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**The Regulation of Genetically Engineered
Plants: Is Peter Rabbit Safe in Mr. McGregor's
Transgenic Vegetable Patch?**

by

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THE REGULATION OF GENETICALLY ENGINEERED PLANTS: IS PETER RABBIT SAFE IN MR. MCGREGOR'S TRANSGENIC VEGETABLE PATCH?

BY
DAVID J. EARP, PH.D.*

| | | |
|------|--|------|
| I. | INTRODUCTION | 1634 |
| II. | BACKGROUND | 1635 |
| III. | THE STATUTORY BASIS FOR USDA REGULATION OF TRANSGENIC PLANTS | 1640 |
| | A. <i>The Development of a Federal Regulatory Policy</i> | 1640 |
| | B. <i>USDA Regulation of Transgenic Plants</i> | 1641 |
| IV. | THE SCIENCE UNDERLYING THE CREATION OF TRANSGENIC PLANTS | 1643 |
| | A. <i>Traditional Plant Breeding</i> | 1643 |
| | B. <i>Production of New Plant Varieties by Genetic Engineering</i> | 1645 |
| | C. <i>Examples of Transgenic Plants Approved for Field Testing</i> | 1648 |
| | 1. <i>An Example from USDA's Old Permitting System: Virus Resistant Plants Containing Virus Coat Protein Genes</i> | 1649 |
| | 2. <i>An Example from the EPA Permitting System: Insect Resistant Plants Containing Bacterial Toxin Genes</i> | 1650 |
| | 3. <i>Tomato Plants Containing Antisense Fruit-Ripening Genes</i> | 1652 |

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|-------|---|------|
| V. | ENVIRONMENTAL CONSIDERATIONS REGARDING FIELD TESTING TRANSGENIC PLANTS | 1653 |
| VI. | REGULATION AND DEREGULATION OF TRANSGENIC PLANTS | 1655 |
| | A. <i>Federal Policy</i> | 1655 |
| | B. <i>Deregulation of the Flavr Savr™</i> | 1658 |
| | C. <i>APHIS's Proposed Rules under the Bush Administration</i> | 1661 |
| | D. <i>APHIS's Final Rules under the Clinton Administration</i> | 1662 |
| VII. | AN ASSESSMENT OF THE CURRENT REGULATIONS | 1665 |
| VIII. | CONCLUSION | 1671 |

I. INTRODUCTION

In a 1992 interpretive ruling, the United States Department of Agriculture announced that it would no longer regulate a genetically engineered tomato produced by the biotechnology company Calgene. This was the first genetically engineered crop plant approved for general, unregulated release into the environment. The Calgene tomato is now on sale in U.S. supermarkets under the brand name "MacGregor's."¹ In 1993, the USDA issued new rules for the regulation of field trials of genetically engineered plants, which generally streamline the regulatory process. As a result, biotechnology companies can now field test a range of genetically engineered plants without obtaining specific release permits. In addition, companies now can petition to have a particular transgenic plant completely exempted from USDA regulation. This comment reviews federal oversight of the release of genetically engineered plants into the environment and determines that the current regulations afford sufficient environmental protection, but that the law and regulations should be expanded to explicitly apply to all transgenic plants, and should contain monitoring requirements for large-scale releases.

1. Dick Russel, *Miracle or Myth? Is Biotech the Coming Alternative to Chemical Agriculture, or a Clone of the Past?*, AMICUS J., Spring 1993, at 20. Calgene's folksy marketing strategy and the title of this piece are referring to Beatrix Potter's classic children's story about the naughty Peter Rabbit and his adventures in Mr. McGregor's vegetable garden. BEATRIX POTTER, *THE TALE OF PETER RABBIT* (1903).

II. BACKGROUND

Advances in molecular genetics facilitated the genesis of the modern biotechnology² industry in the 1980s and continue to expand our ability to modify the genetic characteristics of living organisms. Biotechnology is currently a \$10 billion-a-year industry³ and will likely be a \$50 billion-a-year industry by the end of the 1990s.⁴ Companies make biotechnological products for a wide range of applications, including healthcare, agriculture, and bioremediation.⁵

Biotechnology depends, in large part, upon recombinant DNA (rDNA) technology.⁶ In the early days of genetic engineering, assurances that genetically engineered microorganisms could not "escape" to the environment largely assuaged public fears regarding biotechnology's potential dangers.⁷ Such assurances were effective because the organisms involved were primarily microorganisms confined to laboratory conditions in culture vessels.⁸ In recent years, however, biotechnology has advanced to the point

2. Biotechnology is "any technique that uses living microorganisms . . . to make or modify products, to improve plants or animals, or to develop microorganisms for specific uses." OFFICE OF TECH. ASSESSMENT, U.S. CONGRESS, COMMERCIAL BIOTECHNOLOGY: AN INTERNATIONAL ANALYSIS 3 (1984). This definition encompasses traditional practices such as brewing, baking, and animal husbandry. *Id.* Modern biotechnology (referred to in this comment as "biotechnology") encompasses those practices that involve the *in vitro* manipulation of genetic materials, commonly referred to as genetic engineering.

3. The biotechnology industry had \$10 billion in product sales and revenues in 1992, an increase of 20% from 1991. G. STEVEN BURRILL & KENNETH B. LEE, BIOTECH 94 LONG-TERM VALUE SHORT-TERM HURDLES viii (1993) (Ernst & Young's Eighth Annual Report on the Biotechnology Industry).

4. Russel, *supra* note 1, at 21 (citing predictions by the Bush administration).

5. See generally OFFICE OF TECH. ASSESSMENT, *supra* note 2, at 61-262; NAT'L BIOTECHNOLOGY POL'Y BD., 1992 NATIONAL BIOTECHNOLOGY POLICY REPORT, reprinted in 12 BIOTECHNOLOGY L. REP. 127 (1993).

6. Recombinant DNA is "[t]he hybrid DNA produced by joining pieces of DNA from different organisms together *in vitro*." OFFICE OF TECH. ASSESSMENT, *supra* note 2, at 595.

7. Martin Kenney, *The Debate Over the Deliberate Release of Genetically Engineered Organisms: A Study of State Environmental Policy Making*, in BIOTECHNOLOGY AND THE NEW AGRICULTURAL REVOLUTION 73, 79 (Joseph J. Molnar & Henry Kinnucan eds., 1989).

8. *Id.*

where biotechnologists routinely genetically engineer not only microorganisms but also plants and animals.⁹ Moreover, many of these genetically altered organisms are specifically intended for release into the environment. A major goal of the agricultural biotechnology industry is to develop genetically engineered¹⁰ crop plants with improved growth characteristics. This comment focuses on the environmental release of such genetically engineered crop plants.

Biotechnologists can now transform¹¹ numerous plant species, including maize, wheat, cotton, rice, sugarbeet, and sunflower.¹² The traits introduced through genetic transformation include resistance to particular herbicides, resistance to viruses and insects, improved fruit ripening characteristics such as delayed spoilage, and improved nutritional value, which is achieved through modifying plant carbohydrate and oil composition.¹³ Perhaps the best known product of agricultural biotechnology to date is the Flavr Savr™ tomato, produced by Calgene, Inc.¹⁴ The Flavr Savr™, which is claimed to have improved shelf life and flavor,¹⁵ is currently sold in supermarkets in northern California and Chicago under the brand name "MacGregor's."¹⁶

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

10. Genetically engineered plants are interchangeably referred to as "transgenic plants." For the purposes of this comment, both terms refer to plants into which recombinant DNA has been introduced.

11. Transformation, as used in this context, is the process of introducing genetic information into a cell using purified DNA. OFFICE OF TECH. ASSESSMENT, *supra* note 2, at 597.

12. Jan Leemans, *Ti to Tomato, Tomato to Market, a Decade of Plant Biotechnology*, 11 BIO/TECHNOLOGY S22 (1993).

13. *Id.* at S24-S26.

14. See generally *Tomato Researchers Vie for the Perfect Taste*, WASH. POST, Aug. 31, 1993, at 16; Joel Achenbach, *Attack of the Subversive Tomatoes*, WASH. POST, July 18, 1993, at f1; Alex Barnum, *Biotech Poses Key Test for Clinton Administration: New Leadership Faces a Balancing Act Between the Environmental and High-Tech Sectors*, S.F. CHRON., Jan. 4, 1993, at B1.

15. *Tomato Researchers Vie for the Perfect Taste*, *supra* note 14, at 16.

16. Tessa DeCarlo, *Tasting the Flavr Savr™*, WALL ST. J., Aug. 3, 1994 at A10. Although early reports suggest brisk sales, there has also been some well-organized consumer protest to Flavr Savr™, including a coalition of chefs that has agreed not to use the tomato or other genetically engineered foods. Pat Dailey, *Chefs Speak Out; Collaboration Leads the Way Against Genetically Engineered Foods and Other Innovations*, CHI. TRIB., Feb. 10, 1994, at C3.

Two federal agencies primarily regulate the release of transgenic plants into the environment: the U.S. Department of Agriculture (USDA) and the Environmental Protection Agency (EPA).¹⁷ After review by the USDA and the National Institutes of Health (NIH), the federal government granted the first permit for field testing a genetically engineered plant in 1986.¹⁸ Since then, regulatory approval has been granted for hundreds of field tests of other genetically modified plants.¹⁹ Such field tests generally involve small numbers of plants being grown in a controlled and contained area.²⁰ While some experts have expressed confidence in the environmental safety of such releases,²¹ many have criticized the regulatory oversight of such releases.²² For example,

17. See *infra* part III.B.

18. The first field test of a transgenic plant comprised the planting of 200 tobacco seedlings by Agracetus, a Wisconsin biotechnology company, in 1986. Marjorie Sun, . . . *While First Outdoor Test of Engineered Plant Begins*, 232 SCIENCE 1340 (1986).

19. Between 1987 and March 2, 1993, the USDA Animal and Plant Health Inspection Service (APHIS) alone granted 365 environmental release permits for transgenic organisms "developed with genetic material from known plant pests." Genetically Engineered Organisms and Products; Notification Procedures for the Introduction of Certain Regulated Articles; and Petition for Nonregulated Status, 58 Fed. Reg. 17,044, 17,045 (Mar. 31, 1993) (final rule, codified at 7 C.F.R. Part 340) [hereinafter APHIS Final Rule].

20. COMMITTEE ON SCIENTIFIC EVALUATION OF THE INTRODUCTION OF GENETICALLY MODIFIED MICROORGANISMS AND PLANTS INTO THE ENVIRONMENT, NAT'L RES. COUNCIL, FIELD TESTING GENETICALLY MODIFIED ORGANISMS: FRAMEWORK FOR DECISIONS 68-69 (1989) [hereinafter COMMITTEE ON SCIENTIFIC EVALUATION]. The USDA currently mandates that small-scale field trials be surrounded by a one hundred yard barrier of barren ground. Norman Ellstrand, *How Ya Gonna Keep Those Transgenes Down on the Farm?*, AMICUS J., Spring 1993, at 31.

21. COMMITTEE ON SCIENTIFIC EVALUATION, *supra* note 20, at 66-69.

22. See generally William Allen, Note, *The Current Federal Regulatory Framework for Release of Genetically Altered Organisms into the Environment*, 42 FLA. L. REV. 531 (1990); Stuart Auchincloss, *Does Genetic Engineering Need Genetic Engineers?: Should the Regulation of Genetic Engineering Include a New Professional Discipline?* 20 B.C. ENVTL. L. REV. 37 (1993); Keith Bastian, *Biotechnology and the United States Department of Agriculture: Problems of Regulation in a Promotional Agency*, 17 ECOLOGY L.Q. 413 (1990); Valerie M. Fogleman, *Regulating Science: An Evaluation of the Regulation of Biotechnology Research*, 17 ENVTL. L. 183 (1987); Ruth E. Harlow, Note, *The EPA and Biotechnology Regulation: Coping with Scientific Uncertainty*, 95 YALE L.J. 553 (1986); Karen Goldman Herman, Comment, *Issues in the Regulation of Bioengineered Food*, 7 HIGH TECH. L.J. 107 (1992); Diane E. Hoffmann, *The Biotechnology Revolution and its Regulatory Evolution*, 38 DRAKE L. REV. 471 (1988-1989); Peter Mostow, *Reassessing the Scope of Federal Biotechnology*

some commentators note with concern that Congress did not design the statutes authorizing the present regulatory scheme to oversee the genetically engineered products of modern biotechnology.²³ Others suggest that current regulatory policies may not sufficiently account for the possible ecological impacts of releasing genetically engineered organisms into the environment.²⁴ Despite such criticism, no environmental injury resulting from the field tests of genetically engineered plants has yet been reported.²⁵ As genetic engineering technology becomes more routine, the number of transgenic plants produced for field testing will almost certainly increase, and the burdens placed on the regulatory agencies will increase correspondingly.²⁶

After completing initial small-scale field trials, some biotechnology companies are now seeking to grow transgenic plants in larger scale productivity tests, where containment is more difficult. Most of these plants are produced with the hope of replacing existing crop plants, and thus companies ultimately intend their genetically engineered plants for unrestricted commercial release.²⁷ In 1992, after conducting field trial experiments with its transgenic tomato for a number of years under USDA's regulatory oversight, Calgene successfully petitioned the USDA to exempt the

Oversight, 10 PACE ENVTL. L. REV. 227 (1992); Sidney A. Shapiro, *Biotechnology and the Design of Regulation*, 17 ECOLOGY L.Q. 1 (1990).

23. Allen, *supra* note 22 at 644. For example, the USDA derives its statutory authority, in part, from the Federal Plant Pest Act which was enacted in 1957, and failed to grant specific regulatory authority over, or even to contemplate, genetically engineered products. See 7 U.S.C. §§ 150aa-150jj (1988); see *infra* part III.B.

24. Wes Jackson, *Listen to the Land*, AMICUS J., Spring 1993, at 32; Russel, *supra* note 1 at 21; see also Ellstrand, *supra* note 19, at 31.

25. See Goldman Herman, *supra* note 22, at 111. I am aware of only one report where a field test of a genetically engineered plant resulted in an uncontrolled environmental release: the severe flooding that affected the midwest in the spring and summer of 1993 washed out a field of experimental insect-resistant transgenic corn outside of Johnston, Iowa. The corn was immature and, according to a spokesman for the company that owned the plants, would be unable to re-root or transfer their genetic material to any other plants. *Flood Uproots Transgenic Crop*, 261 SCIENCE 1271 (1993).

26. Five field tests of transgenic plants were performed in 1987; between 2,000 and 3,000 field tests are expected to be performed in 1995. Alex Barnum, *More Bio-Engineered Crops on the Way: Next in Line—A Squash from Upjohn*. S.F. CHRON., May 25, 1994, at B1.

27. See Ellstrand, *supra* note 20, at 31.

Flavr Savr™ from regulation for commercial scale-up.²⁸ The Flavr Savr™ is the first transgenic plant to reach the commercial production stage, but others are close behind.²⁹

In 1993, the USDA announced new rules that appear to streamline and relax regulation for certain classes of transgenic plants.³⁰ These rules replace a permitting procedure, which involved a detailed agency evaluation of each planned release, with a simple notification procedure.³¹ EPA proposed a similar notification scheme for certain pesticides made from genetically engineered microorganisms.³² The new USDA rules also allow an applicant to formally petition to exempt a transgenic plant from USDA regulation entirely.³³

The new USDA rules represent a subtle but significant shift in the regulation of transgenic plants in two respects. First, the notification-only requirement for certain releases shows that the USDA has reached a degree of comfort and familiarity with this technology that enables it to approve releases without detailed individual determinations. Second, the new rules anticipate the transition from the current small-scale, contained field trials of transgenic plants to general, unregulated releases for agricultural production. The possibility of widespread and unregulated cultivation of transgenic plants raises new issues regarding environmental interactions between those plants and existing ecosystems.³⁴

This comment analyzes the recent USDA regulations that govern the release of transgenic plants into the environment and

28. Interpretive Ruling on Calgene, Inc., Petition for Determination of Regulatory Status of FLAVR SAVR™ Tomato, 57 Fed. Reg. 47,608, 47,608 (Oct. 19, 1992) [hereinafter Interpretive Ruling].

29. ICI, Monsanto, DNAP, and Agritope all have their own enhanced-shelf-life transgenic tomatoes and are expecting to bring these to market in 1993. BURRILL & LEE, *supra* note 3, at 45. Other transgenic plants that companies expect to grow on a commercial scale in the next five years include herbicide-resistant cotton plants, insect-, disease- and herbicide-resistant corn, virus-resistant potatoes and enhanced-shelf-life raspberries. *Id.* at 45 fig. 24.

30. APHIS Final Rule, *supra* note 19, 58 Fed. Reg. at 17,044.

31. *Id.*

32. Microbial Pesticides; Experimental Use Permits and Notifications, 58 Fed. Reg. 5878 (Jan. 22, 1993) (proposed rule not yet codified as of October, 1994).

33. APHIS Final Rule, *supra* note 19, 58 Fed. Reg. at 17,044.

34. See Ellstrand, *supra* note 20, at 31.

assesses the effectiveness of these regulations in promoting both useful technology and environmental protection. This analysis begins in Part III with a review of the statutory basis for the USDA regulatory scheme. Part IV then reviews the science behind the creation of transgenic plants, and illustrates, with three examples, the USDA permitting procedure for field testing such plants. Part V looks at the environmental concerns engendered by the environmental release of transgenic plants. Part VI reviews the development of regulatory policy for biotechnology and analyzes the new USDA rules. Finally, Part VII considers the impact of the new USDA rules on environmental protection afforded by USDA regulatory oversight.

III. THE STATUTORY BASIS FOR USDA REGULATION OF TRANSGENIC PLANTS

A. *The Development of a Federal Regulatory Policy*

Regulation of genetic engineering began in the 1970s with agreements between scientists to abstain from performing certain experiments in containment facilities available at the time.³⁵ As the technology evolved and its applications became more diverse, federal agencies assumed jurisdiction over the products of genetic engineering that fell within their traditional fields of regulation.³⁶ In 1985, the Biotechnology Science Coordinating Committee (BSCC) was established to coordinate the policies of the various agencies having authority to regulate biotechnology products.³⁷

In 1986, the Office of Science and Technology Policy (OSTP) published the "Coordinated Framework for the Regulation of Bio-

35. Paul Berg et al., *Asilomar Conference on Recombinant DNA Molecules*, 188 SCIENCE 991, 992 (1975).

36. Agencies that have jurisdiction over the products produced by genetic engineering include the USDA, EPA, the Food and Drug Administration, the National Science Foundation, the National Institutes of Health, and the Occupational Safety and Health Administration. A matrix of statutory authorities related to biotechnology was published by the Office of Science and Public Policy, *Coordinated Framework for Regulation of Biotechnology; Establishment of the Biotechnology Science Coordinating Committee*, 50 Fed. Reg. 47,174, 47,176 (Nov. 14, 1985). See generally Allen, *supra* note 22, at 531; Auchincloss, *supra* note 22, at 37; Fogleman, *supra* note 22, at 183; Mostow, *supra* note 22, at 227 (reviewing the development of biotechnology regulation up to 1992).

37. 50 Fed. Reg. at 47,174.

technology.³⁸ In it, the OSTP concluded that biotechnology regulation required no new statutory authority, and that biotechnology's diverse products justified dividing regulatory oversight among several agencies.³⁹ Further, the OSTP recommended that conventional product-based review be used to regulate biotechnology products, rather than review based on the biotechnological process through which they were produced.⁴⁰ Thus, for example, the Food and Drug Administration (FDA) would continue to regulate items such as food, food additives, and human drugs, while the USDA would continue to regulate plants, seeds, animal biologics, and plant pests, regardless of whether such products were genetically engineered.⁴¹

B. USDA Regulation of Transgenic Plants

In accord with the 1986 Coordinated Framework, two agencies, the USDA and EPA, regulate the release of transgenic plants into the environment at the federal level.⁴² Both agencies draw their regulatory authority from pre-existing statutes dealing with plant pests. Since transgenic plants are not considered pests *per se*, they may be exempt from regulation if they do not fall within one of the agencies' jurisdictional categories. Most transgenic plants, however, do trigger oversight by one or both agencies because the plants incorporate some genetic material from plant pests.

The EPA regulates genetically engineered plants that may have pesticidal properties under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).⁴³ Such plants constitute a minority of transgenic plants, and hence most transgenic plant releases fall within the USDA's jurisdiction. Under certain situations, the regulatory authority of EPA and USDA may overlap. In these situations, one of the agencies is designated the lead agency,

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

39. NAT'L BIOTECHNOLOGY POL'Y BD., *supra* note 5, at E4.

40. *Id.*

41. Coordinated Framework, *supra* note 38, 51 Fed. Reg. at 23,304.

42. *See generally id.* at 23,302.

43. 7 U.S.C. §§ 136-136y (1988 & Supp. V 1993).

and the two agencies cooperate to regulate the transgenic plant's release.⁴⁴

The USDA derives its authority to regulate releases from the Federal Plant Pest Act (FPPA)⁴⁵ and the Plant Quarantine Act (PQA).⁴⁶ Congress enacted the FPPA in 1957 as "gap filling" legislation designed to protect American agriculture against "plant pests and diseases which are new to or not theretofore known to be widely prevalent or distributed within and throughout the United States."⁴⁷ The FPPA also provides the USDA with broad statutory authorization to regulate crops that might subsequently be found injurious to cultivated crops.⁴⁸ Under this authority, and through its Animal and Plant Health Inspection Service (APHIS), the USDA regulates "the movement of plants . . . developed through genetic engineering" if they present "a risk of plant pest introduction, spread or establishment."⁴⁹

Utilizing its statutory authority fully, the USDA, through APHIS, promulgated regulations that govern the introduction of genetically engineered plants "which are plant pests or which there is reason to believe are plant pests."⁵⁰ A "plant pest" is 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."⁵¹ These regulations prohibit the "introduction" of "regulated articles" without agency authorization. "Introduction" includes both movement into or through the United States and environmental release.⁵² Since any environmental release of a plant pest could constitute a significant threat to agriculture throughout the nation, APHIS regulates all environmental

44. Coordinated Framework, *supra* note 38, 51 Fed. Reg. at 23,303.

45. 7 U.S.C. §§ 150aa-150jj (1988 & Supp. V 1993).

46. 7 U.S.C. §§ 151-64, 166-67 (1988).

47. Department of Agriculture; Final Policy Statement for Research and Regulation of Biotechnology Processes and Products, 51 Fed. Reg. 23,336, 23,342 (June 26, 1986).

48. *Id.*

49. *Id.*

50. Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which are Plant Pests or Which There is Reason to Believe are Plant Pests, 7 C.F.R. §§ 340.0-.9 (1994). See part VI *infra* for a discussion of recent amendments to these regulations.

51. 7 C.F.R. § 340.1.

52. *Id.*

releases of possible plant pests, even if they initially involve only intrastate and not interstate movement.⁵³ "Regulated articles" 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) which APHIS otherwise determines to be a plant pest; or (c) which APHIS has reason to believe is a plant pest.⁵⁴

Using this regulatory scheme, therefore, APHIS may categorize 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 utilized in the genetic engineering process to produce the plant. Accordingly, some knowledge of the basic processes involved in creating transgenic plants is necessary to fully understand the regulations that govern their release into the environment.

IV. THE SCIENCE UNDERLYING THE CREATION OF TRANSGENIC PLANTS

A. *Traditional Plant Breeding*

Humans have propagated crop plants for millennia by selecting plants that possess desirable characteristics such as higher yields or better taste, and then using seeds from these plants for the next year's crop.⁵⁵ More recent advances in the understanding of inheritance led breeders to further improve crop plants by intentionally crossing individual plants to introduce new characteristics into existing breeding lines.⁵⁶ Centuries of selection and modern breeding have culminated in the creation of many plant varieties not previously existing in nature.⁵⁷ These unique variet-

53. *Id.* 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.*

54. *Id.*

55. S.D. Tanksley et al., *RFLP Mapping in Plant Breeding: New Tools for an Old Science*, 7 *BIO/TECHNOLOGY* 257 (1989).

56. *Id.* The controlled mating of plants is termed "hybridization." COMMITTEE ON SCIENTIFIC EVALUATION, *supra* note 20, at 10.

57. Thus, early farmers created wheat over 5,000 years ago by somehow combining the genomes of three different species into one plant. Diter von Wettstein, *Perspectives for the Genetic Engineering of Plants for Agriculture, Horticulture and Industry*, 13 *PLANT MOLECULAR BIOLOGY* 313 (1989). Ears of

ies now form the basis of modern agriculture, and they include almost every common crop plant, including grains, vegetables, and fruits.

The concept behind traditional plant breeding is simple: by crossing two varieties of a plant, it is possible to combine the most desirable characteristics of each in the offspring.⁵⁸ For example, if an otherwise productive variety of tomato (variety A) is susceptible to infection by a particular virus, a breeder will locate another variety of tomato (variety B) that, although it may not be a productive variety (for example, it may not produce good fruit), is resistant to the virus. By crossing plants of the two varieties, the breeder hopes to obtain a plant that has the desirable characteristics of both parent plants. The breeder selects from the resulting offspring those plants that are both virus-resistant and produce superior fruit.

However, along with the genetic determinants that confer resistance to virus infection, the offspring also inherit other characteristics of variety B that may not be desirable. To obtain a plant that has, insofar as possible, the superior characteristics of variety A but also the virus resistance of variety B, the breeder will repeatedly "back-cross" the offspring with the original variety A, selecting in each generation those plants which most closely resemble variety A, but which retain the virus resistance characteristic of variety B.

This traditional method of plant breeding is subject to two major constraints: 1) removing undesirable characteristics from the original cross can take generations of cross-breeding, sometimes requiring years before a new variety is available; and 2) only closely related plant species can be directly bred together.⁵⁹ This

maize discovered in the tombs of pre-Inca Peruvian indians are similar to the varieties of maize grown in Peruvian villages today, but the plant has never been found growing in a wild state and appears unable to perpetuate, except in cultivation. HOWARD S. REED, *A SHORT HISTORY OF THE PLANT SCIENCES* 21-22 (1942).

58. See generally COMMITTEE ON SCIENTIFIC EVALUATION, *supra* note 20, at 10.

59. INDUSTRIAL BIOTECHNOLOGY ASS'N, *AGRICULTURE AND THE NEW BIOLOGY* 1 (1987). *In vitro* manipulation can be used to facilitate some inter-species hybridization, although the resulting plants often show reduced fertility. COMMITTEE ON SCIENTIFIC EVALUATION, *supra* note 20, at 10.

latter constraint can prevent desirable characteristics from being transferred between species and may even mean that a highly-bred crop species cannot be crossed with its wild ancestors,⁶⁰ severely limiting the gene pool available for breeding purposes. As discussed in the next section, genetic engineering technology can overcome both of these problems.

B. Production of New Plant Varieties by Genetic Engineering

Through molecular techniques, it is now possible to introduce a single gene⁶¹ into a plant, thus eliminating the need for generations of back-crossing.⁶² In the above example, researchers could simply isolate the gene conferring virus resistance from variety B and transfer it into variety A, producing the desired plant in a single plant generation. Furthermore, there are no limitations on the source of the genes; researchers can introduce genes into a plant not only from other plant species, including those that cannot be crossed with the recipient plant, but also from microorganisms and animals.⁶³ Hence, genetic engineering allows the crea-

60. For example, modern alfalfa plants are now so different from wild alfalfa plants that the two cannot be interbred. INDUSTRIAL BIOTECHNOLOGY ASS'N, *supra* note 59, at 1.

61. A gene is the basic unit of heredity; it comprises "an ordered sequence of nucleotide bases, comprising a segment of DNA." OFFICE OF TECH. ASSESSMENT, *supra* note 2, at 592. The hereditary information carried in a gene is "expressed" through the processes of transcription and translation. Transcription of a gene produces a messenger ribonucleic acid (RNA) copy of the genetic information. Subsequent translation of the messenger RNA in the cell by ribosomes produces a protein; it is the protein that confers a particular characteristic on a cell. For example, the protein may be an enzyme that catalyzes a particular biochemical reaction in the cell, or it may be a structural protein that forms the framework for a part of the cell. Proteins are polymers of amino acids; the characteristics of the protein that is produced depend on the sequence of its constituent amino acids. In turn, this amino acid sequence is determined by the arrangement of nucleic acid bases that make up the DNA in the gene encoding the protein. Hence, the DNA sequence of a gene determines the amino acid sequence of the protein encoded by that gene and thus controls a particular characteristic of the cell. BOARD ON AGRIC., NAT'L RES. COUNCIL, GENETIC ENGINEERING OF PLANTS: AGRICULTURAL RESEARCH OPPORTUNITIES AND POLICY CONCERNS 15-18 (1984). For a detailed discussion of molecular genetics, see generally BENJAMIN LEWIN, GENES IV (1990).

62. BOARD ON AGRIC., *supra* note 61, at 12.

63. *Id.*; COMMITTEE ON SCIENTIFIC EVALUATION, *supra* note 20, at 11.

tion of plants that could not be produced through conventional plant breeding.

There are three main steps in creating a transgenic plant: 1) isolating a gene to be transferred to the plant from a source organism; 2) modifying the gene so that it will be properly expressed in the plant into which it is transferred; and 3) transferring the gene to the plant.

As described above, determining whether a particular genetically engineered plant falls under USDA or EPA regulation because it is a plant pest or a possible plant pest depends on the nature and source of the genetic material transferred into the plant and the phenotype⁶⁴ that this transferred DNA confers on the plant. At the first step, if the source of the gene to be transferred to the plant is classified as a plant pest or a pesticide, USDA or EPA regulation will apply, respectively.⁶⁵ However, many genes of interest will not be isolated from such sources, so regulatory oversight may not be triggered at this step. The second step generally involves the addition of regulatory DNA sequences to the ends of the gene, allowing the plant to properly express the gene.⁶⁶ Researchers often derive such regulatory DNA sequences

64. Phenotype is "the appearance or other characteristics of an organism, resulting from the interaction of its genetic constitution with the environment." LEWIN, *supra* note 61, at 815. A plant that is not ordinarily a plant pest could be rendered a plant pest by the introduction of new genes into the plant. Such a plant would exhibit a phenotype (such as enhanced ability to tolerate herbicides) that would make it a plant pest.

65. 7 C.F.R. §§ 340.0-9.

66. Although the genetic code—the code that determines the amino acid sequence of the protein encoded by a particular nucleic acid sequence—is universal, the regulatory signals that control a gene's expression within an organism can vary considerably among species. OFFICE OF TECH. ASSESSMENT, *supra* note 2, at 35. Thus, a bacterial gene complete with the bacterial regulatory signals transferred into a plant may not be expressed efficiently, if at all. However, the same bacterial gene, if linked to plant regulatory sequences, will be expressed in the plant. Such regulatory signals include "promoter" and "terminator" DNA sequences. See *generally*, LEWIN, *supra* note 61, at 223-32. Certain regulatory sequences can direct expression of the gene to particular tissues in the plant (such as the roots or the leaves) or can regulate expression of the gene so that it only occurs in response to environmental stimuli, such as wounding or light. Hence, these sequences allow very precise control of the expression of introduced genes. COMMITTEE ON SCIENTIFIC EVALUATION, *supra* note 20, at 12.

from plant viruses, and, as a result, the USDA will regulate the genetically engineered plant as a plant pest. For example, one regulatory sequence commonly used to express genes in plants is derived from the Cauliflower Mosaic Virus (CaMV).⁶⁷ Since the CaMV is a plant virus, transformed plants containing this regulatory sequence will be subject to USDA/APHIS oversight.⁶⁸

The third step of producing a transgenic plant is generally based on the observation that plants, unlike animals, are totipotent; that is, a whole plant can be regenerated from a single plant cell.⁶⁹ Hence, by transferring a gene (with accompanying regulatory sequences) into a single plant cell and then growing this single cell into a whole plant, it is possible to produce a plant in which all cells contain copies of the introduced gene.⁷⁰ Researchers generally use two approaches to introduce genes into plant cells. One approach uses biological "vectors," while the other uses physical methods.⁷¹ Biological methods are the most commonly used, and typically employ the soil bacterium *Agrobacterium tumefaciens* as a vector to shuttle genes into the

67. This sequence is a promoter sequence (it directs initiation of transcription of the gene), called the CaMV 35S promoter. See *generally* Interpretive Ruling, *supra* note 28, 57 Fed. Reg. at 47,609, 47,613.

68. 7 C.F.R. § 340.2.

69. OFFICE OF TECH. ASSESSMENT, *supra* note 2, at 172.

70. *Id.*

71. COMMITTEE ON SCIENTIFIC EVALUATION *supra* note 20, at 55. Physical methods of introducing genes into plants include microinjection of the genes into the plant cell and biolistic delivery—coating tungsten microparticles with DNA and then accelerating these microparticles into the plant cell using a microprojectile gun. *Id.*

plant cell.⁷² Because *Agrobacterium* is a plant pest,⁷³ the USDA regulates the release of plants transformed with *Agrobacterium* vectors.

C. Examples of Transgenic Plants Approved for Field Testing

This section considers three examples of transgenic plants—transgenic corn, insect-resistant plants, and the Flavr Savr™ tomato—that have been released into the environment in small-scale field trials. These releases exemplify current transgenic plant research and serve to illustrate the application of USDA and EPA regulations to such releases. The USDA and the EPA granted permission for field testing these plants under the currently existing permitting procedure, which was the only mechanism available prior to 1993. An application for permission to field test the transgenic corn described in the upcoming example 1 could now be made under the USDA notification procedure discussed *infra* at Part VI.D. Example 3 discusses the Flavr Savr™ tomato which, as discussed in Part VI.B., the USDA has declared exempt from regulation. Nevertheless, permission to release these plants can also be sought under the permitting procedure, and these examples typify the regulatory mechanism applicable to all plants that cannot yet be released under the notification procedure.

72. *Id.* *Agrobacterium tumefaciens* is a natural plant pathogen that can cause crown gall disease in certain plant types; it infects stems and produces tumors on the plant. BOARD ON AGRIC., *supra* note 61, at 21-24. *Agrobacterium* contains a plasmid (an extrachromosomal, self-replicating, circular DNA molecule), *id.* at 18, termed the Ti (tumor-inducing) plasmid. *Id.* at 21-24. In the course of infecting a plant, the Ti plasmid is transferred into the infected plant cell. *Id.* A portion of the Ti plasmid termed the T-DNA (transferred DNA) then integrates into the plant cell's genome and is replicated and expressed along with the plant's own genes. *Id.* It is the expression of the *Agrobacterium* genes on the T-DNA that results in crown gall tumors forming on the plant. *Id.* By replacing the disease-causing genes in the T-DNA with the cloned gene of interest (leaving intact the genes that facilitate transfer of the T-DNA into the plant genome), *Agrobacterium* can be used as a natural vector to deliver genes into plants. COMMITTEE ON SCIENTIFIC EVALUATION, *supra* note 20, at 55.

73. 7 C.F.R. § 340.2.

1. *An Example from USDA's Permitting System: Virus Resistant Plants Containing Virus Coat Protein Genes*

Plant viruses are a major source of crop losses worldwide. However, a plant can be rendered resistant to some viruses by transforming the plant with some of the viruses' genes, specifically genes that code for viral coat (or "capsid") proteins.⁷⁴ Moreover, the expression of a viral capsid protein gene in a transgenic plant can produce resistance to not only the virus type from which the gene was derived, but also to related virus types.⁷⁵

However, because the virus from which the viral coat protein gene is derived is a plant pathogen, the USDA/APHIS regulates field testing of a transgenic plant containing a viral coat protein gene. After receiving an application for a permit to release a genetically engineered plant, APHIS first publishes, in the *Federal Register*, a "Notice of Receipt of a Permit Application for Release into the Environment of Genetically Engineered Organisms," and then invites public comment. APHIS issues permits in accordance with the National Environmental Policy Act (NEPA),⁷⁶ USDA regulations, and APHIS guidelines implementing NEPA.⁷⁷ Prior to issuing a release permit, APHIS prepares an environmental assessment, and, if necessary, an environmental impact statement. Generally, the environmental assessment entails an evaluation of scientific data provided by interested persons, and a review of comments from the affected state and the public, regarding "not only the potential for plant pest risk, but also a broad range of potential effects on the human environment."⁷⁸ Before issuing a permit to release a transgenic plant in a field test, APHIS must determine that release of the transgenic plant, under the conditions defined in the permit, does not constitute a risk of intro-

74. Nils Tumer et al., *Expression of Alfalfa Mosaic Virus Coat Protein Gene Confers Cross-Protection in Transgenic Tobacco and Tomato Plants*, 6 EUROPEAN MOLECULAR BIOLOGY ORGANIZATION J. 1181 (1987).

75. COMMITTEE ON SCIENTIFIC EVALUATION, *supra* note 20, at 58.

76. National Environmental Policy Act of 1969, 42 U.S.C. §§ 4321-4370d (1988 & Supp. V 1993).

77. Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which are Plant Pests or Which There is Reason to Believe are Plant Pests, 52 Fed. Reg. 22,892, 22,906 (June 16, 1987) (codified at 7 C.F.R. §§ 340.0-9 (1994)).

78. APHIS Final Rule, *supra* note 19, 58 Fed. Reg. at 17,054.

ducing a plant pest.⁷⁹ APHIS publishes a Finding of No Significant Impact in the *Federal Register* for successful permit applications.⁸⁰

By way of illustration, on March 1, 1993, the Pioneer Hi-Bred seed company applied to field test corn plants genetically engineered to express a viral coat protein gene.⁸¹ APHIS published a notice of receipt of the application and invited public comment.⁸² Subsequently, APHIS performed an environmental assessment and concluded that the release "will not present a risk of plant pest introduction or dissemination and will not have a significant impact on the quality of the human environment."⁸³ On May 14, 1993, APHIS issued permit number 93-060-02, allowing Pioneer to field test its transgenic corn.⁸⁴

2. *An Example from the EPA Permitting System: Insect Resistant Plants Containing Bacterial Toxin Genes*

Bacillus thuringiensis (B.t.) is a bacterium found in soil and on plants. Under low nutrient conditions, B.t. produces a dormant spore and, concomitantly a crystalline protein,⁸⁵ which is highly toxic to particular types of insects.⁸⁶ When a susceptible insect ingests the spore and its accompanying crystal, it becomes paralyzed and dies.⁸⁷ Home gardeners have used the B.t. toxin as an insecticide for over twenty years.⁸⁸ By isolating the gene that en-

79. 7 C.F.R. § 340.1.

80. Generally, only successful permit applications are published; APHIS works closely with a permit applicant in evaluating applications and permit applications that fail to satisfy APHIS requirements are either modified appropriately or withdrawn by the applicant. Telephone Interview with Dr. Arnold Foudin, Deputy Director of Biotechnology Permits, APHIS (Nov. 1, 1993) [hereinafter Foudin Telephone Interview].

81. Receipt of Permit Applications for Release into the Environment of Genetically Engineered Organisms, 58 Fed. Reg. 17,825, 17,825 (Apr. 6, 1993).

82. *Id.*

83. Availability of Environmental Assessments and Findings of No Significant Impact Relative to Issuance of Permits to Field Test Genetically Engineered Organisms, 58 Fed. Reg. 32,642, 32,643 (June 11, 1993).

84. *Id.* at 32,642.

85. David A. Fischhoff et al., *Insect Tolerant Transgenic Tomato Plants*, 5 *BIO/TECHNOLOGY* 807, 807 (1987).

86. *Id.*

87. *Id.* at 811.

88. INDUSTRIAL BIOTECHNOLOGY ASS'N, *supra* note 59, at 5. Commercial for-

codes this toxin and introducing it into plants, researchers can produce transgenic plants that express the insecticidal toxin in their tissues, thus making those plants resistant to insect damage.⁸⁹ The production of crop plants that synthesize this biological insecticide should reduce the need for environmentally destructive chemical insecticides.⁹⁰

Because the B.t. toxin is an insecticide, field testing of plants containing the toxin gene requires an Experimental Use Permit (EUP) from EPA. However, many of these plants either also contain regulatory regions from plant viruses or have been transformed using the *Agrobacterium* vector and so are also subject to APHIS regulation as plant pests. Where both agencies have the authority to regulate a planned release, one is designated the lead agency.⁹¹

For example, on October 22, 1992, the Monsanto Company applied to the EPA for an EUP to field test potatoes transformed with a B.t. toxin gene effective against the Colorado Potato Beetle.⁹² Monsanto planned to conduct the field tests on test sites in fourteen states, ranging in size from one-fifth of an acre to fifteen acres.⁹³ On April 29, 1993, EPA granted Monsanto a one-year EUP, stating that "the containment procedures as described by Monsanto in their EUP application, and subsequently modified by

mulations of *Bacillus thuringiensis* toxin are marketed under various brand names including Dipel™, which is produced by Abbott Laboratories. Fischhoff et al., *supra* note 85, at 807.

89. See generally Fischhoff et al., *supra* note 85; Michael G. Koziel et al., *Field Performance of Elite Transgenic Maize Plants Expressing an Insecticidal Protein Derived from Bacillus thuringiensis*, 11 *BIO/TECHNOLOGY* 194 (1993); Hideya Fujimoto et al., *Insect Resistant Rice Generated by Introduction of a Modified Delta-endotoxin Gene of Bacillus thuringiensis*, 11 *BIO/TECHNOLOGY* 1151 (1993). The narrow specificity of the *Bacillus thuringiensis* toxins expressed in these plants is such that the transgenic plants are not toxic to other organisms, including humans. Mark Vaeck et al., *Transgenic Plants Protected from Insect Attack*, 328 *NATURE* 33, 33 (1987).

90. Goldman Herman, *supra* note 22, at 111.

91. Coordinated Framework, *supra* note 38, 51 Fed. Reg. at 23,305.

92. Receipt of an Application for an Experimental Use Permit for a Transgenic Plant Pesticide, 57 Fed. Reg. 59,112, 59,112 (Dec. 14, 1992).

93. *Id.* Monsanto subsequently filed a request to amend the EUP application, removing Hawaii from the list of test sites. Receipt of an Application for an Experimental Use Permit for a Transgenic Plant Pesticide, 58 Fed. Reg. 8758 (Feb. 17, 1993).

EPA are adequate to prevent any significant pesticide production outside of the test site.⁹⁴ EPA collaborated with APHIS in issuing the EUP; APHIS assessed the risk of plant material escaping into the environment and the possible effects of such escape on other plant species.⁹⁵

3. *Tomato Plants Containing Antisense Fruit-Ripening Genes*

Researchers seeking to extend the shelf-life of fruits and vegetables have focused on genes that encode proteins involved in the ripening process. One such gene isolated from tomato encodes polygalacturonidase (pg), an enzyme that causes cell walls to soften during ripening in tomatoes. By introducing an "antisense"⁹⁶ copy of this gene into a tomato plant, the activity of the native pg enzyme in the fruit is inhibited and the tomato fruit remains firm, even when "vine-ripened." This antisense pg gene is present in Calgene's Flavr SavrTM tomato.⁹⁷

Since the pg gene in the Flavr SavrTM is linked to regulatory DNA sequences derived from plant pests⁹⁸ and was introduced into the tomato by *Agrobacterium*-mediated transformation,⁹⁹ the field testing of Flavr SavrTM tomatoes fell under APHIS jurisdiction. Calgene field tested the Flavr SavrTM tomato under eight APHIS permits at sites in California and Florida.¹⁰⁰ In issuing one such typical permit, APHIS concluded that a proposed field trial of the plants would have no significant environmental impact for

94. Issuance of an Experimental Use Permit for Four Transgenic Plant Pesticides, 58 Fed. Reg. 33,815, 33,817 (June 21, 1993).

95. *Id.* at 33,817-18.

96. The antisense pg gene encodes a reverse, complementary copy of the RNA molecule that is transcribed from the pg gene in the tomato plant. The antisense RNA molecule binds to the normal pg RNA and prevents this RNA from being translated into a protein, thereby preventing expression of the pg enzyme. As a result, the tomatoes do not soften as quickly as untransformed varieties.

97. See Availability of Environmental Assessment and Finding of No Significant Impact Relative to Issuance of a Permit to Field Test Genetically Engineered Tomato Plants, 55 Fed. Reg. 47,355, 47,356 (Nov. 13, 1990) [hereinafter Environmental Assessment].

98. *Id.*

99. *Id.*

100. 57 Fed. Reg. 47,608, 47,610 (1993).

three reasons. First, the introduced gene could not spread to other plants by cross-pollination since the test-plot was a significant distance from any plants capable of cross-pollination with the test plants. Second, there was no known mechanism for horizontal transfer of the introduced genes, and finally, the DNA sequences derived from plant pests did not confer plant pest characteristics on the test plant.¹⁰¹ As described later in Part VI.B., APHIS subsequently exempted the Flavr Savr™ from regulation altogether.

V. ENVIRONMENTAL CONSIDERATIONS REGARDING FIELD TESTING TRANSGENIC PLANTS

The deliberate release of a transgenic plant can be viewed from two perspectives:¹⁰² in one, releases resemble introductions of "exotic" species into a particular environment, while in the other perspective, a transgenic plant is simply an existing species with an altered gene.¹⁰³ The two imply different levels of environmental risk from transgenic plants. These analogies are not useful in the regulatory context, however, because while most transgenic plants that have been field tested do indeed differ from domestic crops by only one or two traits,¹⁰⁴ small genetic alterations can produce significant changes in a plant's ability to colonize a particular ecosystem.¹⁰⁵

The major concern associated with the introduction of a transgenic plant is whether the plant could become a weed,¹⁰⁶ reflecting experiences with introductions of some exotic plant species such as kudzu.¹⁰⁷ The fear is that transgenic plants could be

101. Environmental Assessment, *supra* note 97, 55 Fed. Reg. at 47,356.

102. See generally Upton Hatch & Fred Kuchler, *Regulation of Agricultural Biotechnology: Historical Perspectives*, in BIOTECHNOLOGY AND THE NEW AGRICULTURAL REVOLUTION 61 (Joseph J. Molnar & Henry Kinnucan eds., 1989).

103. *Id.*

104. See generally *supra* part IV.B.

105. COMMITTEE ON SCIENTIFIC EVALUATION, *supra* note 20, at 40-42. For example, a small genetic change could make a plant more tolerant of arid conditions, allowing it to colonize environments where it would not normally be found.

106. *Id.* at 37. The definition of a weed varies depending on whether it is being viewed from an ecological or agronomic perspective. *Id.* The term is used to denote both perspectives in this comment; a weed is both an unwanted plant in a "human environment" and a plant not usually found in a natural ecosystem.

107. COMMITTEE ON SCIENTIFIC EVALUATION, *supra* note 20, at 37. For exam-

come agricultural pests or could colonize natural ecosystems, disturbing existing ecological balances. This issue is particularly relevant where the transgenic plant has characteristics, such as drought tolerance or insect resistance, that would allow it to compete successfully with native plants.¹⁰⁸

A related concern is the possibility that a transgenic plant would hybridize with a related wild species, introducing the modified gene into the wild population.¹⁰⁹ The characteristics conferred on recipient wild plants could enhance the ability of these plants to spread and survive, becoming weeds and disturbing ecological balances. Transgenic plants could also transfer their genes to existing weed species, enhancing their "weediness." Of course, this phenomenon requires that wild relatives of the transgenic plant grow in the geographical regions where the transgenic plant will be introduced.

A 1989 study of field tests of genetically modified organisms by the National Research Council (NRC) addressed concerns related to "enhanced weediness" of transgenic crops in detail.¹¹⁰ This study noted that many domesticated crops, including soybeans, corn, and wheat, have been bred to the point where "they can no longer compete effectively with wild species in the natural ecosystem [and that] [t]hese crops are unlikely to revert to weedy condition upon further genetic modification."¹¹¹ Further, it observed that since most United States agricultural crops are of foreign origin, there would be little risk of hybridization between transgenic plants and their wild relatives in the United States.¹¹²

The NRC study concluded that established practices for confining new plant varieties produced by conventional breeding "are

ple, kudzu was originally introduced into the U.S. from China and Japan at the end of the 19th century as an ornamental; it has now become a problematic weed in the southeastern U.S. *Id.* at 39-40.

108. Kenney, *supra* note 7, at 80.

109. COMMITTEE ON SCIENTIFIC EVALUATION, *supra* note 20, at 43-52.

110. *Id.* at 37-53. "The potential for enhanced weediness is the major environmental concern surrounding the introduction of genetically modified plants." *Id.* at 68.

111. *Id.* at 52.

112. *Id.* at 43. The study, however, did note the likely need for precautions to prevent the transfer of genes from crops to wild relatives where the two do co-exist. *Id.*

almost always successful" and that these practices are equally suitable for field testing genetically engineered plants.¹¹³ However, the authors of the NRC study were careful to point out that their research was limited to "small-scale experimental introductions" and not "large-scale introductions and commercialization" of transgenic plants.¹¹⁴ The study noted that "[o]versight mechanisms should remain flexible to accommodate the transition that will occur as testing of crops modified by molecular methods proceeds from isolated field crops to large-scale, multisite testing."¹¹⁵

The scientific press has recently given attention to another safety concern: transgenic plants engineered to be resistant to certain virus types by transformation with viral coat protein genes may provide an environment for interactions between the introduced genes and other virus types.¹¹⁶ Although the magnitude of this risk is currently unknown, there are already strategies available which should eliminate it entirely.¹¹⁷

VI. REGULATION AND DEREGULATION OF TRANSGENIC PLANTS

A. Federal Policy

In 1990, the Office of Science and Technology Policy (OSTP) published a policy statement on federal oversight of biotechnology.¹¹⁸ The 1990 policy statement significantly modified the

113. COMMITTEE ON SCIENTIFIC EVALUATION, *supra* note 20, at 69.

114. *Id.*

115. *Id.*

116. See Ann E. Green & Richard F. Allison, *Recombination Between Viral RNA and Transgenic Plant Transcripts*, 263 SCIENCE 1423 (1994); Bryce W. Falk & George Bruening, *Will Transgenic Crops Generate New Viruses and New Diseases?*, 263 SCIENCE 1395 (1994); Roger Hull, Letter to the Editor, 264 SCIENCE 1649 (1994); Mark Gibbs, Letter to the Editor, 264 SCIENCE 1650 (1994).

117. J.A. Lindbo & W.G. Dougherty, *Pathogen-Derived Resistance to a Potyvirus: Immune and Resistant Phenotypes in Transgenic Tobacco Expressing Altered Forms of a Potyvirus Coat Protein Nucleotide Sequence*, 5 MOLECULAR PLANT MICROBE INTERACTIONS 144 (1992).

118. Principles for Federal Oversight of Biotechnology: Planned Introduction into the Environment of Organisms with Modified Hereditary Traits, 55 Fed. Reg. 31,118 (July 31, 1990) [hereinafter Principles for Federal Oversight]. This document was prepared based on a review by the President's Council on Competitiveness, headed by then Vice President Quayle. The Council on Competi-

scope of federal regulation under the influence of the President's Council on Competitiveness by declaring that: "to the extent permitted by law, planned introductions into the environment of organisms with deliberately modified hereditary traits should not be subject to oversight . . . unless information concerning the risk posed by the introduction indicates that oversight is necessary."¹¹⁹ It set forth six examples of categories of genetically engineered organisms that could be excluded from oversight¹²⁰ and suggested that regulating agencies should determine whether these or other exempted categories were relevant to their statutes and "develop measures to implement the principles" set forth in the policy statement.¹²¹

In February 1992, the OSTP published a subsequent announcement of policy and a "final statement" on the scope of federal oversight for environmental releases of biotechnology products.¹²² The statement's purpose was to "guide the exercise of agencies' oversight, within the scope of authority afforded by statute, to ensure the safety of planned introductions of biotechnology products into the environment while not unduly inhibiting the benefits of such introductions."¹²³ While this final statement generally reiterates previous policies (risk-based regulation¹²⁴ fo-

tiveness was generally known to favor a policy of stringently applying cost-benefit analysis to regulations as promulgated in President Reagan's Executive Order No. 12,291 of February 17, 1981. Mostow, *supra* note 22, at 235 n.36.

119. Principles for Federal Oversight, *supra* note 118, 55 Fed. Reg. at 31,120.

120. Categories of plants suggested for exclusion from oversight were: (1) plants produced through traditional breeding techniques such as mutagenesis and hand pollination; (2) plants regenerated from tissue culture, including those produced through selection of mutants; (3) plants modified through the introduction of non-coding, non-expressed DNA sequences that caused no phenotypic or physiological changes; (4) plants produced by intra-genomic rearrangements; and (5) plants with new phenotypic traits which confer "no greater risk to the target environment than the parental strain, which is considered to be safe." *Id.* at 31,121.

121. *Id.*

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

123. *Id.* at 6755.

124. The 1992 policy announcement states that, within statutory authorities, federal agencies shall regulate planned environmental releases of biotechnology products if there is evidence that the risk posed by the release is "unreason-

cused on the product rather than the biotechnological process by which it was produced¹²⁵), it nevertheless contains two principal differences. First, the final statement observes that agencies are not simply faced with a choice between oversight and no oversight; instead, an agency should elect that degree of oversight that "achieves risk reduction at net benefit and least cost."¹²⁶ Thus, effective confinement techniques may reduce the risk and thus the need for oversight of a particular release.¹²⁷ Second, the OSTP removed the six "categories for exclusion" suggested in the 1990 policy statement¹²⁸ and instead encouraged agencies to develop their own risk-based exclusion categories.¹²⁹

The 1992 final statement suggests that agencies should determine the risk associated with a particular planned release based on criteria such as the "organism's ecological niche, potential for gene exchange, ability to monitor and to mitigate persistence and spread and potential consequences of dissemination into the greater environment."¹³⁰ In determining the risks, moreover, the OSTP recommends that agencies should consider both the nature of the organism and the target environment.¹³¹

Finally, the final statement suggests that not all planned releases will require such detailed risk evaluations, but that agencies can determine the risk associated with a particular release by comparing it with a previous introduction of a comparable organism into a comparable target environment.¹³² By encouraging

able." *Id.* at 6756. An unreasonable risk is defined as "when the value of the reduction in risk obtained by additional oversight is greater than the cost thereby imposed." *Id.* at 6753. This standard, the policy statement suggests, will "accomplish the most net beneficial protection of public health and the environment while allowing useful, safe innovations to proceed." *Id.* at 6756.

125. Planned Introductions, *supra* note 121, 57 Fed. Reg. at 6753.

126. *Id.* at 6756.

127. *Id.* at 6757.

128. *Id.* at 6758.

129. *Id.* at 6759.

130. *Id.* at 6757.

131. *Id.*

132. *Id.* Notably, this comparative risk method of evaluation allows a biotechnology product to be compared to a "previously used . . . product regardless of the process by which that . . . product [was] produced." *Id.* Further, an introduction of a biotechnology product, such as a genetically modified organism, into a target environment "should be subject to no greater degree of oversight than was a comparable organism . . . previously used in past safe intro-

risk analysis and regulation based on prior comparable releases, the statement further invites agencies to establish categories for exclusion after they develop experience and familiarity with certain types of release. Notably, the OSTP explicitly broadened this approach to include not only "initial small-scale field trials" but also "introductions in the course of research and in commercial and other applications."¹³³ The 1992 policy announcement, therefore, opened the way for deregulation of large-scale environmental releases of transgenic plants, based on a determination of risk and comparison with prior, small-scale releases of the plant.

B. Deregulation of the *Flavr Savr*TM

In June 1992, Calgene filed a petition with APHIS seeking a determination that the *Flavr Savr*TM tomato should no longer be considered a "regulated article" (*i.e.* that APHIS should no longer classify the *Flavr Savr*TM as a plant pest), and thus that APHIS should exempt it from regulation.¹³⁴ While acknowledging that APHIS could regulate the *Flavr Savr*TM as a plant pest because Calgene developed it using regulatory DNA sequences and a biological transformation vector derived from plant pathogens, Calgene's petition argued that these plant-pathogen-derived elements posed no risk of a plant pest introduction or dissemination.¹³⁵ Based on prior field trials of the *Flavr Savr*TM and data submitted by Calgene, APHIS concluded that the *Flavr Savr*TM did not present any plant pest risk.¹³⁶ It therefore issued a proposed

ductions in a comparable target environment." *Id.* Thus, a comparable introduction of a biotechnology product, such as genetically engineered plant, should be regulated to no greater extent than a comparable traditional product, such as a plant produced by conventional plant breeding.

133. Planned Introductions, *supra* note 122, 57 Fed. Reg. at 6757.

134. Proposed Interpretive Ruling in Connection with Calgene, Inc. Petition for Determination of Regulatory Status of FLAVR SAVRTM Tomato, 57 Fed. Reg. 31,170, 31,170 (July 14, 1992).

135. *Id.*

136. *Id.*

ruling that the Flavr Savr™ was not subject to APHIS regulation and solicited public comment on its proposal.¹³⁷

In October 1992, APHIS published a final interpretive ruling on the Calgene petition, holding that the Flavr Savr™ “does not present a plant pest risk and is not a regulated article” subject to APHIS regulation.¹³⁸ APHIS made this determination based on data submitted by Calgene, the comments received, “a review of the scientific literature, and expert opinion from tomato breeders and pathologists.”¹³⁹ Based on its review and analysis of this information, APHIS held that the Flavr Savr™:

(1) Exhibits no plant pathogenic properties; (2) is no more likely to become a weed than the non-engineered parental varieties; (3) is unlikely to increase the weediness potential for any other cultivated plant or native wild species with which the organism can interbreed; (4) does not cause damage of processed agricultural commodities; and (5) is unlikely to harm other organisms beneficial to agriculture.¹⁴⁰

APHIS also determined that there was “no reason to believe” that tomato lines bred from the Flavr Savr™ variety would present a plant pest risk.¹⁴¹

In response to the comments received,¹⁴² APHIS explicitly made its ruling applicable only to Calgene’s Flavr Savr™ tomatoes previously field tested under APHIS permits and their genetic descendants; the ruling did not exclude other tomatoes from regulation.¹⁴³ Neither did the ruling exclude from regulation other plants containing the genes introduced into the Flavr Savr™, Flavr Savr™ tomatoes into which additional genes were subsequently introduced, or other tomato plants independently made by other individuals using the same genes Calgene used in the Flavr Savr™.¹⁴⁴

137. *Id.*

138. Interpretive Ruling, *supra* note 28, 57 Fed. Reg. at 47,609.

139. *Id.* at 47,608.

140. *Id.*

141. *Id.* at 47,610.

142. There were nineteen respondents to the deregulation proposal; fifteen expressing support and four expressing caution or disapproval. *Id.* at 47,608.

143. *Id.* at 47,609.

144. *Id.*

The comments received by APHIS in response to its proposal to deregulate the Flavr Savr™ included concerns about weediness and the possibility that, through hybridization, the Flavr Savr™ genes could be transmitted to wild relatives. In its final ruling, APHIS responded that tomato is not considered a weed in the United States, that tomato volunteers are easily controlled and that data from Calgene's field trials showed that the Flavr Savr™ had little potential to become a successful weed.¹⁴⁵ Additionally, APHIS observed that since tomatoes are almost exclusively self-pollinating and do not naturally cross-pollinate with other plants in the United States, there was "little possibility of a cross . . . between the Flavr Savr™ tomato and another plant."¹⁴⁶

Margaret Mellon, Director of the Biotechnology Policy Board at the National Wildlife Federation, criticized the deregulation of the Flavr Savr™ as a "big mistake," noting that many wild relatives of cultivated tomato are found in Mexico.¹⁴⁷ APHIS considered this point in its ruling but concluded that while it had no authority to regulate plants outside of the United States, it would "consult with regulatory officials of other nations upon request."¹⁴⁸

Several commentators stated that APHIS should delay approval of the Calgene petition until new regulations were promulgated to specifically address large-scale release.¹⁴⁹ While rejecting this argument on the basis that its regulations were not scale-dependent, APHIS acknowledged that it expected to receive an increasing number of petitions for deregulation and so, to facilitate such petitions, it would prepare a proposal to formalize the petition process.¹⁵⁰

145. *Id.* at 47,614.

146. *Id.* at 47,615. However, APHIS did note that the cherry tomato (thought to be the wild progenitor of the cultivated tomato) can hybridize with the cultivated tomato and is a successful weed in some parts of the U.S., but dismissed the possibility of gene transfer from the Flavr Savr™ to the cherry tomato as "almost nil since the rate of outcrossing in [cultivated tomato] is low." *Id.* at 47,614-15.

147. *Biotechnology: Calgene's Flavr Savr (R) Tomato Deregulated by USDA Under Plant Pest Act*, 16 Chem. Reg. Rep. (BNA), 1283, 1284 (Oct. 23, 1992).

148. Interpretive Ruling, *supra* note 28, 57 Fed. Reg. at 47,612.

149. *Id.* at 47,611.

150. *Id.* at 47,610-11. A second petition for determination of regulatory status was filed with APHIS in July, 1992. Notice of Proposed Interpretive Ruling in Connection with the Upjohn Company Petition for Determination of Regula-

C. APHIS's Proposed Rules under the Bush Administration

In November 1992, APHIS published a proposed amendment to its rules.¹⁵¹ The amendment sought to "reduce regulatory constraints . . . to achieve the Federal policy goal of oversight commensurate with risk."¹⁵² APHIS proposed two major regulatory changes. First, it proposed to establish a notification procedure to allow field trials of specified categories of genetically engineered plants to proceed without a prior permit from APHIS.¹⁵³ Second, APHIS proposed adding new rules which would set out the data and information required to support a petition to have a transgenic plant exempted from APHIS regulation.¹⁵⁴ This second proposal was intended to clarify the procedure through which Calgene had successfully petitioned to have the Flavr Savr™ declared not to present a plant pest risk and therefore not to be a regulated article.¹⁵⁵

The proposed notification procedure would apply to six listed crops: corn, cotton, potato, soybean, tobacco, and tomato.¹⁵⁶ These were the crops with which APHIS had the most experience in field trials—APHIS had issued approximately 85% of its field trial permits for these six crops.¹⁵⁷ Under the proposed notification procedure, if the transgenic plant to be released was one of these crops and was certified to meet certain criteria,¹⁵⁸ re-

tory Status of ZW-20 Virus Resistant Squash, 57 Fed. Reg. 40,632, 40,632 (Sept. 4, 1992). This was a petition for a determination that a squash plant transformed with a viral coat protein gene was not a plant pest and was therefore exempted from APHIS regulation. *Id.* at 40,633.

151. Genetically Engineered Organisms and Products; Notification Procedures for the Introduction of Certain Regulated Articles; and Petition for Nonregulated Status, 57 Fed. Reg. 53,036 (Nov. 6, 1992) (to be codified at 7 C.F.R. Part 340) (proposed Nov. 6, 1992) [hereinafter Proposed Notification Procedures].

152. *Id.* at 53,036.

153. Proposed § 340.3. *Id.* at 53,036-39.

154. Proposed §§ 340.0-9. *Id.* at 53,039-40.

155. Proposed § 340.3(b)(1)(i). *Id.* at 53,039; *see also* Interpretive Ruling, *supra* note 28, 57 Fed. Reg. 47,610-11.

156. Proposed Notification Procedures, *supra* note 151, 57 Fed. Reg. at 53,037.

157. *Id.*

158. Under proposed § 340.3(b)(1)(ii)-(iv), the researcher would have to certify that the transferred gene was "well characterized" and contained no

searchers could conduct field tests of these crops simply by notifying APHIS on the day of the release.¹⁵⁹

Furthermore, APHIS proposed a second notification option for genetically engineered plants that were not one of the six listed for notification.¹⁶⁰ Under this option, a researcher could introduce a regulated article under the notification procedure if, after prior consultation with an Institutional Biosafety Committee, "the researcher has determined that the introduction of the regulated article is unlikely to pose a greater risk as a plant pest in the test environment than the unmodified plant from which it was derived."¹⁶¹

One critic of biotechnology viewed this proposal as "outrageous . . . the triumph of the [President's] Council on Competitiveness," and "wholesale deregulation."¹⁶² The proposal generated such comments because it would essentially have allowed a biotechnology company to make its own determinations as to whether a particular release posed an environmental risk, and, having made the determination that it did not, proceed with the release without further review.

D. APHIS's Final Rules under the Clinton Administration

APHIS adopted its final rule on regulation of genetically engineered plants in March 1993,¹⁶³ and some have seen it as a turnaround from the rule APHIS proposed under the Bush administration.¹⁶⁴ In response to comments received on the proposed

genes which could produce plant disease in the host plant, that the introduced genetic material was "stably integrated" in the plant genome and introduced no infectious material or any material toxic to desirable, non-target organisms, that the genetic material does not pose a significant risk of the creation of any new plant virus, and that the plant contained no functional genes derived from human or animal pathogens. *Id.*

159. *Id.* at 53,042.

160. Proposed § 340.3(b)(2). *Id.* at 53,037.

161. *Id.*

162. *Biotechnology: Department of Agriculture Proposed Rule would Deregulate Field Testing for Six Crops*, 16 Chem. Reg. Rep. (BNA) 1341, 1341 (Nov. 6, 1992) (comments by Margaret Mellon, Director of the Biotechnology Policy Board at the National Wildlife Federation).

163. APHIS Final Rule, *supra* note 19, 58 Fed. Reg. 17,044.

164. *Biotechnology: Clinton Administration Does About-Face From Prede-*

amendments,¹⁶⁵ APHIS substantially modified both the substantive and procedural requirements of the notification scheme and amended the petition for exemption procedure to allow for greater public input.¹⁶⁶

Rather than allowing researchers to notify APHIS on the day of an environmental release, as stipulated in the proposed rule, the final rule requires notice at least thirty days prior to the planned release.¹⁶⁷ Under the final rule, APHIS will then review the notification and, within thirty days, either confirm that the notification is appropriate or inform the applicant that it cannot release the plant without a permit.¹⁶⁸ Furthermore, APHIS eliminated the notification procedure for crops other than the six named crops.¹⁶⁹ However, APHIS stated that it will be receptive to information supporting the addition of other species to the list in section 340.3(b)(1)(i) and that it would make additions to the list through notice and comment rulemaking.¹⁷⁰

The final rule sets forth eligibility criteria that researchers must meet, in addition to the requirement that the plant proposed for release is one of the six listed species, in order for a release to go forward under the notification scheme.¹⁷¹ These requirements are similar to those previously proposed,¹⁷² but include additional restrictions on plants containing genes derived from plant viruses.¹⁷³ Furthermore, researchers must also meet enunciated

cessor in *Final APHIS Rules*, 17 Chem. Reg. Rep. (BNA) 3, 3 (Apr. 2, 1993) [hereinafter *Clinton Administration*].

165. The number of comments was substantial, and came from a wide range of interested parties. Specifically, "APHIS received 84 comments on the proposed amendments from State, Territorial and Commonwealth officials, universities, industry, environmental and consumer organizations, business and professional associations, members of Congress, Federal agencies, individuals and unions." APHIS Final Rule, *supra* note 19, 58 Fed. Reg. at 17,044.

166. *See generally id.* at 17,057.

167. *Id.*

168. *Id.*

169. *Id.* at 17,044.

170. *Id.* at 17,045.

171. 7 C.F.R. § 340.3 (1994).

172. *See supra* note 151 and accompanying text.

173. APHIS Final Rule, *supra* note 19, 58 Fed. Reg. at 17,056-57. For example, § 340.3(b)(5) requires that:

To ensure the introduced genetic sequences do not pose a significant risk of the creation of any new plant virus, they must be: (i) Noncoding

performance standards for any introductions under the notification procedure, including a requirement that "[t]he regulated article will not persist in the environment."¹⁷⁴ While APHIS will not require any individual environmental assessments to be performed, under the notification procedure, the agency believes 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

APHIS received approximately 300 notifications in the first seven months after the new regulations went into force and expects to receive between 1,000 and 2,500 notifications in 1994.¹⁷⁶ Moreover, it expects that approximately eighty-five percent of all future releases will be made under the notification procedure.¹⁷⁷ While APHIS approves the large majority of these notifications, it rejects a small number, and rejected applicants must apply for a permit in order to field test the plants in question.¹⁷⁸ Reasons for rejection include instances where the organism from which genetic material introduced into the plant was derived was not fully characterized and instances where the introduced genetic material included a viral gene from a plant virus that was not prevalent and endemic in the proposed test area.¹⁷⁹

In addition to expanding its notification procedure, APHIS amended the petition for exemption from regulation procedure to

regulatory sequences of known function, or (ii) Sense or antisense genetic constructs derived from viral coat protein genes from plant viruses that are prevalent and endemic in the area where the introduction will occur and that infect plants of the same host species, or (iii) Antisense genetic constructs derived from noncapsid viral genes from plant viruses that are prevalent and endemic in the area where the introduction will occur and that infect plants of the same host species.

7 C.F.R. § 340.3(b)(5) (1994).

174. 7 C.F.R. § 340.3(c) (1994).

175. APHIS Final Rule, *supra* note 19, 58 Fed. Reg. at 17,054.

176. Foudin Telephone Interview, *supra* note 80. These notifications included notifications for imports of transgenic plants from other countries, interstate movement of transgenic plants, releases of transgenic plants in field trials, and combined interstate movement and release notifications. *Id.*

177. *Id.*

178. *Id.*

179. *Id.*

require the agency to publish a notice in the *Federal Register* when such petitions are received and to allow a sixty-day comment period.¹⁸⁰ APHIS views this public comment requirement, in conjunction with its review process, as providing "adequate peer review" of data submitted by an applicant in support of a petition.¹⁸¹ APHIS had received three petitions for exemption up to November 1, 1993.¹⁸²

The final rule thus substantially deregulates the release of transgenic plants belonging to six species for small-scale field trials and affords a formal petition mechanism whereby a previously field tested transgenic plant can be exempted from further regulation for the purpose of large-scale environmental releases. In issuing the new rules, APHIS specifically noted that Congress intended the FPPA and PQA to "protect American agriculture and the environment against . . . plant pests" and that they are not commercialization statutes.¹⁸³ Hence, the agency views the petition process allowing for exemption from regulation as an "interim measure pending adoption of . . . [a] policy for reviewing and approving applications to commercialize genetically engineered plants."¹⁸⁴

VII. AN ASSESSMENT OF THE CURRENT REGULATIONS

The more cautious approach to regulating releases of transgenic plants taken by the Clinton administration received a relatively favorable review from environmental interest groups¹⁸⁵ in part, perhaps, because these groups saw the rules as a basis for "high level reexamination" of "the imminent commercialization of genetically engineered organisms in agriculture."¹⁸⁶ The biotechnology industry also received the new rules favorably.¹⁸⁷

180. 7 C.F.R. § 340.6(d)(2) (1994).

181. 7 C.F.R. § 340.6(d)(2) (1994); see also APHIS Final Rule, *supra* note 19, 58 Fed. Reg. at 17,052.

182. Foudin Telephone Interview, *supra* note 80.

183. APHIS Final Rule, *supra* note 19, 58 Fed. Reg. at 17,051.

184. *Id.*

185. *Clinton Administration*, *supra* note 164, at 4.

186. *Id.* (quoting a statement by the Environmental Defense Fund).

187. *Biotechnology: Favorable Regulatory Climate said to Foster Industry Optimism*, 17 Chem. Reg. Rep. (BNA) 1161, 1161 (Oct. 1, 1993).

Adoption of a notification system for field testing of transgenic plants clearly reflects a growing familiarity at the regulatory level with the technology of genetic engineering, based in part on the perceived safety of previous field trials.¹⁸⁸ Regulation based on familiarity, as proposed in the 1992 Federal Oversight document,¹⁸⁹ has been criticized as "not really a method of risk assessment at all, but rather an exhortation to compare risk assessments presumably already made."¹⁹⁰ This "comparability determination" has been perceived as "regulation by analogy" that might tend to allow "ever more risky organisms to avoid federal oversight."¹⁹¹ However, the new APHIS rules for notification actually represent a determination that plants meeting specific criteria and released under enunciated performance standards do not constitute a plant pest. In other words, APHIS has now classified relatively broad (but also well defined) categories of releases as "safe." The agency now reviews applications for release under the notification procedure only to confirm that they fall within the defined category of approved releases. This limited oversight streamlines the process without relaxing the actual regulation; if a plant can be released under the notification procedure, it would, by definition, have been approved for release under the permitting system.

Some commentators have argued that the notification procedure is based on unproven assumptions; Miller and Gunary argue that APHIS is erroneously assuming that there is no risk associated with field testing transgenic plants belonging to the group of six species, even if the introduced gene has never before been tested.¹⁹² Miller and Gunary also argue for risk assessment focussed on the characteristics of the plant species rather than the transgenic nature of the plant *per se*.¹⁹³ Although these two criticisms are mutually incompatible, a close examination of the new APHIS notification rules shows that APHIS has addressed both of

188. APHIS Final Rule, *supra* note 19, 58 Fed. Reg. at 17,045.

189. Exercise of Federal Oversight Within Scope of Statutory Authority: Planned Introductions of Biotechnology Products Into the Environment, 57 Fed. Reg. 6753 (Feb. 27, 1992).

190. Mostow, *supra* note 22, at 255, 257.

191. *Id.* at 257.

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

193. *Id.*

these issues. The investigation that led APHIS to permit release of certain genetically engineered forms of six plant species via the simplified notification procedure is a clear example of risk assessment based on the characteristics of the host plant (including such factors as the occurrence of wild relatives). APHIS has recognized and addressed the variability in the characteristics conferred on transgenic plants by different introduced genes by placing limitations on the types of genes that can be introduced into plants that qualify for the notification procedure.

Most of the criticism leveled at the new rules is focused on the procedure whereby APHIS will exempt certain transgenic plants from regulation. A determination that a previously regulated transgenic plant can be exempted entirely from APHIS regulation will effectively require that two tests be met: first, APHIS will need to conclude that field trial releases show that the plant does not constitute a risk of being a plant pest; and second, APHIS will have to conclude that the results from field trials can be extrapolated to large-scale general releases. The validity of this second conclusion has been questioned; one criticism is that predictions from small-scale releases are necessarily restricted to local environments. Thus, one commentator has pointed out that the general release of transgenic crop plants with wild relatives in the United States, such as sunflowers, might pose "a risk too great for commercialization."¹⁹⁴ However, as exemplified by APHIS's review of the risks associated with general release of Calgene's Flavr SavrTM,¹⁹⁵ APHIS will duly consider such risks.

On a more basic level, commentators have expressed concerns that the present field tests may be too contained and may not present reasonable opportunities for identification of hazards.¹⁹⁶ Margaret Mellon has analogized thus: "If what you are worried about is dogs biting people and you do the tests in cages, then you really don't know if the dog will bite people. What you really need is to let the dogs walk around among the people and find out whether they bite."¹⁹⁷ Mellon has suggested that field trials could be made more realistic by relaxing containment proce-

194. Ellstrand, *supra* note 20, at 31.

195. See *supra* part VI.B.

196. Miller & Gunary, *supra* note 192, at 1501; Keith Schneider, *Science Group Asks Delay on Gene-Altered Foods*, N.Y. TIMES, Dec. 21, 1993, at A23.

197. Schneider, *supra* note 196, at A23.

dures and allowing interaction between the test crops and native plants. While better risk assessment tests are certainly feasible,¹⁹⁸ there is a danger that such an approach would invite a continual expansion of the testing required before general release; each experiment could be made "more realistic" by increasing interactions, or by repetition in other environments and geographic regions. This would lead to excessive costs, hindering the development of agricultural biotechnology and delaying the benefits that this technology will bring. However, new risk assessment experiments allowing a greater degree of environmental interaction would be useful to fill gaps in current scientific understanding¹⁹⁹ and to make risk assessment by extrapolation less uncertain. Such experiments would be best performed by researchers outside of the context of commercial field trials.

The risk analyses APHIS has performed reflect due consideration of risks as currently understood and as exemplified in the 1989 National Research Council Report.²⁰⁰ However, as with all new technologies, the actual risks may as yet be unknown; recall that the adverse effects of DDT were unknown when the pesticide was first released.²⁰¹ The determination that a transgenic plant can be released into the environment at all, whether by permit, notification, or being exempted from regulation, constitutes a decision by APHIS that the release does not present a risk of introducing a plant pest under the conditions, if any, APHIS specifies for that release. Thereafter, APHIS requires companies conducting authorized field tests, whether by permitting or notification, to provide it with field test reports detailing "all deleterious effects on plants, nontarget organisms, or the environment."²⁰² This requirement demonstrates APHIS's recognition that unforeseen risks may later become apparent and its willingness to monitor releases for such risks and to regulate accordingly. Such continuous monitoring of field trials allowed APHIS

198. See generally Miller & Gunary, *supra* note 192, at 1501.

199. *Id.*

200. See *supra* part V.

201. Joseph J. Molnar & Henry Kinnucan, *Introduction: The Biotechnology Revolution*, in *BIOTECHNOLOGY AND THE NEW AGRICULTURAL REVOLUTION* 1, 7 (Joseph J. Molnar & Henry Kinnucan eds., 1989).

202. 7 C.F.R. § 340.3(d)(4)(ii) (1994); APHIS Final Rule, *supra* note 19, 58 Fed. Reg. at 17,057.

to reach confidence levels with six crops that resulted in the development of the notification system.

In contrast, APHIS does not require reports on releases of plants exempted from regulation; after it has deregulated a plant, APHIS has no authority to require such monitoring. Since the transition from small-scale field tests to general release will unquestionably create enhanced opportunity for interaction between the transgenic plants and natural ecosystems, APHIS should require continued monitoring of these releases (for perhaps one to five growing seasons after general release) in order to evaluate whether such interactions might be producing unanticipated undesirable results. This continuous monitoring would allow APHIS to make decisions concerning general release with more confidence and will also increase public confidence in the system.

APHIS will be formulating specific rules for reviewing and approving applications to commercialize genetically engineered plants, which would be an appropriate time to instigate a continuous monitoring requirement. Under these new rules, APHIS could grant companies petitioning for exempt status a temporary permit for general release that requires continued environmental monitoring for a specified test period. Deregulation would then be contingent upon a showing of environmental safety during the test period.

The foregoing discussions relate to environmental releases of transgenic plants that are classifiable as possible plant pests and which therefore fall within the jurisdiction of APHIS. As illustrated in Part III, most transgenic plants are currently produced with materials derived from plant pests and thus trigger APHIS jurisdiction. However, researchers can now produce transgenic plants without using material derived from a plant pest. Such plants might not trigger APHIS jurisdiction and, unless they constitute plant pesticides, and are thus regulated by EPA, these plants could potentially be released into the environment in an unregulated manner.²⁰³

203. For example, a gene isolated from one line of maize could be transferred to another line using a physical transformation method. Since the maize regulatory sequences already present on the gene will function in the recipient line, there would be no need to utilize regulatory sequences derived from plant pests. In this instance, since the gene in question was not derived from a plant

While such unregulated releases might be seen as a new potential environmental problem, new varieties of plants produced by conventional breeding are regulated in exactly the same manner—if APHIS does not classify them as possible plant pests, they may be released into the environment without regulation. The present regulatory policy presumes that plants produced through genetic engineering present no greater threat *per se* than plants produced by conventional breeding techniques,²⁰⁴ and there is good scientific evidence to support this presumption.²⁰⁵ Thus, if there are concerns about the safety of environmental releases of transgenic plants that are outside of USDA regulatory authority, there logically ought to be similar concerns about equivalent releases of plants produced by conventional breeding. However, such logic is unlikely to prevail outside of the (regulated) scientific community until genetic engineering in general has achieved a greater level of public confidence.

The simple solution to this problem—giving USDA the statutory authority to regulate all transgenic plants—could be achieved quite easily by amending the FPPA to declare that all transgenic plants are potential plant pests. This solution would, of course, be unfortunate in one respect: some people would interpret the provision as confirmation that genetically engineered plants do indeed pose a greater environmental threat than plants produced by conventional plant breeding. Such a solution would appall some members of the scientific community; however, scientific analysis alone is unlikely to engender public acceptance of this new technology. Public confidence in the technology is more likely to arise from a record of safety and a comprehensive regulatory structure.

pest, APHIS could only regulate the release of the plant if it had “reason to believe” that the plant was a possible plant pest. In instances where the gene conferred enhanced survival characteristics on the plant (for example, enhanced tolerance to herbicides), APHIS could reasonably invoke jurisdiction and regulate the plant. However, where the gene does not confer enhanced survival characteristics on the plant (for example, a gene that increased the nutritive value of the corn by providing increased levels of certain amino acids), APHIS would likely regard the plant as presenting “no identifiable risks” and thus APHIS regulation would not be triggered. Telephone Interview with Dr. Arnold Foudin, Deputy Director of Biotechnology Permits, APHIS (Dec. 1, 1993).

204. Coordinated Framework, *supra* note 38, 51 Fed. Reg. at 23,302.

205. COMMITTEE ON SCIENTIFIC EVALUATION, *supra* note 20, at 3; *see also* Miller & Gunary *supra* note 192, at 1501.

Amending the FPPA would ensure that APHIS reviews all planned releases of genetically engineered plants and would likely assuage public concerns about unregulated releases.

VIII. CONCLUSION

Agricultural biotechnology offers an opportunity not only to improve crops in terms of yields and crop quality, but also to reduce a dependency on chemicals in agriculture. There are risks associated with any new technology, and the regulation of transgenic plants reflects a recognition that genetic engineering of plants is no exception. The only truly safe way of regulating an unknown risk is to prohibit all activities giving rise to the risk. Such an approach has not been implemented for the environmental release of genetically engineered plants. The present USDA/APHIS regulatory structure represents a sound risk-based regulation that both fosters technological development *and* protects the environment against known risks. Release of most transgenic plants is only allowed once the agencies and researchers have established that the release presents no known risk of significant impact to the environment; this is true whether the release is authorized under the permitting system or the notification procedure.

The existing requirements for monitoring environmental releases of plants in small-scale field trials under both the APHIS notification and permitting systems provide an opportunity to monitor for unexpected risks. This monitoring also provides valuable information for subsequent large-scale releases of the plants under test. These monitoring requirements should be applied to initial large-scale environmental releases of a particular transgenic plant in order to evaluate whether new risks are presented by expanded opportunities for environmental interaction.

Finally, the USDA's statutory authority extends only to releases of those genetically engineered plants which could arguably be said to present some risk of release of a plant pest. Therefore, the USDA should be given extended authority to regulate all releases of genetically engineered plants.