
MOTHER FRANKENSTEIN, DOCTOR NATURE, AND THE ENVIRONMENTAL LAW OF GENETIC ENGINEERING

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INTRODUCTION

As the new millennium dawns, the realm of the possible is expanding with a second “Big Bang.” Unlike the primordial explosion that is postulated to have spawned the universe, the current tumult is of human creation. It is manifested both in a phenomenal array of new scientific and technological advancements and in the response to those advancements by some environmentalists.

A prime example is the advent of genetically engineered plants, animals, and microorganisms.¹ Viewed by some as a lifeline for an increasingly populous, resource-hungry world, these modern innovations are seen by others as a potential environmental and public health catastrophe of unprecedented proportions. It is a matter of the highest importance to determine, as quickly and conclusively as possible, which of these two polar opposite opinions is closer to the truth, and to implement appropriate legal measures.

This Article first traces the history of genetic engineering and the sometimes violent opposition to it. Parts IV and V critically examine the means by which genetically engineered life forms are currently regulated,

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1. The terms “genetically engineered,” “genetically modified,” “recombinant DNA,” “gene-spliced,” “bioengineered,” and “transgenic” are essentially synonymous. For sake of convenience and consistency, this Article generally uses the terms “genetically engineered” or “transgenic.”

both within the United States and internationally. The Article concludes with a proposal for a new, more effective and coherent approach to environmental regulation that recognizes both the potential benefits and the harms from human manipulation of genetic code.

I. A BRIEF HISTORY OF GENETIC ENGINEERING

If genetic engineering is defined in its broadest sense as any human-directed modification of the genetic material of an organism, the practice can be traced back to ancient agricultural, horticultural, and animal husbandry techniques. Long before the 1860s, when Gregor Mendel drew upon his simple experiments with cross-pollination of plants to elucidate the fundamental principles of modern genetics and heredity, people were attempting to improve their crops, decorative plants, and livestock by selectively breeding them.² For example, if a person wanted to raise larger cattle, he or she would examine the available stock of animals and mate the largest male with the largest female. It was a commonsensical, if inexact, method of influencing the characteristics of the next generation of livestock. Similarly, farmers for thousands of years have identified plants with the most desirable traits, such as taste, size, and appearance, and used their seeds to generate the next crop.³ They have also employed hybridization, with varying degrees of sophistication,⁴ to control the mating of plants with optimal traits and to improve the quality of subsequent generations.⁵

2. See Sara M. Dunn, Comment, *From Flav'r Sav'r to Environmental Saver? Biotechnology and the Future of Agriculture, International Trade, and the Environment*, 9 COLO. J. INT'L ENVTL. L. & POL'Y 145, 148 (1998). In addition to human manipulation, of course, "[p]ests and drought have always influenced genetic composition through the process of natural selection." *Id.*

3. S.D. Tanksley, N.D. Young, A.H. Paterson & M.W. Bonierbale, *RFLP Mapping in Plant Breeding: New Tools for an Old Science*, 7 BIO/TECHNOLOGY 257, 257 (1989).

4. At the most basic level, hybridization proceeds by crossing two varieties of a plant so as to combine the most desirable characteristics of each in the offspring. For example, if a flavorful variety of corn is prone to infection by a certain virus, the farmer may try to hybridize it with a somewhat different strain of corn that is resistant to the virus. By cross-pollinating plants of the two varieties, the goal is to obtain a corn plant that has the most desirable characteristics of both parent plants. The breeder will select from the first generation of resulting offspring those plants that are both virus-resistant and produce superior corn and use that offspring as the basis for further crosses. Eventually, to obtain a corn plant that has the best traits of both parent strains, the breeder will repeatedly "back-cross" the offspring with the original flavorful variety, selecting in each generation those plants that most closely resemble the tasty strain of corn, but that retain the virus resistance characteristic of the other strain. See David J. Earp, Comment, *The Regulation of Genetically Engineered Plants: Is Peter Rabbit Safe in Mr. McGregor's Transgenic Vegetable Patch?*, 24 ENVTL. L. 1633, 1644 (1994).

5. COMM. ON SCIENTIFIC EVALUATION OF THE INTRODUCTION OF GENETICALLY MODIFIED MICROORGANISMS & PLANTS INTO THE ENV'T, NAT'L RESEARCH COUNCIL, FIELD TESTING

Much more recently, researchers discovered the molecules that comprise the actuating material underlying all of genetics. Deoxyribonucleic Acid (DNA) itself, now part of the common lexicon, was unknown to science until the mid-twentieth century.⁶ Modern genetic engineering, i.e., the actual *in vitro* modification of DNA at the molecular level, was first reported in the scientific literature in 1973.⁷ The technique involves recombinant DNA (rDNA)⁸ technology, wherein the genetic molecules are methodically broken and recombined.

Although there are various techniques, the method by which genetic engineering places new or “foreign” DNA into an organism is usually as follows. First, the target genetic material is identified. An enzyme, i.e., a biological catalyst, is then employed to excise the desired DNA segment from one organism. Next, through the use of a second enzyme, the new segment is spliced into some of the recipient organism’s preexisting DNA. To facilitate this process, foreign DNA is often joined to a small circular piece of bacterial DNA called a plasmid, which contains the necessary biochemical signals to exist and to replicate within a cell. A plasmid with newly inserted foreign DNA is considered genetically engineered or rDNA. To get the recombinant plasmid into the recipient organism, the plasmid is sometimes chemically treated under temperature-controlled conditions. Alternatively, DNA encoding the desired trait is painted on microscopic metal particles that are loaded into a so-called “gene gun” and fired as projectiles at plant cells growing in the laboratory. These miniature, gene-carrying “bullets” penetrate the cells where the fluids inside wash the DNA off the metal particles. In either method, the mixture is then returned to normal culture conditions so the cells can recover and grow.⁹

GENETICALLY MODIFIED ORGANISMS: FRAMEWORK FOR DECISIONS 10 (1989) [hereinafter FIELD TESTING].

6. See generally JAMES D. WATSON, *THE DOUBLE HELIX* (1968) (describing the discovery of the structure of DNA).

7. Judith P. Swazey, James R. Sorenson & Cynthia B. Wong, *Risks and Benefits, Rights and Responsibilities: A History of the Recombinant DNA Research Controversy*, 51 S. CAL. L. REV. 1019, 1023 (1978). See also Stanley N. Cohen, Annie C.Y. Chang, Herbert W. Boyer & Robert B. Helling, *Construction of Biologically Functional Bacterial Plasmids In Vitro*, 70 PROCEEDINGS NAT’L ACAD. SCI. 3240 (1973); Stanley N. Cohen, *The Manipulation of Genes*, SCI. AM., July 1975, at 24, 25.

8. Recombinant DNA has been defined as “[t]he hybrid DNA produced by joining pieces of DNA from different organisms together in vitro.” OFFICE OF TECH. ASSESSMENT, 98TH CONG., *COMMERCIAL BIOTECHNOLOGY: AN INTERNATIONAL ANALYSIS* app. I, at 595 (1984).

9. See DAVID FREIFELDER, *ESSENTIALS OF MOLECULAR BIOLOGY* 215–22 (1985); JUNE GOODFIELD, *PLAYING GOD* 12–21 (1977); BERNARD PERBAL, *A PRACTICAL GUIDE TO MOLECULAR CLONING* 411–16 (2d ed. 1988); JAMES D. WATSON, JOHN TOOZE & DAVID T. KURTZ, *RECOMBINANT*

Conceptually similar to traditional forms of selective breeding and Mendelian genetics, genetic engineering has been used to give organisms a panoply of useful traits, including the ability to resist ice damage,¹⁰ to metabolize pollutants into nontoxic products,¹¹ and to produce large amounts of human insulin and interferon inexpensively.¹² In the area of food crops, genetic engineering has created new varieties with enhanced resistance to pests and herbicides, better nutritional characteristics, and prolonged post-harvest shelf lives.¹³ Although the state of the art at the present time is more advanced with regard to plants and microorganisms, genetic engineering is also being used on various species of animal life, including vertebrates.¹⁴ As the genes of more species are mapped and become known, the process will become increasingly precise and powerful.

One of the most well-known examples of genetic engineering is "Bt" corn and other Bt crops.¹⁵ Mixtures of Bt, a bacterium that is toxic to insects, have been used to spray crops for over fifty years. When used conventionally, however, the Bt toxin generally loses its effectiveness in the environment within a few days, sometimes necessitating frequent spraying.

Conventional crops now have been modified to incorporate genetic material from the Bt bacterium. In transgenic crops, Bt toxin is

DNA: A SHORT COURSE 58–90 (1983); Larry Thompson, *Are Bioengineered Foods Safe?: Methods for Genetically Engineering a Plant*, FDA CONSUMER, Jan.–Feb. 2000, at 18, 22.

10. See FIELD TESTING, *supra* note 5, at 87 (describing ice-nucleation-deficient *Pseudomonas* mutants).

11. See *Diamond v. Chakrabarty*, 447 U.S. 303, 305 (1980) (describing a type of bacterium that thrives on a diet of crude oil); David A. Hopwood, *The Genetic Programming of Industrial Microorganisms*, SCI. AM., Sept. 1981, at 90, 97 (same).

12. See Arnold L. Demain & Nadine A. Solomon, *Industrial Microbiology*, SCI. AM., Sept. 1981, at 66, 74 (stating that interferon and insulin can be produced by rDNA technology and that, as a result, the cost of interferon may decrease from about \$2 million for fifty impure milligrams to as little as pennies per pure milligram).

13. See Karen L. Werner, *Increased Yields, Reduced Insecticide Use Seen as Result of Use of Engineered Crops*, 22 Int'l Env't Rep. (BNA) 626 (July 21, 1999). See generally STEPHEN NOTTINGHAM, *EAT YOUR GENES: HOW GENETICALLY MODIFIED FOOD IS ENTERING OUR DIET* 37–79 (1998) (discussing properties of genetically engineered foods).

14. See Jerry E. Bishop, *A Biotech Primer: Understanding the Tools of the Trade*, WALL ST. J., May 20, 1994, at R5.

15. See Earp, *supra* note 4, at 1650–51.

Bacillus thuringiensis (B.t.) is a bacterium found in soil and on plants. Under low nutrient conditions, B.t. produces a dormant spore and [a particular type of] protein, which is highly toxic to particular types of insects. When a susceptible insect ingests the spore and its accompanying crystal, it becomes paralyzed and dies. . . . By isolating the gene that encodes this toxin and introducing it into plants, researchers [have created genetically engineered plants that contain] the insecticidal toxin in their tissues, thus making those plants resistant to insect damage.

Id. (citations omitted).

continuously produced and is protected from the elements, thereby retaining its ability to kill insect pests during the entire growing season. Also, the toxin is expressed in essentially every part of the plant, including internal tissues that are difficult to protect with topically applied pesticides. This internal toxin production supplies protection against pests that are internal feeders such as the pink bollworm in cotton and the European corn borer in corn. The result is crops that contain their own chemical-free protection from insect pests.

Particularly in regions such as the tropics and near-tropics, where insect pests pose a major threat to modern monocultural agriculture, such Bt crops can greatly increase food production while significantly decreasing the need for costly and environmentally harmful chemical pesticides.¹⁶ Commercial transgenic varieties of corn, cotton, and potato that express the Bt protein have been successful in reducing the incidence of pest damage and in reducing use of chemical pesticides in many cases.¹⁷ First approved for sale in 1996, Bt corn has swiftly gained a large market share, reaching about one-third of the U.S. crop by 1999.¹⁸ But the constant presence of Bt toxin in genetically engineered crops throughout the growing season has led to concerns about its persistence in the environment and the increased probability of pests evolving to overcome the protection mechanism.¹⁹

Another prominent use of genetic engineering in contemporary agriculture is "Roundup-Ready" crops. These plants are genetically modified to be resistant to the common herbicide glyphosate, so that when fields are treated with such potent herbicides the crops will be unharmed and only the "weeds" will be destroyed.²⁰ Roundup-Ready crops have proven so successful that they comprised more than half of the U.S. soybean crop in 1999.²¹

16. See Werner, *supra* note 13, at 626. One estimate maintains that, in 1998, 4 billion more pounds of corn were produced as a result of Bt technology than would have been grown without it, and about 2 million fewer acres of corn fields were treated with chemical insecticides. *Id.*

17. COMM. ON GENETICALLY MODIFIED PEST-PROTECTED PLANTS, NAT'L RESEARCH COUNCIL, GENETICALLY MODIFIED PEST-PROTECTED PLANTS: SCIENCE AND REGULATION 33 (2000), available at <http://www.nap.edu/openbook/0309069300/html/R1.html> [hereinafter NRC 2000].

18. See Rick Weiss, *EPA Restricts Gene-Altered Corn in Response to Concerns; Farmers Must Plant Conventional 'Refuges' to Reduce Threat of Ecological Damage*, WASH. POST, Jan. 16, 2000, at A2.

19. NRC 2000, *supra* note 17, at 28.

20. See Kristin Dawkins, *Unsafe in Any Seed: U.S. Obstructionism Defeats Adoption of an International Biotechnology Safety Agreement*, MULTINATIONAL MONITOR, Mar. 1999, at 10, 11.

21. *Id.*

There is a key difference between such examples of genetic engineering and the traditional breeding techniques, a difference that is at the heart of the enormous potential benefits, as well as the risks, of modern genetic modification. Whereas the venerable Mendelian cross-breeding techniques were limited to members of the same species, modern genetic engineering allows us to “cross the species barrier” and place portions of DNA from one species into the DNA of a different species.²² In dramatic contrast to traditional cross-breeding, genetic engineering can cross barriers even greater than the species divide. Genetic material can be transferred between organisms from different genera, families, orders, classes, phyla, and even kingdoms.²³ The evolutionary chasms separating members of such widely disparate taxonomic groups could never have been crossed without the aid of modern genetic engineering.²⁴ This technique greatly expands our power to modify life forms far beyond the boundaries of natural processes and to shift desired genetic traits between species that could never mate or produce viable offspring in nature.²⁵

Transgenic crops were first planted commercially in the 1995 growing season. Since then, their use has increased rapidly. In 1997, 20.3 million acres of transgenic crops were planted in the United States. This rose to 50.2 million acres in 1998 and 70 million in 1999. A total of 98 million

22. NOTTINGHAM, *supra* note 13, at 5.

23. NRC 2000, *supra* note 17, at 23–24.

24. See FIELD TESTING, *supra* note 5, at 13–14; Clifford Grobstein, *The Recombinant-DNA Debate*, SCI. AM., July 1977, at 22, 24.

25. The concept of “species” is more complex than most people realize:

It may surprise non-scientists to hear that the very notion of a species has long been the subject of intense debate [and disagreement] within the scientific community. Most of us are accustomed to identifying “species” by visual characteristics, and to labeling them with the common names we learned as children. For example, when we see a large day-flying insect with orange-and-black wings of a familiar pattern, we habitually categorize it as a “Monarch butterfly.” [We] are probably unaware of its proper scientific name, *Danaus plexippus*, and we are certainly not inclined systematically to evaluate its morphology through use of a taxonomic key, or to study its ability to reproduce with other similar and dissimilar organisms. But for [scientific professionals], there is a great deal of controversy even as to whether the concept of the species has validity.

The most commonly taught concept is that of the biological species. In greatly simplified form, the concept holds that a species is a population of organisms that can at least potentially breed with one another, but do not breed with other populations. Many scientific professionals reject this concept, however, arguing that it disregards and obscures the phylogenetic relationships between different species. As an alternative, the phylogenetic concept has been proposed that defines species as the smallest recognizable cluster of individuals that share a common trait and have a common pattern of ancestry. Still other scientists contend that this approach would meaninglessly designate too many groups as species. A third approach, the genealogical concordance method, compares large numbers of gene sequences in various organisms, attempting to measure “genetic drift” [that occurs between distinct species]. Through this means, it is hoped that reproductive isolation and phylogenetic history will both be given their due when identifying species.

John Charles Kunich, *The Fallacy of Deathbed Conservation Under the Endangered Species Act*, 24 ENVTL. L. 501, 505–57 (1994) (footnotes and citations omitted).

acres were planted with transgenic crops worldwide in 1999.²⁶ There are indications that this has contributed to significant reductions in the use of conventional chemical pesticides.²⁷ For example, as a result of the planting of genetically engineered cotton, a reduction of 2 million pounds of chemical insecticide was achieved from 1995 to 1998, a decrease of over 5 million acre-treatments.²⁸

In a remarkably brief period of time, genetically engineered organisms have gained a position of prominence in the marketplace and produced annual revenues in the tens of billions of dollars.²⁹ For example, beginning from a baseline of zero in 1996, a majority of U.S. soybean plantings are now genetically modified to carry resistance to herbicides, and the market share at one time was expected to grow rapidly (but now may be in decline).³⁰ Some studies indicate that genetically engineered varieties now constitute approximately 32% of corn and 38% of soybeans grown in the United States and up to 58% of Canada's canola oil output.³¹ One projection holds that virtually all crops in the United States will, by the year 2010, either be genetically modified or mixed with genetically modified products.³² Clearly, a scientific and agricultural revolution is underway. But, as with political revolutions, there is another side to the matter, which has already become a full-fledged counterrevolution.

II. PUBLIC OPPOSITION TO GENETIC ENGINEERING

The counterrevolution has manifested itself both in consumer resistance and in various acts of protest. Although until recently there was

26. NRC 2000, *supra* note 17, at 32–33.

27. A number of traditional chemical pesticides are considered human carcinogens. Therefore, human health benefits as well as environmental advantages could arise from reductions in the application of chemical pesticides due to the commercial use of transgenic pest-protected crops. *Id.* at 63.

28. LEONARD P. GIANESSI & JANET E. CARPENTER, NAT'L CTR. FOR FOOD & AGRIC. POL'Y, AGRICULTURAL BIOTECHNOLOGY: INSECT CONTROL BENEFITS (July 1999), http://www.bio.org/food&ag/ncfap/ag_bio.htm.

29. Earp, *supra* note 4, at 1635 (citing, among others, G. STEVEN BURRILL & KENNETH B. LEE, BIOTECH 94: LONG-TERM VALUE, SHORT-TERM HURDLES viii (1993) (Ernst and Young's eighth annual report on the biotechnology industry)).

30. See Nigel Williams, *Agricultural Biotech Faces Backlash in Europe*, 281 SCIENCE 768, 768 (1998); Weiss, *supra* note 18.

31. See James Walsh, *Alien Seed?: As Genetically Engineered Crops Begin to Enter the Food Chain, Europe Remains a Holdout Against What Eco-Warriors Call "Frankenstein Foods"*, TIME (Int'l ed.), Aug. 24, 1998, at 38, 1998 WL 14835316.

32. See Guy de Jonquie`res, *Genetically Modified Trade Wars: Widespread Worries in Europe About Genetically Altered Crops Could Result in a Transatlantic Trade War and Even the Worldwide Marginalisation of European Farming*, FIN. TIMES (London), Feb. 18, 1999, at 15.

little evidence of a counterrevolution in the United States, the situation in Europe has been quite different. For years, public opinion polls have indicated that high percentages of Europeans favor mandatory labeling, complete separation from “natural” products, and even an outright ban of genetically engineered food products.³³ The pejorative nicknames “Frankenstein foods” and “Frankenfoods”³⁴ have been widely used in reference to genetically engineered products in Europe, where even Prince Charles has publicly voiced his opposition to the new technologies.³⁵

Protests have ranged from mild to violent. In Great Britain, some demonstrators stood naked on London rooftops to protest what they viewed as a genetic cover-up, while others carried large inflatable Frankenstein monsters through the streets.³⁶ To highlight the lack of consistent labeling standards, British consumers and Greenpeace activists filled supermarket carts with food and demanded that the cashiers tell them which products contained genetically engineered organisms.³⁷ On the more destructive side, environmental activists in Ireland dug up fields of genetically engineered sugar beets in late 1997.³⁸ Portions of a field of herbicide-resistant oilseed rape plants were similarly destroyed near London.³⁹

Recently, acts of “eco-terrorism” have also taken place in the United States. The Michigan State University agriculture building was burned by

33. See Richard Kamchen, *Gene-Altered Foods Face Uphill Battle in EU*, J. COM., Nov. 5, 1998, at 4A, 1998 WL 20945001 (citing a British poll reporting that 85% of respondents wanted genetically engineered foods to be completely segregated from other products and 77% supported a total ban of genetically engineered foods).

34. Phillip J. Longman, *Baby Food Fight Averted*, U.S. NEWS & WORLD REP., Aug. 9, 1999, at 43, 43; Richard A. Melcher, Amy Barrett, John Carey, Geir Smith & Jack Ewing, *Fields of Genes*, BUS. WK., Apr. 12, 1999, at 62, 65.

35. Prince Charles wrote in a newspaper article in 1998 that he would never knowingly eat or serve genetically modified food. He added, “I happen to believe that this kind of genetic modification takes mankind into realms that belong to God, and to God alone.” HRH the Prince of Wales, *Seeds of Disaster: HRH the Prince of Wales, Who Farms Organically, Says the Genetic Modification of Crops Is Taking Mankind into Realms That Belong to God, and God Alone*, DAILY TELEGRAPH (London), June 8, 1998, at 16, 1998 WL 3022871.

36. Julia Flynn, John Carey & William Echikson, *Seeds of Discontent*, BUS. WK., Feb. 2, 1998, at 62, 62.

37. Walsh, *supra* note 31.

38. See Flynn et al., *supra* note 36, at 62.

39. See Walsh, *supra* note 31. Following the incident, the British Agriculture Ministry ordered the destruction of the remainder of the field, because it was discovered that the crop had pollinated other nearby plants. Christopher Leake, “*Superweed*” Scare in Test Crop Blunder, MAIL ON SUNDAY (U.K.), Oct. 25, 1998, at 17, 1998 WL 14344859. See also Tom Paulson, *Dispute Over Genetically Altered Food: For Public, It's a Big Harvest vs. Safety and Control Issues*, SEATTLE POST-INTELLIGENCER, Nov. 23, 1999, at A1 (describing French farmers' protests against United States' high-technology agricultural techniques, in which the farmers deposited manure in front of several McDonald's fast-food restaurants).

arsonists on New Year's Eve, 1999, to destroy research being conducted on genetically engineered sweet potatoes, corn, and other crop vegetables.⁴⁰ During the latter half of 1999, environmentalist groups such as Future Farmers and Reclaim the Seeds destroyed genetically engineered crops on virtually a weekly basis from Maine to California, including a research cornfield at the University of California at Davis.⁴¹ The controversy is now reflected in U.S. commerce as well, with at least two major "natural foods" supermarket chains having banned foods containing genetically engineered ingredients.⁴²

There are some indications that the cause of banning or restricting genetic engineering, particularly with regard to food products, may be fast becoming a popular political position for some famous individuals in the United States. For example, a group of celebrity and award-winning American chefs helped to launch the "Keep Nature Natural Campaign" on May 8, 2000. These chefs had earlier urged a moratorium on the use of genetically engineered foods, beginning with their own exclusive restaurants. The campaign demands labeling and stricter safety and environmental regulations of genetically engineered foods. In addition to the celebrity chefs, a coalition of more than fifty consumer, environmental, scientific, farm, and health groups, plus the Whole Foods Market and Wild Oats natural food retailers, has joined the campaign. At the heart of the campaign is a petition issued by the Center for Food Safety, calling for the establishment of stringent premarket safety testing regulations and mandatory labeling for genetically engineered foods. The Center for Food Safety also has ongoing lawsuits against both the Food and Drug Administration (FDA) and the Environmental Protection Agency (EPA) concerning the safety of genetically engineered foods.⁴³

The opposing camp has attempted to respond with its own celebrities, although the pro-transgenic position has not been able to attract as many famous adherents. A group of agricultural scientists from the developing nations of the world criticized the celebrity chefs' call for a moratorium, citing the importance of biotechnology to ensuring adequate crop plants for

40. John J. Miller, *Against the Grain: Enviro-Terrorists Target Farms*, NAT'L REV., Mar. 6, 2000, at 22, 22.

41. *Id.* at 22-24. These groups have used Internet web sites to share information on how to uproot or burn crop fields effectively. *Id.* at 22.

42. Whole Foods Market, Inc., and Wild Oats Markets, Inc., have banned such products. See Melinda Fulmer, *2 Chains Ban Engineered Foods*, L.A. TIMES, Dec. 31, 1999, at C1.

43. *Nations Top Chefs Call for Labeling and Stricter Safety and Environmental Regulations of Genetically Engineered Food*, BUS. WIRE, May 8, 2000, available at LEXIS, News Library, Business Wire File.

less prosperous nations. A “Declaration of Scientists in Support of Agricultural Biotechnology” was circulated, and has been signed by more than 2,000 scientists from around the world. Nobel Prize winners James Watson and Norman Borlaug are among the signatories.⁴⁴

The reasons underlying public opposition can be categorized in two main groups. First, from an environmental or ecological standpoint, some people contend that genetically engineered organisms could drastically disrupt the natural ecosystems into which they are either intentionally released or into which they might accidentally escape.⁴⁵ Second, considering the issue from a public-health perspective, some persons argue that there may be health risks, whether short term or long term, to consumers of genetically engineered foods and food products, and that those risks are at present unknown and unknowable.⁴⁶

Is there a rational basis in scientific fact for this counterrevolution against genetic engineering? Or is the opposition merely overreacting to minor problems because of an unfounded fear of the unknown?

III. SCIENTIFIC OBJECTIONS TO GENETIC ENGINEERING

Very little objective evidence currently exists that supports the public’s fears.⁴⁷ The potential for transgenic plants “to pose a threat to human or animal health must be considered against the background of existing information. To date no such effects have been shown with commercialized transgenic crop plants.”⁴⁸ Given the extremely recent advent of the phenomenon of modern genetic engineering, however, and

44. See Press Release, AgBioWorld, Nobel Prize Winners Endorse Agricultural Biotechnology: James Watson and Norman Borlaug Sign Pro-Biotechnology Declaration (Feb. 7, 2000), <http://www.AgBioWorld.org/pr/watson.html>.

45. See John Stephen Fredland, Note, *Unlabel Their Frankenstein Foods!: Evaluating a U.S. Challenge to the European Commission’s Labeling Requirements for Food Products Containing Genetically-Modified Organisms*, 33 VAND. J. TRANSNAT’L L. 183, 187–88 (2000).

46. See *id.* at 188–89. Some members of the general populace also fear that the corporations that produce genetically engineered products would allow the profit motive to override any ecological or health concerns. *Id.* See also Valerie M. Fogleman, *Regulating Science: An Evaluation of the Regulation of Biotechnology Research*, 17 ENVTL. L. 183, 195–96 (1987) (summarizing the public’s fears regarding biotechnology).

47. The 1987 National Academy of Sciences white paper *Introduction of Recombinant DNA-Engineered Organisms into the Environment* stated that the risks presented by all types of transgenic organisms are the “same in kind” as those associated with the introduction of unmodified organisms and life forms modified by other methods, and that there was no evidence of unique hazards in the use of genetic engineering or in the movement of genes between unrelated organisms. NRC 2000, *supra* note 17, at 42–43.

48. *Id.* at 67–68.

the very short amount of time such organisms have been widely produced, used, and consumed, the relative paucity of experiential evidence is not dispositive. It is precisely this very newness that has led some commentators to urge a cautious approach, lest unforeseen environmental hazards manifest themselves only after many years of intensive penetration of transgenic organisms into the environment.⁴⁹ Our lack of prolonged experience in this field means that there are many aspects of the practical, real-world application of genetic engineering that remain conjectural.⁵⁰ In the absence of extensive empirical evidence, therefore, it is necessary to examine the theoretical scientific problems to gain some perspective on what might happen in a future world in which the food industry is dominated by genetically engineered crops and livestock.

The incident concerning the herbicide-resistant oilseed rape plant provides a small window into one of the principal scientific difficulties with genetically engineered life forms.⁵¹ There, the British government ordered the destruction of an experimental field of herbicide-resistant oilseed rape plants because these genetically engineered forms had

49. See, e.g., Symposium, *Transgenic Agriculture: Biosafety and International Trade*, 4 B.U. J. SCI. & TECH. L. 4 para. 18 (1998) (comments of Professor Sheldon Krinsky). Professor Krinsky states:

Simply because scientists have higher levels of skill at creating technological applications for the fields of biology and agriculture does not mean that they necessarily have the insight to foretell, or predict the consequences of the technology, such as the properties of a living modified organism. The result is an unfounded leap from understanding genotypes to thinking we understand phenotypes to believing we can predict ecological impacts. There is no knowledgeable basis for moving from understanding genotypes to predicting ecological effects.

Id. (citations omitted).

Professor Krinsky pointed out that transgenic plants were initially presumed to pose little if any environmental danger, because herbicide-resistant crops were unlikely to develop the invasive properties of weeds, but that this was subsequently shown to be false. "Three years later, researchers found an environmental problem: the genetically engineered herbicide resistance may have spread to nearby weeds through ordinary cross-pollination." *Id.* para. 18 n.57.

50. See Robin A. Chadwick, Note, *Regulating Genetically Engineered Microorganisms Under the Toxic Substances Control Act*, 24 HOFSTRA L. REV. 223, 242-44 (1995). Due to our limited experience with both genetic engineering and the environmental release of transgenic organisms, only a few such organisms have been observed in the environment, i.e., outside controlled, laboratory-type conditions. Also, little is known about the biochemical determinants of competitiveness in nature, or about the exchange of genetic material between closely or distantly related organisms under natural conditions. It is difficult to evaluate, in advance of extensive experimentation, the prospect that any given organism will successfully colonize an environment, in part because the environment itself is ever changing and differs from place to place. There is a complex interplay of factors at work, such that the success of an organism in any ecosystem at any given point of time and under any given set of circumstances cannot be predicted solely on the basis of the organism's genetic structure and composition. Moreover, even the simplest microorganisms are extremely complex on the molecular and genetic level, with many structures and functions remaining a mystery. *Id.*

51. See Leake, *supra* note 39, at 17.

successfully pollinated nearby “natural” plants; such spread might have created a new breed of “superweeds” resistant to herbicides and capable of displacing other plant life.⁵²

Theoretically, the problem is not easily dismissed. Plants, animals, and microorganisms are genetically engineered to give them certain advantages, and among those advantages are resistance to herbicides, insecticides, natural pests, unfavorable weather conditions, and other impediments to naturally occurring organisms. Additionally, the altered organisms can be given faster growth rates, increased productivity and reproductive potential, larger size, and other advantages.

When confined to commercially produced species under controlled conditions, these modifications are generally thought to be very positive developments that translate into more and better food at lower prices. Indeed, it can be persuasively argued that genetic engineering is an environmentally beneficial practice, because fewer acres of irreplaceable natural land will need to be cleared for agriculture, and less herbicide, fungicide, and insecticide will be required.⁵³ Under this view, more productive, more self-protective crops and livestock should translate into significant ecological benefits. Natural habitat can be conserved for wild species and the preservation of biodiversity rather than converted to inefficient agricultural uses, and greatly diminished quantities of pesticide would be introduced into the environment, thus lessening the attendant unintended harms to plants and wildlife that accompany pesticide use.⁵⁴

On the other hand, if the genetically engineered “super species” escape into the general environment, their artificially enhanced characteristics could give them enormous advantages over native life forms and make them very difficult to control through conventional means. Escape could eventuate either by the genetically modified forms themselves entering and colonizing the neighboring habitats, or by combining with their wild relatives which in turn would proliferate in the environment. This is chiefly a possibility in the case of plants that are pollinated by the wind or by insects; the gametes from a genetically modified plant would be distributed and dispersed in a largely uncontrollable fashion by these instruments of nature, with somewhat unpredictable consequences.

52. *Id.*

53. Mae-Wan Ho, *Diversity; the Basis of Food Security*, 28 *ECOLOGIST* 182, 184 (1998) (reviewing MIGES BAUMANN, JANET BELL, FLORIANEE KOECHLIN & MICHEL PIMBERT, *THE LIFE INDUSTRY: BIODIVERSITY, PEOPLE AND PROFITS* (1996)).

54. *Id.*

The escape of novel resistance traits into free-living populations of wild relatives is often cited as an undesirable consequence of commercial-scale use of transgenic crops.⁵⁵ The National Research Council, in its 2000 report, stated:

The ecological and evolutionary benefits conferred by crop genes that enter wild populations are difficult to evaluate. This is an issue that lies at the crux of concerns about gene flow from transgenic and conventional crops. We know little about the extent to which insects and diseases limit wild, weedy populations that are sexually compatible with cultivated species. Critics of biotechnology argue that the spread of beneficial traits could quickly lead to the spread of weeds; advocates of transgenic crops maintain that this risk is small or nonexistent. Empirical data with which to address the question are lacking.⁵⁶

In the event of either escape or cross-breeding, the same advantageous phenotypic traits that were transferred to these organisms as desirable features could then allow them to out-compete native species, possibly to the exclusion of all others within certain geographical limits. Over time, the modified species or their evolutionary descendants might drive out other life forms entirely, especially those with an already tenuous grasp on a limited ecological niche such as endangered or threatened species. And if they are resistant to pesticides, as many genetically engineered life forms are, these organisms would present a difficult challenge in the path of any human attempt to curtail their expansion.⁵⁷

A corollary of this problem is the threat of “genetic erosion,” i.e., a loss of diversity within the gene pool.⁵⁸ Theoretically, genetically engineered organisms might contribute to genetic erosion in their environs by reducing the number of highly variable naturally occurring life forms available for cross-breeding. If the transgenic strains crowd out the native varieties, biodiversity would be diminished, with concomitant reduction in the raw material available for future natural selection.⁵⁹ With reduced

55. NRC 2000, *supra* note 17, at 83–84. See also Ingrid M. Parker & Peter Kareiva, *Assessing the Risks of Invasion for Genetically Engineered Plants: Acceptable Evidence and Reasonable Doubt*, 78 *BIOLOGICAL CONSERVATION* 193, 193 (Special Issue 1996); Alan F. Raybould & Alan J. Gray, *Will Hybrids of Genetically Modified Crops Invade Natural Communities?*, 9 *TRENDS ECOLOGY & EVOLUTION* 85, 85 (1994).

56. NRC 2000, *supra* note 17, at 87–88.

57. See Dawkins, *supra* note 20, at 11. Roundup-Ready crops, if cross-bred with naturally occurring weeds, could spawn an herbicide-resistant strain of “superweed” that might cause a variety of harmful effects to the environment. *Id.*; Magen Griffiths, Recent Development, *Biosafety Protocol*, *COLO. J. INT’L ENVTL. L. & POL’Y* 1998 Y.B. 113, 113–14 (1999).

58. Dawkins, *supra* note 20, at 11.

59. *Id.*

biodiversity comes lessened flexibility to respond to new and different evolutionary pressures, and diminished overall vigor of the ecosystem.

Some types of genetically engineered organisms, such as Bt corn and other Bt crops, present an additional potential threat. Because of their general nonspecific toxicity to insects, these plants may kill not only insect pests but also aesthetically desirable, utilitarian-beneficial, and commercially profitable insects and other “non-target” species that also happen to feed on them.⁶⁰ A famous example is the case of the Monarch butterfly.

A widely reported study found that pollen from Bt corn could threaten Monarch butterfly larvae, which feed on the milkweed plants often found near fields of cultivated corn. Although the larvae do not eat the corn plant itself, the experiment indicated that pollen from Bt corn can be carried by wind up to sixty meters away from the corn stalk that produced it and can coat nearby milkweed plants.⁶¹ Monarch larvae reared on milkweed leaves dusted with pollen from Bt corn were found to eat less food, have a slower growth rate, and exhibit a higher mortality rate than similar larvae fed milkweed leaves dusted with non-Bt corn pollen or leaves without any pollen.⁶²

Another possible risk arising from widespread use of Bt crops is the development of resistant insects. This is akin to the problem of resistant strains of disease agents evolving in response to overuse of antibiotics. If Bt crops are widely employed for a prolonged period, there is a chance that some species of insect pests may adapt and produce strains that are immune to the Bt toxin. The resulting insect pests could be much more harmful and difficult to control than their ancestors, necessitating use of greater quantities of more environmentally deleterious chemical insecticides.⁶³

More speculative, but still potentially significant, is the risk that some escaped super species might eventually mutate, cross-breed, or otherwise

60. *Id.*

61. John E. Losey, Linda S. Rayor & Maureen E. Carter, *Transgenic Pollen Harms Monarch Larvae*, 399 NATURE 214, 214 (1999). This study has become controversial; in light of other reported findings, its results must be viewed as preliminary at this stage. *See, e.g.*, NRC 2000, *supra* note 17, at 76–77.

62. Losey et al., *supra* note 61, at 214.

63. *See* Dawkins, *supra* note 20, at 11. In recognition of this problem, the EPA promulgated new restrictions on Bt corn on Jan. 14, 2000. The new rules mandate that farmers plant a “structured refuge” of non-Bt corn near their fields of Bt corn to reduce Bt effects on insects and “delay” the evolution of resistant pest populations. There is now a requirement that farmers plant twenty to fifty percent of their corn acreage with conventionally bred corn. NRC 2000, *supra* note 17, at 35.

evolve into as yet unknown new variants.⁶⁴ These future-generation descendants of the original genetically engineered organisms theoretically could be even more competitive, control-resistant, and otherwise environmentally harmful. Particularly in the case of microorganisms, their extremely rapid reproductive rate and other characteristics would render this possibility, as well as the prospect of new and unpredictable phenotypic traits, a considerable concern.⁶⁵ Traits very different from those of the parent strain may emerge after release of microorganisms into the environment.⁶⁶

Again, there is a contrary scientific position. Some scientists have argued that genetic engineering actually offers greater safety and predictability than “natural” methods of cross-breeding because of the greater precision offered by modern gene-splicing techniques.⁶⁷ Conventional cross-breeding usually selects for traits that are controlled by several genes, so such techniques may be more likely simultaneously and inadvertently to select for an additional undesirable characteristic than would the introduction of a single gene or even a small number of genes through genetic engineering. In fact, both animal and plant breeding of the traditional type have yielded examples of accidental selection of undesirable characteristics.⁶⁸ Rather than crudely transferring large numbers of genes on a largely trial-and-error basis over numerous generations, genetic engineering allows the movement of only the specific genes desired, usually in one efficient step. The U.S. National Research

64. See Thomas P. Redick, William A. Reavey & Dirk Michels, *Private Legal Mechanisms for Regulating the Risks of Genetically Modified Organisms: An Alternative Path Within the Biosafety Protocol*, 4 ENVTL. LAW. 1, 7 (1997).

65. See STAFF OF HOUSE SUBCOMM. ON INVESTIGATIONS & OVERSIGHT, 98TH CONG., THE ENVIRONMENTAL IMPLICATIONS OF GENETIC ENGINEERING 19 (Comm. Print 1984) [hereinafter 1984 STAFF REPORT]. An incident has been reported in which two microorganisms, neither of which was ordinarily pathogenic in nature, were combined. To the surprise of the investigators, the results included one pathogenic isolate and another isolate that killed tree seedlings. See *id.*

66. See *id.*; EDWARD A. BIRGE, BACTERIAL AND BACTERIOPHAGE GENETICS 378 (3d ed. 1994). For example, cloned DNA could be “perfectly harmless in the bacterium in which it was originally cloned but might confer unwanted antibiotic resistance, pathogenicity, and so forth, on other bacteria.” *Id.*

67. See ORG. FOR ECON. CO-OPERATION AND DEV., RECOMBINANT DNA SAFETY CONSIDERATIONS 31 (1986). “Transgenic methods can improve the precision of plant breeding and lead to many advantages over current pest control methods. With careful planning and appropriate regulatory oversight, commercial cultivation of transgenic pest-protected plants is not generally expected to pose higher risks and may pose less risk than other commonly used chemical and biological pest-management techniques.” NRC 2000, *supra* note 17, at 45–46.

68. NRC 2000, *supra* note 17, at 68. See also Mendel Friedman & Gary M. McDonald, *Potato Glycoalkaloids: Chemistry, Analysis, Safety, and Plant Physiology*, 16 CRITICAL REV. PLANT SCI. 55 (1997).

Council has endorsed this view, stating that “[w]ith organisms modified by molecular methods[,] we are in a better, if not perfect, position to predict the phenotypic expression.”⁶⁹

The other main objection to genetically engineered species, i.e., health risks for consumers, is at present only a matter of conjecture. Although human health risks associated with transgenic pest-protected plants tend to be potential rather than apparent, some regard these potential risks as important. The risks are generally related to the possibility of introducing new allergens or toxins into food-plant varieties or into pollen, or the possibility that previously unknown protein combinations now being produced in food plants will have unforeseen secondary effects.⁷⁰

Some people have asserted that these novel life forms might expose consumers to new or unexpected allergens without effective treatment and may disturb the normal balance of microorganisms residing within the human digestive tract.⁷¹ Although allergenicity caused by transgenic gene products has been highlighted as a human health concern, genetic engineering can also be used to reduce the allergenic risks associated with the food supply.⁷² Despite the fact that there does not appear to be any evidence that harmful allergic responses have happened or are likely to happen, it has been suggested that the recent unfortunate controversy surrounding “mad cow disease” has predisposed European consumers to be skeptical regarding scientific manipulation of their food sources.⁷³

To what extent has the current array of environmental laws effectively guarded against any or all of these potential hazards, while also allowing for the safe use of highly promising and beneficial new products? The answer is uncertain, as the next Part shows.

69. FIELD TESTING, *supra* note 5, at 14.

70. See NRC 2000, *supra* note 17, at 62–63; Rebecca J. Goldberg & Gabrielle Tjaden, *Are B.T.K. Plants Really Safe to Eat?*, 8 *BIO/TECHNOLOGY* 1011, 1012–13 (1990) (discussing ways to investigate possible side effects of Bt.k.).

71. Walsh, *supra* note 31. See also Erik Millstone, Eric Brunner & Sue Mayer, *Beyond “Substantial Equivalence”*, 401 *NATURE* 525 (1999) (arguing that genetically engineered foods should be treated in the same way as novel chemical compounds such as pharmaceuticals, pesticides, and food additives, i.e., requiring a range of toxicological tests, the results of which would be used to set acceptable daily intake amounts).

72. NRC 2000, *supra* note 17, at 35–36.

73. See Steven Milloy, *European Caution Carries Risks: A Badly Defined EU Principle Designed to Promote Safety Is Being Used to Block Technologies and Trade*, *Argues Steven Milloy*, *FIN. TIMES* (London), Mar. 10, 2000 (Am. ed.), at 11.

IV. THE REGULATION OF GENETICALLY ENGINEERED ORGANISMS UNDER CURRENT ENVIRONMENTAL LAW

At present, the environmental risks posed by genetically engineered organisms are not addressed in a coherent manner. There is no single federal statute that governs the subject matter. The regulatory regime that does exist only confronts a few aspects of the issue, and then only in a piecemeal, haphazard fashion. And there is no federal agency with overarching responsibility for the topic; rather, multiple agencies are charged with monitoring disparate portions of it, with no effective means for ensuring comprehensive and consistent coverage. Consequently, there are sizable gaps in coverage, with the concomitant risk of significant harms slipping through the cracks and into the environment. Additionally, proponents of new and potentially important genetically engineered “products” are forced to navigate a confusing maze of agencies and statutes, with resulting inefficiency and needlessly steep economic and opportunity costs and delays for industry and the general public.⁷⁴

The patchwork regulatory scheme is perhaps understandable given the relative newness of the concept of modern genetic engineering and the even more recent advent of large-scale application of the new technology. Also, because the subject matter is unique—living organisms designed by humans for human purposes—there is no easy fit within any of the statutes that were drafted to handle more traditional environmental concerns. Congress is accustomed to dealing with challenges in the well-established environmental categories of clean air, clean water, hazardous waste, and the like, but genetically engineered plants, animals, and microorganisms present a very different set of issues.

The following is a summary and analysis of the existing legal framework that applies to the environmental aspects of modern genetically engineered organisms. This presentation has been made as systematic as possible under the circumstances, but, owing to the multiple statutes and agencies involved and the punctuated gaps in coverage, it is somewhat difficult to synthesize a concise synopsis.

In 1986, a White House committee formed under the auspices of the Office of Science and Technology Policy (OSTP) published the Coordinated Framework for the Regulation of Biotechnology. The Framework is predicated on the principle that techniques of genetic

74. See OFFICE OF TECH. ASSESSMENT, 100TH CONG., NEW DEVELOPMENTS IN BIOTECHNOLOGY: U.S. INVESTMENT IN BIOTECHNOLOGY 11 (1988).

engineering are not inherently risky and that genetic engineering should not be regulated as a process, but rather that the products of biotechnology should be regulated in the same way as products of any other technology. The Framework sketched in somewhat general terms the roles and policies of federal agencies as related to genetic engineering.⁷⁵

At present, no fewer than three major federal agencies have significant roles in regulating the use of genetically engineered organisms: the EPA, the United States Department of Agriculture (USDA) and its Animal and Plant Health Inspection Service (APHIS), and the FDA. Additionally, some responsibility also resides in the National Institutes of Health (NIH), the National Science Foundation (NSF), and the Occupational Safety and Health Administration (OSHA).⁷⁶ Because of the absence of new legislation specifically focused on the issue, these organizations by default have relied on the existing federal statutes to promulgate regulations and develop policies regarding the environmental ramifications of genetic engineering.⁷⁷ The following sections of this Part outline the principal statutes in this area, including an analysis of each as to its efficacy in dealing with the unique characteristics of genetically engineered organisms.

A. TOXIC SUBSTANCES CONTROL ACT

The EPA administers the Toxic Substances Control Act (TSCA)⁷⁸ to test and to classify “chemical substances” for “unreasonable risk” to health and the environment before those substances are produced.⁷⁹ TSCA mandates that persons who intend to manufacture or to process a new chemical substance must first submit a formal notice⁸⁰ to the EPA detailing

75. NRC 2000, *supra* note 17, at 25–26.

76. See Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302 (Office of Sci. & Tech. Policy June 26, 1986). The Coordinated Framework is basically an interagency cooperative agreement intended to integrate the functions of these federal agencies with regard to the regulation of biotechnology, including genetic engineering. *Id.* at 23,302–03. It states that “agencies will seek to operate their programs in an integrated and coordinated fashion and together should cover the full range of plants, animals and microorganisms derived by the new genetic engineering techniques.” *Id.* at 23,303. Agency jurisdiction is primarily predicated on the type and function of the genetically engineered organism and the intended use of the resulting product. See *id.* at 23,304.

77. See generally Robert Saperstein, Comment, *The Monkey’s Paw: Regulating the Deliberate Environmental Release of Genetically Engineered Organisms*, 66 WASH. L. REV. 247 (1991) (discussing the inadequacy of current regulatory schemes for providing appropriate responses to environmental release of genetically engineered organisms).

78. 15 U.S.C. §§ 2601–2692 (1994).

79. *Id.* § 2604(a)–(f). TSCA defines “chemical substance” as any “organic or inorganic substance of a particular molecular identity,” which includes “any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature.” *Id.* § 2602(2)(A).

80. *Id.* § 2604(a).

the structure, proposed use, production amount, byproducts, disposal methods, and all existing data concerning the environmental and health effects of the chemical substance.⁸¹

The EPA is allotted ninety days within which to evaluate the premanufacture notification (PMN) so as to assess whether the chemical substance poses an “unreasonable risk of injury to health or to the environment.”⁸² If the EPA makes such a finding, the agency is empowered under TSCA to limit production of the chemical substance either permanently⁸³ or temporarily.⁸⁴ In those situations where the EPA lacks sufficient information to make its risk determination, it can promulgate rules requiring further testing of the chemical substance upon a finding that the substance “may present” an unreasonable risk⁸⁵ or if “substantial quantities”⁸⁶ of the chemical substance are or will be produced.

It is apparent from even a cursory reading of these provisions that TSCA was drafted to regulate chemical substances as that term is ordinarily

81. *Id.* §§ 2604(d), 2607(a)(2). The focus is on preexisting tests and data, not on any further testing.

82. *Id.* § 2604(a)–(b).

83. *Id.* § 2604(f). The EPA may initiate rulemaking or issue a proposed order to limit production of a chemical substance when there is a reasonable basis to believe that the substance presents an unreasonable risk to health or the environment. *Id.*

84. *Id.* § 2604(e). The EPA may temporarily suspend production for the purpose of collecting further information to determine whether permanent limits on production are warranted. As with the requirements for permanent limits, these temporary limits on production also require a finding that the chemical substance may present an unreasonable risk. *Id.*

85. TSCA provides that the EPA may order testing of a chemical substance if it finds that:

(i) the manufacture, distribution in commerce, processing, use, or disposal of a chemical substance or mixture, or that any combination of such activities, may present an unreasonable risk of injury to health or the environment,

(ii) there are insufficient data and experience upon which the effects of such manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and

(iii) testing of such substance or mixture with respect to such effects is necessary to develop such data[.]

Id. § 2603(a)(1)(A).

86. The EPA may order testing under this provision of TSCA if it finds that:

(i) a chemical substance or mixture is or will be produced in substantial quantities, and (I) it enters or may reasonably be anticipated to enter the environment in substantial quantities or (II) there is or may be significant or substantial human exposure to such substance or mixture,

(ii) there are insufficient data and experience upon which the effects of the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and

(iii) testing of such substance or mixture with respect to such effects is necessary to develop such data[.]

Id. § 2603(a)(1)(B).

understood.⁸⁷ There is nothing in the statutory language or legislative history to suggest that Congress originally intended to include genetically engineered organisms within the purview of TSCA.⁸⁸ This is not surprising in light of the fact that modern genetic engineering had only recently been invented when TSCA was enacted in 1976. Rather than this very new and then-obscure phenomenon, it was conventional “chemical substances and mixtures” that motivated Congress to enact TSCA.⁸⁹

Nonetheless, the EPA has employed TSCA as a statutory mechanism to exert control over certain aspects of genetic engineering. Most notably, the EPA’s TSCA Biotechnology Program office has asserted authority over genetically engineered microorganisms under TSCA by defining a microorganism as a chemical substance.⁹⁰ On one level, it is certainly true that any given genetically engineered microorganism fits within the “chemical substance” definition of an “organic or inorganic substance of a particular molecular identity,” which includes “any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature.”⁹¹ On the other hand, literally every naturally occurring plant, animal, or microorganism in existence, from apple trees to zebras, could arguably come within the meaning of this extraordinarily broad definitional interpretation.

Although Congress did not include within TSCA a definition of “unreasonable risk,”⁹² it did provide that the EPA must take into account the “environmental, economic, and social impact” of any action taken

87. *Id.* §§ 2601, 2602(2). *See also* S. REP. NO. 94-698, at 3–6 (1976), *reprinted in* 1976 U.S.C.C.A.N. 4491, 4493–96.

88. *See* 1984 STAFF REPORT, *supra* note 65, at 33–35 (outlining the argument that no evidence exists that Congress intended TSCA to cover genetically engineered organisms).

89. 15 U.S.C. § 2601.

90. EPA Reporting Requirements and Review Processes for Microorganisms, 40 C.F.R. § 725.8(c)(1) (2000) (reporting requirements and review processes for genetically engineered microorganisms).

91. 15 U.S.C. § 2602(2)(A) (1994).

92. *Chem. Mfrs. Ass’n v. EPA*, 859 F.2d 977, 984 (D.C. Cir. 1988). TSCA, however, does contain some enumerated considerations to be employed in assessing whether a chemical substance presents an unreasonable risk:

(A) the effects of such substance or mixture on health and the magnitude of the exposure of human beings to such substance or mixture,

(B) the effects of such substance or mixture on the environment and the magnitude of the exposure of the environment to such substance or mixture,

(C) the benefits of such substance or mixture for various uses and the availability of substitutes for such uses, and

(D) the reasonably ascertainable economic consequences of the rule, after consideration of the effect on the national economy, small business, technological innovation, the environment, and public health.

15 U.S.C. § 2605(c)(1) (1994).

under TSCA.⁹³ In contrast to other environmental statutes, TSCA was drafted specifically to require a form of cost-benefit analysis, mandating that the EPA consider both the risks and the benefits in any finding of unreasonable risk.⁹⁴

When the EPA finds that a chemical substance presents an unreasonable risk, the agency may promulgate TSCA regulations to require testing⁹⁵ or to limit the production⁹⁶ of that substance. Greater evidence of risk is needed to limit production than to require testing.⁹⁷ Under the former situation, commonly referred to as section 6 of TSCA, the EPA must have a “reasonable basis” to find that a chemical substance constitutes an unreasonable risk, and any production-limiting rulemaking based on that finding must utilize the “least burdensome requirements.”⁹⁸ On the other hand, the EPA need only find that the chemical substance “may present” an unreasonable risk in order to require health or environmental testing under TSCA section 4.⁹⁹ The EPA need only find that a “more-than-theoretical basis” exists for concluding that a chemical substance presents a sufficient risk to warrant testing.¹⁰⁰ This risk assessment entails consideration of both the toxicity of the chemical substance and the amount of human exposure.¹⁰¹

As applied to genetically engineered organisms, TSCA has rather limited utility. Because the primary focus of TSCA is information-gathering pursuant to the commercial production of chemicals, its provisions are generally restricted to testing and, if warranted, limitations on production. Although it is certainly desirable to obtain more information about these novel life forms, TSCA would have little or no effect over “escaped” specimens or subsequent generations of evolving life forms that have already become established in the environment. It is true that the expansive definition of “chemical substance” under TSCA theoretically enables the EPA to bring virtually anything within its ambit, but the modest teeth TSCA brings to the regulatory fight mostly vitiate its

93. 15 U.S.C. § 2601(c).

94. S. REP. NO. 94-698, at 13 (1976), *reprinted in* 1976 U.S.C.C.A.N. 4491, 4503.

95. 15 U.S.C. § 2603 (1994).

96. *Id.* § 2605.

97. *See Chem. Mfrs. Ass'n*, 859 F.2d at 985–86.

98. 15 U.S.C. § 2605 (1994). *See also* *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201, 1214–15, 1220 (5th Cir. 1991) (discussing the EPA’s burden under TSCA).

99. 15 U.S.C. § 2603(a)(1)(A).

100. *Chem. Mfrs. Ass'n*, 859 F.2d at 991. *See also* *Ausimont U.S.A. Inc. v. EPA*, 838 F.2d 93, 97 (3d Cir. 1988) (remanding for further findings to ensure that testing was based on “scientific uncertainty” rather than mere “speculation”).

101. *Chem. Mfrs. Ass'n*, 859 F.2d at 991; *Ausimont*, 838 F.2d at 96.

boardinghouse reach. And even that reach has been limited through regulatory exemption of certain categories of genetically engineered microorganisms.¹⁰²

The TSCA regulations created a reporting vehicle specifically designed for genetically engineered microorganisms featuring genes from two or more different genera. The Microbial Commercial Activity Notice (MCAN) is required to be submitted when persons intend to use intergeneric microorganisms for commercial purposes in the United States.¹⁰³ The MCAN is supposed to aid the EPA in determining whether the microorganisms may present an unreasonable risk to human health or the environment. To that end, submissions are to include extensive information as to the phenotypic and genotypic characteristics of genetically engineered microorganisms, including health and environmental effects data.¹⁰⁴ On a genotypic level, there is evidently an attempt to acquire sufficiently precise and specific information as to the genetic features involved to enable planners to make reasonably prudent decisions, including risk assessments, although it is questionable whether the right information is being collected or properly analyzed.¹⁰⁵

The TSCA regulations also establish specific procedural requirements governing intergeneric microorganisms used in research and development for commercial purposes, with a vehicle for reporting on the testing of new microorganisms in the environment, the TSCA Experimental Release

102. EPA Reporting Requirements and Review Processes for Microorganisms, 40 C.F.R. §§ 725.400–.470 (2000).

103. *See id.* § 725.105.

104. *Id.* §§ 725.155–.160. Among the numerous items of required information are data concerning “[s]urvival and dissemination under relevant environmental conditions including a description of methods for detecting the new or recipient microorganism(s) in the environment and the sensitivity limit of detection for these techniques[.]” and under laboratory and relevant laboratory conditions “[a] description of anticipated biological interactions with and effects on target organisms and other organisms such as competitors, prey, hosts, symbionts, parasites, and pathogens; a description of host range; a description of pathogenicity, infectivity, toxicity, virulence, or action as a vector of pathogens; and capacity for genetic transfer.” *Id.* § 725.155(d)(3)(ii)–(iii).

105. *See Chadwick, supra* note 50, at 245–50 (criticizing the new rules as inadequate from a risk-assessment viewpoint). The regulations require submission of, *inter alia*,

A detailed description of the genetic construction of the new microorganism, including the technique used to modify the microorganism (e.g., fusion of cells, injection of DNA, electroporation or chemical poration, or methods used for induced mutation and selection). The description should include, for example, a description of the introduced genetic material, including any regulatory sequences and structural genes and the products of those genes; how the introduced genetic material is expected to affect behavior of the recipient; expression, alteration, and stability of the introduced genetic material; methods for vector construction and introduction; and a description of the regulatory and structural genes that are components of the introduced genetic material, including genetic maps of the introduced sequences.

40 C.F.R. § 725.155(d)(2)(iii).

Application (TERA).¹⁰⁶ Similar to the MCAN, the TERA process involves advance submission and EPA evaluation of detailed information about the genetically engineered microorganism and its likely effects.¹⁰⁷

These procedural rules notwithstanding, the substantive standards of TSCA are inadequate to cover the multiplicity of difficult issues presented by genetically engineered organisms. The lack of a detailed definition of “unreasonable risk,” which is one of the key factors in determining whether the EPA may require further testing,¹⁰⁸ means that regulators are left without useful guidance in assessing transgenic life forms. Similarly, the other key factor regarding further testing, i.e., release of “substantial quantities” into the environment, is also not defined.¹⁰⁹ The result of this absence of specific standards is a considerable degree of subjectivity and discretion vested in regulators who may be poorly equipped to evaluate the complex scientific parameters relevant to the potential risks presented by genetically engineered organisms. Even expert scientists disagree on the dangers, and there is much that remains unknown even to them, let alone nonspecialists.¹¹⁰

Depending on the predilections of regulators, this amount of subjectivity and discretion could cause inappropriate levels of intervention. Regulators are free either to impose testing requirements in cases where there may be little actual need for them or to afford too much deference to the proponents of transgenic organisms through misguided over-reliance on whatever preexisting data they present.

The first error would unduly burden the biotechnology industry, perhaps resulting in failure to bring some beneficial strains to the market, with attendant lost opportunity for society in general. Widespread and arbitrarily imposed demands for additional testing, which is both costly and time-consuming, could delay or even preclude the availability of many useful developments. In addition to the negative financial effects on the biotechnology industry and the broader economy, this might also deprive the public of desirable or even life-saving advancements. Particularly in

106. 40 C.F.R. § 725.200 (2000).

107. *See id.* § 725.250, .255. The EPA has sixty days to evaluate TERA applications. *Id.* § 725.270(a).

108. 15 U.S.C. § 2603(a)(1)(A) (1994).

109. *Id.* § 2603(a)(1)(B). *See also* Chem. Mfrs. Ass’n v. EPA, 899 F.2d 344 (5th Cir. 1990) (rejecting industry challenge to the vague standard and rejecting the argument that the “substantial quantities” rule is limited to chemicals presenting a high degree of risk).

110. *See* BACTERIAL GENETICS IN NATURAL ENVIRONMENTS vii (John C. Fry & Martin J. Day eds., 1990) (noting that few researchers have expertise both in bacterial genetics and bacterial ecology); Chadwick, *supra* note 50, at 245–46.

regions of the world where the need for basic essentials of life is both greatest and most tenuously satisfied, any unwarranted obstacles placed in the path of innovation in food production or medicine can have serious consequences for human health and the environment.

The latter error, perhaps equally dangerously, could approve some harmful strains for environmental release without the safeguard of rigorous prior screening. If regulators fail to ask the pertinent questions when reviewing the data submitted in compliance with the basic TSCA PMN requirements, or if they lack the training or specialized scientific acumen to discern problematic aspects of the data, they will be unable to know whether further testing is advisable. There may be a tendency to defer to the superior scientific and technical knowledge of the proponents of transgenic organisms and, in effect, rubber-stamp their assurances that the organisms are safe. If such deference is misplaced, there could be highly adverse consequences for human health and the environment. Some commentators have suggested that TSCA is structured in such a way as to be biased in favor of product approval to avoid impeding technological innovation.¹¹¹ If so, this “undue deference” error could be more serious than its “undue strictness” counterpart.

One particularly significant problem with the TSCA PMN/MCAN process is the limited amount of time allotted to the EPA to evaluate proposals. If the EPA fails to make a determination of “unreasonable risk” so as to trigger testing requirements within ninety days of PMN/MCAN submission, TSCA allows the environmental release to proceed without further evaluation.¹¹² Given the practical exigencies that confront overworked and often unspecialized regulators, these time constraints exert great pressure in favor of pro forma rubber-stamp approval of PMN packages.

These deficiencies are exacerbated by the deferential approach courts bring to bear in reviewing EPA decisions under TSCA and other federal environmental statutes. Where, as here, EPA decisionmaking involves determinations of scientific and technical matters thought to be within the particular expertise of the agency, judicial review is generally limited to the “arbitrary and capricious” standard.¹¹³ Under this standard, it is unlikely

111. See, e.g., Saperstein, *supra* note 77, at 256.

112. *Id.* There is, however, a possibility of an extension to allow the EPA an additional ninety days. 15 U.S.C. § 2604(c) (1994); 40 C.F.R. § 725.170 (2000).

113. E.g., *Balt. Gas & Elec. Co. v. Nat'l Res. Def. Council*, 462 U.S. 87, 97–98 (1983). See also Devra Lee Davis, *The “Shotgun Wedding” of Science and Law: Risk Assessment and Judicial Review*, 10 COLUM. J. ENVTL. L. 67, 97 (1985) (discussing the problem in some detail).

that ill-advised decisions will be disturbed by the judiciary, even assuming that judges are any more capable than regulators of assessing subtle scientific issues regarding genetically engineered organisms.¹¹⁴

In short, use of TSCA as a catch-all statute to regulate the environmental consequences of transgenic organisms is not an effective method of addressing the problem. TSCA provides a very poor fit for regulating entities other than chemical substances as the term is ordinarily understood. As a result, the lack of regulatory specificity creates excessive ambiguity and the potential for abuse of either the over-intrusive or under-intrusive variety. There is too much at stake regarding genetically engineered life forms to shoehorn the topic into the TSCA scheme.

B. FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

In addition to TSCA, the other statutory hook the EPA uses to regulate some aspects of genetically engineered organisms is the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).¹¹⁵ FIFRA gives the EPA authority over the distribution, sale, and use of pesticide products and mandates the registration of pesticides before distribution or use. The term “pesticide” is broadly defined under section 2 of FIFRA as “any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, . . . [or] . . . intended for use as a plant regulator, defoliant, or desiccant.”¹¹⁶

FIFRA has been employed by the EPA to regulate genetically engineered organisms (mostly plants and microorganisms) that may have pesticidal properties. As with TSCA, FIFRA is usually thought of as regulating conventional chemicals, not living organisms. Biological control agents, however, including genetically engineered life forms, may be used as pesticides, and in that event they become subject to regulation under FIFRA unless specifically exempted by regulation.

114. This deferential standard makes it very difficult for industry to mount a successful challenge to an EPA testing order. *See, e.g.*, *Chem. Mfrs. Ass'n v. EPA*, 859 F.2d 977 (D.C. Cir. 1988); *Ausimont U.S.A. Inc. v. EPA*, 838 F.2d 93 (3d Cir. 1988). Of course, the converse is also true; if the EPA decides not to require further testing, it is unlikely a court will compel such a requirement.

115. 7 U.S.C. §§ 136–136y (1994).

116. *Id.* § 136(u). FIFRA defines “plant regulator” as “any substance or mixture of substances intended, through physiological action, for accelerating or retarding the rate of growth or rate of maturation, or for otherwise altering the behavior of plants or the produce thereof.” *Id.* § 136(v). This definition has been interpreted to include plant hormones (such as auxin, gibberellin, cytokinin, and ethylene). *Plant Pesticides Subject to the Federal Insecticide, Fungicide, and Rodenticide Act and the Federal Food, Drug, and Cosmetic Act*, 59 Fed. Reg. 60,496, 60,506–07 (EPA Nov. 23, 1994).

Primarily a procedural rather than a substantive statute, FIFRA functions chiefly by requiring the registration of pesticides with the EPA as a precondition of their sale, distribution, or use.¹¹⁷ In general, the registration process entails submitting data in support of registration, including information as to the “level and degree” of potential beneficial or adverse effects on humans and the environment.¹¹⁸ This information collection function is the main thrust of FIFRA; however, it also specifies certain requirements for the labeling¹¹⁹ of registered pesticides and training and certification requirements for applicators.¹²⁰

Specifically, every pesticide (including genetically engineered varieties) must be registered under section 3 of FIFRA before it may be marketed as a commercial product.¹²¹ In order to secure registration by the EPA, the pesticide must be documented with sufficient data to determine that, when used according to widespread and commonly recognized practices, it will not cause unreasonable adverse effects in humans or the environment.¹²² Applicants usually conduct field studies to gather information concerning product performance, use, and other types of data necessary to support the registration of their product. The applicable regulations concerning field trials require an Experimental Use Permit (EUP),¹²³ but they also include a presumption that EUP’s are not required for experimental use in a contained facility (such as a laboratory or greenhouse)¹²⁴ or for some types of small-scale tests of new pesticides conducted on a cumulative total of no more than ten acres.¹²⁵

The main FIFRA precondition for registration of a pesticide is the EPA determination that the pesticide will not cause “unreasonable adverse effects on the environment” when used properly.¹²⁶ This standard is intended to take into account the “economic, social, and environmental

117. 7 U.S.C. § 136a (1994).

118. *Id.* § 136a(c)(2)(A)–(B).

119. *Id.* § 136a(c)(9).

120. *Id.* § 136i(a).

121. *Id.* § 136a.

122. *Id.*

123. 40 C.F.R. § 172 (2000).

124. *Id.* § 172.3(b)(1)(i).

125. *Id.* § 172.3(c)(1). The EPA requires some genetically engineered microbial pesticides to undergo a particularly rigorous review before being excluded from EUP requirements at the small-scale testing stage. The EPA must be notified and the applicant must obtain prior approval if the research phase requires any type of field trial or when a laboratory does not meet containment standards. *Id.* § 172.3(d).

126. 7 U.S.C. § 136a(c)(5)(D).

costs and benefits” of the pesticide.¹²⁷ Specifically, registration may be denied at the outset or, once granted, may be suspended¹²⁸ or canceled¹²⁹ upon EPA determination that it “appears” that a pesticide “generally causes unreasonable adverse effects on the environment,” considering the economic, social, and environmental costs and benefits of the use of the pesticide.¹³⁰

FIFRA contains an important and controversial exemption in the case of pesticides produced solely for export to a foreign nation. In such instances, the pesticide need only satisfy certain labeling requirements and be produced by a registered applicant subject to FIFRA record-keeping mandates.¹³¹

In 1994, after lengthy review of regulatory options, the EPA announced a proposed rule intended to regulate the pesticidal substances produced by pest-protected plants, but not the plants themselves. Confusion has resulted, and many people believe that the EPA is using FIFRA to regulate the plants themselves as pesticides.¹³² Although the proposed rule has never been finalized, the EPA has been implementing its essential elements in registration actions since 1996.¹³³

Genetically engineered pesticides are, for the most part, subject to all FIFRA data submission and other registration requirements.¹³⁴ However, the EPA’s proposed FIFRA regulation sets forth three categories of plant-pesticides that would be exempt from regulation under FIFRA: (1) those whose genetic material encodes for a pesticidal substance that is derived from plants that are sexually compatible; (2) those that act by affecting the plant so that the target pest is inhibited from attaching to or invading the plant tissue by acting as a structural barrier or by inactivating toxins

127. *Id.* § 136(bb).

128. Suspension also requires a showing that the pesticide constitutes an imminent hazard to humans or to the environment. *See* *Envtl. Def. Fund v. EPA*, 548 F.2d 998, 1003 (D.C. Cir. 1976).

129. Courts have found that the EPA must find at least a “substantial question of safety” in order to initiate cancellation proceedings. *See, e.g., Nat’l Coalition Against the Misuse of Pesticides v. EPA*, 867 F.2d 636, 643–44 (D.C. Cir. 1989).

130. *Ciba-Geigy Corp. v. EPA*, 874 F.2d 277 (5th Cir. 1989) (quoting 7 U.S.C. §§ 136d(b), 136(bb)); *Love v. Thomas*, 858 F.2d 1347, 1350, 1357 (9th Cir. 1988).

131. 7 U.S.C. § 136(a); 40 C.F.R. § 152.30(d) (2000).

132. NRC 2000, *supra* note 17, at 150.

133. *Id.* at 151.

134. The EPA has registered ten pesticidal substances expressed in genetically engineered potato, cotton, or corn plants and has established corresponding exemptions from the requirement of a tolerance for these pesticidal substances under its proposed regulations. Seven additional pesticidal products are considered exempt from FIFRA registration because they consist of coat proteins of plant viruses. *Id.* at 157.

produced by the target pest; and (3) substances that are coat proteins of plant viruses.¹³⁵

Other than these exemptions, the existing FIFRA pesticide data requirements and the regulations governing large-scale field testing¹³⁶ and registration¹³⁷ are applicable to all transgenic pesticides.¹³⁸ The process can be time-consuming and costly, particularly for pesticides featuring a previously untested active ingredient.¹³⁹

As a regulatory hook facilitating EPA oversight of genetically engineered organisms, FIFRA is subject to even more serious limitations than TSCA. FIFRA only applies to such life forms that are intended for use as commercial pesticides¹⁴⁰ because that is its sole focus as an environmental protection statute. FIFRA is a narrowly tailored statute devoted to the testing, registration, labeling, and use of insecticides, fungicides, and rodenticides.¹⁴¹ It has no mechanism for regulating any genetically engineered life forms other than those designed for marketing as pesticides. Although genetic engineering has extended into the realm of pesticides,¹⁴² there are many other applications of this technology that are completely unrelated to pesticides, and FIFRA cannot reach them.

Even within the limited subset of genetically engineered organisms that constitute pesticides as defined under FIFRA, there is an unsatisfactory level of regulatory control possible. FIFRA is in essence a procedural, informational statute, and does not exert command and control over

135. *Id.* at 30.

136. 40 C.F.R. §§ 158, 172 (2000).

137. *Id.* §§ 158, 162.

138. "Novel" microbial pesticides (defined to include both genetically engineered and nonindigenous microorganisms functioning as pesticides) are subject to additional data or information requirements on a case-by-case basis depending on the particular microorganism, its parent microorganism, the proposed pesticide use pattern, and the manner and extent to which the microorganism has been genetically engineered. *Id.* § 158.65(2).

139. See Judith E. Beach, *No "Killer Tomatoes": Easing Federal Regulation of Genetically Engineered Plants*, 53 FOOD & DRUG L.J. 181, 189-90 (1998) (describing the FIFRA process and discussing the attendant transaction costs).

140. 7 U.S.C. § 136a(a) (1994) (stating "no person may distribute or sell" a pesticide that is not registered).

141. *Id.*

142. Genetic engineering has been employed to transform some crop plants into self-protecting pest-resistant strains, which are the legal equivalent of pesticides under FIFRA. For example, as discussed later, Bt corn and other plants are genetically engineered to be resistant to insect damage while not harming other organisms. Advocates of such plants claim that the production of crop plants that produce their own biological insecticide should reduce the need for environmentally destructive chemical insecticides. Commercial formulations of Bt toxin are marketed under various brand names including Dipel™, which is produced by Abbott Laboratories. See Earp, *supra* note 4, at 1650 & n.88, 1651.

pesticides in a comprehensive “cradle to grave” manner. Its power to require testing and data collection is not a substitute for substantive regulation.

FIFRA is also inadequate in terms of providing useful guidelines for industry. In part because the EPA does not have final regulations indicating the scope of products subject to FIFRA registration, relatively little formal guidance is available to industry as to the type of data and information that must be developed to support EPA registration of the pesticidal substances expressed by these plants. The EPA imposes data requirements on a case-by-case basis, with a resulting lack of overall guidance.¹⁴³

Some of the same factors that render TSCA of marginal utility as a means of safeguarding the environment from potentially harmful effects of genetically engineered organisms also apply to FIFRA. Living things are unlike chemical pesticides because they can evolve, move under their own power, mate with “natural” species, and reproduce. Beyond the testing and registration phase, FIFRA cannot govern the carriers of genetically engineered pesticides that transmogrify into new life forms. Either by mutation or by cross-breeding with other specimens, these living pesticides might become something entirely new, something different from the organisms that were subjected to FIFRA preregistration testing and data collection. Those tests and data would likely be inapplicable to the new strains, which might not even be covered by the registration of the original “product.”

Similarly, the EPA might place restrictions on the use of a given pesticide under FIFRA, perhaps limiting the geographical areas or types of habitats within which it can lawfully be applied, but such strictures may be ineffective when the pesticide has legs, wings, or the ability to drift airborne on the winds. For example, pesticidal substances within genetically engineered organisms may be marketed as pesticides solely for export, and thus escape most of FIFRA procedural rules, yet these life forms could cross international boundaries into other nations that have not consented to their importation. Conceivably, such mobile organisms could find their way back to the United States and invade the domestic environment without ever passing through the full array of FIFRA procedures. This would give a new and potentially harmful meaning to the concept of “illegal aliens.” Likewise, the labeling requirements and controls on means of application were intended to work with conventional

143. NRC 2000, *supra* note 17, at 168.

chemical pesticides. Walking, flying, self-reproducing life forms do not lend themselves to such mandates.

Also, as with the TSCA trigger of “unreasonable risk,” FIFRA employs a standard that only allows for meaningful regulatory action under limited and poorly defined circumstances. FIFRA does not allow the EPA to deny registration of a pesticide or EUP unless the EPA evaluation of the proponent’s initial data submission results in a finding of “unreasonable adverse effects” on the environment.¹⁴⁴ Essentially the identical statutory standard applies to subsequent decisions to suspend or cancel registration, although courts have imposed additional obstacles in the path of the EPA before those actions may be taken.¹⁴⁵ Although lacking in detailed guidance, this is, on its face, a rather difficult standard for regulators to meet. Moreover, as with TSCA, FIFRA is basically set up to encourage technological innovation and to eliminate excessive impediments on commerce. The “unreasonable adverse effects” standard expressly includes consideration of the “economic, social, and environmental costs and benefits” of the pesticide.¹⁴⁶ Therefore, scientific risks must be balanced against profit and other factors in a cost-benefit analysis before the regulators can deny, suspend, or cancel registration.

In addition to the difficulties inherent in the “unreasonable adverse effects” test itself, there is a further problem regarding its practical application. Depending on the reliability and thoroughness of the data submitted in the original application, regulators may be unable to make an informed decision on potential risks, particularly where the regulators are not equipped to discern hazards unique to transgenic organisms. Certainly, regulators have far less experience in dealing with these organisms than with conventional pesticides, and they probably have less training as well. The poorly defined, yet pro-industry standard, in concert with the thinly stretched resources of EPA regulators, renders FIFRA a poor mechanism for safeguarding the environment in the case of these novel life forms.¹⁴⁷

At the present time, FIFRA and TSCA are the only two statutes the EPA has systematically brought to bear on the issue of genetically

144. 7 U.S.C. § 136a(c)(5).

145. Courts have required a showing that the pesticide constitutes an imminent hazard to humans or to the environment in order to support suspension of registration, *Env'tl. Def. Fund v. EPA*, 548 F.2d 998, 1003 (D.C. Cir. 1976), and have ruled that the EPA must make a finding of a “substantial question of safety” in order to initiate cancellation proceedings, *Nat'l Coalition Against the Misuse of Pesticides v. EPA*, 867 F.2d 636, 643–44 (D.C. Cir. 1989).

146. 7 U.S.C. § 136(bb) (1994).

147. See Saperstein, *supra* note 77, at 256–57.

engineered organisms. In addition to the other problems noted, neither statute affords the general public a significant opportunity to participate in decisions to release genetically engineered organisms into the environment.¹⁴⁸ For example, there is no requirement for the EPA to notify local communities of such planned releases in their area, although this could be a matter of great interest and concern to the people in the affected region.¹⁴⁹ The Coordinated Framework does not provide any significant supplement to the FIFRA and TSCA public participation provisions.¹⁵⁰

Certainly, the protests and other forms of public outcry described previously are evidence that the public has an opinion on transgenic organisms; this opinion should be given an opportunity for meaningful expression. In light of the fact that these are matters of considerable complexity and scientific sophistication, there is also an important educational purpose to be served by public meetings in which experts can directly address specific concerns on a case-by-case basis. Without an adequate foundation in theory and scientific principle, the general populace is not prepared to participate in the decisionmaking process on any basis other than emotion and prejudice.¹⁵¹ Yet the current statutory framework available to the EPA does nothing to improve this situation. In light of all of these deficiencies in the EPA's coverage, the next Section examines the means by which the USDA and its suborganization APHIS deal with this issue.

C. USDA REGULATORY MECHANISMS

The USDA, like the EPA, has no direct statutory mandate to regulate genetically engineered organisms per se, but it has played a role in the process nonetheless. The USDA derives its authority in this area from the Federal Plant Pest Act (FPPA)¹⁵² and from the Plant Quarantine Act

148. The only notification requirement under FIFRA is a Federal Register notice of a contemplated release. See 40 C.F.R. § 172.11 (2000) (FIFRA EUP applications of "regional or national significance" are published in the Federal Register, with public hearings made possible if supported by "sufficient interest"). But this would be unlikely to reach local citizens, nor would it generate productive dialogue among the concerned parties. Under TSCA, PMN submissions (with confidential business information redacted) are maintained by the EPA for public review and comment for a period of thirty days. See Saperstein, *supra* note 77, at 258.

149. Saperstein, *supra* note 77, at 258.

150. See *id.*

151. See generally W.R. Derrick Sewell & Timothy O'Riordan, *The Culture of Participation in Environmental Decisionmaking*, 16 NAT. RESOURCES J. 1, 16-17 (1976) (discussing problems with participatory decisionmaking in the context of wide-scale problems such as global or international environmental policy).

152. 7 U.S.C. §§ 150aa-150jj (1994).

(PQA).¹⁵³ Neither the FPPA nor the PQA specifically deals with genetically engineered species.

The FPPA sets forth a permit system that has been expanded by the USDA into a comprehensive pre-release review system for potential plant pests. Building on that system, which had already been in place for many years, the USDA issued rules in 1987 designed specifically to regulate genetically engineered organisms before their release into the environment or their movement in commerce.¹⁵⁴

The FPPA was enacted in 1957, prior to the advent of modern genetic engineering. It was intended to be a “gap filling” statute that would protect American agriculture from “plant pests and diseases which are new to or not theretofore known to be widely prevalent or distributed within and throughout the United States.”¹⁵⁵ Additionally, the FPPA confers considerable statutory authorization upon the USDA to regulate plants that might subsequently be found injurious to cultivated crops.¹⁵⁶ The USDA uses this authority, through the auspices of the Animal and Plant Health Inspection Service (APHIS), to regulate “the movement of plants . . . developed through genetic engineering” if they present “a risk of plant pest introduction, spread or establishment.”¹⁵⁷

The USDA, through the APHIS, has used this foundation to promulgate regulations that govern the introduction into the environment of genetically engineered plants “which are plant pests or which there is reason to believe are plant pests.”¹⁵⁸ The regulations define “plant pest” as an invertebrate or bacterial organism or substance “which can directly or indirectly injure or cause disease or damage in or to any plants or parts thereof.”¹⁵⁹ APHIS regulations prohibit the “introduction,”¹⁶⁰ including both movement into or through the United States and “release into the environment,”¹⁶¹ of “regulated article[s]”¹⁶² without APHIS authori-

153. *Id.* §§ 151–64, 166–67.

154. NRC 2000, *supra* note 17, at 146.

155. Dep’t of Agric., Final Policy Statement for Research and Regulation of Biotechnology Processes and Products, 51 Fed. Reg. 23,336, 23,342 (June 26, 1986).

156. *Id.*

157. *Id.*

158. 7 C.F.R. § 340.0–.9 (2000).

159. *Id.* § 340.1.

160. “Introduction” is defined to include environmental release as well as movement into or through the United States. *Id.*

161. Environmental release is defined as “the use of a regulated article outside the constraints of physical confinement that are found in a laboratory, contained greenhouse, or a fermenter or other contained structure.” *Id.*

zation.¹⁶³ In practical effect, the APHIS thereby regulates all environmental releases of potential plant pests, even if they initially involve only intrastate and not interstate movement, because any environmental release of a plant pest could be deemed to constitute a significant threat to agriculture throughout the nation.¹⁶⁴ Given the manner in which the regulations define key terms, therefore, the APHIS can classify a genetically engineered plant as a plant pest or possible plant pest based not only on the type of the plant, but also on the materials and methods that were used during the genetic engineering process to produce the plant.¹⁶⁵

The APHIS is the lead agency for purposes of regulating the field testing or movement of genetically engineered plants. It has issued approximately 887 permits for genetically engineered organisms since the program began in 1987, mostly for limited field tests of crop plants.¹⁶⁶ Based on its experience with the permit program, the APHIS eventually developed several exemptions for “articles” that it determined do not pose a plant pest risk. One of the most important exemptions allows the introduction of certain regulated articles without a permit so long as the APHIS is notified in advance.¹⁶⁷ The APHIS has acknowledged approximately 4,400 such notifications for field tests (about forty percent of which involved transgenic plants), while about 260 have been denied, withdrawn, or otherwise voided.¹⁶⁸

Persons who wish to conduct such testing may use a simple, streamlined procedure to notify the APHIS.¹⁶⁹ The APHIS then has thirty days to review the notification prior to any testing and either confirm that the notification is appropriate or inform the applicant that no release may take place without a permit.¹⁷⁰ Also, before a genetically engineered crop

162. “Regulated articles” are defined to include any plant (a) “altered or produced through genetic engineering, if the donor organism, recipient organism, or vector or vector agent” belongs to a defined list of plant pests; (b) that the APHIS otherwise determines to be a plant pest; or (c) that the APHIS has reason to believe is a plant pest. *Id.*

163. *Id.* § 340.0.

164. *See id.*

165. *See* Earp, *supra* note 4, at 1643.

166. Where a permit is actually required, the APHIS has followed the environmental assessment procedures set forth in the National Environmental Policy Act (NEPA). NRC 2000, *supra* note 17, at 146. Because so many situations are exempt from the permit process, however, the NEPA has not played a major role in the analysis of environmental impacts of genetically engineered plants.

167. NRC 2000, *supra* note 17, at 145.

168. *Id.* at 146–47.

169. *See* 7 C.F.R. § 340.3 (2000). These procedures represent recent relaxation of earlier requirements, which previously had been limited to only six types of crops with which the APHIS had had the most experience in field trials: corn, cotton, potato, soybean, tobacco, and tomato.

170. *Id.*

plant can be produced on a wider scale and sold commercially, its creators must petition the APHIS for a “determination of non-regulated status” based on information they supply.¹⁷¹ These petitions are published in the Federal Register, with an opportunity for public comment, albeit not on a local, community-focused level. The APHIS grants petitions upon finding that the new plant is as safe to use as more traditional varieties.¹⁷²

The notification procedure may be used, provided that the proponent certifies, inter alia, that the transferred gene is “well characterized” and would not induce disease in the host plant; the introduced genetic material is “stably integrated” into the DNA and introduces no infectious material or material toxic to desirable, non-target organisms; the genetic material does not pose a significant risk of creation of any new plant virus; and the plant contains no functional genes derived from human or animal pathogens.¹⁷³ There are also performance standards, including a provision that the “regulated article will not persist in the environment.”¹⁷⁴

The APHIS does not mandate that any individual environmental evaluations be performed under the notification procedure. The agency’s view is that “the constraints imposed by the eligibility criteria and the performance standards effectively eliminate the potential for significant impact to the environment that would occasion any case-by-case analysis.”¹⁷⁵ The APHIS has been criticized for relying too heavily on existing scientific literature rather than requiring applicants to develop new experimental data directly relevant to risks that may be posed by specific transgenic plants.¹⁷⁶

Because of the limits of the underlying statutory authority, the USDA and the APHIS can only regulate to any significant extent those genetically engineered plants, invertebrates, or microorganisms that either are “plant pests” or have received a portion of their DNA from “plant pests,” as defined. Vertebrate animals are out of reach, as are all other organisms that are free of genetic material from plant pests.

171. 7 C.F.R. § 340.6 (2000).

172. 7 C.F.R. § 340.3(b)(2).

173. *Id.* § 340.3(b).

174. *Id.* § 340.3(c).

175. 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 (Dep’t of Agric. Mar. 31, 1993).

176. Colin B. Purrington & Joy Bergelson, *Assessing Weediness of Transgenic Crops: Industry Plays Plant Ecologist*, 10 TRENDS ECOLOGY EVOLUTION 340, 341 (1995); R.P. Wrubel, S. Krimsky & R.E. Wetzler, *Field Testing Transgenic Plants*, 42 BIOSCIENCE 280, 288 (1992).

Even within plants, the threshold definition of “plant pests” may be inadequate to keep up with the moving target presented by transgenic varieties. Previously unregulated types of plants may become “pests” upon cross-pollination with other species, but can anyone be held retroactively responsible for the “introduction” of such a new life form into the environment? If individuals bring a non-pest transgenic plant into a new region of the country, this act does not violate the APHIS regulations. Subsequent evolution, cross-pollination, or other transformation of the originally introduced plants might render the progeny subject to classification as a pest, but by then the introduction has already, quite legally, taken place.

In the case of transgenic crops that are designed to incorporate certain useful genetic material from previously classified plant pests, the primary means of APHIS enforcement is the requirement of prior APHIS authorization.¹⁷⁷ But this is obtained almost as a matter of routine course under the notification procedures.¹⁷⁸ And once such authorization is issued, there is no control over the later escape of the modified plants, either in their original form or as eventually evolved or cross-pollinated with other varieties. The requisite APHIS authorization for introduction would have been properly obtained, and the unintended migration of undesirable traits into the environment would be beyond the reach of the APHIS.

Even with regard to the APHIS authorization process, there are substantial practical concerns. Absent explicit and usable regulatory guidance, the regulators are inadequately prepared to conduct a realistic risk assessment of genetically engineered plants.¹⁷⁹ APHIS regulators are not apt to possess the highly specialized scientific acumen needed to identify swiftly and accurately potential hazards on a case-by-case basis as myriad new, supposedly advantageous crops are aggressively pushed towards approval by their proponents. The natural tendency in most instances will be to rely on the assurances offered by the proponent of the new crop variety and to adopt whatever scientific and technical data are furnished in support of the crop’s introduction.

This Part has exhaustively reviewed the substantive federal environmental options applicable to genetically engineered organisms.

177. See 7 C.F.R. § 340.0(1) (2000).

178. See Earp, *supra* note 4, at 1664.

179. See Henry I. Miller & Douglas Gunary, *Serious Flaws in the Horizontal Approach to Biotechnology Risk*, 262 SCIENCE 1500, 1501 (1993).

Because the issue of food safety has been so controversial and so widely publicized, however, and because it is at least tangentially connected to environmental concerns, it is necessary briefly to discuss the role of the federal government in that area as related to transgenic organisms and the products and ingredients derived from them.

D. FDA REGULATION

The FDA has broad authority under both the Federal Food, Drug, and Cosmetic Act (FFDCA)¹⁸⁰ and the Public Health Service (PHS) Act¹⁸¹ to regulate various human health issues. As with other foods, food additives, medical devices, and drugs, the FDA is charged with ensuring the safety and effectiveness of genetically engineered products. It does not address environmental concerns directly, but only the safety and efficacy of products. However, because the FDA is one of the major players in the regulation of genetically engineered products, this Section examines its role for sake of completeness.

The FDA uses section 402(a)(1) of the FFDCA,¹⁸² the “adulteration” provisions, as its chief legal vehicle for regulating the safety of whole foods, including foods derived from genetically engineered animals and plants. With regard to food additives, section 409¹⁸³ confers authority upon the FDA to regulate genetically engineered substances that are expected to become components of food in those cases wherein, as modified, the substances are not “generally recognized as safe” (GRAS) or otherwise exempt from regulation.

There appears to be no legitimate scientific reason to presume that these statutory mechanisms are inadequate to enable the FDA to assess and to ensure the safety of new food ingredients, drugs, and foods derived from new varieties of animals and plants, whether produced by genetic engineering or by more traditional methods.¹⁸⁴ The FDA itself has formally stated this as its position on the issue of substances derived from genetic engineering. For example, in the Coordinated Framework for

180. 21 U.S.C. §§ 301–395 (1994).

181. 42 U.S.C. §§ 262–263a (1994).

182. 21 U.S.C. § 342 (1994).

183. *Id.* § 348.

184. *See generally* David A. Kessler, Michael R. Taylor, James H. Maryanski, Eric L. Flamm & Linda S. Kahl, *The Safety of Foods Developed by Biotechnology*, 256 *SCIENCE* 1747 (1992) (arguing that the FDA’s approach is scientifically adequate to ensure the safety of genetically engineered foods).

Regulation of Biotechnology,¹⁸⁵ the FDA did not recommend any modification of its regulatory policy. It was the agency's position that most issues concerning the safety of genetically engineered products, as with other products, would be covered by either the general adulteration provisions or the food additive and related provisions of the FFDCFA.¹⁸⁶

The FDA went further in expressing its lack of concern when it issued a policy statement in 1992 to revise and to clarify its views on foods derived from new plant varieties, including genetically engineered plants.¹⁸⁷ In the 1992 policy, the FDA stated that foods developed through genetic engineering are not inherently dangerous and, except in rare cases, should not require special premarket testing or regulation. In essence, the FDA policy is that such foods should be regulated as ordinary foods unless they contain substances or demonstrate attributes that are not usual for the product.¹⁸⁸ The FDA declared that, under the FFDCFA, foods derived from new plant varieties that were developed using genetic engineering would require only premarket notification, not premarket approval, and would not require special labeling of such food products unless there were questions of allergic reaction or there had been a significant change in composition of the substances in question.¹⁸⁹

Over forty-five genetically engineered plants have passed through the FDA consultation process. The FDA has not required that any of the proteins added to such plants be reviewed as food additives.¹⁹⁰

185. The Coordinated Framework for Regulation of Biotechnology was intended to be a comprehensive presentation of federal policy on the safety and other aspects of genetic engineering research and products. 51 Fed. Reg. 23,302 (Office of Sci. & Tech. Policy June 26, 1986). Within this Coordinated Framework, the FDA, as well as the USDA and the EPA, published statements of their initial regulatory policies. The Coordinated Framework provided direction for agency policies, but it did not authorize agency action that could not have otherwise taken place. Rather than providing for new authority, the Coordinated Framework required each agency to make decisions and to issue regulations based on its then-existing statutory authority. See *Found. on Econ. Trends v. Johnson*, 661 F. Supp. 107, 109 (D.D.C. 1986) (holding that the Coordinated Framework was intended to guide policymaking, not to regulate).

186. See 21 U.S.C. §§ 321(s), 342, 348 (1994). See generally Eric L. Flamm, *How FDA Approved Chymosin: A Case History*, 9 *BIO/TECHNOLOGY* 349, 350-51 (1991) (describing the FDA's approval process).

187. Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22,984 (May 29, 1992).

188. *Id.*

189. At the time of its 1992 plant policy statement, the FDA used the term "substantial similarity," but since 1997 has been using the term "substantial equivalence" when evaluating the safety of foods derived from genetic engineering and other new plant varieties. Substances Generally Recognized as Safe, 62 Fed. Reg. 18,938, 18,945 n.2 (Apr. 17, 1997).

190. NRC 2000, *supra* note 17, at 30.

Even premarket notification was made voluntary for a period of several years so long as the substance was generally recognized as safe under the GRAS exemption.¹⁹¹ The FDA has indicated, however, that it “believes that it is in the best interests of the regulated industry and the agency” for developers to inform the FDA, prior to commercial distribution, about foods or feed derived from new plant varieties, including those derived using genetic engineering.¹⁹²

As to the issue of requiring special labels for foods derived from genetic engineering, which has been so prominent in the European nations and the controversies therein, the FDA has not considered this necessary. So long as genetic engineering of an organism does not “significantly change its composition,” the FDA does not mandate that any derived product feature labels informing consumers of the genetically engineered

191. See OFFICE OF PREMARKET APPROVAL & OFFICE OF SURVEILLANCE & COMPLIANCE, FOOD & DRUG ADMIN., GUIDANCE ON CONSULTATION PROCEDURES FOR FOOD DERIVED FROM NEW PLANT VARIETIES (Oct. 1997), <http://vm.cfsan.fda.gov/~lrd/consulpr.html> [hereinafter GUIDANCE ON CONSULTATION PROCEDURES]. Ever since the ruling by the FDA in May, 1994, that “Calgene Inc.’s FLAVR-SAVR™ tomato [is] ‘as safe as tomatoes bred by conventional means,’” the FDA has not conducted comprehensive scientific reviews of products derived from genetically engineered organisms. Beach, *supra* note 139, at 185 (quoting *Biotechnology of Food*, FDA BACKGROUNDER (FDA), May 18, 1994).

192. GUIDANCE ON CONSULTATION PROCEDURES, *supra* note 191. The FDA’s Biotechnology Evaluation Team was organized to handle these situations. *Id.* The FDA has developed a guidance document setting forth the appropriate procedures for informing the FDA about plans to market a new product containing genetically engineered material. The guidance recommends that the developer submit to the FDA a “Summary of the Safety and Nutritional Assessment” as part of the consultation process for the new food product. *Id.* This summary should contain information in enough detail to enable the FDA scientists to understand the approach followed in addressing all relevant issues.

The summary ordinarily includes the following:

- the name of the bioengineered food and the crop from which it was derived;
- a description of the various applications or uses of the bioengineered food;
- information concerning the sources of introduced genetic materials;
- information on the purpose of the intended effect of the genetic modification and whether the modification is expected to affect the composition or characteristics of the food;
- information concerning the identity and function of introduced genetic material and of expression products encoded by the introduced genetic material, including an estimate of the concentration of any expression product encoded by the introduced genetic material when the expression product is expected to become a major component of the bioengineered food;
- information concerning the identity and function of additional genetic materials;
- information comparing the composition or characteristics of the bioengineered food to that of food derived from the parental variety or other commonly consumed varieties;
- information relating to toxicants that occur naturally in the food;
- a discussion of the available information that addresses whether the potential for the food to induce an allergic response has been altered by the recombinant DNA modification; and
- any other information relevant to the safety assessment of the bioengineered food.

Beach, *supra* note 139, at 185–86. See also GUIDANCE ON CONSULTATION PROCEDURES, *supra* note 191 (listing relevant issues ordinarily included in summary).

component.¹⁹³ Although section 403(i) of the FFDC¹⁹⁴ requires the producer of a food product to describe the product by its common or usual name or, in the absence thereof, an appropriately descriptive term,¹⁹⁵ and to disclose all facts that are material in light of representations made or suggested by labeling or with respect to consequences that may result from use,¹⁹⁶ the typical examples of genetic engineering do not implicate these requirements.¹⁹⁷

The FDA does, however, require appropriate labeling if a food derived from a new plant variety has special safety or usage requirements.¹⁹⁸ For example, if a given food plant is genetically engineered to include material from a different plant that might induce an allergic reaction in a susceptible population, a label declaration would be required to alert consumers who are allergic to the donor plant so that they could avoid that product.¹⁹⁹ If the label fails to include this information, the label would be misleading in violation of section 403(a) of the FFDC.²⁰⁰

In May, 2000, the FDA announced some modifications and tightening of its prior approach, based in part on input received from the general public.²⁰¹ Moving away from the previous system of purely voluntary notifications, the FDA will publish a proposed rule mandating that developers of genetically engineered foods and animal feeds notify the agency at least 120 days before marketing such products.²⁰² The FDA will require that specific information be submitted to help determine whether the foods or animal feeds pose any potential safety, labeling, or adulteration problems. The FDA also announced plans to draft labeling guidance to assist manufacturers who wish voluntarily to label their foods being made with or without the use of genetically engineered ingredients. The

193. Food Labeling: Foods Derived From New Plant Varieties, 58 Fed. Reg. 25,837 (Apr. 28, 1993).

194. 21 U.S.C. § 343(i) (1994).

195. 21 C.F.R. § 101.3 (1997).

196. 21 U.S.C. §§ 321(n), 343(a) (1994).

197. Food Labeling: Foods Derived From New Plant Varieties, 58 Fed. Reg. at 25,837. For example, a variety of corn that has been genetically engineered to be less susceptible to certain diseases would not require a special label, just as a "naturally" cross-bred strain of corn would be free from any particular labeling requirement.

198. Statement of Policy: Foods Derived From New Plant Varieties, 57 Fed. Reg. 22,984, 22,991 (May 29, 1992).

199. *Id.*

200. *Id.*; 21 U.S.C. § 343(a).

201. News Release, U.S. Dept. of Health & Human Servs., FDA to Strengthen Pre-Market Review of Bioengineered Foods (May 3, 2000), <http://www.fda.gov/bbs/topics/NEWS/NEW00726.html>.

202. *Id.*

guidelines are intended to help ensure that any such labeling is “truthful and informative.” The FDA stated that it will develop these guidelines with the use of consumer focus groups and will seek public comment on the draft guidelines.²⁰³

Clearly, the FDA did not make these recent decisions in response to any new scientific evidence that genetically engineered foods are unsafe, because there has been no such evidence. Rather, the FDA’s actions are a sign that the federal government is beginning to feel pressure to take more restrictive action in this area, as has been happening in Europe for several years.

Although interested persons may disagree as to the adequacy of the FDA’s regulations for purposes of ensuring the safety of foods produced through genetic engineering, it is clear that these regulations afford no protection to the environment. This is not the fault of the FDA nor of the legislators who drafted the FFDCFA. It is simply the inevitable consequence of the fact that the FDA has a different organizational mandate and a mission focused on important concerns other than environmental protection. The patchwork-quilt approach of the Coordinated Framework has forced a portion of the transgenic problem on the FDA’s plate, but it is only a portion, and it is the only portion that could properly come within the FDA’s purview. No reading of the FFDCFA, even if as innovative and freewheeling as the interpretations that accorded TSCA a role in transgenic regulation, could confer upon the FDA the power to regulate the environmental releases of genetically engineered organisms or the consequences thereof.

V. INTERNATIONAL APPROACHES AND THE CARTAGENA BIOSAFETY PROTOCOL

Part II described the protests against genetic engineering, both violent and peaceful, that have taken place around the world. Until recently, such activity was largely confined to nations other than the United States. The more prolonged and intense European public resistance to genetic engineering has been reflected in legislation, regulation, and international agreement.

For example, although the European Union (EU) approved the use of Bt corn in early 1998, both Austria and Luxembourg immediately responded by passing laws preventing the genetically engineered corn from

203. *Id.*

being introduced into their territories.²⁰⁴ The French government also decided to ban the sale of Bt corn, at least temporarily,²⁰⁵ and Norway banned all products derived from crops containing antibiotic-resistant genes.²⁰⁶ Meanwhile, in response to public fears within the United Kingdom, “managed development” was introduced, which entails curbs on production and new monitoring arrangements for foods derived from genetically engineered organisms. There is an outright ban on insect-resistant crops and strict scrutiny of other genetically engineered forms.²⁰⁷ These measures are aimed at identifying and countering any unexpected effects and complement the already-stringent British safety assessments required before such foods are allowed to reach the market.²⁰⁸ On the other hand, Swiss citizens overwhelmingly rejected a referendum in 1998 that would have imposed a nationwide ban on the release of genetically engineered organisms, the creation of transgenic animals, and the patenting of new life forms.²⁰⁹

On the multinational level, the European Communities adopted Commission Regulation 1813/97 of September 19, 1997²¹⁰ and Council Regulation 1139/98 of May 26, 1998,²¹¹ both concerning compulsory labeling of certain food products derived from genetically engineered soybeans and corn marketed within the European Community. This was intended to fill a gap in coverage left by the Novel Food Regulation, which went into effect May 15, 1997.²¹² The stated purpose of the regulations

204. Susan Boensch Meyer, Recent Development, *Genetically Modified Organisms*, COLO. J. INT'L ENVTL. L. & POL'Y 1998 Y.B. 102, 103 (1999). The Austrian law, inter alia, increased sixfold the fine for illegally releasing genetically engineered organisms into the environment and provided that corporations would be liable for any environmental harms caused by their genetically engineered organisms. Some biotechnology industry representatives declared that the Austrian provisions are the strictest in the world. *Id.* at 110.

205. *Id.* at 104.

206. See Nigel Williams, *Agricultural Biotech Faces Backlash in Europe*, 281 SCIENCE 768, 768 (1998).

207. See Fredland, *supra* note 45, at 189.

208. Meyer, *supra* note 204, at 107–08.

209. *Id.* at 109–10. The Swiss pharmaceutical industry had warned that the proposed law would threaten jobs in Switzerland as well as obstruct new medical treatments. *Id.*

210. 1997 O.J. (L 257) 7.

211. 1998 O.J. (L 159) 4.

212. See Council Regulation 258/97 of January 27, 1997 on Novel Foods, 1997 O.J. (L 43) 1, 6. See also Nyaguthii Chege, Comment, *Compulsory Labeling of Food Produced from Genetically Modified Soya Beans and Maize*, 4 COLUM. J. EUR. L. 179, 179 (1998). The Novel Food Regulation governs the marketing and labeling of “novel foods,” including genetically engineered foods and food products, but, because it lacks retroactive application, it does not cover genetically engineered soybeans and corn regulated under a Council Directive concerning the deliberate release into the environment of genetically modified organisms. *Id.* at 179 & n.3.

was to require uniform labeling rules for food products containing genetically engineered organisms. The European Commission indicated that this uniformity was needed because of measures adopted by some individual European nations that were “liable to impede the free movement of those foods and food ingredients and thereby adversely affect the functioning of the internal market.”²¹³ An additional purpose was to inform consumers of “any characteristic or food property” that “renders a food or food ingredient no longer equivalent to an existing food or food ingredient.”²¹⁴ Thus, free trade and public information, rather than protection of the environment or human health, were the stated rationales behind the regulations.

Such regulations are not limited to Europe. In the Philippines, which imports large quantities of soybeans and corn, guidelines have been issued regulating the release of genetically engineered organisms.²¹⁵ The legislature in Ghana has also been considering controls on transgenic plants.²¹⁶

The international response culminated recently with the Biosafety Protocol,²¹⁷ which was adopted by 133 countries on January 29, 2000, in Montreal, Canada.²¹⁸ It is formally called the Cartagena Protocol on Biosafety to honor Colombia, which hosted the Extraordinary Conference of the Parties in Cartagena in 1999. Upon entry into force, this first Protocol to the Convention on Biological Diversity (CBD)²¹⁹ will provide a

213. Council Regulation 1139/98, 1998 O.J. (L 159) 4 para. 4.

214. *Id.* at 5 para. 9.

215. Meyer, *supra* note 204, at 111. Soybeans and corn frequently feature transgenic forms, so the restrictions are expected to have a significant impact. *Id.*

216. *Id.*

217. Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Jan. 29, 2000, art. 1, *reprinted in* SECRETARIAT OF THE CONVENTION ON BIOLOGICAL DIVERSITY, CARTAGENA PROTOCOL ON BIOSAFETY TO THE CONVENTION ON BIOLOGICAL DIVERSITY: TEXT AND ANNEXES 3 (2000), available at <http://www.biodiv.org/biosafe/BIOSAFETY-PROTOCOL.htm> [hereinafter Cartagena Protocol]. See generally *Report of the Sixth Session of the Open-Ended Ad Hoc Working Group on Biosafety and the First Extraordinary Session of the CBD Conference of the Parties: 14–23 February 1999*, EARTH NEGOTIATIONS BULL., Feb. 26, 1999, at 1 [hereinafter *Working Group Report*].

218. See *Report of the Resumed Session of the Extraordinary Meeting of the Conference of the Parties for the Adoption of the Protocol on Biosafety to the Convention on Biological Diversity: 24–28 January 2000*, EARTH NEGOTIATIONS BULL., Jan. 31, 2000, at 1, 1 [hereinafter *Report of Resumed Session*]. See also Andrew Pollack, *130 Nations Agree on Safety Rules of Biotech Food*, N.Y. TIMES, Jan. 30, 2000, at A1.

219. The CBD was produced by the United Nations Conference on Environment and Development (the “Earth Summit”), held in Rio de Janeiro, Brazil, in 1992. See *Convention on Biological Diversity, opened for signature* June 5, 1992, 31 I.L.M. 818 [hereinafter CBD]. The United States has not ratified the CBD, nor is it a signatory to the Biosafety Protocol. See *Focus of Biosafety*

framework for addressing environmental impacts of bio-engineered products (referred to as living modified organisms or “LMO’s”) that cross international borders. In accordance with its Article 36, the Protocol will be open for signature at the United Nations Office at Nairobi, Kenya, by States and regional economic integration organizations from May 15 to 26, 2000, and at the United Nations Headquarters in New York from June 5, 2000 to June 4, 2001.²²⁰ It will enter into force shortly after fifty members of the CBD ratify it.²²¹

The Biosafety Protocol is intended to be an environmental agreement focusing on agricultural genetically engineered organisms, and does not address the issue of food safety.²²² Article 1 sets forth its objective:

In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.²²³

The Protocol contains prefatory language recognizing “the rapid expansion of modern biotechnology and the growing public concern over its potential adverse effects on biological diversity, taking also into account risks to human health,” while also noting that “modern biotechnology has great potential for human well-being if developed and used with adequate safety measures for the environment and human health.”²²⁴ The Protocol, reflective of the position of numerous developing nations, also is intended to take into account “the limited capabilities of many countries, particularly

Protocol Should Be on Deliberate Release of LMOs, U.S. Says, 22 Int’l Env’t Rep. (BNA) 136 (Feb. 17, 1999) [hereinafter *Focus of Biosafety Protocol*].

220. *Report of Resumed Session*, *supra* note 218, at 10.

221. *Id.* at 10. Article 36 requires instruments of ratification or acceptance, not simply signature. As of February 28, 2001, there were eighty-five signatories, but only two ratifications. Convention on Biological Diversity, *Parties to the Convention on Biological Diversity/Cartegna Protocol on Biosafety*, at <http://www.biodiv.org/world/parties.asp?lg=0> (updated on Feb. 28, 2001).

222. CBD, *supra* note 219, at 822–23.

223. Cartagena Protocol, *supra* note 217, at 3 art. 1.

224. *Id.* at 2. The Protocol defines “modern biotechnology” as the application of:

- a. In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or
- b. Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection[.]

Id. at 4 art. 3(i).

developing countries, to cope with the nature and scale of known and potential risks associated with living modified organisms.”²²⁵ The substantive provisions of the Protocol reflect a moderate approach in light of both the benefits and risks of modern genetic engineering.

The Protocol requires signatories to “ensure that the development, handling, transport, use, transfer and release of any living modified organisms are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account risks to human health.”²²⁶ Signatories are expressly permitted to promulgate their own regulations and other measures that are “more protective of the conservation and sustainable use of biological diversity than that called for in this Protocol,” if consistent with the objective and the provisions of the Protocol and in accordance with the signatories’ other obligations under international law.²²⁷

The centerpiece of the Protocol is the Advance Informed Agreement (AIA) set forth in Articles 8 through 10 and Article 12, with special provisions in Article 11 for genetically engineered organisms “intended for direct use as food or feed, or for processing.”²²⁸ The AIA provisions generally apply “prior to the first intentional transboundary movement of living modified organisms for intentional introduction into the environment of the Party of import.”²²⁹ The AIA does not apply to transgenic organisms intended for use as human pharmaceuticals,²³⁰ to “living modified organisms in transit,”²³¹ or to “the transboundary movement of living modified organisms destined for contained use undertaken in accordance with the standards of the Party of import.”²³² There is also an exemption for organisms previously identified as being “not likely to have adverse

225. *Id.* at 2. “Living modified organism” is defined as “any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology.” *Id.* at 4 art. 3(g).

226. *Id.* at 3 art. 2, para. 2. To implement these requirements, the Protocol provides that “[e]ach Party shall take necessary and appropriate legal, administrative and other measures to implement its obligations under this Protocol.” *Id.* para. 1.

227. *Id.* para. 4. With regard to non-signatories, the Protocol provides that “[t]ransboundary movements of living modified organisms between Parties and non-Parties shall be consistent with the objective of this Protocol. The Parties may enter into bilateral, regional and multilateral agreements and arrangements with non-Parties regarding such transboundary movements.” *Id.* at 18 art. 24, para. 1.

228. *Id.* at 6 art. 7, para. 3. For a discussion of the requirements under Article 11, see *infra* notes 242–48 and accompanying text.

229. Cartagena Protocol, *supra* note 217, at 6 art. 7, para. 1.

230. *See id.* at 5 art. 5.

231. *Id.* art. 6, para. 1.

232. *Id.* at 6 art. 6, para. 2.

effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.”²³³

The idea underlying AIA is essentially informed consent with right of refusal. Before an exporting nation sends the first shipment of any new form of genetically engineered organism to another nation, the exporter must inform the importer²³⁴ in detail as to various facts concerning the new organism.²³⁵ The importing nation must acknowledge receipt of this notification in writing, and then decide whether to agree to receive the shipment.²³⁶ Nevertheless, a decision to reject a shipment of new genetically engineered organisms must be based on scientific findings.²³⁷

233. *Id.* art. 7, para. 4. Such determinations are to be made “in a decision of the Conference of the Parties serving as the meeting of the Parties” to the Protocol. *Id.*

234. The notification is required to be in writing and sent to “the competent national authority of the Party of import.” *Id.* art. 8, para. 1.

235. *See id.* annex I, at 26–27. The required information is as follows:

- (a) Name, address and contact details of the exporter.
- (b) Name, address and contact details of the importer.
- (c) Name and identity of the living modified organism, as well as the domestic classification, if any, of the biosafety level of the living modified organism in the State of export.
- (d) Intended date or dates of the transboundary movement, if known.
- (e) Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.
- (f) Centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate.
- (g) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.
- (h) Description of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics of the living modified organism.
- (i) Intended use of the living modified organism or products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology.
- (j) Quantity or volume of the living modified organism to be transferred.
- (k) A previous and existing risk assessment report consistent with Annex III.
- (l) Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.
- (m) Regulatory status of the living modified organism within the State of export (for example, whether it is prohibited in the State of export, whether there are other restrictions, or whether it has been approved for general release) and, if the living modified organism is banned in the State of export, the reason or reasons for the ban.
- (n) Result and purpose of any notification by the exporter to other States regarding the living modified organism to be transferred.
- (o) A declaration that the above-mentioned information is factually correct.

Id.

236. *Id.* at 7 art. 9. The acknowledgment of receipt is to be made in writing and within ninety days of receipt, and must inform the exporter as to any additional information needed, *inter alia*. *Id.* However, “failure by the Party of import to acknowledge receipt of a notification shall not imply its consent to an intentional transboundary movement.” *Id.* art. 9, para. 4.

237. *Id.* at 8 art. 10, para. 6. The Protocol recognizes, however, that the scientific data may be less than definitive:

An importing nation may revisit and revise its initial decision to accept or to reject a particular organism in light of new scientific information.²³⁸ The Protocol also provides for an importing nation to use “simplified procedures” expediting or eliminating the usual AIA steps, “provided that adequate measures are applied to ensure the safe intentional transboundary movement of living modified organisms.”²³⁹

The Protocol establishes a centralized, Internet-based Biosafety Clearing-House for information collection and dissemination.²⁴⁰ The AIA is intended to feed and to draw from the Clearing-House to facilitate informed decisionmaking. When, under the AIA, a nation agrees to accept a genetically engineered organism for importation, it must inform the Clearing-House of this decision, as well as supply information about the organism.²⁴¹ In this way, information will be readily available as to which nations have accepted any given genetically engineered organism, along with technical and scientific data about such organisms. This is meant to assist nations in their decisions whether to accept or reject these life forms for importation.

The Biosafety Clearing-House is also to be used under the Article 11 procedures governing genetically engineered organisms intended for direct use as food or feed or for processing. It mandates that a nation that makes “a final decision regarding domestic use, including placing on the market, of a living modified organism that may be subject to transboundary movement for direct use as food or feed, or for processing, shall, within fifteen days of making that decision, inform the Parties through the Biosafety Clearing-House.”²⁴² Through this means, the internal decisions

Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism . . . shall not prevent [an importer] from taking a decision, as appropriate, with regard to the import of the living modified organism in question . . . in order to avoid or minimize such potential adverse effects.

Id.

238. *Id.* at 10 art. 12.

239. *Id.* art. 13.

240. *Id.* at 15 art. 20. The stated purpose of the Clearing-House is to:

(a) Facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms; and

(b) Assist Parties to implement the Protocol, taking into account the special needs of developing country Parties, in particular the least developed and small island developing States among them, and countries with economies in transition as well as countries that are centres of origin and centres of genetic diversity.

Id. art. 20, para. 1.

241. *Id.* at 7–8 art. 10, para. 3.

242. *Id.* at 8 art. 11, para. 1.

of a nation regarding such uses will be shared with other nations and can be considered by them in their own decisionmaking.

The Article 11 procedures are similar to those under the AIA, but with a somewhat different list of information requirements.²⁴³ The chief difference is the mandated risk assessment.

As provided in Annex III, risk assessment is intended to identify any dangers associated with direct use of genetically engineered organisms as food or feed as compared with dangers from traditional equivalents.²⁴⁴ Annex III requires certain “points” to be considered, as appropriate in each individual case, during the risk assessment.²⁴⁵ As a method of identifying

243. As set forth in Annex II, the requirements are as follows:

- (a) The name and contact details of the applicant for a decision for domestic use.
- (b) The name and contact details of the authority responsible for the decision.
- (c) Name and identity of the living modified organism.
- (d) Description of the gene modification, the technique used, and the resulting characteristics of the living modified organism.
- (e) Any unique identification of the living modified organism.
- (f) Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.
- (g) Centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate.
- (h) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.
- (i) Approved uses of the living modified organism.
- (j) A risk assessment report consistent with Annex III.
- (k) Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.

Id. annex II, at 29.

244. Annex III, paragraph 8 states that risk assessment entails, as appropriate, the following steps:

- (a) An identification of any novel genotypic and phenotypic characteristics associated with the living modified organism that may have adverse effects on biological diversity in the likely potential receiving environment, taking also into account risks to human health;
- (b) An evaluation of the likelihood of these adverse effects being realized, taking into account the level and kind of exposure of the likely potential receiving environment to the living modified organism;
- (c) An evaluation of the consequences should these adverse effects be realized;
- (d) An estimation of the overall risk posed by the living modified organism based on the evaluation of the likelihood and consequences of the identified adverse effects being realized;
- (e) A recommendation as to whether or not the risks are acceptable or manageable, including, where necessary, identification of strategies to manage these risks; and
- (f) Where there is uncertainty regarding the level of risk, it may be addressed by requesting further information on the specific issues of concern or by implementing appropriate risk management strategies and/or monitoring the living modified organism in the receiving environment.

Id. annex III, at 29 para. 8.

245. *Id.* annex III, at 29–30 para. 9. The Annex states that, depending on the case, risk assessment takes into account the relevant technical and scientific details regarding the characteristics of the following subjects:

- (a) *Recipient organism or parental organisms.* The biological characteristics of the recipient organism or parental organisms, including information on taxonomic status,

and evaluating the potential adverse effects of genetically engineered organisms on the “conservation and sustainable use of biological diversity in the likely potential receiving environment, taking also into account risks to human health,”²⁴⁶ risk assessment is to be “carried out in a scientifically sound and transparent manner, and can take into account expert advice of, and guidelines developed by, relevant international organizations.”²⁴⁷ The Protocol provides that the importing nation may require the would-be exporter to conduct the risk assessment or absorb its costs in order to aid in making the decision to accept or to reject an organism.²⁴⁸

Article 16 of the Protocol mandates certain risk management measures. Signatories are required to “take appropriate measures to prevent unintentional transboundary movements of living modified organisms, including such measures as requiring a risk assessment to be carried out prior to the first release of a living modified organism.”²⁴⁹ Additionally, measures “shall be imposed to the extent necessary to prevent adverse effects of the living modified organism on the conservation and sustainable use of biological diversity, taking also into account risks to human health, within the territory of the Party of import.”²⁵⁰ The Protocol also encourages, for each genetically engineered organism, both imported and locally-developed, “an appropriate period of observation that is commensurate with its life-cycle or generation time” prior to first use.²⁵¹

common name, origin, centres of origin and centres of genetic diversity, if known, and a description of the habitat where the organisms may persist or proliferate;

(b) *Donor organism or organisms.* Taxonomic status and common name, source, and the relevant biological characteristics of the donor organisms;

(c) *Vector.* Characteristics of the vector, including its identity, if any, and its source or origin, and its host range;

(d) *Insert or inserts and/or characteristics of modification.* Genetic characteristics of the inserted nucleic acid and the function it specifies, and/or characteristics of the modification introduced;

(e) *Living modified organism.* Identity of the living modified organism, and the differences between the biological characteristics of the living modified organism and those of the recipient organism or parental organisms;

(f) *Detection and identification of the living modified organism.* Suggested detection and identification methods and their specificity, sensitivity and reliability;

(g) *Information relating to the intended use.* Information relating to the intended use of the living modified organism, including new or changed use compared to the recipient organism or parental organisms; and

(h) *Receiving environment.* Information on the location, geographical, climatic and ecological characteristics, including relevant information on biological diversity and centres of origin of the likely potential receiving environment.

Id.

246. *Id.* annex III, at 28 para. 1.

247. *Id.* para. 3.

248. *Id.* at 12 art. 15, paras. 2–3.

249. *Id.* art. 16, para. 3.

250. *Id.* para. 2.

251. *Id.* para. 4.

For emergency situations such as unplanned releases or movements of genetically engineered life forms, Article 17 establishes some requirements. The Biosafety Clearing-House is again employed to gather and disseminate information quickly concerning any release of such organisms “that leads, or may lead, to an unintentional transboundary movement” and “is likely to have significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.”²⁵² In addition, direct and immediate notification is to be made to all nations likely to be affected by these incidents.²⁵³

Finally, in recognition of the public outcry in several European nations and after lengthy and contentious negotiations, the Protocol mandates certain labeling of genetically engineered organisms.²⁵⁴ Initially, the labeling requirement has been couched in general terms, such as a label that a shipment “may contain” living genetically engineered organisms, but the Protocol provides for decisions regarding more detailed requirements for organisms intended for direct use as food or feed or for processing within two years after entry into force.²⁵⁵ Article 18 sets forth labeling provisions for various circumstances.²⁵⁶

252. *Id.* at 13 art. 17, para. 1. Direct notifications to other nations and international organizations are also required, as appropriate. *Id.*

253. *Id.* para. 4.

254. See Gareth W. Schweizer, Note, *The Negotiation of the Cartagena Protocol on Biosafety*, 6 ENVTL. LAW. 577, 599–600 (2000).

255. Cartagena Protocol, *supra* note 217, at 14 art. 18, para. 2(a).

256. *Id.* art. 18. Article 18, paragraph 2 provides that each Party shall take measures to require that documentation accompanying:

(a) Living modified organisms that are intended for direct use as food or feed, or for processing, clearly identifies that they “may contain” living modified organisms and are not intended for intentional introduction into the environment, as well as a contact point for further information. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall take a decision on the detailed requirements for this purpose, including specification of their identity and any unique identification, no later than two years after the date of entry into force of this Protocol;

(b) Living modified organisms that are destined for contained use clearly identifies them as living modified organisms; and specifies any requirements for the safe handling, storage, transport and use, the contact point for further information, including the name and address of the individual and institution to whom the living modified organisms are consigned; and

(c) Living modified organisms that are intended for intentional introduction into the environment of the Party of import and any other living modified organisms within the scope of the Protocol, clearly identifies them as living modified organisms; specifies the identity and relevant traits and/or characteristics, any requirements for the safe handling, storage, transport and use, the contact point for further information and, as appropriate, the name and address of the importer and exporter; and contains a declaration that the movement is in conformity with the requirements of this Protocol applicable to the exporter.

Id. para. 2.

The Protocol has expressly reserved politically contentious issues of liability and redress of damage for future determination. The goal is to have a process in place within four years after entry into force.²⁵⁷

Reflecting the political and scientific controversy regarding the merits and risks of genetically engineered organisms, and the forcefully divergent views regarding some of its key provisions, the Protocol affirms the "Precautionary Principle" as its overarching guiding principle.²⁵⁸ The Precautionary Principle holds, in essence, "that where there is a threat of significant reduction or loss of biological diversity, lack of full scientific certainty should not be used as a reason for postponing measures to avoid or minimize such a threat."²⁵⁹ This principle is included in several declarations and treaties and is rapidly becoming a basic tenet of international environmental law.²⁶⁰

The United States is not a signatory, despite, or perhaps because of, its role as the world leader in biotechnology and the leading exporter of genetically engineered products.²⁶¹ Among the points of contention during the years of negotiations and debate that preceded the Protocol were the issues of undue burdens on producers, exporters, and international trade in general as well as the scope of the Protocol, its relationship to other international accords, and the potential liability for environmental damage caused by transgenic organisms.²⁶² In contrast, numerous developing nations signed the Protocol because they were fearful of environmental damages from unregulated use and argued that the Protocol would help compensate for their lack of sufficient resources to assess the risks themselves.²⁶³ In addition, these nations hoped to avoid economic hardship

257. *Id.* at 20 art. 27.

258. *Id.* at 2 (reaffirming "the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development").

259. CBD, *supra* note 219, at 822.

260. *See* Schweizer, *supra* note 254, at 593. *See generally* James E. Hickey, Jr. & Vern R. Walker, *Refining the Precautionary Principle in International Environmental Law*, 14 VA. ENVTL. L.J. 423 (1995).

261. *Focus of Biosafety Protocol*, *supra* note 219, at 177. Although the United States has not ratified the CBD, the parties to the CBD afford equal weight to opinions of the United States because about three-quarters of the world's farmland growing transgenic crops is within the United States. Dawkins, *supra* note 20, at 10.

262. Other major exporters of these products also opposed the Protocol, including Canada, Australia, Argentina, Chile, and Uruguay. *See* Susan Ladika, *Informal Talks Seen to Reaffirm Commitment of All Parties to Agree on Biosafety Protocol*, 22 Int'l Env't Rep. (BNA) 786 (Sept. 29, 1999).

263. *See* Schweizer, *supra* note 254, at 587-88. Although generally in a more favorable economic and technological posture, the European Union nations mostly shared the position of the developing nations. *See id.* at 588-89.

resulting from the competitive advantages other countries that are more capable of producing genetically engineered products could enjoy.²⁶⁴

The United States was also concerned that notification and labeling requirements would present very difficult practical problems, including the challenge of keeping track of and segregating genetically engineered products as opposed to their often phenotypically identical unmodified counterparts.²⁶⁵ Such requirements were believed to be overly burdensome, expensive, and not justified by the available evidence on risks.²⁶⁶

Partially in response to the Protocol, the United States and the European Union concluded an agreement in Lisbon, Portugal on May 31, 2000, to establish a Consultative Forum to review and to assess the benefits and risks of biotechnology and to prepare a report for the December 2000 United States-European Union Summit.²⁶⁷ The Forum will include individuals from outside government covering a broad range of perspectives, expertise, and interests, including people with backgrounds in labor, academia and business, scientists, ethicists, environmental interests, farmers, and consumers. They will look at factors such as the food security needs of developing countries, food safety, health, and the environment.²⁶⁸

The Protocol will only exert such indirect influence on this nation until and unless the United States becomes a signatory. Depending on the manner in which various provisions of the Protocol are implemented by each signatory, however, there could be a significant impact on American exports. As nations impose some form of labeling requirement for genetically engineered organisms and derived commodities, or even outright bans on such imports, American producers will face difficult challenges and threats to their continuing profitability. If there is sufficient international market pressure, American producers may find it necessary to develop effective segregation procedures, and to institute labeling of all transgenic commodities regardless of whether they are intended for export

264. Dawkins, *supra* note 20, at 12–13.

265. Schweizer, *supra* note 254, at 587, 592–94. See generally *Working Group Report*, *supra* note 217 (summarizing discussions among members of the Biosafety Working Group).

266. Schweizer, *supra* note 254, at 587, 592–94. According to the Clinton Administration, lack of public confidence in the European food safety system has led to a standstill on approval of biotech foods. This is significantly undermining progress on food security in developing nations, causing uncertainty in markets around the world and harming U.S. farm exports. The European Union's prevention of U.S. corn exports to Spain and Portugal has reportedly cost U.S. producers about \$200 million per year in lost corn sales since 1998. *U.S.-E.U. Cooperation on Biotechnology: White House Fact Sheet* (May 31, 2000), <http://www.usis.hu/biotech.htm> [hereinafter *White House Fact Sheet*].

267. *White House Fact Sheet*, *supra* note 266.

268. *Id.*

or import. The alternatives would be either to have totally different procedures and labels, depending on the intended destination, or unilaterally to curtail the use of genetic engineering in food production. The preferred option among this short menu of bad choices would depend on the degree to which international restrictions affect the profitability of genetically engineered commodities.

As mentioned, issues of liability for damage caused by genetically engineered organisms have been reserved for future determination under the Protocol.²⁶⁹ One can only guess what form the liability provisions might eventually take, but they are certain to provoke further controversy. The prospect of potential civil or criminal liability for such harms in the international arena may become another factor arguing against further expansion of the use of genetic engineering when added to new labeling mandates, spiraling public opposition throughout the world, and mounting consumer resistance to transgenic products. Rather than fight legal battles initiated by plaintiffs in a host of different nations under various legal standards and in unpredictable international venues, industry leaders may decide that, at last, the costs outweigh the benefits. Old-fashioned, less-productive, pesticide-dependent crops may experience a perverse resurgence, bringing with them their own set of environmental impacts.

For those nations that sign on to the Protocol, they will find that its main short-term effect will be in the area of information flow. Use of the Biosafety Clearing-House, the AIA procedures, and the labeling requirements will require nations to adjust their standard practices to comply with the several forms of information sharing and dissemination. The Biosafety Clearing-House in particular may prove to be a valuable tool as it becomes the central repository for information concerning the movements and effects of genetically engineered organisms and products. Eventually, there could be sufficient experiential data to fuel further legislative initiatives, whether on the side of stricter controls or the reverse. Given that the primary problem with the transgenic revolution is the paucity of reliable, experience-based information as to the long-term positive and negative effects, the Biosafety Clearing-House may one day supply answers to some of the key questions. In the interim, however, the Protocol and other international legal measures may inflict considerable damage on the biotechnology industry and its beneficiaries worldwide.

269. Cartagena Protocol, *supra* note 217, at 20 art. 27.

VI. A PROPOSAL FOR A UNIFIED APPROACH: THE TRANSGENIC RELEASE ACT

The Article thus far has discussed the serious legal, scientific, and public policy disputes that swirl around the phenomenon of genetic engineering like a “dirt devil” whirlwind. The controversy is rapidly moving, furiously powerful, unpredictable, and riddled with potential hazards. If the wrong regulatory decisions are made, including the decision to do nothing at all, we may “inherit the wind,” with calamitous consequences.

The factor that makes this an especially vexing problem is the extreme weightiness of both the potential benefits of genetically engineered organisms and the potential harms to the environment they might cause. If either side of the equation were less substantial, the proper course of action would be much easier to discern.

If continued or even expanded use of genetically engineered organisms did not hold a justifiable claim to offering enormous environmental and human benefits, the logical response would be strict, comprehensive command-and-control regulation, perhaps including an outright ban. But this technology can greatly increase the productivity and efficiency of agriculture, thereby feeding more people with fewer acres diverted to food production from natural uses. Obviously, in light of the burgeoning global population and dwindling natural resources, particularly in some developing nations such as India, China, and much of sub-Saharan Africa, this is a matter of great significance. Through the use of Bt and similar crops, farmers can cut back on their use of traditional chemical pesticides, thus reducing the substantial environmental harms generated by such toxins, while at the same time boosting the quantity and quality of the food they produce.²⁷⁰

Conversely, if the potential environmental risks presented by widespread genetic engineering were not rooted in plausible scientific principle, they could be dismissed as the stuff of Grade B science fiction films. The appropriate approach, in light of the great aforementioned benefits, would be swift and wide-sweeping deregulation, perhaps including generous federal subsidies to encourage more advancements in genetic engineering. The rallying cry would be, “Let a thousand transgenic

270. See generally ADVANCES IN INSECT CONTROL: THE ROLE OF TRANSGENIC PLANTS (Nadine Carozzi & Michael Koziel eds., 1997); ENGINEERED ORGANISMS IN ENVIRONMENTAL SETTINGS: BIOTECHNOLOGICAL AND AGRICULTURAL APPLICATIONS (Morris A. Levin & Eitan Israeli eds., 1996); LOUIS MARIE HOUEBINE, TRANSGENIC ANIMALS: GENERATION AND USE (1997).

flowers bloom!" But this is still a very young field of scientific and practical endeavor, and our base of experience is quite small. There are legitimate theoretical scientific concerns on multiple grounds.²⁷¹ The lack of a catastrophic incident to date should not motivate us to declare victory and go home. Given the brief period of significant use, and the array of theoretically serious environmental hazards, there is a need for vigilance backed up with regulatory muscle.

The fears expressed by some vocal members of the general public, as sometimes expressed through violent protest, are not easily brushed aside. They may often be based more on rumors, unfounded assumptions, and fear of the unknown than on scientific principles or controlled experiments.²⁷² This is itself symptomatic, however, of some of the defects in the current regulatory scheme—the paucity of opportunities for meaningful public involvement at all levels, the dearth of information flow, and the failure to educate the public.

Some doubt exists even among scientists. The advantages genetic engineers have conferred upon plants and animals could enable them to out-compete native species and reduce biodiversity, with possible loss of some species entirely. These advantageous traits, such as pesticide resistance, could be transferred to weeds or other potentially intrusive and harmful species, and may lead to uncontrollable profusion of the new

271. See generally GENETICALLY ENGINEERED MARINE ORGANISMS: ENVIRONMENTAL AND ECOLOGICAL RISKS AND BENEFITS (Raymond A. Zilinskas & Peter J. Balint eds., 1998); GÖSTA KJELLSSON & VIBEKE SIMONSEN, METHODS FOR RISK ASSESSMENT OF TRANSGENIC PLANTS: I. COMPETITION, ESTABLISHMENT AND ECOSYSTEM EFFECTS (1994); METHODS FOR RISK ASSESSMENT OF TRANSGENIC PLANTS: II. POLLINATION, GENE-TRANSFER AND POPULATION IMPACTS (Gösta Kjellsson et al. eds., 1997); METHODS FOR RISK ASSESSMENT OF TRANSGENIC PLANTS: III. ECOLOGICAL RISKS AND PROSPECTS OF TRANSGENIC PLANTS, WHERE DO WE GO FROM HERE? A DIALOGUE BETWEEN BIOTECH INDUSTRY AND SCIENCE (Klaus Ammann et al. eds., 2000); TRANSGENIC ORGANISMS: BIOLOGICAL AND SOCIAL IMPLICATIONS (J. Tomiuk et al. eds., 1996); TRANSGENIC ORGANISMS: RISK ASSESSMENT OF DELIBERATE RELEASE (K. Wöhrmann & J. Tomiuk eds., 1993).

272. There has been a profusion of mass-market books in recent years expounding the supposed evils of genetic engineering. While generally lacking scientific rigor, these books reflect the public's suspicions and concerns. See, e.g., LUKE ANDERSON, GENETIC ENGINEERING, FOOD, AND OUR ENVIRONMENT (1999); MICHAEL W. FOX, BEYOND EVOLUTION: THE GENETICALLY ALTERED FUTURE OF PLANTS, ANIMALS, THE EARTH . . . AND HUMANS (1999); MAE-WAN HO, GENETIC ENGINEERING—DREAM OR NIGHTMARE?: THE BRAVE NEW WORLD OF BAD SCIENCE AND BIG BUSINESS (1998); ALAN MCHUGHEN, A CONSUMER'S GUIDE TO GENETICALLY MODIFIED FOOD: FROM GREEN GENES TO RED HERRINGS (2000); JANE RISSLER & MARGARET MELLON, THE ECOLOGICAL RISKS OF ENGINEERED CROPS (1996); MARTIN TEITEL & KIMBERLY A. WILSON, GENETICALLY ENGINEERED FOOD: CHANGING THE NATURE OF NATURE—WHAT YOU NEED TO KNOW TO PROTECT YOURSELF, YOUR FAMILY, AND OUR PLANET (1999); LAURA TICCIATI & ROBIN TICCIATI, GENETICALLY ENGINEERED FOODS: ARE THEY SAFE? YOU DECIDE (1998).

strains. Like a super-powered version of pest plants such as kudzu, these variants could drive out crops and naturally growing species. Any attempts to control their spread, even if ultimately successful, would ironically require widespread use of very large amounts of new and possibly highly toxic pesticides, which in turn would cause considerable environmental harm. These and other specters cannot be dismissed out of hand at the present time.

Thus, we are faced with a momentous issue. We have a new technology that glitters with promise, offering the world's rapidly growing, largely undernourished population the possibility of desperately needed relief. The hungry, environmentally stressed developing nations could have significantly more food, of better nutritional value and longer shelf life, while disturbing less wild land and using lower quantities of toxic pesticides. But this new technology arrived only yesterday, in a sense, and it came gift-wrapped in a shiny, inviting, but mysterious package. Right now, no one is certain what we will find once we remove all the ribbons, bows, paper, and packing materials. Pandora's Box at first looked good, too, but once it was flung open it was too late, not only for Pandora, but for the whole world.

Unfortunately, we do not have a system in place to address both the substantial environmental and other benefits and the substantial environmental risks of genetic engineering. Each federal agency now involved defines genetically engineered entities in terms consistent with its own regulatory authority, with the result that there is no uniform interagency definition or agreement as to the scope of entities regulated and there are potential gaps in regulatory coverage.²⁷³ There is also a substantial level of duplication of effort, with multiple agencies demanding the submission of similar information from industry.²⁷⁴

The EPA has only FIFRA and TSCA in its arsenal; these statutes were not drafted with this problem in mind, nor are they capable of adequately addressing it as an afterthought. There are gaps in coverage, and the regulatory mechanisms are inappropriate for this unique, multifaceted problem. Also, because of the lack of resources within the EPA that have been exclusively devoted to transgenic organisms, there are difficulties in implementation. The USDA/APHIS is not primarily in the business of environmental protection, and its statutory hook, the FPPA, was not meant to handle genetically engineered organisms. So, as with the EPA and its

273. NRC 2000, *supra* note 17, at 158-59.

274. *Id.* at 162-65.

FIFRA/TSCA statutes, the involvement of the USDA/APHIS is incomplete and less than effective in terms of addressing the environmental risks and benefits.

The FDA role, of course, does not extend to environmental protection. Although the FDA has used the FFDCA to regulate certain aspects of genetically engineered organisms as foods or food ingredients in a rational and responsible manner, the agency cannot solve the environmental part of the puzzle, nor should it try. The Coordinated Framework has properly given the FDA the only portion of this issue that fits within its purview.

We therefore have a confusing and ineffective regulatory scheme in place with which to handle the difficult environmental questions posed by transgenic organisms. We have multiple agencies involved, some of them attempting to regulate genetic engineering with statutory mechanisms that simply cannot do the job. Although it might be necessary to use a shoe to pound in a nail if no hammer is handy, the current system governing the environmental regulation of transgenic organisms is equivalent to forcing a nonspecialist to perform brain surgery with a fingernail clipper.

With no single federal agency primarily or exclusively responsible for oversight, there is reduced opportunity and incentive to hire the appropriate experts or to develop in-house the specialized expertise needed for intelligent regulatory decisions. Furthermore, the regulated community must deal with a multiplicity of agencies, each with its own people, policies, and procedures; this leads to inefficiency, duplication of effort, and unnecessarily high transaction costs, which translate into higher prices for consumers and prolonged delays in bringing useful products to market.

There is far too much at stake, on both sides of the balance, to be satisfied with the status quo.²⁷⁵ This Article proposes a unified approach that gives appropriate weight to each of the competing issues.

The subject of the environmental effects, both positive and negative, of genetically engineered organisms deserves better than the piecemeal, force-fitted treatment it currently receives under the FIFRA, TSCA, and

275. Other commentators have noted the need for reform in this area. See Scott D. Deatherage, *Scientific Uncertainty in Regulating Deliberate Release of Genetically Engineered Organisms: Substantive Judicial Review and Institutional Alternatives*, 11 HARV. ENVTL. L. REV. 203 (1987); Judy J. Kim, *Out of the Lab and Into the Field: Harmonization of Deliberate Release Regulations for Genetically Modified Organisms*, 16 FORDHAM INT'L L.J. 1160 (1993); Gary Merchant, Note, *Modified Rules for Modified Bugs: Balancing Safety and Efficiency in the Regulation of Deliberate Release of Genetically Engineered Microorganisms*, 1 HARV. J.L. & TECH. 163 (1988); Saperstein, *supra* note 77; Michael P. Vandenberg, Note, *The Rutabaga That Ate Pittsburgh: Federal Regulation of Free Release Biotechnology*, 72 VA. L. REV. 1529 (1986).

FPPA patchwork quilt of statutes. The subject is new, emerging, and unique. It requires a statute drafted specifically to address the particular risks and benefits presented by this cutting-edge technology.

Genetically engineered organisms should no longer be regulated under FIFRA, TSCA, or the FPPA. As discussed previously, these statutes were written to handle entities quite different from transgenic life forms. It has taken strained interpretation and agency overreaching to bring these organisms within the applicable definitions of pesticide, chemical substance, or plant pest. The poor fit has translated into incomplete and ineffective regulation. The EPA and the USDA/APHIS should drop genetically engineered organisms from consideration under these statutes.

As an alternative, it is proposed herein that Congress enact a new statute, provisionally entitled the Transgenic Release Act (TRA). As envisioned, the TRA would be administered solely by the EPA. The TRA would be the only federal statute regulating the environmental effects of genetically engineered organisms.

The TRA would be a very important statute because of the critical interests that could be adversely affected by either overly intrusive or excessively lax regulation. If Congress attempts to draft such a statute, it would be advisable to remain cognizant of some of the problems that have plagued other federal environmental laws, such as the Endangered Species Act (ESA)²⁷⁶ and the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA).²⁷⁷ Key terms must be clearly defined in a practical, usable manner. Streamlined procedures and avoidance of bureaucratic bottlenecks are necessary for effective functioning. Liability provisions must be fair, and be perceived as fair, with an eye toward the danger of creating perverse incentives. There should be an effective mechanism for educating the general public and creating a productive dialogue with people in the communities most directly affected. Above all, the TRA must make sense on a scientific level, with realistic and level-headed provisions that give appropriate weight to both the risks and benefits of genetic engineering.

With these overarching concerns in mind, I suggest that the TRA contain the following major provisions.

276. 16 U.S.C. §§ 1531–1534 (1994).

277. 42 U.S.C. §§ 9601–9675 (1994).

A. REGISTER OF TRANSGENIC ORGANISMS

The TRA should mandate creation of an EPA-maintained register of transgenic organisms. This would be a list, or more accurately a database, of all genetically engineered organisms in existence within the jurisdiction of the United States, and perhaps worldwide. The register would include detailed information as to the genetic structure and phenotypic traits of the organism in question, along with corresponding information as to the “parent” organisms. Summaries of field tests, other experiments, and any available information relating to notable phenotypic characteristics of parents and progeny would be part of the data submission. The proponent of any new organism would be responsible for including a risk assessment, describing the best available scientific evidence of the prospects for harm to the environment.

There should be a mechanism for ensuring that creators and producers of new genetically engineered organisms supply the requisite information in a timely manner before releasing them beyond a self-contained laboratory environment. Also, in a process analogous to re-registration of pesticides under FIFRA, organisms that predate the effective date of the TRA must be included in the register within a certain reasonably short period of time.

The onus of providing the information to the EPA would rest on the producers of genetically engineered organisms. These are the people and organizations who stand to profit, and the data submission for the register would be a cost of doing business. Failure to comply in a timely manner would be subject to meaningful administrative fines and penalties. Where the producers cannot be identified or no longer exist, the EPA would be responsible for gathering the information itself.

This is not intended to be an evaluation or approval process. One of the lessons of the ESA is that there can be lengthy administrative delays and wasteful bureaucratic inertia when an agency attempts to screen numerous submissions of scientific and technical data.²⁷⁸ The idea is to collect the information in a central repository as quickly as possible so as to make it available to decisionmakers and the general public. The FDA process under the FFDCAs would remain in place as an effective prophylactic for products intended for use as foods, food additives, and drugs. For all other uses, submission of data for purposes of registration under the TRA would be an administrative task within the responsibility of

278. Kunich, *supra* note 25, at 532–38, 567–71.

the producers of new transgenic organisms. There would be no screening or testing process as a prerequisite to release, and no delays in getting new organisms to the consumer. Any actual harmful effects would be addressed by the liability provisions discussed below.

The register would be available on-line at the EPA web site, as well as in paper form. One key feature would be accessibility to citizens at the local community level. The EPA would be responsible for informing the public about the existence and potential utility of the register, so that concerned citizens would be aware of this tool.

B. INFORMATION-FLOW SYSTEM

A natural corollary of the TRA register would be a system for information sharing similar to that under the Emergency Planning and Community Right-to-Know Act (EPCRA).²⁷⁹ This is intended to provide a partial antidote to the current problem of widespread public misinformation and misunderstanding.

As with the EPCRA, the TRA would require information flow to and between certain organizations within each community as to the presence of genetically engineered organisms. Any life forms on the TRA register would be the subject of mandatory notifications to these organizations, both as to the initial introduction of such organisms into the local area and periodic reports as to the extent of their local prevalence. Moreover, as additional information becomes available on the effects and characteristics of each organism, it would be incorporated into the database and communicated to the relevant communities.

In order to make this information flow useful and meaningful, the TRA should mandate regularly recurring public meetings at which experts address the scientific and environmental concerns. It is not enough to indicate which genetically engineered organisms are present in each community. There must be an explanation, on a level understandable by the layperson, as to the risks and benefits presented by each such organism and what can be done to minimize the dangers. This educational function is extremely important,²⁸⁰ and it should be approached through multiple

279. 42 U.S.C. §§ 11001–11050 (1994).

280. Many of the protests and acts of destruction mentioned earlier are arguably traceable to a lack of public understanding of the dimensions of the risks and benefits of transgenic organisms. For example, it is unlikely that there would be such an outcry against genetically engineered food products if more people had recurring exposure to, and ready access to, all the available evidence pointing to the safety of these commodities.

avenues, including in-person public meetings, periodic press releases on a regional, national, and international scale, and a widely publicized web site.

Because many agricultural activities take place a considerable distance from major metropolitan areas, the TRA should define the relevant communities using at least two criteria. First, and most analogous to the EPCRA model, the municipalities in the proximity of widespread agricultural use of transgenic organisms must be kept informed, with real opportunity for information flow and dialogue on matters that most directly affect them. Second, so as to include urban areas only indirectly affected by agriculture, there should be a more general information-sharing mechanism to apprise citizens of the risks and benefits of the most prevalent transgenic organisms, with particular emphasis on those used in the closest farming areas. Again, there must be an organized educational initiative, to elevate the level of the debate and inform decisionmaking on a broad scale. Most important, the EPA should ensure that widely held misconceptions are appropriately and persuasively addressed.

This portion of the TRA could borrow some of the positive features of the Biosafety Clearinghouse as established by the Cartagena Protocol on Biosafety. Under the TRA, a specifically designated subsidiary organization within the EPA would be responsible for gathering and disseminating as much information as reasonably feasible concerning the varieties, locations, effects, and movements of genetically engineered organisms. Indeed, the EPCRA-like aspects of the TRA could come under the umbrella of a Transgenic Information Exchange (TIE). Similar to the Biosafety Clearinghouse, the TIE would feed useful information to the relevant communities affected by the presence of genetically engineered organisms, and would enable people in these and other communities to track the movements of such life forms and learn more about their potential dangers and benefits.

The horror-film types of fears expressed by many people, first in Europe and now in the United States, have undoubtedly played a major role in shaping public policy decisions and legislation, including the Cartagena Protocol on Biosafety. To the extent these fears are rooted in unsubstantiated and scientifically unsupported assumptions that genetically engineered food products are unsafe and should be banned as "Frankenstein foods," they may spur counterproductive and very costly governmental decisions. We have seen that there are some legitimate, albeit largely theoretical, environmental concerns regarding genetic engineering, but there is essentially no reliable evidence or reasonable hypothesis in support of the Frankenstein foods position. Yet, in response

to the public outcry, nations are taking steps that could eliminate beneficial foods from the market and make food more expensive for everyone, while simultaneously increasing pesticide use. The consequences could range from lost profits to life-threatening food shortages, depending on which nations are affected. It is extremely dangerous to allow governmental decisions to be driven by unfounded fears, particularly where there is evidence available that could allay those fears.

The TRA might make a major contribution by injecting a healthy dose of hard facts and rigorous scientific discipline into the public debate. "Ultimately, the credibility of the regulatory process will depend heavily on the public's ability to understand the process and the key scientific principles on which it is based."²⁸¹ The information-flow mechanism, together with the register of genetically engineered organisms, would be a useful tool for shaping public opinion. By extension, public opinion would be less apt to call for ill-advised and harmful regulatory and legislative actions.

C. CENTER FOR TRANSGENIC RESEARCH AND TESTING

The third portion of the proposed informational/educational triad under the TRA could be a federal Center for Transgenic Research and Testing (CTRTR). A federally funded CTRTR would conduct basic and applied research on genetically engineered organisms, with an eye toward maximizing the benefits derived therefrom while identifying and counteracting any environmentally deleterious effects.

The CTRTR should be staffed with the best scientific and technical experts the EPA can attract, either on a full-time basis or through grants. The EPA would exercise some oversight to steer the research in the direction of those organisms or problems deemed to be most significant to the nation. For example, if the EPA determines that the issue of intractable insect pests evolving in response to Bt crops warrants a top priority, the CTRTR would be directed to conduct experiments relevant to that problem. Likewise, the EPA could use the auspices of CTRTR research grants to fund projects evaluating the question of "Roundup-Ready" weeds emerging as a side-effect of pesticide-resistance crops.

Although such focused, applied research would comprise one aspect of CTRTR activity, there is also value in basic research. If the CTRTR can further the overall state of the art of genetic engineering through gene

281. NRC 2000, *supra* note 17, at 155.

mapping or development of a better working model of how species cross-breed, that could pay practical dividends in a variety of situations in the future.

There should be public dissemination of information as to all past and present research projects undertaken by the CTRT, so that people can understand what is being done and what key topics of inquiry have been identified by the federal government. In addition to the subject matter of each project, there should also be information flow as to the results, with appropriate use of layperson's nomenclature to make the results accessible to the general public. This information would be shared through the TIE clearinghouse and community involvement meetings in a variety of forms. The EPA would use multiple avenues to communicate with concerned citizens to teach them what the best experts believe are the most pressing issues and to demonstrate the best available evidence as to the magnitude of both risks and benefits.

D. REMEDIATION LIABILITY

There must be some mechanism within the TRA to deal with any environmental harms that are caused by genetically engineered organisms. Although not a high probability, there is a chance that these life forms will, at some point, cause some damage to the environment. As proposed, the TRA would not require prerelease testing or certification; this seems appropriate given the evident heavy preponderance of benefits over risks for the genetically engineered organisms in use up until now. There should, however, be a system in place to address any harms that do occur.

In developing a liability scheme, it is easy to miscalculate the appropriate degree of "stick" along the carrot-stick continuum. Such mistakes in other federal environmental statutes of the command-and-control variety have arguably generated perverse incentives, created the public impression of unfairness, spawned endless, contentious litigation, and discouraged innovation.²⁸² This is an especially sensitive matter in areas of promising cutting-edge technology, where it is most important not to stifle creativity and entrepreneurship. Congress would not likely desire to relive the liability controversies brought about by CERCLA and ESA.

It seems appropriate to equip the TRA with a remediation mechanism sufficient to restore the *status quo ante* where genetically engineered

282. See generally Kunich, *supra* note 25 (examining the flaws in the Endangered Species Act that have led to such problems).

organisms cause identifiable harm to the environment. The EPA should be empowered to assess administrative penalties that cover, in effect, the clean-up costs reasonably attributable to such organisms. These penalties would be assessed against the producers, not against the users, unless it can be shown that the users deviated substantially from the producer's recommendations. User liability in any other form would be too powerful a disincentive to trying innovative and probably highly beneficial techniques. Also, there should be no provisions for double or treble damages, only reimbursement of the EPA for the actual remediation costs, so as not to place an overly onerous burden on producers of transgenic organisms.

The EPA would conduct the remediation action in-house rather than compel the producer to do so, using funds from assessed penalties. This would facilitate a consistent federalized approach and allow the EPA to develop expertise. It would also avoid the CERCLA third-party and "potentially responsible party" inefficiencies and inequities.

CONCLUSION

The only aspect of genetic engineering about which there is no controversy is its importance. Proponents and opponents alike agree that this phenomenon is one of the most significant developments in recent history, with huge potential to influence human health and the environment. The great divide, of course, centers on the merits. Is genetic engineering the answer to many of the hunger, health, and environmental problems of the modern world? Or is it potentially the cause of widespread and devastating harm to people and our planet?

This Article has demonstrated that the current statutory and regulatory patchwork quilt is inadequate to bridge the great divide and cannot prevent serious errors on either side. There are too many agencies involved for any one of them to become truly expert in this highly specialized and sophisticated technical domain. The statutes and regulations that have been used to address the phenomenon were never designed for such issues, and the result is a very poor fit. There are gaps in coverage, strained attempts to regulate transgenic organisms as if they were conventional chemicals, and an overall lack of meaningful guidance to the regulated community.

These problems are equaled by the absence of a workable, unified mechanism for information flow and public education on the risks and benefits of genetic engineering. Ill-informed public opinion has already sparked onerous legislation and restrictions in some European nations. The Cartagena Protocol on Biosafety is a first step in the direction of broad-

based international regulation, largely driven by public misconception and fear of the unknown. With opposition to genetic engineering becoming a trendy *cause célèbre*, there likely will be further increases in public concern, which could put pressure on elected officials to impose further restrictions, including within the United States.

This Article proposes replacing the current patchwork scheme with a single statute, the Transgenic Release Act (TRA), administered by a single agency, the EPA. The TRA, as outlined above, would provide an appropriate level of regulation while avoiding unnecessary disincentives to innovation and progress.

Comprehensive legislation such as the TRA would perhaps be most helpful in informing the general public and shaping public debate. The process of enacting such a statute would serve a valuable educational function in itself. Although prominent critics would denounce the TRA as inadequate, many people would learn about the legitimate scientific advantages of genetic engineering as well as the dangers. After the TRA becomes law, its research and EPCRA-like information-flow provisions would allow the federal government both to develop reliable information and to communicate it to the citizenry with a unified voice and in an organized, systematic manner. Such frequent, significant doses of authoritative information should be an antidote to baseless epidemics of fear. If the TRA diminishes the risk that unwarranted public hysteria will force counterproductive policy and legislative decisions, it will be worthwhile for that reason alone.

Perhaps the gravest danger regarding genetic engineering is that misplaced public concern will spawn hastily drafted, unnecessary, and shortsighted quick fixes. The brief history of federal environmental law is in large part a record of governmental reaction to popular pressure, often generated by heavily publicized incidents. Certainly, phenomena such as Love Canal, Three Mile Island, the plight of the bald eagle, and the Exxon Valdez oil spill were symptomatic of larger problems deserving of governmental attention. But in their haste to do something in the face of public demand for action, legislators have too often enacted statutes that fail to give proper weight to all relevant competing interests. Environmental laws along the lines of CERCLA, RCRA, and the ESA were developed too quickly, without appropriate consideration of scientific principles and risk-benefit analysis. The ensuing decades of controversy and ineffectiveness have harmed the environmental movement while not significantly improving the quality of the environment.

It is paramount that we not add to this list with a federal statute that cripples biotechnology. The situation in Europe, where unwarranted but widespread and well-publicized fears regarding genetic engineering have produced a burgeoning array of regulations and restrictions, shows signs of being replicated in the United States.²⁸³ But, as serious as the shortcomings of some other federal environmental statutes have been, a bad law clamping down hard on genetic engineering could be far worse. The wrong decision in this category could literally spell the difference between life and death for multitudes of people in the poorest regions of the globe. Modern food and medicine production could be devastated, with tragic effects on developing peoples. And, in addition to the direct toll on human life and health, the loss of transgenic options could also necessitate the conversion of more irreplaceable natural habitats to agricultural use and the continued increase in utilization of toxic pesticides. The likely benefits to be reaped from genetic engineering are so enormous that a properly balanced approach such as the TRA is essential. The wrong legislation could have negative consequences far beyond any so far seen in the checkered history of environmental regulation.

The TRA would create an effective, risk-appropriate safeguard against the improbable, largely theoretical, but still real hazards posed by some aspects of genetic engineering. There would for the first time be a comprehensive federal means for addressing its risks, while not depriving the world of much-needed advancements in human health and the environment. It is this crucial balance between protecting against mostly potential dangers and keeping the door open for mostly verifiable benefits that is lacking in the current legal framework. Only a specifically tailored federal statute, administered solely by the EPA on a long-term basis, can properly perform the necessary functions that will maintain the balance in a prudent and informed fashion.

Fear of the unknown is a powerful force. When it translates into ill-advised policies and regulations, it can have disastrous and unintended consequences. This Article has illustrated the vast impact that modern genetic engineering has had on the world during its very brief existence. This new technology could save countless human lives and improve the

283. The title of this article is meant to illustrate the horror-film level of fears that have motivated so much of the environmental law in this poorly understood area. The nightmare scenario is that, when Mother Nature meets Doctor Frankenstein, genetic engineering could switch their genes to create uncontrollable, bizarre, and dangerous hybrid monsters. But we have seen that there is little if any objective scientific reason to suppose that modern genetic engineering will unleash either a Mother Frankenstein or a Doctor Nature on a defenseless world. Nonetheless, the laws and policies of great nations are being changed as if this were a real danger.

quality of life for many more, while also protecting the environment from over-development and pesticides. The best available scientific evidence indicates that these benefits are more than a theoretical possibility. At the same time, genetic engineering could cause great harm to health or the environment, but this is almost exclusively in the realm of theory and speculation at present. The legal system must play a key role in focusing the government's attention on the benefits and the risks, not because of baseless fear, but on the basis of solid scientific evidence.