulted in a concentrated political document focused on two themes: 1) a green economy in the context of sustainable development and poverty eradication; and 2) the institutional

91. See Instrução Normativa CTNBio No. 18, *supra* note 37.

92. Doug Farquhar & Liz Meyer, *State Authority to Regulate Biotechnology Under the Federal Coordinated Framework*, 12 *DRAKE J. AGRIC. L.* 440, 446 (2007).

93. See McAllister, *supra* note 36.

94. *Geertson Seed Farms*, 130 S. Ct. at 2746.

95. *Ideas for the World or Few Words on this Year's Biggest Event on Sustainable Development – Rio+20*, ARCTIC PORTAL, <http://www.arcticportal.org/features/785-rio20> (last visited Feb. 5, 2013).

framework for sustainable development.⁹⁶ Food security and sustainable agriculture were identified as priority areas.⁹⁷ Additionally, at the launching of the Secretary General's report of the High Level Panel on Global Sustainability, U.N. Secretary-General Ban Ki-moon highlighted the importance of science as an essential tool for decision-making on sustainability issues.⁹⁸

As the "green economy" was not yet a defined term at the start of the UNCSA, it is far from surprising that nations had difficulty reaching consensus when attempting to delineate exactly which technologies make up this market. Whether GMOs can promote sustainability, and whether international regulations can assure they are used accordingly, seemed to be an essential part of this conversation.⁹⁹ However, deadlock caused a general shift away from international regulation toward the promotion of domestic action.¹⁰⁰

Connected to the green economy are the issues relating to technology transfer. The questions addressing what technologies are actually being promoted and the manner in which technology transfer would occur prompted many at the UNCSA to suggest that the creation of a new United Nations to assess technologies from a more empirical standpoint was needed.¹⁰¹ Such a mechanism would foster disclosure of information regarding agricultural biotechnology and provide a platform to assure nations are aware of the implications these technologies may

96. See *Green Economy in the Context of Sustainable Development and Poverty Eradication*, UNCSA, <http://www.uncsa2012.org/rio20/greeneconomy.html> (last visited Jan. 22, 2013).

97. *Id.*; *Food Security and Sustainable Agriculture*, UNCSA, www.un.org/en/sustainablefuture/food.shtml (last visited Feb. 4, 2013).

98. Press Release, The United Nations Secretary General High Level Panel on Global Sustainability, Global Sustainability Panel Says a "Future Worth Choosing" Must Be Based on True Costs to People and the Environment (Jan. 20, 2012) (on file with author), available at http://www.un.org/gsp/sites/default/files/event_attachments/Addis%20Launch-Press%20Release.pdf.

99. Suan Ee Ong et al., *Examining Rio+20's Outcome*, COUNCIL ON FOREIGN RELATIONS (July 5, 2012), <http://www.cfr.org/energyenvironment/examining-rio20s-outcome/p28669>.

100. *Id.*

101. *The Technology Economy? Know-how, Know-what, Know-why*, UNCSA, <http://www.uncsa2012.org/index.php?page=view&type=1000&nr=495&menu=126> (last visited Jan. 22, 2012).

have if overused in the absence of regulations. This would be the first step to having regulations with clear scientific parameters.

Although the Rio+20 outcome document erred on the side of breadth and lacked this clearly defined path to achieve its aspirations regarding GMOs, the accomplishment or failure of the UNCSD cannot be seen in isolation. The UNCSD helped to catalyze a global call to make sustainable development priorities central to global thinking and action.¹⁰² On December 21, 2012, the sixty-seventh session of the United Nations General Assembly recognized the importance of recent decisions adopted at the eleventh meeting of the Conference of the Parties (COP 11) to the Convention on Biological Diversity (CBD) on Sustainable Development “Rio + 20” - “The Future We Want.”¹⁰³ At COP 11, which took place in India from October 8 to 19, 2012, there was a call for more science-based information, the closure of knowledge gaps, and increased precaution, in the emerging fields of synthetic biology.¹⁰⁴ COP 11 “urges governments to ‘take a precautionary approach’ when addressing the ‘threats of significant reduction or loss of biological diversity’ posed by synthetic biology developments.”¹⁰⁵ The document also “invites countries to synthesise information on synthetic biology, and ‘consider possible gaps and overlaps’ with other provisions in the CBD.”¹⁰⁶ This demonstrates a step in the right direction. The information is likely to be available for consideration by the U.N. Subsidiary Body on Scientific, Technical and Technological Advice (SBSTA) at the next CBD meeting in Korea in 2014.¹⁰⁷

102. See Press Release, United Nations Environment Programme, United Nations General Assembly Resolutions Highlight Contributions of the Convention on Biological Diversity for Oceans Agenda and Implementation of Rio + 20 Outcomes (Dec. 21, 2012) (on file with author), available at <http://www.cbd.int/doc/press/2012/pr-2012-12-21-unga-en.pdf>.

103. *Id.*

104. *Biodiversity Meeting Calls for More Science-Based Information*, SCIDEV.NET (Oct. 22, 2012), <http://www.scidev.net/en/agriculture-and-environment/biodiversity/news/biodiversity-meeting-calls-for-more-science-based-information-.html>.

105. *Id.*

106. *Id.*

107. *Id.*

A common argument against more cautious, scientifically driven GMO regulations is that although this type of policy would promote environmental safety, it would slow trade, thereby hurting nations' overall economic benefit.¹⁰⁸ This ignores the fact that many nations, including the United States and Brazil, subsidize GMO production.¹⁰⁹ Millions of government dollars have been spent, and millions more are likely to be spent on agricultural biotechnology if the future course holds steadfast. However, consideration should be given to the fact that in December 2011, Monsanto's GM corn seed failed again to kill insects that feed on corn plants.¹¹⁰ According to the EPA, at least four states in the U.S. have seen undesirable outcomes from corn plants that were supposed to be immune from rootworm.¹¹¹ If countries are investing such substantial amounts of money into technologies that have unknown effects, not only could this create negative economic consequences, but considering these technologies are connected to seeds, the first step in the food chain, it could have devastating effects on humanity. Therefore, in reassessing the examples of Brazil and the United States regarding ineffective GMO regulations, the question must be asked, can the environment, humanity, or the economy afford not to change?

108. See LYNCH & VOGEL, *supra* note 87.

109. Luis Meranda, *Monsanto's Bt Corn Rendered Obsolete by Mother Nature*, REAL AGENDA (Dec. 11, 2011), <http://real-agenda.com/2011/12/08/monsantos-bt-corn-rendered-obsolete-by-mother-nature/>.

110. *Id.*

111. *Id.*