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ARTICLES

THE ILLUSION OF CARE: REGULATION, UNCERTAINTY, AND GENETICALLY MODIFIED FOOD CROPS

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With all that technology has to offer, it is nothing if it's not accepted. This boils down to a matter of trust. Trust in the science behind the process, but particularly trust in the regulatory process that ensures thorough review— including complete and open public involvement.[1]

One person's unacceptable consequence is another's regrettable necessity.[2]

INTRODUCTION

Genetically modified food crops ("gm" or "transgenic" crops) have been the focus of vitriolic debate.[3] To the participants, the stakes in this debate are exceedingly high. Where some see this technology as a cure-all, others see only disaster in the making.[4]

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[1] Dan Glickman, Remarks of the United States Secretary of Agriculture to the National Press Club (July 13, 1999), *at* http://www.usda.gov/news/releases/1999/07/0285.

[2] Christopher D. Stone, *Is There a Precautionary Principle?*, 31 ENVTL. L. REP. 10790, 10799 (2001).

[3] The debate rages on many fronts, including environmental safety, food safety and consumer choice. This article focuses solely on questions of environmental safety.

[4] *See, e.g.,* Turning Point Project, *Genetic Engineering Series, Ad #5: Biotechnology=Hunger*, *at* http://www.turnpoint.org/biotechad5.pdf (last visited

Sandwiched between the rhetorical excesses of a "new green revolution"[5] and "Frankenstein foods"[6] are real questions about this developing technology. Proponents argue that gm crops will help feed the world's growing human population[7] while preserving what is left of the natural ecosystem.[8] Opponents counter that

Apr. 22, 2002) (part of a series of advertisements published in the *New York Times* from Oct. 11 to Nov. 8, 1999).

[5] *See, e.g., GM food v. manure*, NAT'L POST, Aug. 2, 2001, at A17, *available at* 2001 WL 25978972; J. Madeleine Nash, *Grains of Hope*, TIME INT'L, Feb. 12, 2001, *available at* 2001 WL 5489428; RICHARD MANNING, FOOD FRONTIER: THE NEXT GREEN REVOLUTION (2000).

[6] *See, e.g.,* Turning Point Project, *Genetic Engineering Series*, *at* http://www.turnpoint.org/geneng.html (last visited Apr. 22, 2002); Geoffrey Lean*, Frankenfoods: The Truth at Last*, DAILY MAIL, Feb. 6, 2002, at 12, *available at* 2002 WL 3310510; RICHARD CAPLAN, RAISING RISK: FIELD TESTING OF GENETICALLY ENGINEERED CROPS IN THE UNITED STATES (2001), *available at* http://pirg.org/ge/reports/RaisingRisk.pdf [hereinafter CAPLAN, RAISING RISK]; Ben Lilliston, *Don't Ask, Don't Know: The Biotech Regulatory Vacuum*, MULTINAT'L MONITOR, Jan. 1, 2000, at 9, *available at* 2000 WL 16039144. Prince Charles famously claimed that "genetic modification takes mankind into realms that belong to God and God alone." *See* Kevin Cullen*, Genetically Modified Food Fight Growing Unpalatable,* BOSTON GLOBE, Aug. 3, 1999, at A1, *available at* 1999 WL 6075068.

[7] The dilemma of how to treat transgenic crops must be viewed against the real fact that every year the world's population continues to grow. World population will reach 9-10 billion individuals by 2050, a sixty percent increase from 2000 levels. *See* U.N. Food and Agricultural Organization (FAO), *FAOSTAT*, *Agricultural Database: Population: Long-term Series (Quinquennial) Total/Rural/Urban Population, at* http://apps.fao.org/page/collections (last updated Nov. 20, 2001). Given that 1 in 7 persons in developing countries currently suffers from chronic malnutrition, adequately feeding those new mouths will require a more than sixty percent increase in the food supply. FAO, THE STATE OF FOOD INSECURITY IN THE WORLD (3d ed. 2001), *available at* http://www.fao.org/docrep/003/y1500e/y1500e00.htm. *See also* Kitta MacPherson, *Seeds of Discord: The Battle Over Golden Rice,* STAR LEDGER, Jan. 2002, *available at* http://www.nj.com/specialprojects/index.ssf?/pecialprojects/rice/main.html (four-part series about how genetically engineered strain of rice could prevent millions of children from hunger and blindness). Either more land will have to be converted to farm use or existing farmland will have to be made more productive. The former option raises serious environmental concerns. The sheer scope of rainforest and other wild lands being lost to monoculture farming every year (with an attendant loss of habitat and biodiversity) seriously threatens conservation efforts, and may have impacts on global warming. All things being equal, increased crop yields would therefore be a more environmentally desirable solution to the problem. The process of increasing crop yields can take two very different paths: either reducing crop losses to spoilage and pests or actually increasing the yield per acre. Gm crops have the potential to do both.

[8] *See*, *e.g.*, Indur M. Goklany, *The Future of Food*, 16 F. FOR APPLIED RES. & PUB. POL'Y 59, 60 (2001) (describing the environmental benefits of

uncontrolled use of the technology is ecological roulette.[9] Calling for government either to step out of the way or to form a bulwark of protection, the competing views offer very different assessments of the risks, and advance conflicting visions of the proper role for government regulation of this technology.

Regulators must choose among these competing, plausible, though largely hypothetical, assessments of risk.[10] Their task is to create a regulatory scheme that will unleash the benefits of gm crops while avoiding the pitfalls. Scientific uncertainty is "a fact of life"[11] in this process, and regulators must make choices "on the frontiers of scientific knowledge."[12] In doing so, they walk a fine line. If regulations are too stringent, billions of dollars of unnecessary costs will be imposed on a developing industry, and, even worse, world food supplies will lag further behind a burgeoning population.[13] If standards are too lenient, the scope of resultant environmental harms might be staggering.[14] In making

genetically modified food crops) [hereinafter Goklany, *Future of Food*].

[9] Jeremy Rifkin, *The Biotech Century: Playing Ecological Roulette with Mother Nature's Designs*, E MAGAZINE, May-June 1998, *available at* http://www.emagazine.com/may-june_1998/0598feat2.html. *See also* Turning Point Project, *Genetic Engineering Series, Ad #1: Who Plays God in the 21st Century?* and *Ad #3: Genetic Roulette*, *at* www.turnpoint.org/geneng.html (last visited Apr. 22, 2002).

[10] For a thorough critique of the use and misuse of risk assessment models, see Thomas O. McGarity, *Celebrating Fifty Years of the Administrative Law Review: A Cost-Benefit State*, 50 ADMIN. L. REV. 7 (1998). When scientific information is unavailable or incomplete, claims of "science based" risk assessment merely give a veneer of objectivity to what are inherently political decisions. *Id.* at 15.

[11] *See* EPA, *Policy for Risk Characterization* (Mar. 1995), *available at* http://www.epa.gov/osp/spc/ rcpolicy.htm.

[12] *See, e.g.,* Lead Indus. Ass'n v. EPA, 647 F.2d 1130, 1147 (D.C. Cir. 1980); Ethyl Corp v. EPA, 541 F.2d 1, 27 (D.C. Cir. 1975) (en banc). These questions, which can be posed to science, but not answered by science, have been called "trans-scientific." *See generally* Alvin M. Weinberg, *Science and Trans-science*, 10 MINERVA 209 (1970). In contrast to the uncertainty that is characteristic of all of science in which the "answer" is inevitably accompanied by some level of uncertainty, scientific questions that surround gm crops are uncertain because scientists either cannot or have not performed the experiments that would test the hypotheses. These are questions that science can only go so far in answering.

[13] *See, e.g.,* Norman Borlaug, *We Need Biotech to Feed the World*, WALL ST. J., Dec. 6, 2000, at A22.

[14] Among the environmental evils frequently identified as potentially created by gm crops are: evolving insect resistance; genetic erosion of wild land races; inadvertent creation of super weeds resistant to herbicides; and loss of beneficial insects. Of those questions, the one raising the most pressing regulatory

regulatory choices under these circumstances, the root question becomes how to account for scientific uncertainties in the regulatory process.[15]

Too often, discussions about regulation under these circumstances are entirely theoretical. The hypothetical behavior of imaginary actors is offered as support for *a priori* conclusions.[16] To avoid that problem, this article focuses on the regulatory process for the most common transgenic crop, Bt corn.[17] Using the actual behavior of regulators and the regulated community as a case study, I evaluate whether the existing regulatory framework facilitates relatively safe development and introduction of these new crops. Specifically, I examine how regulatory decisions have used available scientific information and have responded to scientific uncertainty. Without advocating the elimination of Bt crops, or discounting the potential benefits of biotechnology, I conclude that the Bt case study reveals significant regulatory failures that can be remedied only through systemic changes to the regulatory process.

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concerns is how to delay the development of pest resistance. The other issues, though significant, are either not implicated by current planting practices, or are speculative harms for which there is, as yet, no consensus about degree of risk. By contrast, there is some degree of scientific certainty that it is a question of when—not if—insects will develop resistance to gm plants engineered to produce pesticides, herbicides or other "plant-incorporated protectorants."

[15] This article builds on a considerable body of work exploring the sources and nature of scientific uncertainty. For some of the philosophical underpinnings, *see* THOMAS S. KUHN, THE STRUCTURE OF SCIENTIFIC REVOLUTIONS (3rd ed. 1996); KARL R. POPPER, THE LOGIC OF SCIENTIFIC DISCOVERY (1959). For background on how law copes with scientific uncertainty in the regulatory context, *see* Howard Latin, *Good Science, Bad Regulation and Toxic Risk Assessment*, 5 YALE J. ON REG. 89 (1988); Marcia R. Gelpe & A. Dan Tarlock, *The Uses of Scientific Information in Environmental Decisionmaking*, 48 S. CAL. L. REV. 371 (1974).

[16] *See, e.g.,* Frank B. Cross, *The Paradoxical Perils of the Precautionary Principle*, 53 WASH. & LEE L. REV. 851, 861 (1996); Thomas P. Redick et al., *Private Legal Mechanisms for Regulating the Risks of Genetically Modified Organisms: An Alternative Path Within the Biosafety Protocol*, 4 ENVTL. L. 1, 15 (1997). Perhaps the most notorious example of this sort of advocacy can be found in John F. Morall III, *A Review of the Record*, REGULATION, Nov./Dec. 1986, at 25, 30. *See also* Robert W. Hahn, *Regulatory Reform: What Do the Government's Numbers Tell Us*?, *in* RISKS, COSTS AND LIVES SAVED: GETTING BETTER RESULTS FROM REGULATION 208 (Robert W. Hahn ed., 1996) (relying heavily on Morall's work). For a critique of Morall's influential article, see Lisa Heinzerling, *Regulatory Costs of Mythic Proportions*, 107 YALE L.J. 1981, 1984 (1998) and McGarity, *supra* note 10, at 14-16.

[17] For an explanation of Bt corn, *see infra* Section I(B).

Examining the degree to which environmental concerns have or have not been incorporated into the registration requirements of Bt crops, it becomes clear that the regulatory process suffers from many ills. In approving these crops for market, the United States Department of Agriculture (USDA) and Environmental Protection Agency (EPA) repeatedly disregarded significant but unresolved scientific questions about these crops.[18] Seed companies agreed to environmentally protective measures in their crop registrations, but assumed no responsibility for implementing those measures. Instead, the implementation burden fell exclusively on growers who, as third parties to the registrations, were not directly subject to regulatory jurisdiction. No regulatory framework existed (or, for that matter, exists) to monitor and enforce these registration restrictions. I suggest that these defects grow directly from ill-advised fragmentation of the regulatory role and a squeamish unwillingness to engage in necessary, but politically charged, direct regulation that might slow the development of a high-tech industry. These serious regulatory deficiencies call into question the soundness of the entire gm regulatory process, a question ultimately much broader than Bt crops.

After laying out a general explanation of gm technology and Bt crops in Part I, Part II of this Article presents an overview of the United States regulatory framework examined in this case study with particular attention to the conflicting regulatory visions incorporated into that framework. Part III makes the case for erring on the side of protecting the environment when regulating gm crops. Through a detailed analysis of the Bt case study, Part IV explores the ways in which the regulatory process has failed to be sufficiently protective of the environment. This section uses specific regulatory choices about Bt corn to illustrate a troubling pattern of agency decisions that routinely discount uncertainty when estimating and managing risks. As part of this analysis, Part

[18] Unlike "pure science," where the proper response to uncertainty is to reserve judgment, regulators make decisions based on incomplete information. It is common for regulators to make decisions with significant social and economic costs against a background of substantial uncertainty about the scope of a hazard, and the possible benefits of risk reduction. A regulatory decision to reserve judgment is a decision not to regulate that has real-world consequences. As a result, scientists in regulatory proceedings frequently feel pressure to produce "answers" even if highly speculative. For an excellent discussion of how science is used and misused in the regulatory process, see Wendy E. Wagner, *The Science Charade in Toxic Risk Regulation*, 95 COLUM. L. REV. 1613 (1995).

IV also explores the consequences of granting the regulatory approvals necessary to grow and market gm crops without first establishing rigorous enforcement mechanisms to ensure that environmental safeguards are implemented. Part V situates these regulatory failures within a broader dialogue about how to balance risks and benefits in the absence of critical scientific information, and uses a case study to explore what the parameters of a more protective regulatory system might look like. This section ends by making recommendations about how to adapt the regulatory process to account for scientific uncertainty.

I
BACKGROUND

A. *Genetic Modification in a Nutshell*

Humans have been modifying plants and animals since the dawn of agriculture more than 10,000 years ago. What we call "domestication" of a food crop involves selective breeding: the selection and cross-breeding of sexually compatible organisms to enhance or suppress a trait already present in the organisms. Natural variations within species are exploited to develop new strains. The end result can be a radically altered species. For example, corn was domesticated in the Americas around 7,500 years ago.[19] In the domestication process, corn was so significantly modified that it no longer resembles its wild relatives.[20]

Because the process of selective breeding results in changes to a species' genotype,[21] it is a form of genetic modification. An important limitation on this type of genetic modification, however, is that selective breeding can only duplicate reproductive events that might occur in nature. By managing these reproductive events towards a particular end, the randomness that ordinarily drives natural selection[22] can be channeled to achieve human goals.

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[19] Svante Paabo, *Neolithic Genetic Engineering*, 398 NATURE 194, 195 (1999) (describing neolithic genetic manipulation of corn).

[20] *Id.*

[21] Webster's Third New International Dictionary defines genotype as "the totality of genes possessed by an individual or group." WEBSTER'S THIRD NEW INT'L DICTIONARY 947 (Philip Babcock Gove ed., 1993).

[22] For an explanation of how natural selection drives evolution of a species

New genetic engineering technologies have radically expanded human abilities to engage in genetic modification. Because functional genes can now be isolated and transferred from one organism to another, these technologies have freed genetic engineers from the main constraint of selective breeding—the need to start with sexually comparable organisms. Genes can now be transferred across species, class, order and phyla, and can introduce entirely new traits into organisms that never before expressed them. In genetic engineering, genes themselves can be recombined.

As a means of modifying a plant (or animal), this recombinant DNA (rDNA)[23] aspect of genetic engineering technology makes it fundamentally different from selective breeding.[24] Where selective breeding is limited to duplicating events that could occur naturally, rDNA technology permits genetic material to be recombined into entirely novel patterns. It is this modern, technological means of creating new genetic combinations that I refer to with the terms "genetically modified" or "transgenic."

The past few years have seen an explosion in the use of transgenic crops. In 1996, about 1.7 million hectares were planted with these crops.[25] Four years later, 44 million hectares of land were planted with forty transgenic crops.[26] These crops represent

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that is geared towards the non-scientist, see STEPHEN J. GOULD, EVER SINCE DARWIN 21-55 (1977).

[23] Recombinant technology involves the molecular characterization of the gene that controls for a desired trait. That gene is isolated, inserted into a bacteria to create multiple copies of the gene, and then introduced into a new organism. *See* H.I. Miller, *Biotechnology, in* ENCYCLOPEDIA OF GENETICS 224-25 (Sydney Brenner & Jeffrey H. Miller eds., 2002).

[24] Genetic engineering permits a researcher to isolate a particular gene, or series of genes, and to produce many copies of the gene. The technology further enables the researcher to transfer those copies from one organism to another, in such a way that the transferred rDNA material is incorporated into the genome of the transferee and becomes part of that organism's genetic material. *Id.*

[25] Gabrielle J. Persley & John J. Doyle, *Overview*, *in* INTERNATIONAL FOOD POLICY RESEARCH INSTITUTE, FOCUS 2: BIOTECHNOLOGY FOR DEVELOPING-COUNTRY AGRICULTURE: PROBLEMS AND OPPORTUNITIES (Gabrielle J. Persley ed., Oct. 1999), *available at* http://www.ifpri.org/2020/focus/focus02.htm. According to Dan Glickman, former Secretary of Agriculture, 70 million acres were planted with biotech crops in 2000. *See* Dan Glickman, Remarks of the United States Secretary of Agriculture to the Committee on Biotechnology (Nov. 29, 2000), *at* http://usinfo.state.gov/topical/global/biotech/00112901.htm.

[26] Biotechnology Industry Organization (BIO), *Guide to Biotechnology: Agricultural Production*, *at* http://www.bio.org/er/agriculture.asp (last visited Apr. 22, 2002).

sixteen percent of the global land area devoted to agriculture in 2000.[27] The vast majority of these crops were planted in the United States, Canada and Argentina,[28] with a small portion in European and developing countries.[29] Of these countries, the United States is by far the greatest producer of transgenic crops, and accounts for seventy-two percent of the total gm harvest worldwide.[30] Indeed, more than sixty percent of the cotton and about twenty-five percent of the corn grown in the United States in 2000 used seeds that were genetically modified to be resistant to herbicides or insects.[31] These numbers will almost certainly increase in the foreseeable future.

B. *What Are Bt Crops?*

A significant percentage of the corn and cotton planted in the United States is genetically modified to express Bt toxins. Bt crops contain genes introduced from *Bacillus thuringiensis* (Bt), a soil bacteria commonly found in the environment. These transferred Bt genes enable the plants to produce proteins known as Bt toxins[32] that kill certain classes of insects, including some significant agricultural pests.[33] Because they produce these toxins,

[27] *Id.*

[28] *Id.*

[29] *Id. See also* Clive James & Anatole Krattiger, *The Role of the Private Sector*, *in* FOCUS 2, *supra* note 25.

[30] *See* Economic Research Service, USDA, *Agricultural Biotechnology: Adoption of Biotechnology and its Production Impacts*, *at* http://www.ers.usda.gov/briefing/biotechnology/ chapter1.htm (last updated May 21, 2002).

[31] *Id.* Of those totals, Bt Cotton made up thirty-fve percent of the United States cotton harvest in 2000. Bt corn made up about twenty-six percent of the 1999 corn acreage, but dropped to nineteen percent in 2000. *Id.* The reason for this decrease is unknown but may be due to decreased pest pressure and increased uneasiness about export. *Id.*

[32] The gene most commonly used has been Cry1A, which is approved for use in human and animal food. *See* Bacillus thuringiensis Subspecies Kurstaki CryIA(c) and the Genetic Material Necessary for its Production in all Plants; Exemption from the Requirement of a Tolerance, 40 C.F.R. § 180.1155 (2002). One hybrid, StarLink corn, was produced by inserting a different Bt gene, known as Cry9C, into corn hybrids. *See* CENTERS FOR DISEASE CONTROL AND PREVENTION, INVESTIGATION OF HUMAN HEALTH EFFECTS ASSOCIATED WITH POTENTIAL EXPOSURE TO GENETICALLY MODIFIED CORN 4 (2001), *available at* http://www.cdc.gov/nceh/ehhe/Cry9cReport/. Because of allergenicity concerns, Cry9C was not approved for human consumption. *Id.*

[33] The toxins act by disrupting the function of the insects' digestive systems, thereby killing the insects. The insects susceptible to particular strains of Bt

Bt crops can be expected to sustain less insect damage and therefore to produce a higher yield per acre.[34]

Regulation of these Bt crops arises against the backdrop of longstanding use of Bt toxins as a spray pesticide.[35] Spray formulations of Bt have been in use for decades and, when used properly, have not created significant resistance among pest species.[36] Moreover, Bt toxins lack many of the negative properties of conventional broad spectrum insecticides. Because they rapidly break down in the environment, spray Bt pesticides have relatively few effects on non-target organisms, including mammals, birds and most non-target insect species and microorganisms.[37] For this reason, Bt sprays are critical for many organic farming programs.[38]

Currently nine bioengineered crops incorporating Bt proteins are registered for use.[39] Compared to many current pest control regimes, these Bt crops offer the possibility of significant cost

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include, inter alia, European corn borer, southwestern corn borer, tobacco budworm, cotton bollworm, pink bollworm, and Colorado potato beetle. *See* J.F. WITKOWSKI ET AL., NORTH CENTRAL REGIONAL TECHNICAL COMMITTEE ON "ECOLOGY AND MANAGEMENT OF THE EUROPEAN CORN BORER AND OTHER STALK-BORING LEPIDOP-TERA", NC-205, BT CORN & EUROPEAN CORN BORER: LONG-TERM SUCCESS THROUGH RESISTANCE MANAGEMENT (K.R. Ostlie et al., eds. 1997), *available at* http://www.extension.umn.edu/distribution/cropsystems/DC7055.html [hereinafter NC-205 Report].

[34] *See* UNION OF CONCERNED SCIENTISTS, NOW OR NEVER: SERIOUS NEW PLANS TO SAVE A NATURAL PEST CONTROL app. a (Margaret Mellon & Jane Rissler eds., 1998), *available at* http://www.ucsusa.org/index.html.

[35] Bt toxins have been registered with EPA as foliar spray pesticides since 1961. Biopesticides and Pollution Prevention Division, EPA, *Biopesticides Registration Action Document:* Bacillus thuringiensis (Bt) *Plant-Incorporated Protectants,* at II.B.5 (Oct. 15, 2001), *available at* http://www.epa.gov/pesticides/biopesticides/otherdocs/bt_brad2 [hereinafter 2001 BRAD].

[36] Margaret Mellon, *UCS Introduction, in* NOW OR NEVER, *supra* note 34, 1, 2-12.

[37] *See id.* at 2; John J. Obrycki et al., *Transgenic Insecticidal Corn: Beyond Insecticidal Toxicity to Ecological Complexity,* 51 BIOSCIENCE 353, 356 (May 2001), *available at* http://www.biotech-info.net/complexity.html.

[38] *See* NOW OR NEVER, *supra* note 34, at app. b. Bt sprays have not been widely used on non-organic crops (commodity crops) because of their rapid breakdown in the environment. Mellon, *supra* note 36, at 2.

[39] *See* 2001 BRAD, *supra* note 35, at I.25. One of the registered products, StarLink corn, was not approved for human consumption, but only for use as animal feed. EPA Office of Pesticide Programs, *Biopesticide Fact Sheet:* Bacillus thuringiensis *subspecies* tolworthi *Cry9C Protein and the Genetic Material Necessary for Its Production in Corn*, *available at* http://www.epa.gov/pesticides/biopesticides/factsheets/fs006466t.htm (last updated Mar. 29, 2001). StarLink's registration was voluntarily relinquished after the 2000 crisis over the presence of StarLink corn in food products. *Id.*

savings and significant environmental benefits through reduced pesticide usage. Growers can cut expensive pesticide applications, sometimes in half,[40] with no loss of productivity. Because of Bt's narrow spectrum of toxicity, beneficial insects that would be killed by traditional pesticide application survive in the Bt fields, thus providing an additional measure of pest control. In 1999 alone, Bt corn reduced pesticide usage by 1 million acre treatments while increasing production by 66 million bushels.[41]

C. *The Problem*

1. *Resistance In Pest Populations*

The biggest environmental concern raised by widespread use of Bt crops is the potential for evolving insect resistance.[42]

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[40] Mellon, *supra* note 36, at 2.

[41] Goklany, *Future of Food, supra* note 8, at 61. *See also* JANET E. CARPENTER & LEONARD P. GANESSI, NATIONAL CENTER FOR FOOD AND AGRICULTURAL POLICY, AGRICULTURAL BIOTECHNOLOGY: UPDATED BENEFIT ESTIMATES 4 tbls. 3, 4 (Jan. 2001), *available at* http://www.ncfap.org/reports/biotech/updatedbenefits.pdf.

[42] Insect resistance is not the only concern raised by large-scale adoption of Bt crops. Another major area of concern is the potential for harm to non-target species, particularly monarch butterflies. In a 1999 study conducted at Cornell University, researchers reported a potentially harmful impact of Bt pollen on Monarch butterflies feeding on milkweeds. *See* John E. Losey et al., *Transgenic pollen Pollen Harms Monarch Larvae,* 399 NATURE 214 (1999). The release of the Cornell study prompted the European Union to immediately suspend import of Bt corn hybrids that had been approved for sale in Europe. *See* Anthony M. Shelton & Richard T. Roush, *Commentary: False Reports and the Ears of Men*, 17 NATURE BIOTECH. 832, 832 (Sept. 1999), *available at* http://www.nature.com/nbt. The original Monarch butterfly study has been criticized on the ground that it does not represent real life field conditions. *See* Blaine P. Friedlander, Jr., *Researchers Take Issue With Recent Studies on Genetically Engineered Crops*, CORNELL CHRON., Sept. 16, 1999, *available at* http://www.news.cornell.edu/Chronicle/99/9.16.99/Shelton.html. In late September 2000, the EPA released a draft report concluding Bt products do not present a serious threat to insects like Monarch butterflies. *See* FIFRA Scientific Advisory Panel, *Bt Plant-Pesticides Risk and Benefit Assessments: Gene Flow/Outcrossing, Environmental Fate in the Soil and Non-Target Organism Effects, SAP Report No. 2000-07b*, at 55 (Mar. 12, 2001), *at* http://www.epa.gov/scipoly/sap/2000/october/octoberfinal.pdf [hereinafter 2000 Risk Benefit Assessment] (discussing EPA's preliminary assessment as "overly optimistic" in predicting risk to monarchs). Bt toxins target lepidoptera pests, and potential threats to non-pest lepidoptera (such as monarch butterflies) should have been sufficiently obvious to be explored as part of the registration process. Even if EPA's ultimate conclusion is correct (and there does not seem to be any reason to doubt EPA's research or conclusion), this fact should have been

Individuals do not evolve. That is to say, individual pest organisms do not "become" resistant to a pesticide. Instead, pesticides operate on the genetics of a pest population by killing off susceptible individuals, typically most of the population. But variation is ubiquitous in nature and some individuals will possess morphological and physiological traits that convey some measure of genetic resistance to the pesticide. These resistant individuals will survive pesticide exposure. If resistant individuals mate with other resistant individuals, their offspring will likely also be resistant to the pesticide. Pesticide application thus acts as a selection pressure on the variations inherent within a pest population, driving it toward resistance. In a short period of time (much shorter than a natural evolutionary timeline), the entire population will be resistant and the pesticide will no longer be effective.

Although Bt spray applications have not created a significant resistance problem, Bt crops involve a markedly different exposure to Bt toxins. Spray applications typically coat the plant's leaves for a short time. Bt crops, by contrast, constantly produce fairly high doses of Bt toxins in every cell of the plant. It is this property—continuous production of high doses of Bt throughout the plant tissue—that raises concerns about pest resistance.

Because some growers currently rely on Bt to control many corn and cotton pests, Bt resistance could result in crop failures and catastrophic losses. In particular, organic farmers currently rely on Bt as a technique of last resort to control pest infestations. Without Bt as a backup, organic corn and cotton farming might be impossible. Were widespread use of Bt crops to lead to Bt resistance, the viability of those industries would be jeopardized.

2. *Pest Susceptibility As A Common Pool Resource*

Bt susceptibility bears all the dangers of a common pool resource.[43] Susceptible pests are valuable because they can be

established *before* Bt crops were approved for wide scale planting. As such, it is symptomatic of the pattern of regulatory discounting of uncertain risks discussed in this article.

[43] *See* Uri Regev et al., *Pests as a Common Property Resource: A Case Study of Alfalfa Weevil Control*, 58 AM. J. AGRIC. ECON. 186, 195 (1976) (explaining that pests constitute a common property resource as individual farmers are affected by the cumulative effects of other farmers' decisions). The classic description of the fate of common pool resources can be found in Garrett Hardin, *Tragedy of the Commons*, 162 SCIENCE 1243, 1244 (1968).

controlled by use of Bt, either as a foliar spray or in a transgenic crop. Historically, there were relatively few users of this resource and those users were generally organic farmers attuned to the need to avoid resistance problems. Transgenic crops change all that: exploitation of Bt susceptibility is now accessible and attractive to a much larger pool of growers. Each of these growers has an incentive to minimize insect damage in her fields by exploiting Bt susceptibility to its fullest (i.e., by planting more acres with Bt crops.) Any grower who adopts this strategy will increase yield, and thus short-term profits. Every grower shares the same incentive to adopt this individually rational, value-maximizing behavior. Because increased use of Bt will also increase the likelihood of pest resistance, individual decisions to exploit Bt susceptibility will reduce the proportion of susceptible pests in the population generally.

No individual grower acting alone has an incentive to curb Bt use, and thereby conserve Bt susceptibility. Such a grower would be giving up the short-term profits associated with higher yield. Were that grower assured of capturing the long-term benefit of preserved Bt susceptibility, however, the trade off between short-term and long-term benefits might make sense. More likely, another grower will capture the short-term benefit foregone by an ecologically-minded grower who does not exploit Bt susceptibility to its fullest. At most the long-term benefit of preserved Bt susceptibility will inure to all growers equally, while the short-term costs are borne by the ecologically-minded few. Individual, short-term, rational decisions will thus create a downward spiral of lost Bt susceptibility as a result of increased Bt use. Once Bt use exceeds a certain, unknown threshold, growers will exhaust pest susceptibility and drive the evolution of Bt resistance. Ultimately, unless proper precautions are taken, the aggregate of individually rational decisions will result in a resistant pest population for which Bt has little value as a control mechanism.[44] Freedom of the commons thus brings "ruin to all."[45]

This problem is not merely hypothetical. More than 500 species of pests have already developed resistance to conventional

[44] *See* Terrance M. Hurley et al., *Biotechnology and Pest Resistance: An Economic Assessment of Refuges* 1-2 (Center for Agricultural and Rural Development, Oct. 1997) (unpublished working paper 97-WP 183, on file with the New York University Environmental Law Journal).

[45] Hardin, *supra* note 43, at 1244.

insecticides.[46] There is no reason to believe that insects would not similarly develop resistance to Bt. Indeed, laboratory experiments have already demonstrated that insects can develop Bt resistance.[47] This risk is too significant and too probable to ignore. At the same time, the world can ill afford to forego the tantalizing productivity benefits offered by Bt crops.

Without restrictions designed to preserve Bt resistance, use of Bt crops will become overused, and will result in rapid evolution of Bt resistance. Because of the commons problem, relying solely on individual choices is unlikely to prevent this outcome. The solution is neither to abandon the new technology nor to allow its unimpeded use, but instead to craft a regulatory program designed to prevent the evolution of Bt resistance. EPA and USDA defined Bt resistance as an "unreasonable adverse effect"[48] on the environment, and imposed registration restrictions on Bt crops in an attempt to respond to the resistance problem. These restrictions

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[46] *See* Bruce E. Tabashnik, *Evolution of Resistance to* Bacillus Thuringiensist, 39 ANN. REV. ENTOMOLOGY 47-48, 729 (1994). *See also* George P. Georghious, *The Magnitude of the Resistance Problem*, *in* PESTICIDE RESISTANCE: STRATEGIES AND TACTICS FOR MANAGEMENT 14 (Comm. on Strategies for the Mgmt. of Pesticide Resistant Pest Populations, Bd. on Agric., Nat'l Research Council ed., 1986), *available at* http://www.nap.edu/openbook/0309036275/html/14.html (at least 447 species reported resistant as of 1986).

[47] *See* Alan C. Bartlett et al., *An Evaluation of Resistance to Bt Toxins In Native Populations of the Pink Bollworm,* 2 PROC. BELTWIDE COTTON CONF. 885, 885 (1997); William J. Moar, *Development of* Bacillus Thuringiensis *CryIC Resistance by* Spodoptera Exigua *(Hübner) (Lepidoptera: Noctuidae)*, 61 APPLIED & ENVTL. MICROBIOLOGY 2086, 2086 (1995); Bruce E. Tabashnik, *Delaying Insect Adaptation to Transgenic Plants: Seed Mixtures and Refugia Reconsidered,* 255 PROC. ROYAL SOC'Y LONDON SERIES B 7, 7 (1994); Terry B. Stone et al., *Selection of Tobacco Budworm for Resistance to a Genetically Engineered* Pseudomonas Fluorescens *Containing the δ-Endotoxin of* Bacillus Thuringiensis *Subsp.* Kurstaki, 53 J. INVERTEBRATE PATHOLOGY 228, 231 (1989) (demonstrating the potential for resistance to *Bacillus Thuringiensis*). Fifteen insect species have developed resistance to Bt proteins in laboratory settings. *See* Steve Butzen, *Preserving Bt Effectiveness by Managing Insect Resistance*, *at* http://www.pioneer.com/usa/crop%5Fmanagement/agronomic/refuge.htm (last visited Apr. 19, 2002). Similarly, field studies have demonstrated the potential for lepidoptera pests of rice to evolve Bt resistance. *See* J.S. Bentur et al., *Variations in Performance on* Cry1Ab-*Transformed and Nontransgenic Rice Varieties Among Populations of* Scirophaga Incertulas *(Lepidoptera: Pyralidae) from Luzon Island, Philippines*, 93 J. OF ECON. ENTOMOLOGY 1773, 1776-77 (2000), *available at* http://www.bioone.org/bioone/?request=index.html.

[48] *See* 2001 BRAD, *supra* note 35, at II.D.2 ("EPA considers the development of Bt-resistant insects to constitute an adverse environmental effect.").

represent agency decisions that the commons of Bt susceptibility could not be left unmanaged. Unfortunately, in both setting and enforcing these registration restrictions, the agencies failed to properly account for uncertainty. Moreover, the fragmented regulatory framework hampered the development of a coordinated response. As a result, Bt crops were introduced without an adequate safety net.

II
UNITED STATES REGULATORY SYSTEM

Before a genetically engineered organism is approved for commercial use, its purveyor must demonstrate that the organism conforms with the standards set by federal law. Rather than having a single agency responsible for regulating biotechnology, however, the United States doles out administrative responsibilities piecemeal to various federal agencies. This regulatory approach to controlling biotechnology was developed during the Reagan administration under the aegis of the Office of Science and Technology Policy (OSTP). The OSTP drafted a Coordinated Framework for the Regulation of Biotechnology (the "Framework"),[49] with the identified goals of "enabl[ing] a beneficial industry to proceed safely and efficiently . . . and reduc[ing] barriers to trade in biotechnology."[50] With these goals in mind, OSTP began its analysis from the political stance that regulation was largely unnecessary, and from the premise that existing law could adequately address regulatory questions created by the new technologies.[51] The resulting regulatory regime is so convoluted and overlapping that it hinders an integrated regulatory approach.[52]

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[49] Proposal for a Coordinated Framework for Regulation of Biotechnology, 49 Fed. Reg. 50,856 (proposed Dec. 31, 1984).

[50] *Id.*

[51] *Id*. at 50,858. As the OSTP concluded that "at the present time existing statutes seem adequate to deal with the emerging processes and products of modern biotechnology," it thus recommended that no new legislation need be drafted to regulate biotechnology. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302, 23,306 (June 26, 1986).

[52] For example, the FDA (within the Department of Health and Human Services) is the lead regulatory agency for genetically engineered products in the category of "food and food additives," the Food Safety and Inspection Service (within the USDA) has jurisdiction over meat and poultry products, and the EPA

Three agencies share most of the regulatory authority under the Framework.[53] EPA focuses on environmental protection under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA),[54] and the Toxic Substances Control Act (TSCA).[55] The Food and Drug Administration (FDA) regulates the marketing of genetically modified foods under the Federal Food, Drug, and Cosmetic Act (FFDCA),[56] and USDA oversees the use of genetically modified

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sets tolerances for bioengineered pesticides in food. The FDA regulates all food other than meat and poultry products. The Food Safety Inspection Service of the USDA has jurisdiction for domestic livestock and poultry products, and the EPA sets "tolerances" for pesticide residues in food. When agency responsibilities or authorities adjoin or overlap under existing laws, the Framework purports to set out principles for coordinated and cooperative reviews.

[53] The National Institute of Health (NIH) also plays a regulatory role for gm technology. Guidelines for Research Involving Recombinant DNA Molecules, 51 Fed. Reg. 16,958, 16,958-78 (May 7, 1986). The NIH guidelines define rDNA as "molecules which are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or DNA molecules that result from the replication of those molecules." *Id.* at 16,959. This description of rDNA technology applies to some, but not all types of genetic engineering experiments. The NIH guidelines call for the establishment of a Recombinant DNA Advisory Committee (RAC) to advise the NIH on matters concerning rDNA technology and research such as containment levels for various experiments, experiment review, exemptions, etc. *Id.* at 16,964. These regulations apply only to rDNA research activities conducted or sponsored by institutions that receive NIH funding, and thus are outside the scope of this article. *Id.* at 16,959.

[54] 7 U.S.C. §§ 136-136y, (2000).

[55] 15 U.S.C. §§ 2601-2671 (2000).

[56] 21 U.S.C. §§ 301-397 (1994) (amended 1996, 1997, 1998). One big area of controversy has been whether genetic sequences are "food additives" that would subject gm plants to stringent pre-market review. FFDCA, 21 U.S.C. § 348(a) ("A food additive shall . . . be deemed unsafe . . . unless" it has been exempted or has otherwise been approved by the FDA.). The FDA has not promulgated regulations to deal specifically with gm foods but has instead applied existing food additive regulations that focus on the ultimate food product. If the ultimate food product is the "substantial equivalent" of a product already on the market, then neither pre-market review nor labeling is required. The FDA defines plant genetic modification as "the alteration of the genotype of a plant using any technique, new or traditional." Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984, 22,984 n.3 (May 29, 1992). The FDA definition makes no distinction between the manner that traditional techniques of selective breeding alter the genotype of a plant, and the way modern biotechnology can alter the genotype of a plant. Starting from the premise that gm foods are merely variants of existing, well-accepted foods, the FDA concluded that bioengineered plants should be treated no differently from traditionally bred plants. *Id.* ("'Modification' 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."). Consequently, the FDA

plants, animals and microorganisms in agriculture under the Federal Plant Protection Act (PPA).[57] A company developing a Bt crop must demonstrate to USDA that the crop would not pose a danger to agriculture, satisfy EPA that the crop is safe for the environment, and show FDA that the resulting product will be as safe as other foods.[58]

The relevant regulatory authority is thus divvied up among three agencies that administer multiple, unrelated statutes that were pressed into service from vastly different contexts. Each statute has its own mission and its own regulatory structure. Because these statutes were initially enacted to deal with dramatically different concerns, it is hardly surprising that they share no unifying vision of the questions and challenges posed by gm crops, let alone regulatory goals that could serve as a touchstone against which to measure regulatory action. Frequently the identified purposes of these statutes fit awkwardly with, and sometimes even contradict, the Framework's identified goals of smoothing the path for this new technology.

Both USDA and EPA must exercise their regulatory authority before gm crops can be marketed and grown. FDA, on the other hand, need not be involved before the crop has entered the marketplace as human food. Because this analysis focuses on environmental harms posed by growing gm crops, FDA's regulatory authority will be largely outside its scope. USDA and EPA, on the other hand, are central to this story. For that reason, a brief introduction to both agencies and the scope and limits of their regulatory authority follows.

A. *USDA's Regulatory Authority*

USDA regulates the deployment of genetically engineered crops[59] under the Federal Plant Protection Act (PPA).[60] The PPA

requires neither pre-market safety testing review nor labeling of bioengineered food products.

[57] 7 U.S.C. §§ 7701-7772 (2000).

[58] *See* USDA Animal and Plant Health Inspection Service (APHIS), *United States Regulatory Oversight in Biotechnology, at* http://www.aphis.usda.gov/biotech/OECD/usregs.htm (last visited Apr. 25, 2002).

[59] Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302, 23,367 (June 26, 1986).

[60] 7 U.S.C. § 7712. The PPA succeeds two earlier statutes: the Federal Plant Pest Act, U.S.C. §§150aa-jj (1957) (repealed 2000), and the Plant Quarantine Act, 7 U.S.C. §§ 151-164(a) (1912) (repealed 2000). APHIS has primary

gives USDA authority to regulate the movement of organisms that may endanger plant life, and to prevent the introduction, dissemination or establishment of such organisms.[61] USDA's primary regulatory duty is to evaluate whether gm crops will pose a plant pest risk when introduced into the environment and/or interstate commerce.[62] A plant pest is any living organism that directly or indirectly injures, or causes disease or damage, to a plant.[63] Thus, USDA's scope of inquiry is narrowly focused.

Regulation takes one of two paths.[64] First, if the donor or recipient of genetic material used to produce a gm crop is a known plant pest, USDA must issue a permit before the plant can be introduced to the environment.[65] Second, for crops that do not use genetic material from a known plant pest, USDA authorizes introduction without a permit.[66] For these crops, USDA requires only advance notice of intent to conduct field trials.[67] After notification, the agency has a designated period of time in which to either acknowledge that the designated introduction is appropriate, or to deny permission.[68] If USDA does nothing, permission is assumed.[69] By the 1999-2000 growing season, more than ninety-six percent of field trials were conducted under the notification procedure.[70] To date, USDA has authorized thousands of field trials.[71]

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regulatory responsibility over gm crops. *See* Restrictions on the Introduction of Regulated Articles, 7 C.F.R. § 340.0(a); Definitions, 7 C.F.R. § 340.1 (2002) (restricting the introduction of genetically altered organisms without authorization of APHIS). For the sake of clarity, I will refer to the USDA and APHIS collectively as USDA.

[61] 7 U.S.C. § 7712(a).

[62] *See* 7 C.F.R. § 340.0.

[63] 7 C.F.R. § 340.1.

[64] 7 C.F.R. § 340.0.

[65] 7 C.F.R. § 340.1. USDA has issued more than 900 such permits since the program began in 1987. *See* National Biotechnology Information Assessment Program/Information Systems for Biotechnology, *Tables for Field Test Releases*, *at* http://www.isb.vt.edu/cfdocs/isbtables.cfm (last updated Apr. 8, 2002) [hereinafter *Tables for Field Test Releases*].

[66] Notification for the Introduction of Certain Regulated Articles, 7 C.F.R. § 340.3(a) (2002).

[67] *Id.* at §340.3(b).

[68] *Id.* at § 340.3(e).

[69] *Id*.

[70] CAPLAN, RAISING RISK, *supra* note 6, at 4.

[71] According to PIRG, there have been more that 28,000 field trials. *Id.* at 8. By contrast, the National Biotechnology Information Assessment Program

Once a gm crop has been field tested, its developer can petition to obtain "non-regulated" status and approval for commercial sales.[72] If USDA concludes that the product does not present a plant pest risk, the agency must then conduct an Environmental Assessment under the National Environmental Policy Act (NEPA) before approving the petition.[73] USDA can approve the petition if it concludes that granting non-regulated status will not create significant environmental impacts. USDA has approved the vast majority of gm crop petitions for non-regulated status.[74] After a crop obtains "non-regulated" status, USDA places no restrictions or reporting requirements on the distribution of the crop in the United States.[75]

B. *EPA's Regulatory Authority*

EPA has primary responsibility for environmental regulation of biotechnology under the Framework. EPA's regulatory authority is derived primarily from the FIFRA.[76] With few exceptions,[77] no person may sell or distribute any pesticide[78] that is

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reports a little more than 7,000. *Tables for Field Test Releases, supra* note 65. The source of this discrepancy is unclear.

[72] Petition for Determination of Nonregulated Status, 7 C.F.R. § 340.6 (2002). After receiving a petition, USDA publishes a notice in the Federal Register and accepts comments for 60 days. *Id*. USDA has 180 days to deny or approve the petition. *Id*.

[73] Because granting non-regulated status would be a major federal action that might have significant impacts on the environment under NEPA, USDA must conduct an environmental assessment before making a decision on the petition. 42 U.S.C. § 4332 (1994); NEPA Rules, 40 C.F.R. §§ 1500-1508 (2002). *See also* APHIS, *Petition 96-317-01p for Determination of Nonregulated Status for Insect-Resistant/Glyphosate-Tolerant Corn Line MON 802: Environmental Assessment and Finding of No Significant Impact* (May 1997), *available at* http://www.aphis.usda.gov/biotech/dec_docs/9631701p_ea.HTM (May 1997) [hereinafter MON 802 FONSI].

[74] *Tables for Field Test Releases*, *supra* note 65.

[75] *United States Regulatory Oversight in Biotechnology, supra* note 58.

[76] 7 U.S.C. § 136w (2000). EPA also has regulatory authority under the Toxic Substances Control Act (TSCA). 15 U.S.C. § 2602 (2000). Under the definitions in TSCA § 2602, however, the statute can apply only to those products of biotechnology that are not pesticides. Therefore, the statute does not play a major role in regulating Bt crops.

[77] EPA may, by regulation, exempt any pesticide from some or all of the requirements of FIFRA if the pesticide is "of a character which is unnecessary to be subject to" FIFRA in order to carry out the purposes of the Act. 7 U.S.C. § 136w(b)(2) (2000). EPA generally exempts pesticides that pose low probabilities of risk to the environment in the absence of regulatory oversight. *See* Regulations Under the Federal Insecticide, Fungicide, and Rodenticide Act

not registered under FIFRA.[79] Since 1994, EPA has interpreted FIFRA's pesticide registration provisions as encompassing plant-incorporated protectorants (PIPs) such as Bt.[80] EPA thus regulates the pesticide substances in Bt crops, and before a Bt crop can be sold commercially, it must be registered with EPA under FIFRA.

To be registered, a pesticide[81] must not cause "unreasonable adverse effects on the environment."[82] Unreasonable adverse effects are defined as "any unreasonable risk to man or the environment, taking into account the economic, social and environmental costs and benefits of the use of any pesticide."[83] Absolute safety is not the goal.[84] "Unreasonable" (and therefore

for Plant Incorporated Protectants (Formerly Plant-Pesticides), 66 Fed. Reg. 37, 772, 37,772-73 (July 19, 2001) (codified at 40 C.F.R. pts 152, 174) (pesticides that do not qualify for exemption can still be approved for specific uses, but only if they do not "cause unreasonable adverse effects."). *Id.*

[78] The term pesticide is defined broadly to include, inter alia, any substance intended to prevent, destroy or repel undesirable insects, weeds, rodents, bacteria or other living things EPA declares to be a pest. 7 U.S.C. § 136(t), (u) (2000).

[79] 7 U.S.C. § 136a(a). EPA's pesticide regulations are set out in 40 C.F.R. Parts 150-189. FIFRA would not provide any regulatory authority for plants that do not produce pesticides.

[80] EPA has regulatory authority under the FFDCA, 21 U.S.C. § 346a (1994) (amended 1996, 1997, and 1998), to establish a tolerance level for pesticide residues in raw agricultural commodities.

[81] Biopesticides are only exempt from FIFRA requirements if they are derived through the conventional breeding of sexually compatible plants. *See* Plant-Incorporated Protectant from Sexually Compatible Plant, 40 C.F.R. § 174.25 (2002). *See also* General Qualifications for Exemptions, 40 C.F.R. § 174.21 (2002).

[82] 7 U.S.C. § 136a(c)(5). In particular, this section of FIFRA provides that EPA shall register a pesticide if presented with a registration application that demonstrates: (1) the composition of the pesticide warrants the proposed claims for it; (2) the labeling and other materials required to be submitted comply with the requirements of FIFRA; (3) it will perform its intended functions without unreasonable adverse effects to the environment; and (4) when used according with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment. *Id*.

[83] 7 U.S.C. § 136(bb).

[84] Any substance that is a pesticide under FIFRA is automatically also subject to regulation under FFDCA if used in the production of food or food crops. As for conventional pesticides, EPA must establish a tolerance level—a level of pesticide residue that is deemed safe—before permitting foods containing Bt residues to enter the human food chain. *See* FIFRA, ch. 6, §§ 4(g)(2), 103, 110 Stat. 1489 (1996) (current version at 7 U.S.C. § 136a-1(g)(2)). *See also* 21 U.S.C. § 346a (2001). In this context, safe is defined as "a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures." 21 U.S.C. § 346a(b)(2) (2001). Again, the regulatory standard is one of reasonable,

forbidden) risk falls somewhere in the realm of harm that is not certain and risk that is not *de minimis*. Reasonableness is an inherently uncertain statutory mandate. To clarify, Congress helpfully added that, in this context, reasonableness involves a balance between the risks and benefits associated with use of the pesticide.[85] Because EPA considers the potential for insect resistance to be an "unreasonable adverse effect," Bt crops are subject to registration requirements designed to mitigate that risk.[86]

Under the Framework, however, EPA cannot make determinations about the release of gm crops into the environment.[87] Instead, that authority is vested in USDA. That means that EPA regulates Bt toxins as a pesticide, but cannot regulate the plants that produce the toxins. As will be detailed in Part IV, the Framework's reliance on existing law in lieu of new statutes thus not only separates the components of environmental regulation into illogical components, but does so in a way that hinders the development of an effective oversight program.

III
REGULATION OF GENETICALLY MODIFIED CROPS SHOULD ERR ON

rather than absolute, safety. A pesticide residue is not safe unless EPA has issued either a tolerance for the residue (and the residue is within the tolerance limits) or an exemption. 21 U.S.C. § 346a(a)(1). In the absence of a duly promulgated tolerance or exemption, or if the residue level detected in food exceeds the tolerance, the food is deemed adulterated under the FFDCA and is subject to enforcement by FDA. 21 U.S.C. § 346a(a)(3)-(4). Bt genes, and their proteins, have not shown toxicity to humans. EPA has therefore typically granted the Bt crops exemptions from the requirement for a tolerance level. *See, e.g.,* 40 C.F.R. § 180.1155 (2002) (exempting CryIA(c)), 40 C.F.R. § 180.1173 (2002) (exempting CryIA(b)). For an explanation of the decisions to exempt Bt, see 61 Fed. Reg. 40,340 (Aug. 2, 1996) (codified at 40 C.F.R. § 180.1173) and 62 Fed. Reg. 17,720 (Apr. 11, 1997) (codified at 40 C.F.R. § 180.1155). For one Bt crop, StarLink, EPA concluded that there was a real question about the allergic potential of the proteins produced by the transposed Bt gene Cry9C. *See* Kathleen Hart, *Scientists Question Test for StarLink Corn Allergy,* FOOD CHEMICAL NEWS, July 23, 2001, *available at* 2001 WL 12773607. Therefore, EPA did not grant an exemption for human consumption of crops that incorporated the Cry9C gene, namely StarLink Corn. 40 C.F.R. §180.1192 (2002) (limiting exemption to feed corn).

[85] 7 U.S.C. § 136a(c) (2000). *See also* MICHAEL J. MALINOWSKI, BIOTECHNOLOGY: LAW, BUSINESS, AND REGULATION § 11.06[A] (1999).

[86] *See* 2001 BRAD, *supra* note 35, at II.D.2.

[87] Proposed Policy; Plant-Pesticides Subject to the Federal Insecticide, Fungicide, and Rodenticide Act and the Federal Food, Drug, and Cosmetic Act, 59 Fed. Reg. 60,496 (Nov. 23, 1994).

THE SIDE OF CAUTION

It is impossible to discuss the degree of caution necessary for effective regulation without at least mentioning the "precautionary principle,"[88] a concept from international law that has become a ubiquitous buzz word in environmental regulation. There is considerable controversy about how to define a precautionary regulatory approach and how to identify the criteria to guide its implementation.[89] Most articulations of a precautionary principle

[88] For an exhaustive analysis of the precautionary principle in this and other contexts, see HAROLD HOHMANN, PRECAUTIONARY LEGAL DUTIES AND PRINCIPLES OF MODERN INTERNATIONAL ENVIRONMENTAL LAW (1994). *See also* DAVID FREESTONE & ELLEN HEY, THE PRECAUTIONARY PRINCIPLE AND INTERNATIONAL LAW: THE CHALLENGES OF IMPLEMENTATION (1996); PHILIPPE SANDS, PRINCIPLES OF INTERNATIONAL ENVIRONMENTAL LAW I: FRAMEWORKS, STANDARDS, AND IMPLEMENTATION 208-213 (1994); Jonathan H. Adler, *More Sorry Than Safe: Assessing the Precautionary Principle and the Proposed International Biosafety Protocol*, 35 TEX. INT'L L.J. 173, 198-202 (2000) (arguing that too much precaution, as in the case of the International Biosafety Protocol, causes more harm than good).

[89] The most well-known of these precautionary statements in international law, Principle 15 of the Rio Declaration on Environment and Development, states:

> In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.

U.N. ENVIRONMENT PROGRAMME, RIO DECLARATION ON ENVIRONMENT AND DEVELOPMENT, U.N. Sales No. E.73.II.A.14 (1992), *available at* http://www.unep.org/Documents [hereinafter Rio Declaration]. The United States signed the Rio Declaration, but has not yet ratified it. For a list of parties to the Convention on Biodiversity, see Convention on Biological Diversity, *Parties to the Convention on Biological Diversity, at* http://www.biodiv.org/world/parties.asp (last updated Mar. 15, 2002). Relating particularly to gm technology, the Cartagena Protocol on Biosafety, negotiated in early 2000, specifically incorporated this precautionary approach into international law governing the transboundary movement of genetically modified organisms. The United States has not signed the Cartagena Protocol. To view its signatories, see Convention on Biological Diversity, *Cartagena Protocol on Biosafety*, *at* http://www.biodiv.org/biosafety/signinglist.asp (last updated Apr. 9, 2002). For other examples of a precautionary principle in international law, see United Nations Conference on Environment and Development, *Framework Convention on Climate Change*, May 9, 1992, art. 3, para. 3, 31 I.L.M. 849, 854 (1992); Organization of African Unity, *Bamako Convention on the Ban of the Import into Africa and the Control of Transboundary Movement and Management of Hazardous Wastes Within Africa*, Jan. 29, 1991, art. 4, para. (f), 30 I.L.M. 773, 781 (1991); *Convention for the Protection of the Marine Environment of the North-East Atlantic*, Sept. 22, 1992, art. 2, para 2(a), 32 I.L.M. 1069, 1076 (1993). *See also* Bernard A. Weintraub, *Science*, *International Environmental* are nebulous enough to justify almost any outcome favored by their advocates.[90] For that reason, the principle has variously been described as "fuzzy," "vague," and "too general" to be of practical use.[91] Critics point to the ambiguous nature of a directive to "refrain from inaction" and spin out a parade of absurd results that indiscriminate precaution could produce.[92] Although these critics have a point,[93] the idea of precautionary regulation has a solid, relatively simple core: where there is reasonable belief, but no scientific certainty, regarding possible environmental damage from a proposed course of action, risk avoidance should be the decisional norm.[94] Inherent in the principle is the premise that preventing environmental harm from the outset is preferable to attempting after-the-fact remediation.

In the context of gm crops, Congress has given the agencies a precautionary mandate. USDA and EPA are charged with protecting the public, and FIFRA in particular is a precautionary statute.[95] Both agencies have identified Bt resistance as an adverse

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Regulation, and the Precautionary Principle: Setting Standards and Defining Terms, 1 N.Y.U. ENVTL. L.J. 173, 178-80 (1992); James E. Hickey, Jr., & Vern R. Walker, *Refining the Precautionary Principle in International Environmental Law*, 14 VA. ENVTL. L.J. 423, 436 (1995).

[90] At its extreme, some have argued that this principle requires that technology not be used unless and until it is proven safe. *See* Cross, *supra* note 16, at 853. This articulation of the principle may well be a strawman as it seems to be offered predominantly by those opposed to precautionary regulation, rather than by those seeking to apply that version of the principle.

[91] Mark Geistfeld, *Reconciling Cost-Benefit Analysis with the Principle that Safety Matters More than Money*, 76 N.Y.U. L. REV. 114, 173-769 (2001); David Hughes, *The Status of the Precautionary Principle in Law: R v. Secretary of State for Trade and Industry ex parte Duddridge*, 7 J. ENVTL. L. 224, 238 (1995); Daniel Bodansky, *Scientific Uncertainty and the Precautionary Principle,* 33 ENV'T, Sept. 1991, at 4, 5.

[92] *Fear of the Future*, WALL ST. J., Feb. 10, 2000, at A18.

[93] For an example of the sort of vagueness that can haunt the precautionary principle, see Commission of the European Communities, *Communication from the Commission on the Precautionary Principle*, at 11, 27 (Feb. 2, 2000) (leaving critical terms undefined), *available at* http://europa.eu.int/eur-lex/en/com/cnc/2000/com2000_0001en01.pdf.

[94] *See, e.g.*, Timothy O'Riordan & Andrew Jordan, *The Precautionary Principle in Contemporary Environmental Policies*, 4 ENVTL. VALUES 191, 194 (1995). For an argument that the principle has a plausible core meaning that yields a well-defined regulatory approach, see Mark Geistfeld, *Implementing the Precautionary Principle*, 31 ENVTL. L. REP. 11,326, 11,328 (2001).

[95] EPA, *Response of the Environmental Protection Agency to Petition for Rulemaking and Collateral Relief Concerning the Registration and Use of Genetically Engineered Plants Expressing* Bacillus Thuringiensis *Endotoxins,*

environmental consequence. Under NEPA, USDA has the responsibility to explore mitigation strategies.[96] Similarly, the plain language of FIFRA indicates that EPA has no authority to register Bt crops unless appropriate mitigating steps reduce the risk of adverse environmental effects, including pest resistance, to a level that is not "unreasonable." Because Congress has charged the agencies with risk reduction, the agencies should be choosing assumptions and inferences that err on the side of caution.[97] Although debates about the ramifications of a "precautionary principle" may inform the resulting regulatory approaches, Congress, and not a loosely-defined, controversial principle of interpretation, is the source of the precautionary mandate.

Unfortunately, much of the debate about precaution with regard to these crops still uses the language of the "precautionary principle" and focuses on the global issue of whether the technology should be employed at all.[98] The United States has already made the decision to move forward with these crops. That initial decision was a policy choice—a political decision that the potential harms from misuse of the technology were outweighed by the expected benefits from its use. Whether this decision was a wise one only time will tell. As it stands, regulators were charged with turning that policy choice into a regulatory system. It is at this point—the translation of political choices with uncertain environmental repercussions into the regulation that will shape commercial and regulatory reality—that precaution is most critical. It is here that the regulatory system either succeeds or fails to carry out its charge to protect the public.

USDA and EPA maintain that the only appropriate means to

Submitted by Petitioners Greenpeace International, et al., at 90 (Apr. 19, 2000), *available at* http://www.epa.gov/pesticides/biopesticides/petition.pdf [hereinafter EPA Response].

[96] 42 U.S.C. § 4332 (2)(C), (E) (1994). *See also* National Environmental Policy Act Implementing Procedures, 60 Fed. Reg. 6000, 6000-01 (Feb. 1, 1995) (codified at 7 C.F.R. pt. 372).

[97] *See* Envtl. Defense Fund v. EPA, 489 F.2d 1247, 1254 (D.C. Cir. 1973) (interpreting FIFRA).

[98] For an argument that precaution dictates that gm crops not be planted, see Friends of the Earth Europe, *The EU's Moratorium on GMOs, at* http://www.foeeurope.org/gmos/Moratorium.htm (last visited Apr. 24, 2002). For a contrary argument, see Indur M. Goklany, *Precaution Without Perversity: A Comprehensive Application of the Precautionary Principle to Genetically Modified Crops*, 20 BIOTECH. L. REP. 337 (2001).

regulate biotechnology is through use of science-based standards.[99] But, in responding to their statutory directive to prevent unreasonable adverse effects and unreasonable risks, the agencies cannot merely apply "science" to the regulatory problem.[100] They must first make value judgments about acceptable levels of risk,[101] and scientific uncertainty pervades virtually all the estimates of risk in this context.[102] Uncertainty means that science cannot provide answers to many of the most critical questions involved in regulating Bt crops.[103] Prudent regulatory decisionmaking would choose precautionary assumptions and inferences to fill these information gaps.[104]

The case for precaution is even more compelling with regard to gm crops because the uncertainty is over *how* to prevent the risks posed by these crops, not over *whether* there is a risk. Let me repeat, the uncertainty relates not to the possibility of harm but to the degree and kind of care needed to prevent the harm. The risk of resistance is clear. Even though none of the specifics about how insects might evolve resistance to Bt from exposure to Bt crops are known, there is a real, demonstrated biological process of resistance. It has happened before, and in the absence of concrete steps designed to prevent resistance, it will surely happen again. This case study explores the choices EPA and USDA made to resolve this uncertainty in the context of Bt crop regulation. The statutes suggest that precaution should be the decisional norm. Careful examination of the Bt case study reveals that however precautionary the regulatory scheme might appear on paper, it has

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[99] *See, e.g.,* Letter from Janet L. Andersen, Director, Biopesticides and Pollution Prevention Division, EPA, to Bt Corn Registrants (Dec. 20, 1999) *at* http://www.epa.gov/pesticides/biopesticides/otherdocs/bt_corn_ltr.htm; *see generally* EPA Response, *supra* note 95.

[100] For a discussion of the difference, see Alyson C. Flournoy, *Legislating Inaction: Asking the Wrong Questions in Protective Environmental Decisionmaking*, 15 HARV. ENVTL. L. REV. 327, 360-61 (1991) ("A system that sorts facts based on their ability to muster a specified measure of certainty may be inherently inconsistent with good scientific practice and may produce less accurate results.").

[101] *See* Wagner, *supra* note 18, at 1619.

[102] *Id.* at 1620-22. *See also* EPA Science Policy Council, *Risk Characterization Handbook*, EPA 100-B-00-002, at 40-41 (Dec. 2000), *available at* http://www.epa.gov/osp/spc/2riskchr.htm.

[103] *See, e.g.*, Flournoy, *supra* note 100, at 333-38 (describing the types and extent of scientific uncertainty that environmental regulators face).

[104] *See* Wagner, *supra* note 18, at 1621-22.

been anything but precautionary as applied. Because Bt crops are only the first of an expected flood of gm crops involving plant-incorporated pesticides, the failure to be precautionary sets a troubling precedent.[105]

IV
HAS REGULATION BEEN PRECAUTIONARY: THE BT CROPS CASE STUDY

EPA and USDA both identified insect resistance as an unacceptable risk posed by Bt crops. Therefore, both agencies could approve the crops only if satisfied that sufficient steps would be taken to reduce that risk to an acceptable level. Gaps in scientific knowledge admittedly hampered this process. That said, regulators must still assess risks. To do so, they employ default assumptions. These defaults should be the primary province of precaution. There is a range between presuming the worst-case—a regulatory stance that gives rise to critiques of the regulatory state as cumbersome and expensive[106]—and hoping for the best, as seems to have been the standard with regard to Bt crops. Where there are reasoned estimates, based in sound scientific inquiry, these estimates ought not be discounted in the regulatory process simply because they cannot be offered as certainties. At a minimum, regulation should incorporate such estimates as a baseline of precaution and not permit less protective options, based

[105] To date, the public has expressed grave reservations about this new technology. Public resistance to the development and deployment of gm crops is frequently rooted in fear that agencies are not being cautious enough in light of the unknown. *See, e.g.*, CAPLAN, RAISING RISK, *supra* note 6. It is perhaps not surprising that uncertainty and public trust would be inversely related. Willingness to allow experimentation with this technology depends on trust that regulators know the risks involved. EPA and USDA have failed to meet this challenge, and have not produced a regulatory scheme that can account for the very real uncertainties. This failure has serious implications, not just for the fate of Bt crops, but also for the as yet undeveloped crops that will certainly follow.

[106] *See, e.g.*, Richard Stewart, *The Future of Environmental Regulation: United States Environmental Regulation: A Failing Paradigm*, 15 J. L. & COM. 585, 587-88 (1996); Cass R. Sunstein, *Legislative Forward: Congress, Constitutional Moments and the Cost-Benefit State*, 48 STAN. L. REV. 247, 249 (1996). For a thorough discussion of the various alternative initiatives, see Richard B. Stewart, *A New Generation of Environmental Regulation?,* 29 CAP. U. L. REV. 21 (2001). For a critique of the cost-benefit approach, see David M. Dreisen, *The Societal Cost of Environmental Regulation: Beyond Administrative Cost Benefit Analysis*, 24 ECOLOGY L. Q. 545 (1997).

on rosier scenarios, to prevail because of uncertainty.

This section explores the key points at which USDA and EPA made regulatory choices based on incomplete information. The statutory and regulatory scheme examined in Part II would seem to mandate a precautionary approach to regulating gm crops. A look at the actual regulatory process, however, reveals a failure to live up to that mandate. At each key decisional point, there were both precautionary and non-precautionary choices available in the face of imperfect information. Invariably, USDA and EPA selected the less protective, less precautionary option. In doing so, the agencies failed to build in adequate margins of safety in light of the degrees and kinds of scientific uncertainty.

A. *Overview*

To date, only a few plant-incorporated protectorants have been registered. With one exception, all have involved genes that encode Bt proteins.[107] This section examines the entire regulatory process for Bt corn, from the first approval in 1995 to the recent registration renewals in the fall of 2001. In the six years since first approving Bt crops, USDA and EPA have conducted numerous hearings, and made, and then revisited, a series of regulatory decisions.

In 1995, when the first Bt crop was registered, resistance management for Bt crops was already a big question.[108] The possibility of widespread planting of Bt crops raised concerns that pest populations would rapidly develop Bt resistance, thus rendering Bt useless or less effective.[109] Indeed, as early as 1986, scientists were warning about the inadequacy of monitoring systems that merely identified resistance in the pest population, but were unable to detect the beginnings of resistance as it developed.[110] The distinction is critical: if the development of

[107] Monsanto received the other registration for the potato leaf roll virus. *See* Donna U. Vogt & Mickey Parish, *CRS Report for Congress: Food Biotechnology in the United States: Science, Regulation and Issues* tbl.2 (June 2, 1999), *available at* http://usa.or.th/services/irc/gmo_crs.htm.

[108] See FIFRA Scientific Advisory Panel, Final Report of the FIFRA Scientific Advisory Panel Subpanel on Plant Pesticides Meeting held March 1, 1995 (on file with the New York University Environmental Law Journal) [hereinafter 1995 SAP].

[109] *See* Fred Gould, *The Evolutionary Potential of Crop Pests,* 79 AM. SCIENTIST 496, 501-02 (1991); Obrycki, *supra* note 37, at 353.

[110] S*ee* Richard T. Roush & G.L. Miller, *Considerations for Design of*

resistance is detected early enough, growers can take preventive measures and forestall permanent resistance in the pest population.

For many of the factors necessary to develop suitable resistance management options, needed scientific information was either unknown or inadequate.[111] With far less than perfect information, regulators had to determine the degree of precaution needed to ensure that there were "no unreasonable adverse affects on the environment." Rather than confront that question head on, USDA and EPA opted to permit use of the crops and to collect further information as the crops were planted. In making that decision, the agencies gambled that the environmental risk would be low because non-gm crops would dominate and serve as an adequate buffer for gm crops.[112] Bt crops, especially corn, however, were adopted at a rate significantly higher than had been anticipated in 1995.[113]

B. *USDA Did Not Properly Exercise Its Oversight Powers*

Under USDA's field trial program, a company seeking to conduct field trials of a gm crop must perform a risk evaluation. This risk evaluation is narrowly focused on the possibility that the gm crop might be a plant pest. No evaluation of other risks is required before the crop is field tested (and thereby released into the environment, albeit in a controlled fashion).

In satisfying the risk evaluation requirement, USDA does not expect the company to perform an individual risk evaluation based on crop-specific or site-specific factors.[114] USDA instead permits the company to evaluate risks wholly by extrapolating from general, published scientific literature.[115] Given the narrowness of

Insecticide Resistance Monitoring Programs, 79 J. ECON. ENTOMOLOGY 293, 293 (1986).

[111] *See* EPA Office of Pesticide Programs, *EPA and USDA Position Paper on Insect Resistance Management in Bt Crops* (July 12, 1999), *available at* http://www.essentialbiosafety.info/docroot/articles/epa_irm.pdf [hereinafter EPA & USDA Position Paper].

[112] *Id.*

[113] *Id.*

[114] *See* Genetically Engineered Organisms and Products; Notification Procedures for the Introduction of Certain Regulated Articles; and Petition for Nonregulated Status, 58 Fed. Reg. 17,044, 17,054 (Mar. 31, 1993) (codified at 7 C.F.R. pt. 340). *See* Roger P. Wrubel et al., *Field Testing Transgenic Plants*, 42 BIOSCIENCE 280, 286 (1992).

[115] *See* Petition to Amend the List of Organisms, 7 C.F.R. § 340.5(b) (2002).

the risk evaluation it requires, USDA claims that case-by-case analysis is unnecessary.[116] Left unexplained is why no evaluation of other risks is required.

Once a gm crop has been field tested, the company can petition USDA for "non-regulated" status.[117] Depending on the situation, USDA has the discretion to grant the petition fully or partially, or to deny the petition. If USDA concludes that the product does not present a plant pest risk, the agency will grant non-regulated status.[118] Before making that decision, however, USDA must also comply with NEPA, which imposes an additional mandate on every federal agency to evaluate, and seek to avoid, possible environmental harms.[119] Although NEPA imposes no substantive requirements, it does require that environmental concerns be incorporated into the decisionmaking process.[120] Under the Framework, USDA interprets its NEPA mandate narrowly.

Before granting a petition, USDA purports to conduct an environmental assessment as required by NEPA.[121] As part of this assessment, USDA must consider whether cultivation of a crop would reduce the ability to control insects in that or other crops.[122] USDA has stated that, if pests did develop resistance to Bt, it would adversely affect the ability to control those pests in corn and cotton.[123] Despite its recognition of this real and significant concern, USDA concluded that Bt crops do not pose an insect resistance risk.[124] USDA based this "no risk" conclusion solely on the fact that EPA considers insect resistance during the FIFRA registration process.[125]

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[116] *See* 58 Fed. Reg. 17,044, 17,054 (Mar. 31, 1993) (codified at 7 C.F.R. pt 340).

[117] Petition for Determination of Nonregulated Status, 7 C.F.R. § 340.6 (2002). After receiving a petition, USDA/APHIS publishes a notice in the *Federal Register*, and accepts comments for 60 days. *Id.* USDA/APHIS has 180 days to deny or approve the petition. *Id.*

[118] *See, e.g.,* MON 802 FONSI, *supra* note 73.

[119] 42 U.S.C. § 4332 (C), (E) (1994). *See also* MON 802 FONSI, *supra* note 73.

[120] 42 U.S.C. § 4332 (C), (E).

[121] 42 U.S.C. §§ 4321-4370. *See also* MON 802 FONSI, *supra* note 73.

[122] *See, e.g.,* MON 802 FONSI, *supra* note 73.

[123] *Id.*

[124] *Id.*

[125] *Id.*

USDA thus used the Framework's directive that agencies avoid duplication of review efforts[126] to curtail its NEPA obligations. Rather than conduct an independent evaluation, USDA relied entirely on the fact of EPA oversight as its basis for finding no significant impact under NEPA.[127] In doing so, USDA predicated non-regulated status on the presumption that EPA regulations would adequately prevent Bt resistance. But USDA typically grants non-registered status *before* EPA has completed its FIFRA registration process. USDA conducts no follow-up inquiry as to whether EPA registration requirements *in fact* ensure that cultivation of the crop does not reduce the ability to control insects, and takes no responsibility for ensuring that outcome.[128] The Framework thus became a vehicle for USDA to avoid the internalization of the environmental concerns at the heart of NEPA.

USDA has approved the vast majority of petitions submitted for non-regulated status.[129] Although a USDA grant of non-regulated status does not directly limit EPA's regulatory jurisdiction, it makes it virtually impossible for EPA to regulate effectively. By granting non-regulated status, USDA frees the applicant from any obligation to keep track of, or report, where the crop is grown. Because EPA has no independent authority to require that information, a grant of non-regulated status ensures that there is no systematic means of knowing which fields have been planted with gm crops. Without that information, EPA has no ability to monitor and enforce the various environmental

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[126] *See* Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302, 23,303 (June 26, 1986).

[127] *See*, *e.g.,* MON 802 FONSI, *supra* note 73; APHIS, *Determination on a Petition 94-308-01p of Monsanto Agricultural Company Seeking Nonregulated Status of Lepidopteran-Resistant Cotton Lines 531, 757, 1076: Environmental Assessment and Finding of No Significant Impact* (June 1995), *available at* http://www.aphis.usda.gov/biotech/dec_docs/9430801p_ea.HTM; APHIS, *Petition 94-319-01 for Determination of Nonregulated Status for Event 176 Corn: Environmental Assessment and Finding of No Significant Impact* (May 1995), *available at* http://www.aphis.usda.gov/biotech/dec_docs/9431901p_ea.HTM. These and other determinations are available at http://www.aphis.usda.gov/biotech/dec_docs.

[128] Under the Framework, USDA and EPA have coordinated their reviews to avoid overlap. This means that USDA does not double-check whether EPA has fulfilled its tasks. For a brief explanation, see APHIS, *Determination on a Petition 94-308-01p, supra* note 127.

[129] *See Tables for Field Test Releases*, *supra* note 65.

requirements that USDA assumes EPA builds into FIFRA registrations.[130] The Framework's division of regulatory authority prevents the collection of otherwise knowable information and thus produces a vicious cycle of ineffective regulation.

C. *EPA Failed to Adopt Precautionary Science-Based Standards*

It is unclear whether EPA views its regulatory mandate as actually preventing resistance or merely delaying the onset of resistance for a few years. The fact that EPA has defined the development of resistance to be an "adverse environmental effect" would seem to suggest the former. There is general consensus in the scientific community, however, that pest populations will develop resistance to Bt toxins currently incorporated into Bt hybrids:[131] it is only a matter of time. Perhaps responding to that consensus, EPA has been conspicuously ambiguous on this point. Its many position papers describe the resistance management strategy as a "philosophy" rather than a mandatory precondition of pesticide registration.[132] EPA has also characterized its regulatory approach as having the potential to delay the development of resistance at least *for the period of the registration*.[133] This sort of goal confusion is highly problematic.

Without knowing the level of protection that EPA has deemed necessary, there is no standard by which to assess the reasonableness of regulatory requirements. If the goal is to prevent resistance, then an approach that neither targets that goal, nor clearly identifies it as such, is doomed to fail. A regulated community unaware of the regulatory goal is unlikely to achieve it. If the goal is merely to delay the onset of resistance—a goal inconsistent with EPA's definition of such resistance as an unreasonable risk under FIFRA—the cost-benefit analysis needs to incorporate an entirely new range of costs. Regardless of whether EPA views its regulatory objective as preventing or merely

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[130] See section IV(C)(3), *infra*, for a discussion of this USDA decision's impact on EPA's regulatory regime.

[131] *See* Mark Sears & Art Schaafsma, *Responsible Deployment of Bt Corn Technology in Ontario*, *at* http://www.inspection.gc.ca/english/plaveg/pbo/bt/btcormai2e.shtml (last modified Feb. 11, 2002).

[132] *See, e.g.,* EPA Office of Pesticide Programs, *EPA/USDA Workshop on Bt Crop Resistance Management* (June 18, 1999), *available at* http://www.epa.gov/pesticides/biopesticides/otherdocs/btcornproceedings.htm [hereinafter *EPA/USDA Workshop*]; EPA Response, *supra* note 95, at 6-11.

[133] *See* 2001 BRAD, *supra* note 35, at I.1.

delaying resistance, however, FIFRA clearly requires EPA to condition Bt crop registration on measures that will inhibit the development of insect resistance to Bt as a pesticide.

The cornerstone of EPA's plan to inhibit resistance to Bt is a high dose/structured refuge strategy.[134] Under this strategy, every Bt crop planting must be accompanied by a "refuge" zone—a planting of non-Bt crops not sprayed with Bt foliar spray. This refuge serves to maintain a large pool of adult insects unexposed to, and therefore susceptible to, Bt. To prevent resistance, the refuge must be large enough that any resistant adult who survives the pesticide in the Bt crop will likely mate with a susceptible insect from the refuge, thus diluting the frequency of resistance genes and delaying or preventing the spread of resistance.

A high dose/structured refuge strategy has three essential components: 1) plant tissue must be very toxic (the objective being sufficient toxicity to kill all resistant heterozygotes);[135] 2) resistance alleles must be sufficiently rare that nearly all resistance alleles will be in heterozygotes; and 3) refugia must be planted to maximize the probability that any resistant homozygotes will mate with susceptible homozygotes, thus producing heterozygous progeny that cannot survive the toxicity of the crop.

1. *Overview*

The 1995 FIFRA Scientific Advisory Panel Sub-Panel on Plant-Pesticides (1995 SAP)[136] identified seven essential principles

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[134] *See, e.g.,* EPA Response, *supra* note 95, at 26-29.

[135] Every individual maintains two sets of chromosomes–one maternal and one paternal. A heterozygous individual inherited different alleles for the same gene from each parent. Eye color is the classic example for explaining this simple Mendelian principle. Blue eyes are a recessive trait, controlled by a single gene locus. Only an individual who receives a blue eye allele from both parents, and is thus homozygous for this recessive allele, will have blue eyes. A brown eyed individual could either be homozygous and have two copies of the dominant brown allele, or could be heterozygous with one brown and one blue allele. A heterozygous brown-eyed individual has a fifty-percent chance of having blue-eyed offspring if the other parent is blue-eyed. A homozygous brown-eyed individual will not have any blue-eyed offspring, even if the other parent has blue eyes. Thus, it is only through examining the next generation that we will know if a brown-eyed individual is heterozygous or homozygous for that trait.

[136] Pursuant to FIFRA § 25(d), the Scientific Advisory Panel (SAP) was created in 1975. The panel provides scientific advice on pesticides and pesticide-related issues as to the impact on health and the environment. *See* EPA Office of Science Coordination & Policy, *FIFRA Scientific Advisory Panel (SAP): About*

for a resistance management plan:[137] 1) knowledge of past biology and ecology; 2) appropriate dose expression strategy; 3) appropriate refuges; 4) a plan to monitor and report incidents of pesticide resistance development; 5) employment of integrated pest management; 6) communication and education strategies on use of the product; and 7) development of alternative modes of action.[138] In 1995, these seven principles formed a clear basis for a reasonable resistance management plan, and should have been the basis for formulating the high dose/structured refuge Bt resistance management strategy.

Even a superficial examination of the regulatory history reveals that EPA failed to incorporate these principles into its Bt resistance management strategy. EPA registered Bt crops before any component of the high dose/structured refuge strategy had been established. EPA thus permitted wide-scale use of Bt crops with insufficient information to determine what effective refugia must look like; used uncertainty as an excuse to take no precautionary measures on an interim basis; and failed to construct an adequate oversight program. When EPA approved the Bt registrations, it lacked the evidence necessary to determine that Bt crops would "not cause unreasonable adverse effects on the environment." There was a lack of information period.

EPA no doubt faced considerable informational limitations in making these registration decisions. Although FIFRA provides EPA with the authority to demand additional data from a would-be registrant whenever the agency deems it necessary,[139] there was no way to entirely eliminate the uncertainty. Some of the missing information might not merely have been unknown, but also unknowable, given the current state of science. And, all of it would have been expensive to generate. Extensive pre-market investigation inevitably causes serious delays in the introduction of useful products. EPA was caught between imperfect information and commercial pressure and between the Framework directive to

the SAP, *at* http://www.epa.gov/scipoly/sap/ (last visited July 23, 2002). The role of the SAP has been expanded to that of a peer review body for current scientific issues which may influence the direction of regulatory decisions. *Id.*

[137] *See* FIFRA SAP, *Bt Plant-Pesticides Biopesticides Registration Action Document*, at II.D.3 (2000), *available at* http://www.epa.gov/scipoly/sap/2000/october/brad4_irm.pdf [hereinafter 2000 SAP].

[138] *See id.*

[139] 7 U.S.C. § 136a(c)(2)(B)(i) (2002).

facilitate growth of biotechnology and a statutory duty to register only pesticides that did not pose an "unreasonable risk" to the environment.

In light of this conflict and its lack of information, EPA had three choices. It could either view the uncertainty engendered by this lack of information as a barrier to approval (a purely precautionary approach), it could interpret the dearth of negative data as grounds for approval (a purely promotional approach) or it could employ a hybrid of precaution and promotion. EPA adopted the second approach.

A wiser course would have been to adopt a hybrid precaution/promotion view of the uncertainty. Under a hybrid approach, EPA could have interpreted the uncertainty as grounds for employing precautionary assumptions in the resistance management model, but not as grounds for rejecting the application outright. A hybrid approach would thus have permitted development of Bt crops to proceed, albeit with caution. Instead, seemingly reading no news to be good news, EPA proceeded as though FIFRA had directed the agency to register all pesticides *unless* there was clear evidence of unreasonable adverse effects. In fact, the statute does the exact opposite, directing EPA to register only those pesticides that do not cause adverse effects.[140] The registrant has the initial and continuing burden of demonstrating that the pesticide does not pose an unreasonable risk.

2. *Bt Crops Were Approved Without an Appropriate Dose Expression Strategy*

The first component of EPA's resistance management plan, "high dose," refers to the amount of Bt toxin actually produced by a crop. The 1995 SAP clearly identified an "appropriate dose expression strategy" as essential to any resistance management plan.[141] Bt cultivars must produce enough toxin concentration to kill nearly all of the insects that are heterozygous for resistance. At the time EPA first approved Bt crops for commercial use, no standard for what constituted a "high dose" had been established. Thus, EPA approved these crops without scientific evidence from which it could make decisions about the minimum level of Bt

[140] 7 U.S.C. § 136a(c)(2)(B)(i).
[141] 1995 SAP, *supra* note 108.

toxin expression sufficient to permit an effective resistance management plan.

Today, the defining threshold for "high dose" is 25-times the protein concentration that kills susceptible larvae.[142] The 2000 SAP noted, however, that this threshold is "imprecise and provisional, and may require modification as more knowledge becomes available about the inheritance of resistance."[143] Provisional though it may be, some existing Bt cultivars do not satisfy this criterion.[144]

The 1998 and 2000 SAPs both specifically concluded that certain Bt corn and Bt cotton varieties produce less than a "high dose" for one common pest—the cotton boll worm.[145] Because cultivars that do not meet the criteria for high dose may jeopardize resistance management for those that do, the 2000 SAP, as well as independent researchers,[146] recommended that refuge sizes be increased to hedge against uncertainty.

While acknowledging that non-high dose Bt hybrids represent a vastly enhanced risk of resistance,[147] EPA nonetheless initially approved, and in 2001 re-registered, these non-high dose cultivars.[148] These cultivars were approved, moreover, with the same refuge requirements as for high dose crops, even though their failure to express a high dose of Bt undercut all the assumptions upon which those refuge requirements were based. Such an action

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[142] Memorandum from Elizabeth Milewski, Ph. D., Designated Federal Official, FIFRA Science Advisory Panel, to Lynn R. Goldman, M.D., Assistant Administrator, EPA Office of Prevention, Pesticides and Pollution Prevention 4 (Apr. 28, 1998), *available at* http://www.epa.gov/scipoly/sap/1998/february/finalfeb.pdf [hereinafter Milewski Memo]; 2000 SAP, supra note 137, at II.D.2.

[143] 2000 SAP, *supra* note 137, at II.D.2.

[144] D. A. Andow & W. D. Hutchison, *Bt-Corn Resistance Management, in* NOW OR NEVER, *supra* note 34, at 29 tbl. 2.

[145] 2000 Risk Benefit Assessment, *supra* note 42, at 12-13.

[146] For example, the International Life Science Institute recommended forty percent unsprayed refuges for non-high dose cultivars, or in areas where spraying is routine, eighty percent non-Bt corn refuges. *See* 2001 BRAD, *supra* note 35, at II.D.50. Other scientists also suggested that a separate resistance strategy should be adopted for non-high dose crops. *See* Fred Gould, *Evolutionary Biology and Genetically Engineered Crops*, 38 BIOSCIENCE 26, 32 (1988) (calling for "behavioral and life table studies of target pests on offspring or clones of the transgenic plants"). *See also* Fred Gould & Bruce Tabashnik, *Bt-Cotton Resistance Management, in* NOW OR NEVER, *supra* note 34, at 73, 80.

[147] *See* 2001 BRAD, *supra* note 35, at II.D.50.

[148] *See id.*

was not reasonable, let alone precautionary, in light of the available scientific information.

3. *Bt Crops Were Approved Without an Estimate of Resistance Allele Frequency*

The second component of a successful high dose/structured refuge strategy is a low initial frequency of the resistance allele. This criterion has three different aspects. First, in order for the strategy to even have a chance of success, initial levels of resistance in the wild population must be low. Second, to properly implement the high dose/structured refuge strategy, refugia size must be tailored to the initial frequency of resistance alleles. Finally, a baseline of resistance must be established prior to introduction of the crop—without a baseline, there is no way to evaluate whether a resistance management strategy is succeeding, or failing to prevent resistance.[149] Given the centrality of the initial resistance allele frequency, one might expect EPA to require this information before making any determinations about whether a proposed strategy posed an "unreasonable risk of adverse effects." Or, at the very least, one might expect EPA to make conservative, precautionary estimates of resistance allele frequency to be used until better data can be collected. Yet, Bt crops were registered and widely planted without the development of any of this necessary data, and EPA did not use precautionary defaults.

This initial failure of caution would have been bad enough. But EPA then compounded this problem by failing to require growers or registrants to employ appropriate screening techniques to monitor current levels of resistance in the wild. Resistance detection and monitoring is a difficult and imprecise task. The chance of finding resistant larvae necessarily depends on the frequency of the resistance allele, the number of samples collected, and the sensitivity of the detection technique.[150] As the frequency

[149] *See id.* at II.D.5. *See also*, Roush & Miller, *supra* note 110, at 293-94.

[150] This discussion focuses on single pest species management. In the Midwest, European Corn Borer is the primary above-ground pest of corn. *See* Andow & Hutchison, *supra* note 144, at 36. In Kansas and many southern states, Southwestern Corn Borer is also a major pest, and management of both pests is necessary. No official reports have considered the details of multi-species management. There is an assumption that management of resistance in one pest will simultaneously manage resistance in others, but this assumption has not been tested or evaluated. Adding other pests to the resistance management

of resistant individuals increases, or as the number of collected samples increases, the likelihood of finding a resistant individual also increases.

Current resistance management strategies assume that Bt resistance alleles occur at a frequency of less than one in a thousand ($<10^{-3}$ frequency).[151] On this assumption, more than 3000 samples must be collected to have a ninety-five percent probability of identifying a resistant individual.[152] In its initial Bt crop registrations, EPA only required collection of 100-200 samples per location.[153] EPA has since specifically acknowledged that resistance to Bt could easily develop prior to detection with this sampling frequency.[154] During the 2001 re-registration process, EPA revisited these sampling requirements. Despite the availability of more rigorous sampling techniques, and EPA's clear knowledge that current sampling was inadequate, EPA issued re-registrations that only required registrants to collect more than 200 samples in regions where Bt corn adoption exceeds fifty percent of the total crop, and 100 samples elsewhere.[155]

With this standard, resistance to Bt toxins could be well developed before currently required sampling techniques would be likely to detect it. Experience with conventional pesticides has shown that crop failures occur before resistant individuals are detected with this level of sampling.[156]

4. *Bt Crops Were Approved Without An Appropriate Refuge Requirement*

The final component of EPA's resistance management

picture (especially in the regions where cotton and corn are grown together) may complicate the process in unknown ways. *Id.* at 37. Again, EPA's claim to be using science as the basis for risk assessment is suspect.

[151] Work done in 2001 seems to validate the resistance frequency assumption that underlies the high dose/structured refuge strategy for one susceptible pest, the European Corn Borer. *See* 2001 BRAD, *supra* note 35, at II.D.7-8. Unfortunately, this work was done *six years after* the strategy was adopted for wide-scale commercial exploitation of Bt crops. Data on resistance allele frequencies for other pests are still unknown.

[152] *See* Roush & Miller, *supra* note 110, at 293.

[153] *Id.*

[154] *See* 2001 BRAD, *supra* note 35, at II.D.5.

[155] *See id.* at V.16.

[156] *See id*. Moreover, laboratory research suggests that minor resistance genes are fairly common in at least one of the target pests and that there is substantial genetic variability for resistance in wild populations. *Id.* at II.D.5.

strategy is the use of structured refugia (areas that are untreated with the particular pesticide) to maintain portions of the pest population unexposed to Bt. Structured refugia are built on the assumption that resistance to Bt is recessive[157] and is conferred by a single gene locus with two alleles.[158] Thus, there will be three genotypes: SS-susceptible homozygotes; SR-heterozygotes, and RR-resistant homozygotes.

For a structured refuge to be successful, mating must be random and the population must contain a low initial frequency of the resistance alleles.[159] Refugia are then designed to produce at least 500 susceptible individuals for every resistant adult. These numbers make it overwhelmingly likely that any resistant insect surviving the Bt crop will mate with a susceptible insect from the refuge.[160]

At the time of the initial 1995 Bt registrations, EPA knew it lacked sufficient information to determine the minimum adequate refuge size or structure.[161] For example, the validity of assumptions about random mating,[162] the frequency of resistance alleles, and the survival rate for the SR heterozygotes[163] were all unknown. The uncertainties engendered considerable conflict over the size of refugia necessary to prevent resistance. Similarly, there was debate over whether EPA should require field refugia by regulation, or whether industry and corn growers should be responsible for a voluntary system of promised refugia.

Missing information made it difficult to determine the appropriate size of a refuge, but there was a background of general agreement that some refuge would be needed. Government scientists proposed refugia that ranged from twenty to fifty percent

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[157] In contrast to this assumption, the Discrimination Concentration Assay—the form of monitoring required by EPA—is most useful when resistance is common or conferred by a dominant allele. *Id.* at II.D.5.

[158] *Id.* at II.D.2.

[159] *See id.*

[160] *See* Milewski Memo, *supra* note 142, at 33; 2000 SAP, *supra* note 137, at II.D.2.

[161] *See, e.g.,* EPA Response, *supra* note 95, at 22.

[162] Recent work provides strong evidence that mating is, in fact, not random and that populations are regionally isolated. *See* Sears & Schaafsma, *supra* note 131.

[163] The survival rates are still unknown because the major resistance genes have not yet been isolated or characterized. *See id.*

non-Bt corn per farm.[164] Industry scientists promoted a much less protective standard. Under these circumstances, a precautionary approach would have been to impose an interim requirement based on available scientific information with the understanding that the question would be revisited as more information was collected.

Rather than follow a precautionary path, however, EPA concluded that market penetration of Bt crops would be slow, and therefore that non-Bt fields could act as refugia while additional research was being conducted.[165] EPA thus used the uncertainty about the proper refuge size to avoid imposing *any* refuge requirement. While this decision was certainly a possible response to the situation, and may have held commercial appeal, it was the response least likely to ensure that the crops created no adverse environmental effects.

Despite a consensus that size, placement and management of refugia would be critical to the success of a high dose/structured refuge strategy, EPA did not require a specific refuge size and permitted registrants to institute voluntary resistance management plans.[166] The registration documents refer to this market-driven arrangement as an "unstructured" refuge.[167] Unsurprisingly, the unstructured refugia recommended by registrants to their growers under the voluntary resistance management plans frequently fell far short of the smallest refuge size suggested by non-industry scientists. For example, while Monsanto and DeKalb instructed growers to plant a five percent refuge,[168] Novartis and Mycogen recommended only that "not all corn acres be planted in Bt corn."[169] In terms of delaying resistance, evidence at the time suggested that a five percent refuge was roughly equivalent to no refuge at all.[170] Despite EPA's conclusion that loss of Bt

[164] EPA Response*, supra* note 95, at 22.
[165] *See id.*
[166] *See id.*
[167] *See id.*
[168] *See, e.g.,* EPA Response, *supra* note 95, at 22-23 n.61.
[169] *Id*.
[170] *See*, Hugh N. Comins, *The Development of Insecticide Resistance in the Presence of Migration*, 64 J. THEORETICAL BIOLOGY 177 (1977); Fred Gould, *Simulation Models for Predicting Durability of Insect Resistant Germplasm: Hessian Fly (Diptera: Cecidomyiidae)-Resistant Winter Wheat*, 15 ENVTL. ENTOMOLOGY 11, 21 (1986) (where ninety percent of wheat planted was single gene resistant, this was not sufficient to sustain resistance overall); Richard T. Roush, *Managing Pests and Their Resistance to* Bacillus thuringiensisnous: *Can*

susceptibility would be an adverse effect prohibited by FIFRA, EPA let uncertainty about refuge size prevent implementation of an obvious precautionary measure. In doing so, EPA permitted the companies to treat Bt susceptibility as a resource to be exhausted.

Conceptually, relying on unstructured refuges had obvious flaws. Although total market penetration of Bt corn might well have been low during the early years, that assumption provides no information about local markets. Even in the early stages of adoption, plantings of Bt corn were likely to be clustered. Farmers who experienced significant corn borer damage in the past were the likely purchasers; they were likely to plant considerable acreage with Bt seed, and to promote the seed to their neighbors. As one grower expressed, "If my neighbor is planting Bt, I'd better plant it too, otherwise I get the corn borers."[171] The resulting Bt plantings were likely to be in relatively large, contiguous patches. Many, if not most, of the plants in these patches were likely to be geographically isolated from the "unstructured refuges" that were the only source of a susceptible insect pool to prevent the evolution of resistance.

Experience bears out these conceptual flaws. Iowa, Michigan, South Dakota, Nebraska, and Indiana, for example, had large growing areas where more than fifty percent of the fields were planted with Bt corn.[172] Even larger portions of these and other corn growing states had thirty to fifty percent Bt corn.[173] According to all the scientific advice provided to EPA, twenty percent refugia were adequate only if the amount of Bt corn

Transgenic Crops Be Better Than Sprays?, 4 BIOCONTROL SCI. & TECH. 501 (1994); Andow & Hutchison, supra note 144, at 28. *But see* James Mallet & Patrick Porter, *Preventing Insect Adaptation to Insect Resistant Crops: Are Seed Mixtures or Refugia the Best Strategy?*, 250 PROC. ROYAL SOC'Y LONDON SERIES B 165, 169 (1992) (suggesting a five to ten percent refugia would be sufficient to reduce selection). Andow modeled the number of years before insect resistance is common enough for a control failure. Andow & Hutchinson, *supra*, at 29 tbl. 2. While a five percent refuge did delay the onset of resistance, it did not delay resistance significantly. Indeed, depending on the assumptions for the dominance of the resistance allele and the survival rate of resistant heterozygotes, the delay could be as little as one year. The authors' best guess of these variables yielded a delay of only three years. *Id*. at 61 fig. 3.

171 *See EPA/USDA Workshop, supra* note 132.

172 *See* National Corn Growers Association, *Bt Corn Distribution Map*, *at* http://www.ncga.com/biotechnology/BtMaps/USMaps1.htm (last reviewed Nov. 19, 2001). *See also*, 2001 BRAD, *supra* note 35, at I.23.

173 *Id.*

planted in an area did not exceed fifty percent.[174] In spite of this divergence between EPA assumptions and real-world use of Bt, the agency made no changes to the refuge requirements in the 2001 Bt re-registrations.

EPA's initial reliance on "unstructured refugia" is particularly troubling because all of the available scientific evidence supported requiring structured refugia from the beginning, and the uncertainties created by missing information only underscored the need for precaution. The only argument against refugia was the weak economic claim that, by definition, refugia would not maximize profits for the registrants who would sell proportionally less Bt seed. Large refugia might also encounter increased grower resistance, as growers bear all of the costs associated with implementing the structured refuge strategy. These costs certainly argue toward planting fewer acres as refuge acres. However, the economic losses from overallocating to refugia are relatively small, while the biological consequences of underallocatingng to refugia—and therefore the ultimate economic costs of such an underallocation—are very large.[175] A decision to take initial precautionary steps would not have had large adverse economic consequences, and there was a strong consensus that planting twenty to thirty percent refuges made both environmental and economic sense.[176] Moreover, preliminary requirements could have been adjusted as empirical data were developed.

Quite aside from the inadequate levels of precaution EPA displayed in approving "unstructured refuges," EPA's approach establishes a troubling philosophical precedent. As discussed above, Bt resistance bears the characteristics of a common pool resource. Without restrictions designed to preserve Bt resistance, the rational choice for an individual grower is to maximize current use of Bt crops, a choice that will result in rapid evolution of Bt resistance and ultimately in the loss of Bt as a tool for controlling these pests. Like the classic "tragedy of the commons" so eloquently described by Garret Hardin,[177] scientific uncertainty

[174] *Id.* at V.5.

[175] Hurley, *supra* note 44, at 15.

[176] *Id.* at 2.

[177] Hardin, *supra* note 43, at 1244. For a succinct introduction to the hurdles that frequently prevent resolution of common resource problems, see Barton H. Thompson, *Tragically Difficult: The Obstacles to Governing the Commons*, 30 ENVT'L L. 241 (2000).

about the speed of resistance evolution, coupled with the conflict between the immediate benefits of planting Bt crops, and the long-term costs of Bt resistance makes voluntary conservation of Bt susceptibility extremely difficult and highly improbable.

It did not have to be this way. EPA had an initial opportunity to enlist grower participation in resistance prevention. By requiring implementation of structured refugia from the outset, EPA could have prevented the confusion and misinformation that inevitably accompanied the demand that farmers make after-the-fact changes to their established growing methods in order to create refugia. Had refugia been required from the beginning, early adopters would have planted Bt with the knowledge—clear from the outset—that responsibility to prevent resistance went hand in hand with use of the new technology. Instead, so-called "non-structured refugia" built free-riding into the expectations of growers and registrants—a choice that does not bode well for the future of refugia. As a perceptual problem, later imposition of refuge requirements appears to growers as a deprivation—the taking away of a "right" to plant more acreage with Bt crops.[178] Ex post policy changes are rarely well received, particularly changes that ask growers to internalize costs that were initially external. Had refugia been a requirement from the first approval of Bt crops, growers would have formed expectations about the use of Bt crops appropriate to their intrinsic risk.

5. *EPA Adopted Structured Refugia Piecemeal*

In 1998, the SAP recommended that EPA mandate specific, structured refugia for Bt corn. The SAP reiterated that resistance management plans should be based on the use of both a high dose of Bt and on structured refugia designed to provide sufficient numbers of susceptible adult insects. Following these recommendations, EPA began mandating specific structured refuge options for new Bt corn registrations, but left existing

[178] Unfortunately, preserving Bt resistance involves requiring farmers to decrease the level of Bt crop use to which they have grown accustomed, and thus believe themselves entitled. For experimental exploration of the difficulties inherent in such an approach, see generally Jane Sell & Yeongi Son, *Comparing Public Goods with Common Pool Resources: Three Experiments*, 60 SOC. PSYCHOL. Q. 118, 120 (1997) (detailing the problem of perceived losses in solving commons problems). S*ee also* Thompson, *supra* note 177, at 257-65 (discussing the psychological and social challenges that frequently prevent solving common pool resource challenges).

registrations to implement their "non-structured" refuge plans.

Growers of different types of Bt corn were thus subject to conflicting requirements. For example, EPA required Novartis to mandate, through grower contracts, that its Bt popcorn be grown with a twenty to thirty percent unsprayed refuge, or a forty percent refuge planted within one-half mile of the Bt corn if the grower treated with non-Bt pesticides.[179] Novartis' Bt field corn was not covered by this requirement. Novartis therefore continued to instruct that field corn be planted with a twenty percent refuge that could be treated with non-Bt pesticides.[180] Different Novartis Bt corns were subject to different refuge requirements, even though the corns contained the same Bt gene and produced the same pesticidal proteins.

Nor was there consistency across registrations. For example, despite having required Novartis to mandate a twenty percent unsprayed refuge or a forty percent sprayed refuge, EPA only required Monsanto to mandate a ten percent unsprayed or twenty percent sprayed refuge within "close proximity" to its Bt field corn.[181] Dekalb voluntarily instructed its growers to adopt a similar refuge plan, while Mycogen instructed Bt field corn growers to plant a twenty percent untreated non-Bt corn refuge, or a forty percent treated refuge.[182] The requirements were confusing and conflicting.

During 1997 and 1998, the USDA NC-205 Research Committee on Ecology and Insect Management published resistance management recommendations suggesting at least a twenty to thrity percent untreated refuge or a forty percent treated refuge planed within close proximity to Bt corn.[183] Based on the available scientific information, the Committee concluded that a twenty percent unsprayed refuge was the minimum needed for

[179] *See, e.g.,* EPA Response, *supra* note 95, at 24-26.

[180] *See id.*

[181] *See id*.

[182] *See id.* at 24.

[183] *See* K.R. Ostlie et al., eds., *Bt Corn & European Corn Borer: Long-Term Success Through Resistance Management*, North Central Regional Extension Publication NCR 602 (1997), *available at* http://www.extension.umn.edu /distribution/cropsystems/DC7055.html [hereinafter NC-205 Report]; Regional Research Committee NC 205, *Supplement to: Bt Corn & European Corn Borer: Long-Term Success Through Resistance Management, NCR-602* (Oct. 1998), *available at* http://www.biotech-info.net/NCR-602_supplement.pdf [hereinafter Supplement to NC-205 Report].

resistance management, and that a thirty percent refuge would provide a hedge against the uncertainties build into the biological and operational models.[184] Similarly, an independent assessment by a Union of Concerned Scientists panel concluded that a twenty-five percent refuge "might be adequate" but allowed little room for error.[185] The panel therefore recommended a fifty percent refuge.[186]

Acting on advice from the NC-205 Committee that it set precautionary standards, advice echoed by the Union of Concerned Scientists, EPA requested that registrants submit refugia strategies. In April 1999, the registrants submitted final refuge strategies for two types of Bt field corn products. Contrary to the governmental and NGO recommendations, the registrants proposed a twenty percent refuge that might be sprayed if levels of crop damage met or exceeded an economic threshold.

In response to industry complaints that its initial proposal was commercially impracticable, the NC-205 Committee made a post-hoc modification to its refuge recommendation to permit spraying in the twenty percent refuge, despite its initial conclusion that if spraying were to occur, a forty percent refuge would be necessary. EPA then adopted the registrants' proposal for a twenty percent sprayed refuge.

Such a result clearly responds to the Framework goal of eliminating obstacles to the technology. Whether the decision is equally responsive to EPA's duty to ensure "no unreasonable adverse environmental effects" cannot be established from the record because it is not clear whether there was a scientific basis for the NC-205 Committee's changed recommendation. Although not conclusive, it is suggestive that Canada's Bt Corn Coalition, a public/private partnership, which worked closely with the United States government, endorsed the original NC-205 recommendations, but not the later revisions that permitted spraying in the twenty percent refuge.[187] The Canadian government adopted a twenty percent unsprayed refuge in 1998.[188]

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184 Supplement to NC-205 Report, *supra* note 183, at 1.

185 *See* Andow & Hutchison, *supra* note 144, at 31.

186 *Id.*

187 *See* Sears & Schaafsma, *supra* note 131.

188 *See* Canadian Food Inspection Agency, *Insect Resistance Management of Bt Corn in Canada* (Feb. 8, 1999), *at* http://www.inspection.gc.ca/english/plaveg/pbo/btcornmaile.shtml.

Not until the year 2000 did all United States Bt field corn have mandatory structured refuge requirements. On January 31, 2000, EPA accepted the Bt Corn Industry's Insect Resistance Management Plan for the 2000 growing season.[189] This plan mandated that all Bt field corn containing the Cry1A(b) gene have a minimum twenty percent non-Bt corn refuge in the corn belt, and a minimum fifty percent non-Bt corn refuge in southern cotton growing areas (because the proximity to Bt cotton increases the selection pressure on certain pest populations that feed on both corn and cotton.)[190] This plan also required growers to locate each refuge within a specified distance from a Bt field.[191] Both the twenty percent and the fifty percent refuges could be treated with non-Bt insecticides if insect damage crossed an economic threshold.[192]

One year after approving these refugia, EPA acknowledged that use of pesticides in refugia might pose an additional risk for insect resistance by reducing refuge efficiency.[193] In the 2001 re-registration, EPA specifically referred to scientific evidence that use of insecticidal sprays was likely to dramatically decrease refuge efficacy.[194] Yet EPA's proposed response to this possibility was to require registrants to conduct years of research on the impact of insecticide use on refugia, but not to increase refuge size as an interim, precautionary measure.[195]

There is solid evidence that spraying diminishes a refuge's ability to serve as a breeding ground for susceptible insects.[196] As a result, refugia will be much less effective. Indeed, available

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[189] *See* Agricultural Biotechnology Stewardship Technical Committee, *Bt Corn Insect Resistance Management Survey: 2000 Growing Season,* at 3 (Jan. 31, 2001), *available at* http://www.ncga.com/biotechnology/insectMgmtplan/pdf/finalIRMsummarysurvey.pdf [hereinafter *Bt Resistance Survey*].

[190] *See, e.g.,* EPA Response, *supra* note 95, at 26.

[191] *Bt Resistance Survey*, *supra* note 189, at 3.

[192] Speaking on behalf of the USDA Committee that originally prepared the twenty percent unsprayed/forty percent sprayed recommendation, Dr. Hellmich and Dr. Higgins recognized the commercial impracticability of their suggestion. *See EPA/USDA Workshop*, *supra* note 132. Farmers would not know, at the time of planting, whether growing conditions would be such that spraying would be necessary. *Id*. For that reason, the committee modified its recommendation to permit spraying if necessary in the twenty percent refuge. *Id.*

[193] *See* 2001 BRAD, *supra* note 35, at V.5.

[194] *Id*.

[195] *See id*.

[196] *See* Andow & Hutchison, *supra* note 144, at 31.

resistance models suggest a significant likelihood that resistance may already have taken hold by the time the research is complete in March of 2003.[197] Precaution would suggest that EPA err on the side of requiring substantial refugia, particularly in light of the economic data suggesting that refugia did not impose significant economic costs. Instead, EPA elected to permit refugia that are, on their face, probably too small. By this action, EPA created an increased risk of resistance evolution.

This decision to approve inadequate refugia calls into question the agency's claim that it employed science-based analysis to determine resistance management standards for Bt crops.[198] There was clear scientific evidence that unsprayed refugia would be more protective than sprayed refugia. Various groups had recommended that if EPA were to permit spraying, the refugia would have to be larger than would otherwise be required. The only objections to expanded refugia were those based on commercial feasibility and the NC-205 Committee offered no explanation for its changed recommendation other than commercial pressures. It is possible that the initial Committee recommendations contained a generous margin of safety that could reasonably be narrowed, but the tenor of those initial recommendations makes it more likely that necessary conditions were compromised, and that the refugia requirement is now meaningless. While it is not clear that a twenty percent sprayed refuge *is* inadequate, such a requirement is certainly not precautionary. If a twenty percent sprayed refuge is adequate, there is very likely no margin of safety and no room for error or for less than full compliance with this standard. The expectation of perfection is particularly troubling in light of EPA's failure to develop a review process capable of monitoring resistance or compliance levels.[199]

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[197] *See, e.g.,* Andow & Hutchison, *supra* note 144. For a discussion of the data that registrants are required to submit to EPA by March of 2003, see 2001 BRAD, *supra* note 35, at Section V.

[198] *See* EPA & USDA Position Paper, *supra* note 111, at 9.

[199] Moreover, recommendations regarding size and distribution of non-Bt refuges have been made primarily with an eye towards preserving a susceptible pool of insects. *See* Sears & Schaafsma, *supra* note 131. Less attention has been paid to the potential effects of Bt corn on agricultural ecosystems and non-target organisms. *Id*. Because of the extensive acreage being devoted to Bt corn, the technology could have widespread and lasting impacts on beneficial insects. *Id*. Potential problems because of substantial decreases in prey organisms could

Clearer regulatory goals would be helpful in evaluating the current regulatory structure. The Framework did not create substantive law and its goals cannot supplant congressionally mandated statutory objectives.[200] All things being equal, consideration of the commercial realities is a desirable attribute in a regulatory system, but permitting commercial interests to substitute for scientific judgment is not. If deference to "commercial realities" prompted EPA to agree to an inadequate refuge system, the purpose of requiring a refuge system has been lost.[201] If growers will not plant Bt crops with scientifically justifiable refugia, whether the crops should be grown at all comes into question. Without pre-judging the answer—which would involve balancing a host of environmental and economic concerns including those raised by the likely pesticide use in the absence of Bt crops—this question is very different from the one EPA claimed to be addressing.

6. *EPA Did Not Require Optimum Placement of Refugia*

In addition to deciding the proper size of refugia, EPA also had to regulate their proper placement. When EPA began requiring refugia in 2000, it merely codified the earlier, voluntary guidelines regarding placement of these refugia.[202] Ignoring the weight of available evidence about how and where refugia should be placed, in 2000, and again during re-registration in 2001, growers were merely encouraged to plant refugia within one-quarter mile of their Bt acreage, and required to plant refugia within one-half mile.[203] Canada, by contrast, requires that refugia be planted within one-quarter mile.[204]

A key assumption underlying the entire high dose/structured refuge system is that the pest populations mate randomly. In the 1998 Supplement to its Report on Resistance Management for Bt

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ripple through other crops and habitats in unpredictable ways. *Id.*

[200] *See* Found. on Econ. Trends v. Johnson, 661 F.Supp. 107, 109 (D.D.C. 1986) (describing Framework as a "first effort" and explicitly concluding that there had been no regulatory rulemaking).

[201] *Cf.* Sierra Club v. Army Corps. of Eng'rs, 772 F.2d 1043 (2d Cir. 1985) (rejecting post hoc rationalizations to data evaluation and voiding a permit because the agency failed to reasonably connect the data developed with the regulatory choice made).

[202] *See* 2001 BRAD, *supra* note 35, at V.9.

[203] *Id.*

[204] *See* Butzen, *supra* note 47.

Corn, the NC-205 Committee called this assumption into question.[205] Data from Minnesota and Nebraska indicated that one common pest controlled by Bt did not disperse as expected, and thus was not mating randomly.[206] In fact, the Committee pointed to evidence that many adult pests did not disperse more than 500 meters, and that pest populations exhibited regional genetic isolation.[207]

The purpose of the refuge requirement is to make it overwhelmingly likely that resistant individuals will mate with susceptible individuals. A simple way to increase the likelihood of those desired matings in light of the evidence produced by NC-205 would have been to require that refugia be planted closer to the Bt corn plantings. Indeed, that is exactly what the NC-205 Committee recommended.[208] EPA failed to adopt this recommendation, both in 2000 when refugia became mandatory, and again during the 2001 re-registration process. EPA instead required an arrangement it had been advised was unlikely to prevent resistance. By electing not to modify refugia placement requirements in light of growing evidence about how the pests actually behaved, EPA again failed to respond with caution to evolving scientific information.

D. *The Registrations Did Not Establish An Enforceable Regulatory Scheme*

As troubling as inadequacies in EPA's chosen high dose/structured refuge strategy might be, an even more fundamental problem is that the requirements are simply not being implemented. Growers are not in the business of raising pest insects. Without a concerted effort to explain the necessity of maintaining refugia despite insect damage, growers are unlikely to comply. To date there has been no systematic examination of the rate of compliance with the resistance management plans first voluntarily and haphazardly implemented, and now required by EPA.

The best information comes from an industry survey conducted after the 2000 growing season to gauge awareness and

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[205] Supplement to NC-205 Report, *supra* note 183, at 4.
[206] *Id.*
[207] *Id.*
[208] *Id.* at 8.

adoption of refugia requirements. [209] Showing a significant talent for understatement, the survey concluded that "there currently remains significant opportunities to educate growers and influence [resistance management] practices."[210] The survey reported that ninety-seven percent of growers believed they had an acceptable refuge in place.[211] An examination of the actual data demonstrated, however, that twenty percent of all growers were entirely unaware that any requirements for managing insect resistance accompanied planting Bt corn.[212] Sixty-five percent either did not know the required refuge size or believed it to be significantly smaller than it was.[213] Half knew that the refuge could be treated but did not know the conditions that had to be met or the insecticide restrictions that existed.[214] Sixty-one percent did not know how close the non-Bt refuge must be to a Bt corn field.[215] Twenty-nine percent of the growers reported being knowingly out of compliance with the distance requirement.[216] These out-of-compliance growers planted thirty percent of the Bt corn acres grown in the United States.[217]

In the corn/cotton region, where concerns about the possibility of evolving insect resistance are greatest,[218] forty-two percent of the growers were unaware of any refuge requirements.[219] Only six percent of the respondents in these areas knew that a fifty percent

[209] *See generally Bt Resistance Survey*, *supra* note 189.
[210] *Id.*at 3.
[211] *Id.* at 4.
[212] *Id.* at 17.
[213] *Id.* at 16, 19 (response to question regarding minimum size of non-Bt corn refuge that must be planted on a farm).
[214] *Id.* at 16.
[215] *Id.*
[216] *Id.* An additional three percent did not know if they were in compliance or not.
[217] *Id.*
[218] For example, *Hellicoverpa zea*, commonly known as the cotton bollworm when attacking cotton, and corn earworm when attacking corn, can have several generations a year and can move from corn to cotton. Neither Bt corn nor Bt cotton produce a high dose of Bt toxins for *H. zea*. Therefore, the chances of insect resistance developing are increased through the added exposure.
[219] *Bt Resistance Survey*, *supra* note 189, at 16. The survey indicates that the sample size of aware farmers in the corn/cotton areas were too small a sample to draw any conclusions. That fact alone is highly revealing: the Industry Survey reported to EPA as evidence of compliance with registration requirements could not identify enough aware farmers to draw any conclusions from their answers in the area where concerns about resistance management are greatest.

refuge was required. Of the remaining ninety-four percent, eight percent believed that the refuge must be twenty percent of the corn planted on a farm. All other respondents either did not know or believed a refuge smaller than twenty percent was allowed.[220]

Although EPA's cooperative effort with the Agriculture Biotechnology Stewardship Technical Committee—the industry-financed scientific group responsible for the survey—has been touted as a success story,[221] the survey itself depicts a woeful failure.[222] Almost a third of all Bt corn acres in the United States were not planted in compliance with IRM requirements.[223] The refuge requirement, the cornerstone of Bt resistance management, has been treated by EPA, registrants and growers alike, as if it were a suggestion, rather than the legal predicate upon which registration was conditioned.

EPA considered the problem of non-compliance during the 2001 re-registration process. For example, EPA now requires that registrants use grower agreements that contractually bind growers to implement specific resistance management requirements.[224] The registrants will then have to conduct a paper inspection via a follow-up survey at the end of the growing season. If the grower self-reports a failure to plant an adequate refuge, the registrant *may* refuse to sell the grower Bt seeds for the next year.[225]

[220] *Id.* at 19.

[221] *See, e.g.,* Stanley H. Abramson & J. Thomas Carranto, *In Depth: Genetically Engineered Agriculture: Crop Biotechnology: The Case For Product Stewardship*, 20 VA. ENVTL. L. J. 241, 259 (2001).

[222] EPA acknowledges that non-compliance may be even higher than suggested by grower surveys. Without confirmatory visits to individual farms, it is impossible to verify the accuracy of grower responses. The lack of verification may tempt growers to exaggerate their degree of compliance. 2001 BRAD, *supra* note 35, at II.D.64.

[223] *Bt Resistance Survey*, supra note 189, at 5. The data in this survey is supported by other evidence. For example, discussions at the 1999 EPA/USDA Workshop on Bt Crop Resistance Management underscored that EPA and the registrants have failed to be effective in getting out the message about the absolute need for a twenty percent refuge and a fifty percent refuge where Bt cotton is grown. *EPA/USDA Workshop*, *supra* note 132. Growers reported that they had never been provided with resistance management information. *Id.* In the 2001 re-registration process, EPA required more efforts at grower education. In light of the other problems with the Bt resistance management plan, however, these new education requirements are too little, too late.

[224] *See* 2001 BRAD, *supra* note 35, at V.10-11. Prior to 2001, some registrants used grower agreements.

[225] *Id.* at V.8.

Although an improvement over having no reporting system, this scheme has obvious flaws. There is no independent verification of grower self-reporting and it is not in a registrant's interest to pursue the matter. In short, there is still no regulatory oversight process that would force either the registrant or the grower to fully incorporate the broader societal interest of preventing resistance to Bt into their individual decisions. The process thus creates a classic externality—not all the costs of a production activity are borne by the person undertaking the activity.[226]

E. *Summary of the Case Study*

Careful examination of the Bt case study reveals numerous points in the regulatory process at which USDA and EPA did not choose precautionary options. USDA granted Bt crops non-regulated status on the assumption that EPA would solve the resistance problem, but took no steps to insure that EPA did so before the crops were widely distributed and planted. EPA approved Bt crops without a requirement that the crops produce high doses of Bt, without an estimate of resistance allele frequency, and without any refuge requirement. Despite their purportedly objective and scientific cast, the regulatory decisions surrounding gm crops failed to respond prudently to the extreme imprecision of the "scientific estimates" that formed the basis for regulatory analysis. At each point in the process, the agencies opted not for precaution, but for the most optimistic estimates of all possible variables.

When EPA finally adopted a structured refuge requirement, it did so piecemeal and without any credible means of monitoring or enforcing the requirement. EPA itself identified enforcement mechanisms as an area that needed improvement.[227] New requirements imposed in the 2001 re-registrations are a vast improvement over the regulatory system in place when the crops were initially approved, but serious accountability problems remain. Under the 2001 re-registrations, a registrant who takes reasonable steps to assure compliance (via grower agreements and

[226] *See* WERNER. Z. HIRSCH, LAW AND ECONOMICS: AN INTRODUCTORY ANALYSIS 5, 8-15 (3d ed. 1979).

[227] *See, e.g.,* EPA Response, *supra* note 95.

education)[228] will not be subject to enforcement actions.[229] EPA concedes that it does not expect 100 percent compliance,[230] but does not know what level of non-compliance would compromise the protection afforded by the twenty percent refugia.[231]

V
LESSONS FROM THE CASE STUDY

Two categories of lessons can be drawn from this case study: global and particular. The global lessons relate to government structure, the particular to Bt crops themselves. These lessons highlight the need for improvement in two basic areas: in structuring an effective regulatory system, and in responding to scientific uncertainty.

A. *The Need For Coordinated Regulatory Authority*

On a global scale, the case of Bt crops reveals the inherent unsuitability of the Framework itself. By reifying previously existing regulatory divisions, the Framework fragments the regulatory evaluation of gm crops into illogical zones of authority that inhibit intelligent priority setting. The Framework lacks a mechanism to coordinate, monitor and evaluate the performance of the various agencies. Similarly, there is no way to ensure that the agencies share information and coordinate regulatory policy. The Bt case study demonstrates that this lack of coordination among the various agencies seriously impairs the soundness of the regulatory system as a whole.[232] It produces a regulatory system with inadequate safety margins and no means to monitor and enforce the requirements that exist on paper.

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[228] For a full list of the compliance assurance steps required as part of the 2001 re-registration process, see 2001 BRAD, *supra* note 35, at V.10-13.

[229] *See id.*

[230] *See EPA/USDA Workshop*, *supra* note 132.

[231] *See* 2001 BRAD, *supra* note 35, at II.D.10.

[232] There is scientific agreement that evolution of Bt resistance is only a matter of time. Therefore, as a prudential matter, one might expect EPA to have devoted significant energy to developing effective responses to resistance, in the form of resistance management plans. However, the registrations require only that registrants notify EPA when adverse environmental effects are identified. 40 C.F.R. § 174.171 (2002). As noted in Section I(C)(2), *supra*, resistance is considered to be an adverse environmental effect. 2001 BRAD, *supra* note 35, at II.D.2.

Lack of a central decisionmaking authority has resulted in undercontrol of the potential environmental problems raised by gm crops. This lack has also resulted in the government's complete inability to tailor regulatory measures to the real world circumstances of agricultural use of gm crops in the United States. Finally, insufficient communication, both inter-agency, and with the regulated community and the public, prevents consensus about regulatory goals and the best means to achieve them.

For a compliance program to be effective, a new regulatory enforcement and compliance framework is required. The stakeholders and regulatory bodies need to create clearly defined compliance rules. Unfortunately, the current fragmentation of regulatory authority hampers the strategic planning and policy coordination needed to establish such a system. For that reason, the Framework's assumption that existing statutes could adequately supervise development and marketing of this new technology should be reexamined. If federal regulatory oversight for biotechnology is to be properly coordinated and directed at well-defined goals, Congress must provide decisive leadership. In a single statutory directive, Congress could solve this problem by centering regulatory authority within one agency. Failing that, a high-level congressional initiative could provide leadership in this critical area of environmental policy and could coordinate the diverse activities of various federal departments and agencies.

The Framework was premised on the assumption of inter-agency coordination within the fragmented regulatory structure. Without a concrete coordinating mechanism, EPA cannot influence the direction of USDA's thinking and vice versa. Under the existing scheme, consultations only happen, if at all, after policy decisions have been made, and after public and private expectations have been formed. Though a unified regulatory structure would provide the best solution to the problem, much more could also be done within the existing structure to make interagency coordination a reality. For example, an explicitly authorized and funded joint working group could coordinate USDA and EPA authority.

The regulatory program would also benefit from stronger and more formalized ties to the university and NGO communities. These researchers are often conducting the most forward-looking and sophisticated research. Better integrating this research into the policymaking process will ensure a better, and more precautionary, regulation.

B. *The Need for More Research*

The second overwhelming message from the case study is the need for more research early in the registration process. Unless applicants are required to develop the necessary scientific information from which informed choices can be made, EPA will continue to regulate in an atmosphere of pervasive uncertainty. Without knowing how effective monitoring techniques are, and without understanding the mechanisms of resistance, EPA cannot engage in informed decisionmaking.

In the absence of a requirement that research be conducted prior to registration, attempts at risk assessment must draw heavily on incomplete data about allele frequency and dominance, and insect mating behaviors. Not all of these questions present intractable uncertainty problems; in many cases this information is merely unknown but not unknowable. The problem has an obvious solution—require the proponent of a gm product to develop the necessary information prior to licensing a crop for wide-scale use. Since FIFRA imposes an initial and continuing burden on registrants to demonstrate that their crop poses no "unreasonable adverse risk,"[233] such a requirement would be well grounded in existing law.

Requiring registrants to develop necessary information prior to regulatory approval will reduce uncertainty, and improve agency decisionmaking. As much of the information will be common for all Bt crops, an industry consortium would be an efficient way to conduct the needed research in a timely and coordinated fashion. The existing Agriculture Biotechnology Stewardship Technical Committee would be a likely candidate for this role. The results of coordinated research should be made public and peer reviewed. In the interim, knowledge gaps mandate that EPA use conservative, precautionary estimations of risk for each uncertain data point in the regulatory process. Precautionary estimates have a further advantage—they provide a clear incentive for registrants who believe the estimates overly conservative to do the necessary research.

[233] *See, e.g.,* Envt'l Defense Fund v. EPA, 489 F.2d 1247, 1250 (D.C. Cir. 1973).

C. *The Need to Incorporate Precaution into the Decision-making Process*

The need to make regulatory decisions in the absence of scientific information is not unique to regulation of Bt crops. Despite the widespread problem, there is little in the way of institutional guidance about how to make decisions under those circumstances. The Bt case study underscores the dangers of ad hoc decisionmaking. Although EPA identified maintaining insect susceptibility to Bt as a "public good,"[234] the agency permitted wide-scale marketing and planting of gm crops before it had a resistance management plan in place. At each stage in the regulatory process, EPA adopted the least precautionary assumptions for every point of scientific uncertainty. As a result, the regulatory controls on gm crops begin from an untenable basis. In order for the existing regulatory scheme to be effective, every step of the process must work perfectly, and every unknown variable must express itself in the least harmful way possible. No safety margins exist. No margin of error protects against inaccuracy in risk projections concerning frequency of resistance alleles, degree of expression of resistance, mating behaviors of various pests, or the farming behaviors of various growers.

The consequences of EPA's failure to adopt any single precautionary estimate of potential risk might not be overly troubling. Indeed, any single failure to take a precautionary stance is, on its own, probably not significant. It is the compounding of the multitude of regulatory decisions, each of which was not precautionary, that raises substantial concerns about the environmental safety of Bt crops. Taken together, these decisions add up to a bias towards discounting uncertain risks.

One way to solve this problem would be to formalize the decisionmaking process, and to set defaults that put a precautionary thumb on the regulatory scale as an antidote to uncertainty.[235] These defaults should include a hybrid of

[234] *See* 2001 BRAD, *supra* note 35, at VI.2.

[235] One example of such precautionary defaults could be restructuring how EPA uses science advisory board opinions. When EPA has convened a science advisory board, it should be required to explain any decision to adopt less precautionary measures than those recommended by the SAP. Such a rule would be the logical extension of existing administrative law, which requires agencies to consider and discuss information that tends to undermine a regulatory decision.

precaution and promotion but need not be so extreme that they prevent experimentation, or consideration of economic costs. That said, more precautionary defaults will undoubtedly raise the costs of bringing these crops to market. But, in the absence of precautionary defaults, those costs still exist, they are merely externalized to other growers, the public and the environment in the form of increased risk of insect resistance. In effect, the current non-precautionary defaults amount to a subsidy from the public, growers and the environment to Bt crop registrants. Precautionary defaults would place the burden of factual uncertainty on those who benefit from selling Bt crops. By forcing registrants to internalize the costs, these defaults ensure that the market price for Bt crops will more accurately reflect their true cost.[236]

There is, of course, a possibility that these new defaults will lead to over-regulation and thus impose unneeded costs on registrants. Current defaults, by contrast, have led to under-regulation and a series of environmental costs externalized to the public. When the risk of regulatory error is borne by the environment and the public, there is little incentive for registrants to reduce that risk. Because precautionary defaults allocate the risk of regulatory error to registrants, registrants will have incentive to finance the research needed to reduce uncertainty, and thus the possibility of regulatory error. Precautionary defaults thus also reinforce the goal of developing information early in the registration process.

D. *The Need For Government Enforcement and Oversight*

The experience with refuge requirements clearly demonstrates the need for an adequate monitoring system. It is not enough to condition a governmental privilege, such as a pesticide registration, on meeting a regulatory requirement. EPA must also take concrete steps to ensure that registrants comply with these regulatory requirements, including developing monitoring methods, refining the management strategies in response to information generated by monitoring activities, and determining response standards for cases of management failure. Governmental oversight and enforcement are vital to the success

236 For a thorough exploration of this role for precautionary regulation, see Geistfeld, *supra* note 91, at 180.

of the regulatory scheme, and should include clear consequences for both the registrant and the growers if registration conditions are not met.

Because the gm seeds are patented, growers purchase the seeds under license agreements that require grower consent to a series of written conditions. Typically these conditions include a promise to comply with registration restrictions. The assumption underlying such license agreements is that, through these contracts and grower education programs, the registrants will ensure grower compliance with the registration requirements. EPA thus relies entirely on registrants to police grower activities. This reliance on industry to privately enforce compliance is a major problem.

Although registrants commit their growers to very specific courses of conduct during the registration process, registrants have no clear obligation to ensure that growers adhere to this bargain. Registrants can disclaim responsibility for lack of compliance by retreating behind the accurate statement that Bt crops are planted by third parties over whom they have no control. Because USDA does not track where Bt crops are planted, EPA has no independent means to verify compliance. Moreover, the government lacks any recourse whatsoever against a grower who fails to comply with registration requirements. No one is responsible.

Recent developments concerning StarLink corn lend urgency to the need for effective monitoring and enforcement. EPA registered StarLink Bt corn for use only as animal feed, or for industrial purposes, and explicitly prohibited its use as human food.[237] The registration also required that StarLink corn be kept out of international commerce.[238] Despite these unambiguous restrictions, in September of 2000, a coalition of groups opposed to biotechnology found StarLink corn in Kraft Taco Shells sold in Washington, D.C.[239] StarLink corn was subsequently discovered

[237] *See* Bacillus Thuringiensis Subspecies tolworthi Cry9c Protein and the Genetic Material Necessary for its Production in Corn; Exemption from the Requirement of a Tolerance, 40 C.F.R. § 180.1192 (2002). The registration required the company to take all actions needed to prevent StarLink from getting into the human food chain. *See* Alejandro E. Segarra & Jean M. Rawson, *CRS Report for Congress, StarLink Corn Controversy: Background* (Jan. 10, 2001), *available at* http://www.cnie.org/nle/crsreports/agriculture/ag-101.cfm.

[238] *Id.*

[239] *See* Marc Kaufman, *Biotech Critics Cite Unapproved Corn in Taco Shells; Gene-Modified Variety Allowed Only for Animal Feed Because of Allergy Concerns*, WASH. POST, Sept. 18, 2000, at A-2.

in over 300 corn products in the United States and in corn exports to Japan, Korea, and the European Union.[240] Not only had registrants and growers disregarded the explicit registration requirements, but, even more troubling, there was no regulatory mechanism to discover and cure these failures. Only the hyper-vigilance of gm opponents brought the situation to light. The systemic failure represented by StarLink argues for closer governmental monitoring of compliance with all registration restrictions, including those directed at insect resistance management through refugia.

A successful regulatory regime must not only obligate growers to follow the registration requirements, but must also impose sanctions for failure to do so. EPA's current enforcement options are severely limited. Refuge requirements are enforceable only against the registrant, not the grower.[241] The only sword the government can brandish is the possibility of license revocation.[242] This remedy is too extreme to be used as a matter of course. Indeed, EPA has not withdrawn a pesticide license in 13 years[243] and the registrants are well aware of this fact. The agency needs a broader arsenal of penalties. For the registrant, the penalties for failing to ensure grower compliance should range from increased reporting to fines and other more severe sanctions, including registration revocation. Ideally, a hierarchy of possible administrative responses could respond to the degree and severity of non-compliance incidents. Early requirements of increased reporting might nip non-compliance problems in the bud, and prevent negative environmental consequences.

Enforcement must also account for actual business conduct. Under the existing scheme, the costs of, and responsibility for, complying with refuge requirements and monitoring obligations fall solely on growers, who are third parties to the registration. The grower has contractual duties to the distributor and/or registrant, but no duties at all to the government. A threat of revocation is not one likely to influence grower conduct. Therefore, an effective regulatory system must bind growers as well as registrants, and must create incentives for growers to comply and for registrants to

240 *See* Segarra & Rawson, *supra* note 237, at 4.
241 *See EPA/USDA Workshop*, *supra* note 132.
242 *Id. See also* 7 U.S.C. § 136d (2000).
243 *See EPA/USDA Workshop*, *supra* note 132.

foster grower compliance.

In the area of unauthorized use of bioengineered seeds, registrants have been vigilant in monitoring and enforcing the conditions included in grower contracts. They need similar incentive to monitor and enforce the other conditions of sale—those imposed by the government to protect the environment and human health. Since FIFRA imposes an ongoing legal duty to demonstrate compliance with the registration requirements,[244] such an allocation is not unreasonable. Registrants would have to fund education programs, and provide incentives for growers to attend. One such incentive could be to require participation in such an educational program before a grower could purchase these Bt products. Registrants would then have responsibility for ensuring that their seeds were sold only to growers who attended these programs. Sales to uncertified growers would be punishable with fines. As part of the 2001 re-registration process, EPA, for the first time, made the funding of grower education programs mandatory. Unfortunately, grower attendance at these programs is not mandatory. EPA must take steps to make attendance a necessary pre-condition for purchasing Bt crops.

Finally, inspections are a critical part of any successful regulatory system. Without an independent means of verifying compliance, EPA is at the mercy of grower and registrant self-reporting. Because EPA relies entirely on self-reporting, and has no power to fine either growers or registrants for noncompliance, there is no "bite" to the registration requirements. Such an arrangement cannot succeed. EPA must work with USDA to develop a means of tracking gm crops so that the agencies have the ability to verify compliance. Once there is a means of verifying compliance, consequences for non-compliance can follow. Aside from the consequences for registrants laid out above, EPA and USDA can also promulgate regulations that bind growers directly. Non-compliant growers can be identified and if necessary sanctioned. They can also be required to take specific corrective measures to bring their acreage into compliance, and to minimize the effects their non-compliance might have produced on pest populations. These measures could then be monitored by follow-

[244] 7 U.S.C. § 136d(b). If new information leads EPA to suspect that a registration can no longer be supported, it may begin proceedings to cancel the registration. *Id*.

up visits from local extension workers and/or government agents. Repeat offenders could be temporarily or permanently banned from purchasing Bt crops.

CONCLUSION

Bt crops represent the vanguard of transgenic crops, and the United States is the vanguard of their use. These crops promise important benefits for an increasingly populated world, but these benefits come with significant risks. Only through precautionary regulation can the United States ensure that exploitation of these crops happens in a responsible and orderly fashion. Such regulation is not now in place, and what little regulation exists is ineffective.

A regulatory system that enjoys the confidence of the public, as well that of the business and farming communities, is essential to the success of biotechnology. As the largest producer of gm crops, the United States must take the lead in developing responsible and precautionary regulatory controls.[245] Not only are the environmental risks too great to permit any other course, but the consequences of public doubt and distrust are also too significant and too corrosive of the faith in regulatory credibility necessary for a viable administrative system.

[245] Few countries have the sort of comprehensive regulatory system necessary to carry out this task, raising an additional layer of concerns if these crops are exported for planting elsewhere.