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Genetically Engineered Plant Pesticides: Recent Developments in the EPA's Regulation of Biotechnology

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GENETICALLY ENGINEERED PLANT PESTICIDES: RECENT DEVELOPMENTS IN THE EPA'S REGULATION OF BIOTECHNOLOGY

*Mary Jane Angelo**

I. INTRODUCTION	258
II. BACKGROUND	261
A. <i>Products of Biotechnology</i>	261
B. <i>The EPA's Primary Legal Authorities for Regulating Biotechnology</i>	263
1. FIFRA	264
2. FFDCA	266
3. TSCA	267
C. <i>History of Federal Regulation of Biotechnology</i>	268
1. The 1986 Coordinated Framework	268
2. The NIH	270
3. The USDA	270
4. The FDA	273
5. The EPA	275
a. FIFRA	275
(i) Biochemical pesticides	275
(ii) Microbial pesticides	278
b. TSCA	282
III. THE RISKS AND BENEFITS OF TRANSGENIC PLANT PESTICIDES	284
A. <i>Benefits</i>	284
B. <i>Risks</i>	286
C. <i>Public Perception</i>	288
IV. THE EPA'S NEW POLICY ON PLANT PESTICIDES	290

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A. <i>The "Plant" vs. the "Substance"</i>	291
B. <i>The Scope of Regulation Under FIFRA</i>	292
C. <i>The Regulatory Process Under FIFRA</i>	294
1. Product Development	294
2. Sale or Distribution	295
D. <i>The Scope of Regulation Under FFDCA</i>	296
E. <i>The Regulatory Process Under FFDCA</i>	298
V. INTERNATIONAL IMPLICATIONS	298
VI. CONCLUSION	302

I do not mean to suggest that every ecosystem now be viewed as a factory of useful products. Wilderness has virtue unto itself and needs no extraneous justification. But every ecosystem, including those in wilderness reserves, can be the source of species to be cultivated elsewhere for practical purposes or of gene transfer to domestic species.

Edward O. Wilson, *The Diversity of Life*

When people are confronted with the visions of new products and miraculous discoveries coming from new technology, they often wonder what is on the other side of the coin.

Albert Gore, Jr., *A Congressional Perspective, in Biotechnology: Implications for Public Policy*

I. INTRODUCTION

The scientific, regulatory, and environmental communities are currently engaged in a debate over the risks and benefits of genetically engineered organisms. On one side is the promise of great benefits to society from the use of these organisms. On the other side, there is apprehension about the uncertainties and appropriateness of these organisms and the new technologies used to create them. The U.S. Environmental Protection Agency (EPA) is the primary regulatory authority for pesticidal biotechnology products. The EPA is at the center of the controversy and is developing a regulatory scheme that will strike the proper balance between the potential risks and benefits to society of genetically engineered pesticide products, while scrambling to keep up with the rapid technological developments.

In 1962, Rachel Carson's now famous book, *Silent Spring*,¹ first

1. RACHEL CARSON, *SILENT SPRING* (1962).

awakened the country to the risks of chemical pesticides. Since then, the public has been skeptical of the Government's ability to protect them and their environment from the hazards of pesticide use. While in recent years public attention has increasingly focused on the risks to consumers of pesticides in food,² many pesticides also may pose significant risks to farm workers and the natural environment. In the three decades since *Silent Spring* was first published, environmentalists and consumer groups have repeatedly called upon the Government, particularly the EPA,³ to reduce pesticide use. Despite these efforts, approximately \$4.1 billion worth of pesticides, roughly 320 million kilograms of pesticides, were used in the United States in 1991 alone.⁴

Nevertheless, some changes have taken place, especially with regard to the small, but increasing number of biological pesticides. These pesticides may potentially lower the risks to man and the environment due to their greater specificity to the target pest, their tendency to have lower toxicity than chemical pesticides, and their tendency to have limited persistence in the environment.⁵ The universe of biological pesticides is large and diverse and includes: (1) microorganisms, such as bacteria, fungi, algae, protozoa, and viruses, that act as pesticides either by producing toxins,⁶ acting as parasites,⁷ or acting through competition;⁸ (2) macroorganisms such as parasitic wasps, or plants that produce substances that exert a pesticidal

2. See, e.g., Paul Rauber, *Trusting to Luck*, SIERRA, Jan.-Feb. 1994, at 30.

3. Since the EPA was created in 1970, it has had responsibility for the regulation of pesticides under both the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. §§ 136-136gg (1994) and the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. §§ 301-392 (1994). Reorganization Plan No. 3 of 1970, 3 C.F.R. at 199 (Comp. 1970), reprinted in 5 U.S.C. app. at 1551 (1994) and in 84 Stat. 2086.

4. David Pimentel et al., *Environmental and Economic Costs of Pesticide Use*, 42 BIOSCIENCE 750, 750 (1992). The EPA has registered over 19,000 pesticides, containing 913 different active ingredients. Sharlene R. Matten et al., *Biological Pesticides and the U.S. Environmental Protection Agency*, in ADVANCED ENGINEERED PESTICIDES 321, 324 (Leo Kim ed., 1993).

5. See Marc Miller & Gregory Aplet, *Biological Control: A Little Knowledge is a Dangerous Thing*, 45 RUTGERS L. REV. 285, 285 (1993) (describing the risks of using living organisms for biological control and concluding that new legislation is necessary to address these risks); see also Dwight Holing, *Looking for Mr. Goodbug*, SIERRA, Jan.-Feb. 1990, at 20 (describing the history of biological control and providing examples of recent success stories with biological pesticides). Despite the oft-cited benefits of biological pesticides, biological controls are not universally accepted as benign forms of pest control. Many past attempts at introducing naturally-occurring organisms from one part of the world to another for pest management have proved disastrous. See generally Incentives for Development and Registration of Reduced Risk Pesticides, 57 Fed. Reg. 32,140 (1992).

6. An example of this type of microbial pesticide is *Bacillus thuringiensis* (*B.t.*). Matten et al., *supra* note 4, at 324.

7. An example of this type of microbial pesticide is *Beauveria*. *Id.*

8. An example of this type of microbial pesticide is viruses that are used in cross-protection of plants. *Id.*

effect; and (3) biochemicals such as pheromones. Specifically, the EPA has registered over 200 microbial pesticides containing twenty-four different active ingredients and approximately 250 biochemical pesticides containing fifty different active ingredients.⁹ In the past several years, the EPA has seen an increase in the development of new biological pesticides. Over this period of time, the quantity of biological pesticides submitted to the EPA for review has more than doubled. In fact, one half of all new registration submissions are for biological pesticides.¹⁰

In addition to regulating "naturally-occurring" biological pesticides, for over ten years the EPA has exercised regulatory oversight over genetically engineered microbial organisms that act as pesticides. Because microbial pesticides are living organisms which can reproduce and spread on their own, they pose the potential for unique risks. Thus, the EPA's regulatory scheme for microbial pesticides is somewhat different from its regulation of conventional chemical pesticides.¹¹ Nevertheless, microbial pesticides are similar to conventional pesticides in that they are "applied to" crops, and thus, are in many ways regulated like traditional chemical pesticides.

Within the past five years, however, the EPA has faced a completely new class of genetically engineered pesticidal products that pose new regulatory challenges. Within this period, significant technological advances have been made in altering plants to produce pesticidal substances. For example, through these new technologies, plants can be made to produce toxins normally produced only by microorganisms such as the *Bacillus thuringiensis* (*B.t.*) insecticidal delta-endotoxin.¹² The EPA considers the pesticidal substances produced by plants and the genetic material necessary to produce them to be "plant pesticides." The EPA does not yet have a comprehensive regulatory scheme to address these types of plant pesticides. Nonetheless, the biotechnology industry is beginning to commercialize these products, and the EPA has been forced to begin regulating them. In fact, the EPA has received several Experimental Use Permit (EUP) applications and several registration applications for the *B.t.* delta-endotoxin produced in various plants. The EPA also has received applications for tolerance exemptions for residues of pesticidal substances produced in plants as a result of genetic engineering. The number of applications for EUPs, registrations, and tolerances for plant

9. *Id.*

10. *Id.*

11. 40 C.F.R. § 172 (1995) (discussing requirements for issuance of federal experimental use permits); 40 C.F.R. §§ 158.65, 172.43, 172.45-.46, 172.48, 172.56-.57, 172.59 (discussing requirements for issuance of federal experimental use permits (EUP) for microbial pesticides). For further discussion of the EPA's microbial pesticide policy, see *infra* part II.C.5.a.(ii).

12. See ROBERT E. PFADT, FUNDAMENTALS OF APPLIED ENTOMOLOGY 239 (3d ed. 1978). *B.t.* acts by forming a protein crystal, referred to as the delta endotoxin, which when ingested by an insect becomes toxic. *Id.*

pesticides will grow at a rapid pace in the future.

The development of these new technologies and the new products that have resulted has led the EPA to develop a comprehensive policy and several rule amendments, which the EPA proposed in 1994, to address the regulation of pesticides produced by plants under both the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)¹³ and the Federal Food, Drug, and Cosmetic Act (FFDCA).¹⁴ This paper examines the EPA's new policy regulating plant pesticides and presents the legal, scientific and policy issues surrounding the regulation of genetically engineered plants. Part II.A. discusses products that have originated from biotechnology. Part II.B. describes the EPA's legal authority for regulating plant pesticides and other biotechnology products. Part II.C. presents the history of federal regulation of biological pesticides and biotechnology products. Part III examines the controversy surrounding the use of genetically engineered plants, including the potential risks and benefits of genetically engineered plants and the public's perception of these products. Part IV describes the EPA's proposed policy and regulations for plant pesticides and discusses the more controversial issues associated with the policy. Finally, part V discusses the international implications of the EPA's policy.¹⁵

II. BACKGROUND

A. *Products of Biotechnology*

Biotechnology, in its broadest sense, is the use of living organisms, either plants, animals or microorganisms, to make or modify products.¹⁶ For

13. 7 U.S.C. §§ 136-136gg.

14. 21 U.S.C. §§ 301-392.

15. This article does not address issues involving the patenting of genetically engineered organisms. For an analysis of these patent issues, see Keith D. Parr, *Developments in Agricultural Biotechnology*, 19 WM. MITCHELL L. REV. 457 (1993); Elizabeth Joy Hecht, Note, *Beyond Animal Legal Defense Fund v. Quigg: The Controversy Over Transgenic Animal Patents Continues*, 41 AM. U. L. REV. 1023 (1992); Ann Sturtz Viksnins, Comment, *Amgen, Inc. v. United States Int'l Trade Comm'n: Designer Genes Don't Fit*, 76 MINN. L. REV. 161 (1991); Mark W. Lauroesch, Note, *Genetic Engineering: Innovation and Risk Minimization*, 57 GEO. WASH. L. REV. 100 (1988).

16. While there does not appear to be one standard definition of the term "biotechnology," most are broad enough to cover a wide array of processes including genetic engineering, traditional processes such as traditional plant breeding, and processes such as fermentation. The United States Government recently defined "biotechnology" as: "[T]he use of various biological processes, both traditional and newly devised, to make products and perform services from living organisms or their components." See Notice of the Exercise of Federal Oversight Within Scope of Statutory Authority: Planned Introductions of Biotechnology Products Into the Environment, 57 Fed. Reg. 6753, 6754 (1992). Others have defined biotechnology in similar ways. See, e.g., UNITED STATES GENERAL ACCOUNTING OFFICE, FOOD SAFETY AND QUALITY: INNOVATIVE STRATEGIES MAY BE NEEDED TO REGULATE NEW

centuries, biotechnology has been used to manufacture products such as bread, beer, wine, yogurt, and cheese.¹⁷ Recently, researchers have been able to "genetically engineer" organisms by moving genes from one organism to another, through the use of recombinant DNA.¹⁸ For the past ten years, the EPA has regulated genetically engineered microorganisms under both FIFRA¹⁹ and the Toxic Substances Control Act (TSCA).²⁰

In the past several years, researchers have been able to move genes easily from microorganisms, animals, or other plants into important crop plants. Some products recently developed through this type of genetic modification include: corn, cotton, and potato plants genetically modified to produce the bacteria *Bacillus thuringiensis* insecticidal toxin,²¹ squash genetically

FOOD TECHNOLOGIES 31 (GAO/RCED-93-142, July 26, 1993) (describing biotechnology as "the use of living organisms or components of organisms, such as enzymes, to produce commercial products and perform industrial processes").

17. See, e.g., S.H. MANTELL ET AL., PRINCIPLES OF PLANT BIOTECHNOLOGY: AN INTRODUCTION TO GENETIC ENGINEERING IN PLANTS 5 (1985).

18. Recombinant DNA technology allows the isolation and characterization of specific pieces of DNA to be transferred from one organism into another organism. See *id.* at 9.

19. 7 U.S.C. §§ 136-136gg. See *infra* part II.C.5.a.ii. for further discussion of the EPA's regulation of microbial biotechnology products under FIFRA.

20. 15 U.S.C. §§ 2601-2692 (1994). See *infra* part II.C.5.b. for further discussion the EPA's regulation of microbial biotechnology products under TSCA.

21. The EPA received the first EUP application for the *B.t.* toxin produced by a genetically engineered plant, cotton, in November of 1991. See Notice of Receipt of an Application for an Experimental Use Permit for a Transgenic Plant Pesticide, 56 Fed. Reg. 65,073 (1991) (announcing receipt of application and soliciting public comment on the EUP application). The EUP application was the subject of a February 25, 1992 Scientific Advisory Panel (SAP) meeting, during which the EPA asked the SAP to address specific risk factors primarily related to whether the field tests to be conducted would be adequately contained. See Notice of Issuance of an Experimental Use Permit for a Transgenic Plant Pesticide, 57 Fed. Reg. 21,655 (1992). The SAP found that the containment provisions would prevent any foreseeable proliferation of the *B.t.* toxin in subsequent generations of cotton, except for the possibility of carryover of viable transformed seed in the soil through a mild winter in the more southern continental U.S. sites. *Id.* Thus, the SAP recommended a twelve-month monitoring program following the test. *Id.* During the SAP meeting, the EPA also heard comments from members of the public. *Id.* While the comments were generally supportive of the EUP, some expressed concern over the potential for weedy species related to cotton to develop and the increased potential for insects to become resistant to *B.t.* if the toxin is produced continually in crop plants. *Id.* The EPA issued the EUP on April 10, 1992. *Id.* In the years following the *B.t.* in cotton EUP, the EPA has granted EUPs for *B.t.* in potatoes and corn. See Notice of Issuance of an Experimental Use Permit for a Transgenic Plant Pesticide, 58 Fed. Reg. 68,409 (1993) (announcing issuance of EUP for *B.t.* in corn); Notice of Issuance of an Experimental Use Permit for Four Transgenic Plant Pesticides, 58 Fed. Reg. 33,815 (1993) (announcing issuance of EUP for *B.t.* in potatoes). On September 3, 1993, the EPA received its first application for a registration of a plant pesticide for *B.t.* in potatoes. See Notice of Receipt of an Application for Pesticide Registration for a Transgenic Plant Pesticide, 58 Fed. Reg. 64,582, (1993). On May 3, 1995 the EPA granted a registration for *B.t.* in potatoes, the first registration for a pesticide produced by a genetically engineered plant. Telephone interview with Mary E. Gleaves, Office of General Counsel, U.S. Environmental Protection Agency, Washington, D.C. (Sept. 5, 1996).

modified to produce a viral coat protein making the plant resistant to infection by some viruses;²² and cotton and soybean genetically modified with bacterial genes, causing the plants to tolerate herbicides applied to the plant.²³ Recombinant DNA techniques are also being used to produce a new class of animal hormones, the somatotropins. The bovine somatotropin (BST) hormone was approved by the Food and Drug Administration (FDA) for use in lactating dairy cows to produce more milk.²⁴

B. *The EPA's Primary Legal Authorities for Regulating Biotechnology*

The EPA's primary regulatory authorities for biological and biotechnological products can be found in three statutes: FIFRA, FFDCA, and

In conjunction with this registration, on May 3, 1995 the EPA published a final rule in the Federal Register exempting residues of the *B.t.* delta-endotoxin and the genetic material necessary for its production in potatoes from a tolerance requirement under the FFDCA. 60 Fed. Reg. 21,725 (1995) (to be codified at 40 C.F.R. pt. 180). Since issuing the first *B.t.* plant-pesticide product in May of 1995, the EPA has issued registrations for *B.t.* in corn (*see* 60 Fed. Reg. 55,575 (1995)) and cotton (telephone interview with Mary Gleaves, *supra*) and has issued tolerance exemptions for the *B.t.* delta-endotoxin in corn (60 Fed. Reg. 42,443 (1995) and 61 Fed. Reg. 5772 (1996)) and in cotton (60 Fed. Reg. 47,871 (1995)).

22. *See* 59 Fed. Reg. 38,149 (1994) (to be codified at 40 C.F.R. pt. 180) (proposed July 27, 1984) (proposing an exemption from the requirement of a tolerance for watermelon mosaic virus-2 coat protein and zucchini yellow mosaic virus coat protein and the genetic material necessary for the production of these proteins in squash plants).

23. *See* Notice of Receipt of an Application for an Experimental Use Permit, 59 Fed. Reg. 19,719 (1994) (announcing receipt of application for an EUP for use of glufosinate-ammonium on herbicide tolerant corn plants); Notice of Receipt of an Application for an Experimental Use Permit, 60 Fed. Reg. 6093 (1995) (announcing receipt of an application for use of glufosinate-ammonium on corn and soybeans); Notice of Receipt of an Application for an Experimental Use Permit, 59 Fed. Reg. 17,536 (1994) (announcing receipt of application for an EUP for use of bromoxynil on herbicide tolerant cotton plants). The plants in this category are not considered to produce plant pesticides because the substances they produce are not intended to prevent, destroy, or repel pests. Thus, these products would not be covered by the plant-pesticide policy or rules. The EPA is planning to develop a separate policy for these plants.

24. *See* 58 Fed. Reg. 59,946 (1993) (codified at 21 C.F.R. §§ 510.6, 522.2112) (the FDA's final rule approving the use of a new animal drug, containing recombinant DNA-derived, somatotropin in lactating cows); *see also* Notice of the FDA's Interim Guidance on the Voluntary Labeling of Milk and Milk Products from Cows that Have Not Been Treated with Recombinant Bovine Somatotropin, 59 Fed. Reg. 6279 (1994). This paper does not explore the regulation of genetically engineered animals or genetically engineered animal drugs. Naturally-occurring macroorganisms are currently exempt from FIFRA regulation pursuant to 40 C.F.R. § 152.20 (1994). Thus far, the EPA has not addressed how, or if, it will regulate genetically engineered animals. *See generally* ANIMAL BIOTECHNOLOGY: OPPORTUNITIES AND CHALLENGES (June F. MacDonald ed., National Agric. Biotechnology Council Rep. No. 4, 1992); James Murray et al., *Workshop Report: Transgenic Animals, in* AGRICULTURAL BIOTECHNOLOGY AT THE CROSSROADS: BIOLOGICAL, SOCIAL AND INSTITUTIONAL CONCERNS 38 (June F. MacDonald ed., National Agric. Biotechnology Council Rep. No. 3, 1991).

TSCA.²⁵ Under FIFRA, the EPA is responsible for regulating the distribution, sale, use, and testing of pesticides to prevent unreasonable adverse effects to humans and the environment. In evaluating the use of a pesticide, the EPA balances the potential human and environmental risks against the potential benefits to society. Under FFDCA, the EPA is authorized to set tolerances for pesticide residues in raw agricultural commodities and to establish food additive regulations for pesticide residues in or on processed foods. In establishing tolerances or food additive regulations, the EPA evaluates the impact of pesticide residue on human dietary exposure. Biological and biotechnological products that are not pesticides, food, or drugs are regulated under TSCA.²⁶ TSCA grants the EPA the authority to screen new chemical substances and impose controls to prevent unreasonable risks. TSCA also allows the EPA to acquire information and impose restrictions to prevent unreasonable risks on existing chemical substances.

1. FIFRA

Section 2(u) of FIFRA defines "pesticide" as: "(1) any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, and (2) any substance or mixture of substances intended for use as a plant regulator, defoliator, or desiccant. . . ."²⁷ This definition is very broad and can include living organisms and substances produced by living organisms, as well as traditional chemical pesticides.

Section 3 of FIFRA provides that no person may distribute or sell in the United States any pesticide that is not registered under the Act.²⁸ Before a pesticide may be registered, section 3(c)(5) requires that the pesticide, when used in accordance with widespread and commonly recognized practice, will not generally cause "unreasonable adverse effects on the environment."²⁹

25. 7 U.S.C. §§ 136-136gg; 21 U.S.C. §§ 301-392; 15 U.S.C. §§ 2601-2692. Although the EPA's primary authority for regulating biotechnology is derived from FIFRA, FFDCA, and TSCA, several other EPA-administered statutes may provide additional regulatory authority. Resource Conservation and Recovery Act, 42 U.S.C. §§ 6901-6992k (1994) (applicable to certain uses of organisms to clean-up hazardous wastes through bioremediation); Clean Water Act, 33 U.S.C. §§ 1251-1387 (1994) (potential applicability to discharges of organisms into waters of the United States); Safe Drinking Water Act, 42 U.S.C. §§ 300f to 300j-26 (1994) (potential applicability to contamination of public drinking water supplies by organisms); the Marine Protection, Research, and Sanctuaries Act, 33 U.S.C. §§ 1401-1421 (1988) (potential applicability to organisms dumped into the marine environment); see also Thomas O. McGarity & Karl O. Bayer, *Federal Regulation of Emerging Genetic Technologies*, 36 VAND. L. REV. 461, 505-09 (1983).

26. 15 U.S.C. §§ 2601-2671.

27. 7 U.S.C. § 136(u).

28. *Id.* § 136a(a).

29. *Id.* § 136a(c)(5).

The term "unreasonable adverse effects on the environment" is defined in section 2(bb) of FIFRA as any unreasonable risk to humans or the environment, taking into account the economic, social, and environmental costs and benefits of using any pesticide.³⁰ Thus, FIFRA involves a balancing of the risks and benefits presented by the use of the pesticide.

The procedures governing the regulation of pesticides are set forth in the *Code of Federal Regulations*.³¹ One of the most important requirements is that the registrant or applicant submit data in support of registration. The *Code of Federal Regulations* sets forth data requirements for conventional pesticides and microbial pesticides³² and provides for the submission of comprehensive health and environmental effects data. The EPA has not yet established specific data requirements for plant pesticides.

An applicant for registration must submit all proposed labeling with the registration application. Section 2(p) of FIFRA defines the term "label" as the written, printed, or graphic matter on, or attached to the pesticide.³³ The term "labeling" under FIFRA includes the label as well as all other written, printed, or graphic matter that accompanies the pesticide or to which reference is made on the label.³⁴ Registered pesticide products must bear a label or labeling that contains certain information, including precautionary statements, warnings, directions for use of the product, and an ingredient statement. FIFRA requires users of pesticides to follow all label directions.³⁵ A product whose label or labeling does not contain the information required by the EPA or which sets forth false or misleading information is misbranded pursuant to FIFRA sections 2(q) and 12(a)(1)(E).³⁶ For conventional pesticides, many risk reduction measures are achieved through labeling restrictions.³⁷ As discussed below, however, labeling restrictions may not be appropriate for plant pesticides.

FIFRA also provides the EPA with a number of other regulatory tools beyond the registration authority. For example, section 3(a) authorizes the EPA to otherwise regulate the use of unregistered pesticides.³⁸ In addition, under section 25(b) of FIFRA, the EPA may exempt FIFRA requirements for any pesticide determined to be (1) adequately regulated by another federal agency, or (2) of a character that is unnecessary to be subject to FIFRA in

30. *Id.* § 136(bb).

31. 40 C.F.R. §§ 152-172 (1995).

32. 40 C.F.R. § 158.740.

33. 7 U.S.C. § 136(p).

34. *Id.* § 136(p)(2).

35. *Id.* § 136j(a)(2)(G). FIFRA provides that it is unlawful for any person to use a pesticide in a manner that is inconsistent with its labeling. *Id.*

36. *Id.* §§ 136(q), 136j(a)(1)(E).

37. 40 C.F.R. § 156 (1995).

38. 7 U.S.C. §§ 136c (experimental use permits), 136a(a).

order to carry out the purposes of the Act.³⁹

2. FFDCA

The EPA regulates pesticide residues in or on food under the authority of sections 408⁴⁰ and 409⁴¹ of FFDCA. Under FFDCA section 408, any poisonous or deleterious pesticide chemical that is not "generally recognized as safe," added to a raw agricultural commodity is deemed to be unsafe unless a tolerance for such pesticide is established, and the pesticide is within the tolerance limits.⁴² The term "pesticide chemical" is defined in section 201(q) of FFDCA as: "any substance which, alone, in chemical combination or in formulation with one or more other substance, is 'a pesticide' within the meaning of [FIFRA] . . . and which is used in the production, storage, or transportation of raw agricultural commodities."⁴³ Thus, pesticide chemicals subject to section 408 of FFDCA are defined by reference to the definition of a pesticide under FIFRA. Section 408(b) of FFDCA authorizes the EPA to establish tolerances for pesticide chemical residues on raw agricultural commodities to the extent necessary to protect the public health.⁴⁴ In establishing such regulations, the EPA must give appropriate consideration to the following factors: (1) the necessity for the production of an adequate, wholesome, and economical food supply; (2) other ways in which the consumer may be affected by the same pesticide chemical or by other related substances that are poisonous or deleterious; and (3) the opinion submitted with a certification of usefulness under the Act.⁴⁵ Thus, as with FIFRA, the EPA's regulatory decisions under section 408 of FFDCA involve a risk/benefit balance. Unlike FIFRA, however, FFDCA only addresses human dietary risks. Section 408(c) of FFDCA authorizes the EPA to promulgate regulations exempting any pesticide chemical from a tolerance that is not necessary to protect the public health.⁴⁶

Pursuant to section 402 of FFDCA, food is deemed to be adulterated if it contains any food additive not authorized by a food additive regulation under section 409.⁴⁷ The EPA has interpreted section 409 as applying to pesticide residues in processed food which result from use of the pesticide in or on raw food as long as the concentration of the pesticide in the

39. *Id.* § 136w(b).

40. 21 U.S.C. § 346a.

41. *Id.* § 348.

42. *Id.* § 346a(a).

43. *Id.* § 321(q).

44. *Id.* § 346a(b).

45. *Id.*

46. *Id.* § 346a(c).

47. *Id.* § 342.

processed food is greater than the appropriate raw food tolerance.⁴⁸ Before issuing a food additive regulation under section 409 of FFDCa, the EPA must determine that the intended use of the food additive, under the conditions of use specified in the regulation, will be safe.⁴⁹ The determination of whether the use of a pesticidal food additive is safe should take into account the net effects of the use of the additive on the food supply.⁵⁰ A section 409 food additive regulation is not required for any substance that is "generally recognized as safe."⁵¹

3. TSCA

Under TSCA, the EPA's regulatory jurisdiction extends to "chemical substances," defined as any "organic or inorganic substance of a particular molecular identity, including . . . any combination of such substances occurring in whole or part as a result of a chemical reaction or occurring in nature."⁵² TSCA does not apply to certain specifically excluded substances that are covered by other regulatory authorities, for example, food, drugs, cosmetics and pesticides.⁵³ Organisms, both naturally-occurring and genetically engineered, are made up of substances of particular identities that occur in nature, or occur in whole or part as a result of a chemical reaction. Thus, organisms are chemical substances under TSCA.

48. *Id.*; see also Plant-Pesticide Policy, 59 Fed. Reg. 60,496, 60,499 (1994).

49. 21 U.S.C. § 348(a).

50. See Plant-Pesticide Policy, 59 Fed. Reg. at 60,499.

51. 21 U.S.C. § 321(s) (excluding from the definition of "food additive," any substance that is "generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use").

52. 15 U.S.C. § 2602(2).

53. Section 3(2) of TSCA provides that the term "chemical substance" does not include:

- (i) any mixture,
- (ii) any pesticide (as defined in [FIFRA] (7 U.S.C. §§ 136-136gg)) when manufactured, processed, or distributed in commerce for use as a pesticide,
- (iii) tobacco or any tobacco product,
- (iv) any source material, special nuclear material, or byproduct material (as such terms are defined in the Atomic Energy Act of 1954 [42 U.S.C. §§ 2011 to 2297g-4 (1994)] and regulations issued under such Act,
- (v) any article the sale of which is subject to tax imposed by section 4181 of the Internal Revenue Code of 1986 [26 U.S.C. §§ 4181-4182 (1988)] [firearms and ammunition]. . . , and
- (vi) any food, food additive, drug, cosmetic, or device (as such terms are defined in section 201 of the [FFDCa] when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device.

15 U.S.C. § 2602(2)(B).

Before imposing restrictions, the EPA must issue regulations, for example, TSCA section 4⁵⁴ test rules, TSCA section 6⁵⁵ restrictive rules, or TSCA section 8⁵⁶ reporting and recordkeeping rules, for most chemical substances, and therefore, for most organisms. Pursuant to section 5 of TSCA, however, all “new chemical substances” are automatically covered and subject to a ninety-day screening mechanism, known as “premanufacture notification” (PMN).⁵⁷ When a PMN for a new chemical substance is submitted, the EPA has ninety days to screen the substance to determine whether to impose controls preventing unreasonable risk or substantial exposure. If the EPA does not take action within the ninety-day period, the substance may be manufactured, processed, distributed, sold, used, or disposed, and the substance will be listed on the TSCA Inventory, which serves as the official record of which substances are not “new.” With regard to biological substances, the EPA interprets a “new” microorganism to be one formed by the deliberate combination of genetic material from source organisms classified in different taxonomic genera (hereinafter intergeneric microorganisms), and not on the TSCA Inventory.

Section 5(h) of TSCA provides exemptions from PMN screening.⁵⁸ Sections 5(h)(3) and 5(h)(4) are the most relevant to biologicals. Section 5(h)(3) exempts from PMN requirements substances manufactured or processed only in small quantities for research and development.⁵⁹ Current section 5(h)(3) regulations exempt virtually all research from PMN review. In addition, section 5(h)(4) of TSCA authorizes the EPA to exempt the manufacture of any new chemical substance if the EPA determines that use of such substance will not present an unreasonable risk of injury to health or the environment.

C. *History of Federal Regulation of Biotechnology*

1. The 1986 Coordinated Framework

The United States Government’s first systematic attempt to address the regulation of biotechnology was the publication of the 1984 document entitled “Proposal for a Coordinated Framework for Regulation of Biotech-

54. *Id.* § 2603.

55. *Id.* § 2605.

56. *Id.* § 2607.

57. *Id.* § 2604.

58. *Id.* § 2604(h)(4).

59. Under section 5(h)(3) of TSCA the term “small quantities” is defined by the Administrator by rule. 15 U.S.C. § 2604(h)(3).

nology.”⁶⁰ The purpose of this document was “to provide a concise index to U.S. laws related to biotechnology, to clarify the policies of the major regulatory agencies that will be involved in reviewing research and products of biotechnology, to describe scientific advisory mechanisms for assessment of biotechnology issues, and to explain how the activities of the Federal agencies in biotechnology will be coordinated.”⁶¹ In 1986, the Office of Science and Technology Policy (OSTP) published in the Federal Register the “Coordinated Framework for Regulation of Biotechnology; Announcement of Policy and Notice for Public Comment” (hereinafter the Coordinated Framework).⁶² This document made clear that the executive branch believed it could adequately regulate biotechnology under its existing authorities and did not intend to seek new legislation to address emerging technologies.⁶³ The coordinated framework described in detail the roles of the five federal agencies with significant involvement in the regulation of biotechnology: the FDA; the United States Department of Agriculture (USDA); the EPA; the National Institutes of Health (NIH); and the Occupational Safety and Health Administration (OSHA).⁶⁴

60. Notice of a Proposal for a Coordinated Framework for Regulation of Biotechnology, 49 Fed. Reg. 50,856 (1984).

61. *Id.* at 50,856.

62. 51 Fed. Reg. 23,302 (1986).

63. *Id.* at 23,303.

[U]pon examination of the existing laws available for the regulation of products developed by traditional genetic manipulation techniques, the working group concluded that, for the most part, these laws as currently implemented would address regulatory needs adequately. For certain microbial products, however, additional regulatory requirements, available under existing statutory authority, needed to be established.

Id.

Despite the conclusion in the Coordinated Framework that existing authorities are adequate to address most biotechnology research and products, many have argued in favor of new legislation specifically designed to address biotechnology. See, e.g., McGarity & Bayer, *supra* note 25, at 539. Although there has been significant Congressional interest in biotechnology dating back to the 1970s, Congress has not yet passed federal legislation for the regulation of biotechnology. See Albert Gore, Jr., *A Congressional Perspective, in BIOTECHNOLOGY: IMPLICATIONS FOR PUBLIC POLICY* 12, 14-17 (Sandra Penem ed., 1985).

64. OSHA's role in the regulation of biotechnology is not discussed in this article. For a discussion of the role of OSHA, refer to the 1986 Coordinated Framework, 51 Fed. Reg. 23,302, 23,347 (1986). For further discussion of the Coordinated Framework, see Thomas O. McGarity, *Federal Regulation of Agricultural Biotechnologies*, 20 U. MICH. J.L. REF. 1089, 1097-1100 (1987) (analyzing the adequacy of existing federal authorities for regulating agricultural biotechnology). See generally UNITED STATES GENERAL ACCOUNTING OFFICE, *BIOTECHNOLOGY: MANAGING THE RISKS OF FIELD TESTING GENETICALLY ENGINEERED ORGANISMS* (June 1988); Michael P. Vandenburg, Note, *The Rutabaga That Ate Pittsburgh: Federal Regulation of Free Release Biotechnology*, 72 VA. L. REV. 1529 (1986).

2. The NIH

The NIH oversees research on genetic engineering through its Guidelines for Research Involving Recombinant DNA Molecules, (NIH Guidelines),⁶⁵ developed under the authority of the Public Health Service Act.⁶⁶ These guidelines apply to all recombinant DNA research conducted at or sponsored by institutions that receive NIH support. While the NIH does not have the authority to impose penalties for failure to comply with the guidelines, noncompliance can result in a loss of federal funding. Additionally, many private research organizations voluntarily comply with the NIH Guidelines.

The primary focus of the NIH Guidelines is contained laboratory experiments and other large-scale contained uses, such as industrial fermentation using genetically modified microorganisms.⁶⁷ Under the NIH Guidelines, different types of activities are categorized based on risk potential. The guidelines are designed to minimize the potential for risk by minimizing the opportunity for exposure, that is, the more likely the organism is to cause a problem, the more it needs to be contained. Four biosafety levels provide a continuum of increasingly stringent containment conditions that specify a combination of laboratory practices and techniques, safety equipment, laboratory facilities and biological barriers.⁶⁸

3. The USDA

The USDA is responsible for preventing the introduction and dissemination of plant pests in the environment, protecting agriculture from threats to animal health, and protecting against the adulteration of foods made from livestock and poultry. The USDA Animal and Plant Health Inspection Service (APHIS) is responsible for preventing the introduction and dissemination of plant pests in the environment and protecting animal health.⁶⁹ The USDA's Food Safety and Inspection Service (FSIS) is responsible for the prevention of adulteration of food products made from livestock and poultry.⁷⁰

65. Notice of Guidelines for Research Involving Recombined DNA Molecules, 51 Fed. Reg. 16,958 (1986) [hereinafter NIH Guidelines].

66. 42 U.S.C. §§ 201 to 300ff-90 (1994).

67. See NIH Guidelines, *supra* note 65, at 16,959. See generally Norman L. Rave, Note, *Interagency Conflict and Administrative Accountability: Regulating the Release of Recombinant Organisms*, 77 GEO. L.J. 1787 (1989) (discussing the NIH's regulation of biotechnology).

68. NIH Guidelines, *supra* note 65, at 16,959-61.

69. 7 C.F.R. §§ 371.1-17.

70. 9 C.F.R. §§ 301.1 to 391.5. For further discussion of the role of the USDA in regulating biotechnology, see UNITED STATES GENERAL ACCOUNTING OFFICE, BIOTECHNOLOGY: AGRICULTURE'S REGULATORY SYSTEM NEEDS CLARIFICATION (1986).

The USDA's regulatory activities most relevant to the EPA's regulation of plant pesticides are carried out by USDA/APHIS. USDA/APHIS regulates the introduction and dissemination of certain biotechnology products into the environment that are considered "plant pests" pursuant to a 1987 regulation on the introduction of genetically engineered organisms.⁷¹ This regulation was promulgated under the authority of the Federal Plant Pest Act⁷² and the Plant Quarantine Act.⁷³ Under the Federal Plant Pest Act, "plant pest" is defined very broadly to include any organism which can directly or indirectly injure, cause disease or damage to any plant or parts thereof, or any processed, manufactured, or other products of plants. The 1987 regulation provides that a person must obtain a permit to import, move interstate, or release into the environment a genetically engineered organism that is a "regulated article."⁷⁴ "Regulated article" is defined very broadly and includes plants and microorganisms engineered using components from plant pests, including those that are intended to have a pesticidal effect.⁷⁵ Pursuant to a 1987 letter of agreement with USDA/APHIS, the EPA has for the past several years cooperatively reviewed small scale field tests of plant pesticides that are under USDA/APHIS' permitting authority.⁷⁶

In 1993, APHIS amended its 1987 regulation to provide for a notification process, in lieu of a permit requirement, for the introduction of certain plants with which USDA/APHIS had sufficient experience to determine that a permit was not necessary to prevent plant pest risks.⁷⁷ Under this scheme,

71. 7 C.F.R. §§ 330, 340 (1995); see 52 Fed. Reg. 22,892 (1987) (codified at 7 C.F.R. §§ 330, 340) (proposed June 16, 1987).

72. 7 U.S.C. § 150aa-jj (1994).

73. *Id.* §§ 151-167.

74. 7 C.F.R. § 340.0 (1995).

75. *Id.* at § 340.1. The term regulated article is defined as:

Any organism which has been altered or produced through genetic engineering, if the donor organism, recipient organism, or vector agent belongs to any genera or taxa designated in § 340.2 meets the definition of plant pest, or is an unclassified organism and/or an organism whose classification is unknown, or any product which contains such an organism, or any other organisms or product altered or produced through genetic engineering which the Director, BBEP, determines is a plant pest or has reason to believe is a plant pest.

Id.

76. Letter from Dr. Amy S. Rispin, Director Science Integration Staff, EPA Hazard Evaluation Division, to Terry Medley, J.D., Director, Biotechnology and Environmental Coordination Staff, APHIS, USDA (Aug. 11, 1987) (on file with *University of Florida Journal of Law & Public Policy*). See generally R. P. Wrubel et al., *Field Testing Transgenic Plants: An Analysis of the US Department of Agriculture's Environmental Assessments*, 42 BIOSCIENCE, Apr. 1992, at 280 (analyzing the USDA's environmental assessments of transgenic plant field tests).

77. See 58 Fed. Reg. 17,044 (1993) (codified at 7 C.F.R. § 340). The stated purpose of the amendment was to relieve unnecessary restrictions on the introduction of regulated articles based on experience and to provide standardized procedures for notification of the introduction

notification in lieu of obtaining a permit would be allowed for regulated articles that are one of six specified plant species (corn, cotton, potato, soybean, tobacco, or tomato) or any additional plant species that the Biotechnology, Biologics, and Environmental Protection (BBEP) division of USDA/APHIS has determined may be safely introduced in accordance with certain specified eligibility criteria and performance standards.⁷⁸ If a regulated article qualifies for notification, the specified eligibility criteria and performance standards, which are designed to reduce risk, must be met.⁷⁹

The 1993 regulation also allows any person to submit to the Director of BBEP a petition to seek a determination that an article should no longer be regulated because it does not present a plant pest risk.⁸⁰ USDA/APHIS has used this process to deregulate several genetically engineered plants, including: tomatoes that have been genetically modified to stay firm longer than other tomatoes (the FLAVR SAVR™ tomato),⁸¹ cotton that has been genetically modified to be tolerant to direct application of the herbicide bromoxynil,⁸² and soybeans that have been engineered to be resistant to the herbicide glyphosate.⁸³ USDA/APHIS currently is evaluating petitions for squash that have been genetically modified to be resistant to infection by plant viruses.⁸⁴

of regulated articles; *see also* 57 Fed. Reg. 53,036 (1992) (to be codified at 7 C.F.R. pt. 340) (proposed Nov. 6, 1992).

78. The eligibility criteria are set forth in 7 C.F.R. § 340.3(b)(2)-(6) (1995) (providing that the introduced genetic material must be stably integrated into the plant genome; the function of the introduced genetic material must be known, and its expression product must not cause plant disease; the introduced genetic material must not be infectious or encoded for a substance that is toxic or intended for a pharmaceutical use; the introduced genetic material must not pose a significant risk of the creation of a new plant virus; and the plant must not have been genetically modified to contain certain specified animal or human pathogens).

79. The performance standards are set forth in 7 C.F.R. § 340.3(c).

80. 7 C.F.R. § 340.6.

81. *See* 57 Fed. Reg. 47,608 (1992) (USDA/APHIS interpretive ruling on Calgene's petition for determination of regulatory status of the FLAVR SAVR™ tomato).

82. *See* Notice of Availability of Determination of Nonregulated Status of Calgene, Inc., Genetically Engineered Cotton Lines, 59 Fed. Reg. 8452 (1994) (USDA/APHIS determination of nonregulated status for cotton genetically engineered to be tolerant to the herbicide bromoxynil).

83. *See* Notice of Availability of Determination of Nonregulated Status of Monsanto Co., Genetically Engineered Soybean Line, 59 Fed. Reg. 26,781 (1994) (USDA/APHIS availability of determination of nonregulated status of Monsanto genetically engineered glyphosate soybeans).

84. *See* Notice of Availability of Determination of Nonregulated Status for Squash Line Genetically Engineered for Virus Resistance, 61 Fed. Reg. 33,484 (1996); Tolerance Exemption for Watermelon Mosaic Virus-2 Coat Protein, Zucchini Yellow Mosaic Virus Coat Protein, and the Genetic Material Necessary for Production of these Proteins in Transgenic Squash Plants, 59 Fed. Reg. 54,824 (1994) (codified at 40 C.F.R. § 180.1132). Notice of Public Meeting Announcing Preliminary Finding of No Significant Impact for Upjohn Co., Virus Resistant Squash, 59 Fed. Reg. 26,619 (1994) (USDA/APHIS announcement of public

4. The FDA

The Reorganization Plan No. 3 of 1970, which created the EPA, granted the EPA authority to establish tolerances and food additive regulations for residues of pesticide chemicals in foods and animal feeds.⁸⁵ Pursuant to this plan, the FDA retained regulatory jurisdiction over all food additives that are not pesticide chemicals. Thus, the FDA has the authority to regulate foods that have been modified to produce substances other than pesticides. Despite the fact that the FDA does not regulate "pesticides," the FDA's regulation of nonpesticidal foods derived from biotechnology is relevant to the EPA's regulation of plant pesticides. Both agencies have worked together to create consistent policies for foods derived from biotechnology.

In 1992, the FDA announced its policy for regulating foods derived from new plant varieties, including food plants modified through genetic engineering.⁸⁶ In this policy statement, the FDA clarified that it will regulate foods derived from new plant varieties, both genetically modified and resulting from traditional breeding practices, primarily through the post market adulteration provisions of FFDCA.⁸⁷ Under this approach, the FDA generally would not require foods derived from new plant varieties to come to the FDA for premarket approval, that is, to obtain a food additive regulation. However, the food must still meet the safety standards of the FFDCA. To assist developers in making decisions, the FDA provided guidance on scientific issues to assure that a food meets the safety standards of FFDCA. If the FDA finds that a particular food contains an unexpectedly harmful substance that may render the food injurious to health, the FDA can

meeting and availability of environmental assessment and finding of no significant impact for determination of nonregulated status of Upjohn virus resistant squash).

85. Reorganization Plan No. 3 of 1970, 3 C.F.R. at 199 (1970 Comp.), *reprinted in* 5 U.S.C. app. at 1551 (1994) and in 84 Stat. 2086.

86. Food and Drug Administration, Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984 (1992).

87. 21 U.S.C. § 342. This section provides that food shall be deemed adulterated:

(a)(1) if it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substances in food does not ordinarily render it injurious to health.

(2)(A) if it bears or contains any added poisonous or added deleterious substance . . . or (B) if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of section 346(a) of this title, or (C) if it is, or bears or contains, any food additive which is unsafe within the meaning of section 348. . . .

Id.

declare that food item adulterated and in violation of FFDCA.⁸⁸ Although the policy does not require premarket review, the FDA has encouraged producers to consult with the EPA prior to marketing.

Under the policy, however, some substances intentionally added to a food would be required to obtain premarket review, that is substances that are not generally recognized as safe.⁸⁹ Food plants that have been genetically modified to contain substances that do not differ substantially from historically safe or "generally recognized as safe" substances would not be required to obtain premarket review. However, food plants that have been genetically modified to contain substances that differ substantially in structure, function, or composition from substances currently found in food or that otherwise raise a safety concern may not be considered "generally recognized as safe," and thus, may require a food additive regulation prior to marketing.⁹⁰ The 1992 policy statement provides detailed guidance to producers of new plant varieties to assist them in determining whether premarket approval is necessary.⁹¹

The FDA received over three thousand comments on the 1992 policy. Although comments from the food and biotechnology industries were generally favorable, comments from consumer and environmental groups indicated a disbelief that the FDA's policy is adequate to protect public health.⁹² While many consumers are wary of all genetically engineered foods and believe that premarket approval is necessary to ensure safety, the most controversial issue of the FDA policy is that of labeling genetically engineered foods.⁹³ In the 1992 announcement, the FDA stated that it would not require labels for genetically engineered foods to disclose the method by which the food was produced.⁹⁴ Supporters of labeling believe

88. Notice of Statement of Policy: Foods Derived from New Plant Varieties, 57 Fed. Reg. 22,984, 22,988-90 (1992). See generally Michele J. Brace, Comment, *Regulation of Genetically Engineered Foods Under the Federal Food, Drug, and Cosmetic Act*, 33 AM. U. L. REV. 899 (1984) (analyzing the FDA's authority to regulate genetically engineered foods).

89. 57 Fed. Reg. 22,985; see FFDCA, 21 U.S.C. § 321(s).

90. 57 Fed. Reg. at 22,990.

91. *Id.* at 22,991-92.

92. See generally UNITED STATES GENERAL ACCOUNTING OFFICE, *supra* note 16, at 31-56 (discussing public comment received in response to the FDA's 1992 policy).

93. See, e.g., Pure Food Campaign, *Comment to the Food and Drug Administration on the Statement of Policy: Foods Derived From New Plant Varieties* (submitted to the FDA on July 27, 1993) (arguing in favor of labeling of genetically engineered foods); *Consumers Union's Comments on Docket No. 92N-0139, Food Labeling: Foods Derived from New Plant Varieties 1* (submitted to the FDA on July 27, 1993) (asserting that all genetically engineered food plants should be labeled as such).

94. 57 Fed. Reg. 22,984, 22,991. The FDA does, however, require that a food bear a proper common or usual name. In addition, labeling may be required to disclose significant changes in the composition of the food or to disclose a safety issue such as the presence of an unexpected allergen in the food. *Id.*

that genetically engineered foods must be labeled to enable consumers to make informed decisions regarding their food choices. In particular, consumers are concerned that genetically engineered foods may contain allergens that, in the absence of labeling, may expose consumers with allergies to specific substances they would otherwise avoid.⁹⁵ Subsequent to the issuance of the 1992 policy statement, the FDA has held public meetings⁹⁶ and published a Federal Register notice requesting data and additional public input on labeling new plant varieties.⁹⁷

Two biotechnology food products that have received a great deal of public scrutiny are milk produced from cows treated with the genetically engineered bovine somatotropin hormone⁹⁸ and the FLAVR SAVR™ tomato.⁹⁹ Although the FDA scientists have expressed confidence that both of these foods are as safe as traditional products, the public reaction suggests a general distrust of genetic engineering, particularly when it involves foods.

5. The EPA

a. FIFRA

(i) Biochemical pesticides

The EPA has exerted its regulatory authority under FIFRA over biochemical pesticides for many years. Biochemicals are a diverse class of substances that can be derived from either natural sources or can be synthesized. Two groups of biochemical pesticides that the EPA actively regulates are semiochemicals and plant regulators. Semiochemicals,

95. For example, if wheat is genetically engineered to contain a gene from a peanut plant, a consumer with an allergy to peanuts would know to avoid peanuts, but would not know to avoid wheat, unless the wheat was labeled in such a way that let the consumer know it contained a peanut gene. *Id.* See generally Pure Food Campaign, *supra* note 93; Consumers Union's Comments, *supra* note 93, at 1. For further discussion of this potential problem, see *infra* note 152 and accompanying text.

96. See Notice of Food & Drug Industry Exchange Meetings on a Policy Statement on Foods Derived From New Plant Varieties, 57 Fed. Reg. 31,428 (1992) (announcing public meetings on policy statement concerning foods derived from new plant varieties).

97. See Food and Drug Administration, Food Labeling: Foods Derived from New Plant Varieties, 58 Fed. Reg. 25,837 (1993) (requesting data and information on food labeling and foods derived from new plant varieties).

98. See Michael Hansen, *Consumer Concerns: Give Us All the Data*, in AGRICULTURAL BIOTECHNOLOGY AT THE CROSSROADS: BIOLOGICAL, SOCIAL AND INSTITUTIONAL CONCERNS 169 (June F. MacDonald ed., National Agric. Biotechnology Council Rep. No. 3, 1991) (discussing consumer concerns about BST milk).

99. See Notice of Availability of Letter to Calgene, Inc. Concluding Consultation, 59 Fed. Reg. 26,647 (1994) (the FDA announcing the availability of a letter from the FDA to Calgene, notifying the firm that the FDA had concluded that the FLAVR SAVR™ tomatoes had not been significantly altered when compared to varieties of tomatoes with a history of safe use).

including pheromones,¹⁰⁰ are chemicals that are emitted by an organism that modify the behavior of the receptor organisms of similar or different species. For example, certain insect mating attractants are used to disrupt mating behavior of insects in agricultural fields. Plant regulators¹⁰¹ are used, among other things, to accelerate or retard the rate of growth of plants, and include such agricultural chemicals as auxins and gibberellins.

The EPA has expressed a strong interest in encouraging the development and use of many of these biochemical pesticides, because they are generally considered to be more environmentally benign than traditional chemical pesticides. In 1992, the EPA issued a Federal Register notice entitled "Incentives for Development and Registration of Reduced Risk Pesticides," which sought comment on potential approaches to encourage the development, registration, and use of pesticides that present lower risks to human

100. EPA regulations define pheromone as "a compound produced by an arthropod which, alone or in combination with other such compounds, modifies the behavior of other individuals of the same species." Exemptions for Pesticides of a Character Not Requiring FIFRA Regulation, 40 C.F.R. § 152.25(b)(1) (1994).

101. In addition to substances that kill, injure, or repel pests, the definition of pesticide under FIFRA includes "any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccant." 7 U.S.C. § 136(u)(2) (1994). The term plant regulator is defined as:

any substance or mixture of substances intended, through physiological action for accelerating or retarding the rate of growth or rate of maturation, or for otherwise altering the behavior of plants or produce thereof, but shall not include substances to the extent that they are intended as plant nutrients, trace elements, nutritional chemicals, plant inoculants, and soil amendments. Also, the term plant regulator shall not be required to include any of such of those nutrient mixtures or soil amendments as are commonly known as vitamin-hormone horticultural products .

...

7 U.S.C. § 136(v) (1994).

Plant regulators were added to the FIFRA definition of pesticide in 1959. Congress' stated reason for extending FIFRA coverage to such substances was to subject these agricultural chemicals to the same regulatory controls and requirements as were then applicable to insecticides, fungicides, weed killers, and rodenticides. H.R. REP. NO. 552, 86th Cong., 1st Sess. (1959). Because virtually every genetic modification to a plant could result in the production of a substance that could be said to "otherwise alter the behavior of the plant," the EPA has had to develop an interpretation of the term plant regulator specific to plant pesticides that does not lead to the absurd result of considering every such substance a pesticide. The EPA has provided an explanation of what substances produced by plants would be considered plant regulators, and thus, subject to its FIFRA and FFDCA authority as a plant pesticide, and what substances produced by plants would not be considered plant regulators, and thus, would be subject to the FDA's jurisdiction. See Plant-Pesticide Policy, 59 Fed. Reg. 60,496, 60,499-503. In general, growth hormones produced by plants would be considered to be plant regulators subject to the EPA's authority. Substances produced by plants that affect food quality, on the other hand, would not be considered to be plant regulators and would be subject to the FDA's authority. *Id.*

health and the environment.¹⁰² In addition, the EPA has encouraged the use of biological pesticides by creating an expedited registration process and waiving certain data requirements for many of these products.¹⁰³ With regard to pheromones, the EPA has taken a number of steps to streamline the regulatory process. First, the EPA has established an exemption for pheromones used in traps, based on the low potential for risk presented by these products.¹⁰⁴ Second, the EPA has recently taken a number of regulatory actions to promote the development of pheromone pesticide products. In 1993 and 1994, the EPA published tolerance exemptions for certain pheromone residues and inert ingredients used in pheromone products.¹⁰⁵ On January 26, 1994, the EPA published a policy that allows environmental testing with certain pheromone products on no more than 250 acres without an Experimental Use Permit (EUP).¹⁰⁶

102. Notice of Incentives for Development and Registration of Reduced Risk Pesticides, 57 Fed. Reg. 32,140 (1992).

103. The EPA evaluates the potential for risk for a particular pesticide using data, generally submitted by the registration applicant, specific to that pesticide. The EPA's data requirements, set forth in 40 C.F.R. § 158 (1995), are designed to evaluate two components of risk: hazard and exposure. Section 158 contains data requirements specific to biological pesticides. Data requirements specific to biochemical pesticides are set forth at 40 C.F.R. § 158.690 (1995), and data requirements specific to microbial pesticides are set forth at 40 C.F.R. § 158.740 (1995). Waivers of these data requirements are frequently granted for biochemical pesticides, which often meet the criteria for data waivers found at 40 C.F.R. § 158.45 (1995).

104. 40 C.F.R. § 152.25(b) (1995) exempts:

Pheromones and identical or substantially similar compounds labeled for use only in pheromone traps (or labeled for use in a manner which the Administrator determines poses no greater risk of adverse effects on the environment than use in pheromone traps), and pheromone traps in which those compounds are the sole active ingredient(s).

105. On March 30, 1994, the EPA published in the Federal Register a final rule exempting from the requirement of a tolerance under the FFDCA the residues of arthropod pheromones resulting from the use of these substances in solid matrix dispensers with an annual application rate limitation of 150 grams/acre for pest control in or on all raw agricultural commodities. 59 Fed. Reg. 14,757 (1994) (codified at 40 C.F.R. § 180.1124 (1995)). On December 8, 1993, the EPA published a final rule exempting certain inert ingredients used in solid matrix dispensers from the requirement of tolerance. 58 Fed. Reg. 64,493 (1993) (codified at 40 C.F.R. § 180.001-.1147 (1995)).

106. Notice of Experimental Use Permits for Arthropod Pheromones, 59 Fed. Reg. 3681 (1994). In this notice, the EPA announced that it was expanding the acreage cut-off for when an EUP is required under FIFRA from 10 acres to 250 acres for a certain pheromone products. The pheromone products covered by the notice are pheromones in solid matrix dispensers used at rates at or below 150 grams/acre/year. Tests conducted on these pheromones under the conditions specified in the notice would not require an EUP at acreages up to and including 250 acres. Tests conducted on acreages exceeding 250 acres or with pheromone products other than those specified would continue to require an EUP. *Id.* at 3684. The scope of pheromone products exempted under this notice is the same as the scope of products exempted from tolerance requirements. 59 Fed. Reg. 14,757 (1994). In addition, the EPA announced that it was considering whether to take additional actions to grant further regulatory relief for

(ii) Microbial pesticides

The EPA has regulated naturally-occurring microbial pesticides, such as *B.t.*, for many years.¹⁰⁷ Microbial pesticides are regulated in much the same way as traditional pesticides at the large-scale testing and registration stages. For the past ten years, however, the EPA has been concerned about the potential for adverse effects associated with small-scale environmental testing of certain microbial pesticides, both naturally-occurring and genetically engineered. Small-scale testing of other types of pesticides generally poses very limited risks, and thus, is not usually regulated by the EPA. However, microbial pesticides are living organisms that have the potential to reproduce and spread in the environment; therefore, even small-scale testing has the potential to present unreasonable adverse effects on the environment.

Section 5 of FIFRA¹⁰⁸ authorizes the EPA to issue EUPs for the testing of new pesticides or new uses of existing pesticides. Under the EPA's existing regulations,¹⁰⁹ EUPs are generally issued for large-scale testing of pesticides. A large-scale test¹¹⁰ includes any terrestrial application on a cumulative acreage of more than ten acres of land or any aquatic application on more than one acre of surface water. The EPA has generally presumed that tests conducted on ten acres or less of land or one acre or less of water (small-scale tests) would not require EUPs. The EPA has determined, however, that small-scale tests conducted with certain genetically engineered microbial pesticides may pose sufficiently different risks from tests conducted with conventional chemical pesticides, and therefore a closer evaluation at the small-scale testing stage is warranted.

In October 1984, the EPA published a policy statement entitled *Microbial Pesticides: Interim Policy on Small Scale Field Testing*.¹¹¹ In June 1986, the EPA reiterated the provisions of the Interim Policy Statement as part of the Office of Science and Technology Policy's (OSTP) Coordinated

other types of pheromone products. 59 Fed. Reg. at 3684.

107. Although *B.t.* was first registered under FIFRA for use as a pesticide in 1959, it was not the first microbe to be used as a pesticide. Between 1939 and 1951, another bacterium, *Bacillus popilliae*, an obligate bacterial pathogen that causes a milky disease in the larvae of the Japanese beetle and other scarab beetles was used in 14 eastern states and the District of Columbia. See PFADT, *supra* note 12, at 239.

108. 7 U.S.C. § 136c (1988) (providing that the Administrator may issue an EUP only if it is determined that the applicant needs such a permit to accumulate information necessary to register a pesticide under section 3 of FIFRA).

109. 40 C.F.R. § 172.

110. *Id.*

111. Statement of Policy Regarding Small Scale Field Testing of Microbial Pesticides, 49 Fed. Reg. 40,659 (1984).

Framework for Regulation of Biotechnology.¹¹² These policy statements described the EPA's concern about potentially adverse effects associated with small-scale environmental testing of certain microbial pesticides. To address this concern, these policy statements specified that the EPA be notified prior to initiating small-scale testing of all nonindigenous and genetically engineered microbial pesticides. Notification would allow the EPA to screen these small-scale tests by conducting an assessment to determine whether the test should be carried out under an EUP that allows the EPA oversight. In addition, the 1986 Policy stated the EPA's future plan to codify the interpretation set out in the policy.¹¹³

After almost ten years of deliberation and a series of EPA and federal government policy statements that were made available to the EPA's Scientific Advisory Panel (SAP)¹¹⁴ and the Biotechnology Science Advisory Committee (BSAC),¹¹⁵ on January 14, 1993, the Administrator signed a proposed rule that was a revised version of the 1986 policy.¹¹⁶ The proposal would codify the early screening procedure in the Coordinated Framework by requiring notification before the initiation of small-scale field testing of certain microbial pesticides in order to determine whether an EUP

112. Statement of Policy Regarding Review of Microbial Pesticides, 51 Fed. Reg. 23,313 (1986).

113. Subsequent to issuance of the 1986 Policy, a number of documents were issued by the EPA and other federal agencies, which were relevant to the FIFRA microbial notification rule, including: a Federal Register notice issued by the EPA in February 1989, requesting comment on issues related to the notification rule, 54 Fed. Reg. 7026 (1989); Federal Register notices issued by the OSTP in July 1990, 55 Fed. Reg. 31,118 (1990), and February 1992, 57 Fed. Reg. 6753 (1992), addressing issues relating to the appropriate scope of federal oversight of introduction into the environment of modified organisms; and a Report on National Biotechnology Policy issued in February 1991 by the Council on Competitiveness. In addition, the EPA made available to the public and to its FIFRA Scientific Advisory Panel (SAP) and Biotechnology Science Advisory Committee (BSAC) several draft proposals addressing the notification scheme for small-scale testing of certain genetically modified microbial pesticides.

114. Section 25(d) of FIFRA requires the EPA to submit proposed draft and final rules to an advisory panel, the SAP, for comment concerning the impact on health and the environment. 7 U.S.C. § 136w(d) (1988), amended by 7 U.S.C. § 136w(d) (Supp. IV 1994). The comments of the SAP and the response of the EPA Administrator must be published in the Federal Register. *Id.* Section 25(d) permits the chairperson of the panel, after consultation with the Administrator, to create temporary subpanels for specific projects to assist the full panel. *Id.* Because of the unique issues associated with the regulation of biotechnology, specialized SAP subpanels have been convened from time to time to address biotechnology matters.

115. In the 1986 Coordinated Framework, the EPA announced that it was establishing BSAC to provide peer review of specific product submissions under FIFRA, TSCA, and other EPA statutes and scientific oversight of the Agency's biotechnology programs. See 51 Fed. Reg. 23,313, 23,318.

116. 58 Fed. Reg. 5878 (1993) (to be codified at 40 C.F.R. pt. 172) (proposed Jan. 22, 1993).

was necessary. Under the proposed rule, testing conducted in facilities designed and operated to adequately contain the microbial pesticide would not be subject to the notification requirements.¹¹⁷

Perhaps the most controversial issue that arose during the lengthy development of this rule was what constituted the appropriate scope of regulation. The proposal identified three options for defining the scope of genetically modified microbial pesticides subject to notification requirements. Option one provided the most clear-cut scope of regulation — microbial pesticides whose pesticidal properties have been imparted or enhanced by the introduction of genetic material that has been deliberately modified.¹¹⁸ This is the definition the EPA developed based on comments from the public in response to earlier Federal Register announcements, the SAP subpanel, the BSAC, and other agencies including the USDA. The EPA preferred this option because it covered the appropriate microbial pesticides and had a high degree of regulatory utility.¹¹⁹ The proposed rule also included a mechanism to exempt, by rulemaking, additional microbial pesticides from the notification requirement as data and experience permit.¹²⁰

In both options one and two, the EPA had directly indicated the pesticides that were included in the scope rather than leaving the risk determination up to the researcher as in Option three. Thus, under both approaches, the EPA has made the initial assessment of the potential risks presented by certain categories of microbial pesticides.¹²¹ However, option two was different than Option one in that it cast a somewhat different net of

117. *Id.* at 5891-92. The EPA received nineteen comments in response to the proposed rulemaking. These comments were from trade associations, business firms, public interest groups, scientific researchers, and state and federal agencies. 59 Fed. Reg. 45,600, 45,602, 45,603 (1994) (codified at 40 C.F.R. § 172).

118. Option one was "microbial pesticides whose pesticidal properties have been imparted or enhanced by the introduction of genetic material that has been deliberately modified." 58 Fed. Reg. 5878, 5882 (1993) (to be codified at 40 C.F.R. pt. 172) (proposed Jan. 22, 1993).

119. *Id.* at 5887-88.

120. *Id.* at 5892.

121. Option two was based on the 1990 OSTP policy statement, and read as follows:

Microbial pesticides that have been deliberately modified in hereditary traits with the exception of:

1) Microorganisms modified solely: a) Through chemical or physical mutagenesis; b) By the movement of nucleic acids using physiological processes including, but not limited to, transduction, transformation, or conjugation; or c) By plasmid loss or spontaneous deletion.

2) Organisms that have been modified by the introduction of noncoding, nonexpressed nucleotide sequences that cause no phenotypic or physiological changes in the parental organism.

3) Organisms resulting from a deletion, rearrangement, or amplification, within a single genome, including its extrachromosomal elements.

58 Fed. Reg. 5882.

coverage. Option two was included in the proposal for illustrative purposes only and comment was not solicited.¹²² Option three was significantly different than options one and two in that, because it is much broader than the other options and provided greater latitude on the part of the researcher in assessing whether the EPA must be notified prior to small-scale environmental testing.¹²³

Sixteen comments were received concerning the merits of the two scope options. Of these, fifteen comments supported the EPA's preferred option, and only one unequivocally supported option three.¹²⁴ They generally believed that the EPA's option was more clear-cut and the decision of whether notification was necessary should not be left solely to the judgment of the researcher.¹²⁵ The EPA agreed with the comments that supported the EPA's preferred option and included this approach in the final rule. The final rule also includes a mechanism to exempt, by rulemaking, additional microbial pesticides from the notification requirement as data and experience permit.¹²⁶

One other controversial issue is whether the EPA should require notification for "nonindigenous" microbial pesticides. Under the EPA's 1984 Policy Statement and the 1986 Coordinated Framework, the EPA had been requiring notifications to be submitted for all small-scale testing of nonindigenous organisms.¹²⁷ In all of the scope options presented in the proposal, the EPA proposed to no longer require notifications for any nonindigenous microbial pesticides that had not been genetically modified. The EPA believed that continued imposition of the notification requirement on these microbial pesticides would constitute duplicative oversight because USDA/APHIS already regulates small-scale testing of these organisms.¹²⁸

Some supported the EPA's decision to exclude nonindigenous microbial pesticides from notification, while others believed that the EPA should regulate any nonindigenous microbial pesticide that was not regulated by

122. *Id.* at 5880.

123. Option three stated:

Indigenous microbial pesticides for which specific pesticidal activities have been created or increased by deliberative processes or techniques. Notification is not required for microbial pesticides whose pesticidal activities have been increased, but which are unlikely to pose a greater risk in the test site environment Notification is not required for microorganisms whose phenotype has been changed only by the microorganisms' introduction into a new environment, but which are unlikely to pose a greater risk in the test site environment

Id. at 5878, 5883.

124. 59 Fed. Reg. 45,600, 45,602-06 (1994) (codified at 40 C.F.R. § 172).

125. *Id.*

126. *Id.* at 45,606-07, 45,614.

127. See 49 Fed. Reg. 40,659-60; 51 Fed. Reg. 23,313, 23,324-25.

128. 58 Fed. Reg. 5878, 5890-91.

another federal agency.¹²⁹ The EPA responded to these comments stating that it continues to believe that the vast majority, if not all, nonindigenous microbial pesticides are reviewed by USDA/APHIS. However, to address the concerns of some who felt that there might be a regulatory gap, the EPA revised the language in the final rule to state that only those nonindigenous microbial pesticides that have not been acted upon by USDA/APHIS are exempt from the notification requirement.¹³⁰

The final rule also contains several provisions that were not controversial and were not therefore changed significantly. In the final rule, testing conducted in facilities designed and operated to adequately contain the microbial pesticide would not be subject to the notification requirements. However, records describing containment would be required.¹³¹

The final rule also includes provisions that will enable the EPA to address situations where small-scale testing results in unanticipated effects. Section 172.57 requires persons using microbial pesticides in small-scale tests to submit any information they obtain concerning the potential for unreasonable adverse effects from the microbial pesticide. In addition, section 172.59 enables the EPA to take immediate action to prevent use of a microbial pesticide if such use would create an imminent threat of substantial harm to public health or the environment.¹³²

Finally, the rule amends section 172.3 to clarify its rationale for presuming that an EUP is not required prior to small-scale testing with most pesticides. As explained in the preamble to the final rule, section 172.3 clarified that the requirement for an EUP would be based on risk considerations, rather than on a definitional presumption concerning whether a substance is a pesticide. This clarification has general applicability to all pesticides and is not limited to microbial pesticides.¹³³

b. TSCA

In addition to regulating biotechnology products that act as pesticides under FIFRA and FFDCA, the EPA also is responsible for regulating non-pesticidal biotechnology products under TSCA. As previously discussed, under section 5 of TSCA, PMNs are required for "new" chemical substances.¹³⁴ Although the EPA has interpreted the term "chemical substance" to encompass living organisms, thus far the EPA has limited itself to consideration of microorganisms. The EPA considers "new" microorganisms to

129. 59 Fed. Reg. 45,600, 45,605.

130. *Id.*

131. *Id.* at 45,605-06.

132. *Id.* at 45,609, 45,615.

133. *Id.* at 45,608-09, 45,611-12.

134. 15 U.S.C. § 2604.

be intergeneric microorganisms formed by the deliberate combination of genetic material from source organisms in different genera. As with the microbial pesticides under FIFRA, one of the most significant issues surrounding the regulation of biotechnology products under TSCA is the appropriate scope of regulation. The EPA first announced its interpretation that a "new" microorganism is an intergeneric microorganism in the 1986 Coordinated Framework.¹³⁵ The rationale behind this interpretation is that intergeneric microorganisms have significant potential for exhibiting new traits or combinations of traits.¹³⁶ Thus, these organisms have the potential to result in new types of risks in the environment.

Another significant issue in the TSCA biotechnology arena is how to address research and development of biotechnology products. Pursuant to the TSCA section 5(h)(3) "small quantity" research and development exemption and its implementing regulations, virtually all research activities, for both traditional chemical substances and microorganisms alike, are currently exempt from PMN requirements.¹³⁷ However, in the 1986 Coordinated Framework, the EPA announced its intent to issue regulations that would change the research and development small-quantities definition for certain microorganisms and requested that companies voluntarily submit PMNs for research and development of new microorganisms.¹³⁸ The rationale is that no amount of microorganisms released into the environment should be considered a "small quantity" because, unlike conventional chemical substances, even very small quantities of microorganisms have the potential to multiply, spread, and become established in the environment.¹³⁹

Until the EPA promulgates rules to change the small quantity definition for microorganisms, the EPA will continue to rely on voluntary submission of PMNs for research and development in the environment with new microorganisms. The EPA staff has stated that to its knowledge no company has released a microorganism without its approval, perhaps because of the fear of adverse publicity.¹⁴⁰ To date, over twenty-five voluntary PMNs have been submitted for research and development field tests.¹⁴¹ Although the EPA had placed restrictions on these tests, the tests were allowed to proceed. In addition to the voluntary PMN submissions for research in the environment, the EPA has reviewed a number of PMNs for "new" microor-

135. 51 Fed. Reg. 23,313.

136. *Id.* at 23,325-26.

137. 15 U.S.C. § 2604(h)(3).

138. 51 Fed. Reg. 23,313, 23,326-30.

139. *Id.* at 23,330.

140. Telephone interview with David Giamporcaro, Office of Pollution Prevention and Toxics, U.S. Environmental Protection Agency (Sept. 24, 1996). For a discussion on the public perception of biotechnology, see *infra* part III.C.

141. *Id.*

ganisms to be used commercially in contained systems. Most have been reviewed within ninety days and have had no restrictions placed on them,¹⁴² because the microorganisms do not have any expected environmental uses and are not expected to survive in the environment.

Section 5(h)(4) allows the EPA to exempt, in whole or in part, any new substance from PMN reporting if the EPA determines that such substance does not present an unreasonable risk.¹⁴³ In 1994 the EPA published a proposed TSCA biotechnology rule which would use this provision to partially exempt certain low risk categories of microorganisms.¹⁴⁴ For example, the EPA plans a conditional exemption for research with microorganisms in the environment by establishing a TSCA Environmental Release Application (TERA), a shortened review limited to authorizing one experiment or experimental program. A PMN would be submitted later, at the general commercial use stage.¹⁴⁵ In addition, the proposed TSCA biotechnology rule addresses which microorganisms constitute a "new chemical substance" subject to automatic PMN review, which commercial research and development should be subject to automatic review, and which types of microorganisms at the experimental stage or in general commercial use should be exempt because they either constitute small quantities or do not present unreasonable risks.¹⁴⁶

III. THE RISKS AND BENEFITS OF TRANSGENIC PLANTS-PESTICIDES

A. Benefits

For many, plant pesticides hold the promise of a less risky substitute for traditional chemical pesticides. The use of rDNA technologies has enabled plant varieties to be developed that either could not have been developed through traditional plant breeding or could only have been developed through

142. Some have suggested that section 5 of TSCA, which required a ninety-day PMN review period, is inadequate for a meaningful assessment by the EPA of a release into the environment of a genetically engineered organism. See Ruth E. Harlow, Note, *The EPA and Biotechnology Regulation: Coping with Scientific Uncertainty*, 95 YALE L.J. 553, 565-67 (1986) (suggesting that amendments to TSCA are necessary to enable the EPA to fully analyze the risks of release of genetically engineered organisms).

143. 15 U.S.C. § 2604(h)(4).

144. See EPA, Microbial Products of Biotechnology: Proposed Regulation Under the Toxic Substances Control Act, 59 Fed. Reg. 45,526 (1994) (to be codified at 40 C.F.R. pts. 700, 720, 721, 723, 725) (proposed Sept. 1, 1994). A draft final rule was submitted to the Office of Management and Budget for review under Executive Order 12866 in Aug. of 1996. Telephone interview with David Giamporcaro, *supra* note 140.

145. *Id.* at 45,529, 45,535-37.

146. *Id.* at 45,526-53.

traditional techniques with a great amount of time and difficulty.¹⁴⁷ Chemical pesticides often are of relatively high toxicity. Moreover, many, but not all, traditional chemical pesticides are toxic to a broad range of organisms, including humans. In addition, traditional pesticides are often applied by spraying large areas, which could result in significant exposure to nontarget organisms.

On the other hand, plant pesticides are generally of low toxicity, target-specific, and produced in relatively small quantities in the plant. Because plant pesticides are generally produced in small amounts in the plant, nontarget organisms are not as likely to be exposed to these pesticides as they are to pesticides that are sprayed over large areas. Moreover, even if nontarget organisms are exposed to plant pesticides, because these pesticides are often of low toxicity and are generally target specific, non-target organisms are not as likely to be adversely affected by these pesticides. For example, the *B.t.* toxin is specific to certain groups of insects (e.g., Lepidoptera) and is not toxic to humans or other mammals.¹⁴⁸ Thus, many believe that these new pesticides pose lower risks than traditional pesticides and the use of plant pesticides will benefit the environment by causing a reduction in the amount of chemical pesticides used.¹⁴⁹

147. Edward O. Wilson has described the cumbersome nature of traditional plant breeding as follows:

The creation of today's domestic tomato was a skilled feat of plant breeding, but one that requires many generations to accomplish. A wild species or race bred into the domestic stock also carries with it baggage of less desirable genes that reduce yield and quality. Breeders must delete these traits through repeated backcrossing, mating the hybrids back to the domestic strains, in a way that preserves only the desirable genes of both domestic and wild forms in the breeding stock. Finally, conventional hybridization can be accomplished solely among species and strains similar enough to be bred together

EDWARD O. WILSON, *THE DIVERSITY OF LIFE* 302 (1992).

148. See 60 Fed. Reg. 21,725, 21,726-27 (1995) (to be codified at 40 C.F.R. pt. 180) (stating "[t]he delta-endotoxin proteins of *B. thuringiensis* products have been intensively studied, and no indications of mammalian toxicity have been reported").

149. Environmental organizations have expressed concerns that plants that have been genetically modified to be tolerant to herbicides could actually result in an increase in herbicide use because herbicides then could be applied directly to plants without killing them. See, e.g., MARGARET MELLON, NATIONAL WILDLIFE FEDERATION, *BIOTECHNOLOGY AND THE ENVIRONMENT: A PRIMER ON THE ENVIRONMENTAL IMPLICATIONS OF GENETIC ENGINEERING* 32 (1988). Industry groups argue that these plants will enable farmers to reduce the number of herbicide applications by allowing farmers to target the timing of herbicide application to after the plant has emerged, when herbicides are most needed. As discussed above, these herbicide tolerant plants do not fall within the domain of plant pesticides. Nevertheless, the intense controversy over herbicide tolerant plants has spilled over into the debate on plant pesticides. For further discussion of issues related to herbicide tolerant plants, see Walter Fehr et al., *Workshop Report: Herbicide Tolerance in Crops*, in *AGRICULTURAL BIOTECHNOLOGY AT THE CROSSROADS: BIOLOGICAL, SOCIAL AND INSTITUTIONAL CONCERNS* 27 (June F. MacDonald ed., National Agric. Biotechnology Council Rep. No. 3, 1991).

One example of a plant pesticide that is believed to have the potential for significant environmental benefits is viral coat protein-mediated resistance. By genetically modifying plants to produce certain viral coat proteins, researchers have been able to produce plants that are resistant to infection by particular viruses. For viruses spread by vectors, such as insects, the most common agricultural practice for preventing viral attack is the use of chemical pesticides to control the insect vector that spreads the virus. However, the use of viral coat protein-mediated resistance may reduce the need for these chemical pesticides. In addition to the environmental benefits of viral coat protein-mediated resistance, there is a high potential for significant economic benefits.¹⁵⁰

Other potential benefits of plant pesticides may not yet be apparent. Nevertheless, many believe that the technological advances in this area hold great promise for the future. The fact that virtually every living species has the potential to contribute its genes to biotechnology products may lead to an increased appreciation for the need to preserve biological diversity in order to protect these potential sources of genetic information.

B. *Risks*

Many of the risk considerations for plant pesticides are similar, if not the same, as those for traditional chemical pesticides. As with any pesticide risk assessment, the underlying considerations for analyzing risks posed by plant pesticides are the potential for humans and other non-target organisms to be exposed to the pesticide as well as the hazard (usually toxicity) that would result. For plant pesticides, as with other pesticides, hazard will be determined by the chemical and toxicological properties of the pesticidal substance. Exposure, on the other hand, will be determined somewhat differently for plant pesticides than for traditional chemical pesticides. For traditional pesticides, the primary factor in determining exposure is the amount of chemical that is introduced into the environment and the likelihood that humans or other non-target organisms will come into contact with the chemical. However, because plant pesticides are produced by living plants, exposure issues are more complex for these substances, and are dependent on the biological characteristics of the plant itself. For example, exposure to a plant pesticide could be determined by analyzing whether the production of the plant pesticide is limited to particular plant parts (for example, leaves, stems, fruit, or roots) and which organisms consume or are

150. See generally EPA, Statement of Policy: Plant-Pesticides Subject to the Federal Insecticide, Fungicide, and Rodenticide Act, and the Federal Food, Drug, and Cosmetic Act 37-38 (Dec. 20, 1993) (Draft, on file with the *University of Florida Journal of Law & Public Policy*) [hereinafter Draft Plant-Pesticide Policy].

associated with those plant parts.¹⁵¹

Moreover, one of the most significant exposure considerations for plant pesticides, which is not seen with chemical pesticides, is the potential for spread of the living plant or the plant's genetic material. Plants can reproduce sexually or asexually, and as a result, the genetic material that was introduced into the plant and that enables the plant to produce plant pesticides could spread through agricultural or natural ecosystems. Thus, if a plant that produces a plant pesticide has the capacity to spread in the environment, or to spread its genetic material to other plants, there would be a greater potential for increased exposure to non-target organisms than there would be for a plant pesticide produced in a plant that can only grow in a limited geographic area or does not have the ability to cross-fertilize with other plants in the environment. This is a particular concern for plant pesticides produced in plants that have wild relatives in the United States. If these wild relatives acquire the ability to produce the plant pesticide, through cross-fertilization, many additional nontarget organisms could potentially be exposed to the pesticide.

The potential for the genetic material necessary to produce plant pesticides to spread from one plant to another raises additional risk issues beyond those of exposure to humans and non-target organisms. One of the most cited concerns about plant pesticides is the concern regarding the potential for the development of "superweeds" through the outcrossing of plants producing plant pesticides to wild relatives. If the ability to produce a plant pesticide that makes a plant resistant to insect or viral pests is spread to a wild relative and passed on to subsequent generations of that relative, there is the potential that the wild relative, by virtue of its newly acquired ability to resist insects or viruses, could become a hardy weed. Development of such a weed has the potential to result in disruption of agricultural or natural ecosystems.¹⁵²

Another issue that has received considerable attention is the potential for plant pesticides in foods to pose a risk of allergenicity to humans. The primary concern is that if a gene leading to the production of a plant pesticide is moved from one plant, for example a peanut, into another plant, for example corn, people who know they are allergic to peanuts will not know to avoid the corn plant. Thus, if the plant pesticide derived from the

151. See generally Plant-Pesticides Subject to the Federal Insecticide, Fungicide, and Rodenticide Act: Proposed Rule, 59 Fed. Reg. 60,519, 60,522 (1994) (to be codified at 40 C.F.R. pts. 152, 174) (proposed Nov. 23, 1994).

152. See generally P.J. Regal, *Scientific Principles for Ecologically Based Risk Assessment of Transgenic Organisms*, 3 MOLECULAR ECOLOGY 5 (1994) (discussing in detail these risk issues); Proposed Rule: Plant-Pesticides Subject to the Federal Insecticide, Fungicide, and Rodenticide Act (Draft, Dec. 20, 1993); MELLON, *supra* note 149, at 32.

peanut plant contains an allergen from the peanut plant, allergic consumers could be put at risk.¹⁵³

Other areas of potential adverse effects on the environment center on specific plant pesticides or categories of plant pesticides. For example, some environmental organizations have expressed their concern that engineering plants to produce viral coat proteins has the potential to result in the development of new unintended viruses.¹⁵⁴ In addition, public interest organizations have articulated other concerns that are more philosophical, ethical, and religious in nature. For example, the movement of genes from animals to plants may be of concern to subpopulations of people with special dietary preferences such as vegetarians or persons who keep kosher (Jewish) or observe halal (Muslim) laws.¹⁵⁵ Other philosophical issues that have been raised include a concern that the prospect of "human-made" organisms, even if they pose no risk to humans or the environment, may threaten the concepts of "wildness" and "wilderness."¹⁵⁶ Some argue that while biotechnology pesticidal products may be environmentally preferable to traditional chemical pesticides, the focus on developing these products may be diverting attention from the more important goal of developing a system of sustainable agriculture.¹⁵⁷

C. Public Perception

The intensity of the public response to the 1992 FDA policy on foods derived from new plant varieties illustrates the important function that public perception will play in defining the role of new biotechnology in the marketplace. While many new technologies soon will be commercially

153. This issue has been raised by the Environmental Defense Fund with regard to both the EPA's policy on plant pesticides and the FDA's policy on new plant varieties. For further discussion of this and related issues, see generally UNITED STATES GENERAL ACCOUNTING OFFICE, FOOD SAFETY AND QUALITY: INNOVATIVE STRATEGIES MAY BE NEEDED TO REGULATE NEW FOOD TECHNOLOGIES 31 (1993); 57 Fed. Reg. 22,984; D. DOUGLAS HOPKINS ET AL., ENVIRONMENTAL DEFENSE FUND, A MUTABLE FEAST: ASSURING FOOD SAFETY IN THE ERA OF GENETIC ENGINEERING (1991). Because of the concerns over this issue, on April 18, 1994 the FDA, USDA/APHIS, and EPA cosponsored a conference to explore the potential for allergenic substances to occur in foods derived from transgenic plants. See Meeting of the National Committee on Vital Health Statistics, 59 Fed. Reg. 15,415 (1994).

154. This issue was raised by the National Wildlife Federation and discussed extensively at the December 18, 1992 SAP meeting. An analysis of this issue, including the findings of the SAP and the EPA's response to the SAP's findings, can be found in Proposed Rule: Plant-Pesticides Subject to the Federal Insecticide, Fungicide, and Rodenticide Act at 30-40 (Draft, Dec. 20, 1993).

155. See HOPKINS ET AL., *supra* note 153, at 51-55.

156. See MELLON, *supra* note 149, at 32.

157. See Margaret Mellon, *Biotechnology and the Environmental Vision*, in AGRICULTURAL BIOTECHNOLOGY AT THE CROSSROADS: BIOLOGICAL, SOCIAL AND INSTITUTIONAL CONCERNS 67 (June F. MacDonald ed., National Agric. Biotechnology Council Rep. No. 3, 1991).

viable, they all will not automatically be put to use — consumers will be the ultimate judge of emerging technologies.¹⁵⁸ The key to the success or failure of new biotechnology products will be the ability of the government regulatory agencies to communicate effectively to the public the risks and benefits of these products. Many people are skeptical of any new technology. This skepticism is even more pronounced with technologies such as biotechnology that may be difficult for the layperson to understand and may have many uncertainties surrounding them.¹⁵⁹ In fact, a recent survey concerning consumer attitudes about the use of biotechnology in agriculture and food production concluded that one of the most important factors influencing public perception of biotechnology will be the perceived credibility of public policies and regulations. This survey found that while the majority of consumers generally supported the use of biotechnology in agriculture and food production,¹⁶⁰ the majority also favored an active role for government agencies in establishing biotechnology regulations that ensure environmental protection and food safety.¹⁶¹ Thus, the EPA must be mindful that the public will be looking to it, not only to evaluate the risks

158. See Thomas Hoban & P. Kendall, *Public Perceptions of the Benefits and Risks of Biotechnology*, in AGRICULTURAL BIOTECHNOLOGY: A PUBLIC CONVERSATION ABOUT RISK 75 (June F. MacDonald ed., National Agric. Biotechnology Council Rep. No. 5, 1993 (citing OFFICE OF TECHNOLOGY ASSESSMENT, SUMMARY: A NEW TECHNOLOGICAL ERA FOR AMERICAN AGRICULTURE (OTA-F-474, 1992)); Charles W. Stenholm & Daniel B. Waggoner, *Public Policy in Animal Biotechnology in the 1990s: Challenges and Opportunities*, in ANIMAL BIOTECHNOLOGY: OPPORTUNITY AND CHALLENGES 25 (June F. MacDonald ed., National Agric. Biotechnology Council Rep. No. 4, 1992).

159. While still a Senator, Vice President Gore summed up this public skepticism: "Public apprehension about technology is not unique to biotechnology. I think there is a growing apprehension about technology in general. When people are confronted with visions of new products and miraculous discoveries coming from new technology, they often wonder what is on the other side of the coin." Gore, *supra* note 63, at 12.

160. See Hoban & Kendall, *supra* note 158, at 76-83. In this survey a total of 1228 telephone interviews were conducted. Survey participants were asked a number of questions designed to uncover consumer attitudes about biotechnology. Almost two-thirds of all respondents indicated that they generally supported the use of biotechnology in agriculture and food production. The most common reason cited for supporting biotechnology was the belief that it would enhance the quality of food products. Other reasons cited included the belief that the use of biotechnology would result in an increase in the quantity of food produced and would benefit society by providing environmental or economic benefits. The most common reason cited in opposition to biotechnology by over one-third of the respondents who opposed biotechnology was a concern that biotechnology could threaten the balance of nature. Some respondents thought that biotechnology would lead to serious impacts on the natural environment, a loss of genetic diversity, or the creation of harmful mutations. Others believed that tampering with nature simply was wrong and that biotechnology is "not natural," against God's will, or contrary to religious beliefs. Other reasons given for opposing biotechnology were the unknown or long-term risks, the application of biotechnology to either humans or animals, increased use of chemicals in farming or food processing, and negative effects on food quality and safety. *Id.* at 80-83.

161. *Id.* at 84.

and benefits of plant pesticides and to develop a protective regulatory program, but also to communicate effectively with the public on these issues.

IV. THE EPA'S NEW POLICY ON PLANT PESTICIDES

On January 21, 1994, the EPA held a joint meeting with a sub-panel of the Agency's SAP and BSAC to address certain scientific issues related to the regulation of pesticidal substances produced in plants. For the meeting, the EPA made available to the public a draft proposal of a comprehensive policy and four proposed draft rules¹⁶² that were developed under FIFRA and FFDCa. On November 23, 1994, the EPA published in the Federal Register slightly modified versions of these draft documents (together referred to as the "proposal").¹⁶³ The proposal is intended to clarify the status of plant pesticides under FIFRA and FFDCa and outline the types of plant pesticides the EPA believes warrant regulation based on risk/benefit considerations. Under the proposal, many plant pesticides now under development would not be subject to regulation because they pose a low potential for risk to humans or the environment. Others would be subject to regulation, but would be regulated somewhat differently than conventional pesticides because of the unique nature of plant pesticides. The proposal

162. The draft documents that were made available were as follows: Statement of Policy: Plant-Pesticides Subject to the Federal Insecticide, Fungicide, and Rodenticide Act and the Federal Food, Drug, and Cosmetic Act (Draft, Dec. 20, 1993); Plant-Pesticides Subject to the Federal Insecticide, Fungicide, and Rodenticide Act (Draft, Dec. 20, 1993); Plant-Pesticides: Proposed Exemption From the Requirement of A Tolerance Under the Federal Food, Drug, and Cosmetic Act (Draft, Dec. 20, 1993); Plant-Pesticides: Proposed Exemption From the Requirement of a Tolerance Under Federal Food, Drug, and Cosmetic Act for Viral Coat Proteins Produced in Plants; Plant-Pesticides: Proposed Exemption From the Requirement of a Tolerance Under Federal Food, Drug, and Cosmetic Act for Nucleic Acids Produced in Plants (Draft, Dec. 20, 1993). Unless otherwise provided, the information contained in this section is a summary of the above-referenced draft documents.

163. The proposal consists of: Proposed Policy: Plant-Pesticides Subject to the Federal Insecticide, Fungicide, and Rodenticide Act, and the Federal Food, Drug, and Cosmetic Act, 59 Fed. Reg. 60,496 (1994) [hereinafter the Plant-Pesticide Policy]; Plant-Pesticides Subject to the Federal Insecticide, Fungicide, and Rodenticide Act: Proposed Rule, 59 Fed. Reg. 60,519 (1994) (to be codified at 40 C.F.R. pts. 152, 174) (proposed Nov. 23, 1994); Plant-Pesticides: Proposed Exemption from the Requirement of a Tolerance Under the Federal Food, Drug, and Cosmetic Act, 59 Fed. Reg. 60,535 (1994) (to be codified at 40 C.F.R. pt. 180) (proposed Nov. 23, 1994); Plant-Pesticides: Proposed Exemption From the Requirement of a Tolerance Under the Federal Food, Drug, and Cosmetic Act for Nucleic Acids Produced in Plants, 59 Fed. Reg. 60,542 (1994) (to be codified at 40 C.F.R. pt. 180) (proposed Nov. 23, 1994); Plant-Pesticides: Proposed Exemption from the Requirement of a Tolerance Under the Federal Food, Drug, and Cosmetic Act for Viral Coat Proteins Produced in Plants, 59 Fed. Reg. 60,545 (1994) (to be codified at 40 C.F.R. pt. 180) (proposed Nov. 23, 1994). To date, the EPA has not published a final plant pesticide policy. On August 3, 1996, President Clinton signed the Food Quality Protection Act of 1995. This Act could affect the development of the final plant pesticide policy, particularly with regard to the FFDCa aspects of the policy.

outlines how the EPA intends to assess plant pesticides at different stages of environmental testing and at the sale and distribution stage. In developing the proposal, the EPA worked closely with USDA/APHIS and the FDA to integrate the three agencies' regulatory programs and minimize duplicative regulation. USDA/APHIS regulates certain genetically modified plants, including plants that are modified to produce pesticidal substances,¹⁶⁴ and the FDA regulates non-pesticidal substances in food plants as food additives under FFDCA.¹⁶⁵

A. *The "Plant" vs. the "Substance"*

As described previously, FIFRA defines the term "pesticide" very broadly, and under this definition, both the "plant" and the pesticidal substances produced in the plant are considered to be "pesticides." However, in 1982, the EPA promulgated a regulation under section 25(b) of FIFRA¹⁶⁶ that exempted all biological control agents from the requirements of FIFRA, except for certain microorganisms.¹⁶⁷ This exemption was promulgated because the EPA found that macroorganisms used as biological control agents were adequately regulated by other federal agencies such as USDA/APHIS. Plants, as biological control agents, were implicitly exempted from regulation under FIFRA through this exemption. The EPA does not believe it is necessary to revoke this exemption for the plant itself, but instead intends to focus on the pesticidal substance produced by the plant. This is consistent with the EPA's past actions. For example, the EPA does not regulate chrysanthemums, but instead regulates the pesticidal substance pyrethrum that is produced by the chrysanthemum when extracted from the plant and applied to other plants as an insecticide.

However, in the past the EPA had not clearly stated its policy for regulating pesticidal substances that are produced in living plants but not extracted from the plants, that is, substances produced in plants naturally, or through genetic engineering or other technologies, that actually exert their pesticidal effect while still in the plant. It is these substances that the EPA considers to be "plant pesticides" and that are the subjects of the proposal.

Another point to emphasize is that in the proposal, the EPA has defined the pesticidal active ingredient as including not only the substance that is produced in the plant for the purpose of inducing the pesticidal effect, but

164. 7 C.F.R. §340 (1996). For further discussion of APHIS' regulatory role, see *supra* part II.C.3.

165. 21 C.F.R. §§ 170-180 (1995). For further discussion on the FDA's regulatory role, see *supra* part II.C.4.

166. 7 U.S.C. § 136w(b) (1994).

167. 40 C.F.R. § 152.20; 47 Fed. Reg. 23,928 (1982) (codified at 40 C.F.R. § 152).

also the genetic material necessary for the production of that substance.¹⁶⁸ The EPA included the genetic material as part of the active ingredient for several reasons. First, it is the genetic material that is actually added to the plant and that leads to the production of the substance that ultimately results in the pesticidal effect.¹⁶⁹ Moreover, the EPA is not only concerned with the environmental risks associated with the pesticidal substance itself, but also is concerned with potential environmental impacts associated with the spread of genetic material.¹⁷⁰ Finally, from a practical standpoint, it may be easier to detect the genetic material in a plant rather than the pesticidal substance itself.¹⁷¹

B. *The Scope of Regulation Under FIFRA*

Under the EPA's definition of plant pesticide, all substances produced by plants and intended for a pesticidal purpose are within the EPA's jurisdiction, whether the plant is genetically engineered or not. However, just because a substance is considered to be a plant pesticide, does not necessarily mean that the EPA will regulate it under FIFRA. The Agency believes there are many plant pesticides that do not warrant any regulation under FIFRA because they pose low risk to humans and will not cause unreasonable adverse effects on the environment. One category of plant pesticides that the EPA believes does not warrant regulation are those that will not cause new exposures to non-target organisms. The EPA is proposing to exempt from FIFRA regulation those plant pesticides that are not new to the plant, that is, they are derived from closely related plants. Thus, the *B.t.* delta-endotoxin would not be exempt when it is produced in corn because the delta-endotoxin is derived from a bacterium rather than from a plant that is closely related to corn. However, a pesticidal substance that is naturally produced by a certain variety of corn and is introduced into another variety of corn would be exempt.

Another category that the EPA is proposing to exempt are those plant pesticides that would not be expected to adversely affect non-target organisms because they are less likely to be directly toxic due to their mechanism of action. This category consists of plant pesticides that act primarily by affecting the plant so that pests are inhibited from attaching to

168. Section 2(a) of FIFRA defines an active ingredient as "an ingredient which will prevent, destroy, repel, or mitigate any pest [or acts as a plant regulator, defoliant or desiccant]." 7 U.S.C. § 136(a) (1994). The draft proposal defines plant-pesticide active ingredients as "the pesticidal substances that are produced in the plant and the genetic material necessary for the production of those substances." Plant-Pesticide Policy, 59 Fed. Reg. 60,496 (1994).

169. Plant-Pesticide Policy, 59 Fed. Reg. 60,496, 60,500.

170. *Id.*

171. *Id.*

the plant, penetrating the plant's surface, or invading the plant's tissue. Thus, a substance that acts by causing a structural barrier to pest penetration in the plant would be exempt. The EPA also believes that coat proteins from viruses pose low risks and thus do not warrant regulation under FIFRA.

In addition to the low potential for risk associated with some categories of plant pesticides, the EPA believes that many plant pesticides could be used as alternatives to more toxic and persistent conventional pesticides. Thus, pursuant to section 25(b) of FIFRA, the EPA believes that certain categories of plant pesticides are of a character that is unnecessary to be subject to the Act in order to carry out the purposes of the Act.¹⁷² Under the proposal, all plant pesticides would be regulated under FIFRA unless they are at least one of the following:

- (a) a plant pesticide that is derived from closely related plants;
- (b) a plant-pesticide substance that acts primarily by affecting the plant so that the pest is inhibited from attaching to the plant, penetrating the plant or invading the plant's tissue; and
- (c) a plant pesticide that is a coat protein from a plant virus.

Although the EPA scientists and the members of the SAP and BSAC have evaluated these exemptions and believe that the plant pesticides proposed for exemption pose low risks, many environmentalists are concerned that the exemptions are too broad.¹⁷³ These concerns seem to stem from the uncertainty surrounding many of the issues and the historical lack of experience with plant pesticides. Some have suggested that the EPA should require ongoing monitoring of exempt plant pesticides.¹⁷⁴ In response to these concerns, the EPA has proposed a regulation that would require reporting adverse effects of exempt plant pesticides.¹⁷⁵ This regulation would be similar to section 6(a)(2) of FIFRA,¹⁷⁶ which requires reporting unreasonable adverse effects for all registered pesticides. If the

172. 7 U.S.C. § 136 w(b) (1994); 47 Fed. Reg. 23,928 (1982) (codified at 40 C.F.R. 3152).

173. At the December 19, 1992 SAP meeting, the National Wildlife Federation commented that the EPA's planned exemption of viral coat proteins was not justified. In response to this comment, the EPA decided to develop an alternative, more limited exemption for viral coat proteins. This alternative exemption would exempt only those viral coat proteins for which a determination had been made that they would not pass on a selective advantage to related plants in the wild. *See* 59 Fed. Reg. 60,519, 60,525-28.

174. This comment was made by the National Audubon Society at the January 21, 1994 joint SAP/BSAC meeting.

175. *See* 59 Fed. Reg. 60,519, 60,522.

176. 7 U.S.C. § 136d(a)(2) (1994) (providing that "[i]f at any time after the registration of a pesticide the registrant has additional factual information regarding unreasonable adverse effects on the environment of the pesticide, [he or she] shall submit such information to the Administrator").

EPA does impose such a requirement, the next issue to consider is how the EPA will react if it finds that a particular plant pesticide is more risky than the EPA believed when it exempted it. Currently, under section 25(b) of FIFRA, to exempt a pesticides, the EPA must go through notice and comment rulemaking.¹⁷⁷ It follows that to repeal an exemption, the EPA also may be required to go through rulemaking. Rulemaking can be a lengthy process, particularly when coupled with the FIFRA requirement of submitting all proposed and final regulations to the SAP and the USDA for comment. A statutory amendment that would authorize the EPA to repeal exemptions with a more abbreviated process would enable the EPA to quickly gain regulatory control over plant pesticides found to pose unreasonable adverse effects.¹⁷⁸

C. *The Regulatory Process Under FIFRA*

Under the proposal, once it is determined that a substance is a plant pesticide subject to FIFRA regulation, the regulatory process is similar to the regulatory process for all pesticides.

1. Product Development

Prior to sale or distribution, if a crop is to be used as food or feed at any test acreage, an EUP would be required.¹⁷⁹ For crops that will not be used as food or feed, and if subject to the authority of the Plant Pest Act, an EUP would still be required when environmental testing will take place on more than ten acres of land or more than one surface acre of water.¹⁸⁰ Currently, for all pesticides, the ten-acre requirement is triggered when the cumulative acreage of environmental tests reaches ten acres.¹⁸¹ In the proposal, the EPA indicates that it is considering changing this requirement for plant pesticides so that an EUP is required when a single environmental test exceeds ten acres. The EPA also is considering a number of other options

177. Section 25(b) of FIFRA provides that

[t]he Administrator may exempt from the requirements of this subchapter *by regulation* any pesticide which he determines either (1) to be adequately regulated by another Federal agency, or (2) to be of a character which is unnecessary to be subject to this subchapter in order to carry out the purposes of this subchapter.

7 U.S.C. § 136w(b) (1994) (emphasis added).

178. Although it may be possible in some situations for the EPA to make such a repeal of an exemption immediately effective by invoking the "good cause" exemption of the Administrative Procedure Act, 5 U.S.C. § 553(b)(3)(B) (1988), a statutory provision setting forth the specific criteria for revoking such an exemption may be of greater utility.

179. 59 Fed. Reg. 45,600, 45,612 (to be codified at 40 C.F.R. § 172).

180. 40 C.F.R. § 172.

181. See Scope of Requirement, 40 C.F.R. § 172.3 (1994).

for EUP triggers. As discussed in part II.C.3., one option is to utilize USDA/APHIS's determination that a plant is no longer a regulated article at the point at which regulatory responsibility is handed off from USDA/APHIS to the EPA. Further, if a plant pesticide is not subject to the authority of the Plant Pest Act, an EUP would be required at first introduction into the environment regardless of acreage. If a producer has been granted an exemption by USDA/APHIS from permitting requirements under the Plant Pest Act, an EUP would be required at the time the exemption is granted.

2. Sale or Distribution

Before sale or distribution of a plant pesticide, a producer must obtain a registration under section 3 of FIFRA for any plant pesticide that is not otherwise exempt. If there is food or feed use at sale or distribution, the potential registrant also would need to fulfill possible FFDCA obligations.¹⁸² Section 3 of FIFRA also requires that all registered pesticides be labeled. Labeling includes written, printed, or graphic material either on or attached to the pesticide or any of its containers or wrappers and all other such material accompanying the pesticide at any time.¹⁸³ An improperly labeled pesticide is considered to be misbranded and in violation of FIFRA.¹⁸⁴

The EPA generally relies on labeling requirements to impose risk reduction measures on the use of traditional pesticide products. For example, the EPA regulations¹⁸⁵ contain extensive labeling requirements dealing with, among other things, warnings and precautionary statements and directions for use. Other labeling restrictions are imposed, case-by-case, through the registration process. Restrictive labeling may include requirements that personal protective equipment such as gloves and respirators be used to reduce risk to pesticide users, or that a buffer zone be provided around fields to prevent risks to bystanders from spray-drift. In addition, geographic restrictions may be required on the use of certain pesticides to reduce risk to endangered species or other beneficial organisms that occur in a limited geographical area. These labeling restrictions are translated into use restrictions via section 12(a)(2)(G) of FIFRA, which provides that it is unlawful for any person to use any registered pesticide in a manner

182. See 40 C.F.R. § 152.55(i) (1988) (requiring an applicant for a food or feed use pesticide registration to submit a statement indicating whether residues of the pesticide are authorized by a tolerance, food additive regulation, or exemption).

183. 7 U.S.C. § 136(p) (1988) (Supp. 1994).

184. See *Id.* § 136(q) (defining "misbranding"); *id.* § 136j(1)(E) (providing that it is unlawful for any person to distribute or sell any pesticide that is misbranded).

185. 40 CFR 156.10.

inconsistent with its labeling.¹⁸⁶

However, the EPA has stated that many types of restrictive labeling may not be appropriate for plant pesticides.¹⁸⁷ For example, geographical limitations on the use of the plant pesticide may not be meaningful if the plant that produces the pesticide can reproduce and spread in the environment beyond those geographical limits. Similarly, other use restrictions (for example, "Do not use within 50 feet of a stream, river, or lake.") may not be particularly useful if seeds from plants that produce plant pesticides are saved and planted during subsequent growing seasons. Such seeds would not be labeled, and therefore it is possible that farmers using these seeds would not be aware that the seeds were from plants that had been engineered to produce a plant pesticide or that the use of such seeds was restricted.

Although the EPA recognizes that the more typical labeling restrictions may not be meaningful for plant pesticides, it is not yet clear how the EPA will adapt its regulatory practice to these new forms of pesticides. The success of the EPA's plant-pesticide program will depend on its ability to diverge from its historical reliance on labeling restrictions to achieve risk reduction. Because traditional restrictive labeling is not likely to result in true risk reduction for plant pesticides, the EPA will need to consider whether registrations should not be granted for plant pesticides that would pose significant risks in the absence of meaningful risk reduction.

Despite the problems with traditional risk reduction labeling, the EPA recognizes that other forms of labeling may be useful for plant pesticides. Specifically, the EPA is considering requiring labeling on bags of seeds containing plants-pesticides that inform farmers or other users of the type of pesticide that the plants will produce and against which pest it is active.¹⁸⁸ This information may help to prevent unnecessary application of additional pesticides to the plants that already produce plant pesticides.

D. *The Scope of Regulation Under FFDCA*

FIFRA and FFDCA are independent statutes; therefore, a plant pesticide that is exempt from regulation under the proposed scope for FIFRA is not necessarily exempt from regulation under FFDCA. Moreover, the two Acts have different, but overlapping, purposes: under FIFRA the EPA considers all environmental and human health risks, whereas, under FFDCA the EPA focuses on the risks posed by human dietary consumption. In the proposal, under section 408(c) of FFDCA, the EPA would exempt certain categories of plant pesticides from the requirement of a tolerance. The plant pesticides

186. *Id.* § 136j(a)(2)(G).

187. *See* Plant-Pesticide Policy, 59 Fed. Reg. 60,496, 60,510.

188. *Id.* at 60,510-11.

that the EPA believes warrant review, and thus would not be exempt, are those that are most likely to result in new or different dietary exposures. The proposal would exempt the following:

- (1) plant pesticides produced in food and derived from closely related food or non-food plants;
- (2) plant pesticides produced in food and derived from food plants that are not closely related to the recipient food plant, but would not "result in significantly different dietary exposure" when produced in the recipient food plant. "Result in significantly different dietary exposure" is defined as:
 - a) [t]he pesticidal substance is produced in inedible portions of the source food plant, but in the recipient plant, the pesticidal substance is present in the plant's edible portions;
 - b) [t]he pesticidal substance is produced in the immature but not in the mature edible portions of the source food plant but, in the recipient plant, the pesticidal substance is present in the mature edible portions;
 - c) [t]he pesticidal substance is from a source food plant normally cooked or processed and is produced in a recipient plant that is not normally cooked or processed prior to consumption; or
 - d) [t]he pesticidal substance is derived from a source food plant that is not a major crop for human dietary consumption (*i.e.*, not wheat, corn, soybeans, potatoes, oranges, tomatoes, grapes, apples, peanuts, rice, or beans or any other crop that the EPA has determined is a major crop for human dietary consumption) and is introduced into a recipient plant that is a major crop for human dietary consumption.¹⁸⁹

The EPA also is proposing to exempt from the requirement of a tolerance coat proteins from plant viruses and nucleic acids. The EPA believes that tolerances are not necessary for coat proteins from viruses because virus-infected plants have always been a part of the human diet without any known adverse effects on human health. It is necessary for the EPA to address nucleic acids under FFDCa because they are considered part of the pesticidal active ingredient. The EPA plans to exempt these substances from the requirement of a tolerance, however, because nucleic acids are present in the cells of every living organism, and thus, are ubiquitous in the food supply. Because of their ubiquity in the food supply and because they lack any toxicity when consumed in food, the EPA does not believe tolerances are

189. Plant-Pesticides: Proposed Exemption from the Requirement of a Tolerance under the Federal Food, Drug, and Cosmetic Act, 59 Fed. Reg. 60,535, 60,537, 60,538 (1994).

necessary for nucleic acids in order to protect the public health.

E. *The Regulatory Process Under FFDCA*

If a plant pesticide is being used in food or feed, the EPA has two options in its regulation under FFDCA: it can either set a tolerance for the plant pesticide or it can exempt the plant pesticide from the requirements of a tolerance.

V. INTERNATIONAL IMPLICATIONS

In addition to regulating plant pesticides in the United States, the EPA must also consider the international implications of genetically engineered plant products. The worldwide concern over the safety of biotechnology products is evidenced by the significant role that biotechnology played in negotiations of the United Nations Convention on Biological Diversity.¹⁹⁰ The agreement that was eventually reached contained a number of provisions that are relevant to biotechnology. Two provisions in particular, Article 8 ("In-situ Conservation") and Article 19 ("Handling of Biotechnology and Distribution of its Benefits") address international concerns with biotechnology products.

Article 8 of the Convention requires that contracting parties establish a means to regulate, manage or control the risks associated with the use and release of domestic living modified organisms resulting from biotechnology that could affect the conservation and sustainable use of biological diversity.¹⁹¹ However, the policy does not address the broader concern of risk to biological diversity internationally. This raises two significant issues. First, it is conceivable that a plant pesticide that does not pose an unreasonable risk in the United States could pose an unreasonable risk if it was exported to another country. As previously discussed, many of the risks associated with plant pesticides relate to their ability to outcross to wild relatives. This is a very different situation from that of conventional

190. United Nations Conference on Environment and Development: Convention on Biodiversity, June 5, 1992, 31 I.L.M. 818 (1992). Although most parties to the Convention signed on in Rio De Janeiro in the summer of 1992, the United States did not sign the convention until June 4, 1993. Convention on Biodiversity, S. Treaty Doc. No. 20, 103d Cong., 1st Sess. 1994.

191. 31 I.L.M. at 825. Article 8 provides:

Each Contracting Party shall, as far as possible and as appropriate:

(g) Establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking into account the risks to human health.

pesticides. For conventional chemical pesticides, the risks posed by the substance will tend to be similar regardless of the country or part of the world. For example, if a pesticide is highly toxic to humans or other mammals in the United States, it will also be highly toxic to humans or mammals in other countries.¹⁹² The risks associated with plant pesticides, on the other hand, may vary significantly with location depending on a number of factors, including the presence of wild relatives.¹⁹³ It would be extremely difficult, if not impossible, for the EPA to evaluate all risks of a plant pesticide in every country in the world. Moreover, to conduct the unreasonable adverse effects analysis required by FIFRA, the EPA also must look at the societal benefits associated with the pesticide. It would seem infeasible for the EPA to conduct such an analysis for every importing country. The EPA is not in a position to evaluate the economic and societal benefits that an importing country derives from a particular pesticide or chemical substance.

The second impediment to the EPA addressing risks of plant pesticides in other countries is that FIFRA provides the EPA with very limited authority to regulate exported pesticides. The export of pesticides is regulated under section 17 of FIFRA. The primary emphasis of this section concerns information sent by the EPA to foreign governments about a limited subset of pesticides. Section 17 mandates two systems of notification: a notice to the government of an importing country concerning the export of unregistered pesticides (section (a)(2))¹⁹⁴ and a notice to all countries concer-

192. Of course, exposure scenarios may be different depending on the country. For example, in the United States a pesticide found on a food that is eaten only in very small quantities may not be of concern. However, if that same food is consumed in large quantities in a different country, there may be a concern with the pesticide in that country.

193. For example, one concern about plant pesticides is that if a favorable ecological niche exists for the modified plant in its new environment that enables it to thrive, it might become invasive and disrupt the balance of that ecosystem. The EPA may evaluate a particular plant pesticide under FIFRA and find that it does not pose an unreasonable environmental risk in the United States because a suitable niche does not exist for the modified plant. To determine whether the plant pesticide poses an unreasonable risk in another country, however, the exporting company (or the EPA) would be required to identify the ecosystems of that country and determine the likelihood of the modified plant thriving or spreading in that environment. To do this, the exporting company (or the EPA) would have to address an array of issues to determine whether the pesticide produced by the plant gives it a selective advantage in the new environment. Such a determination would depend on a number of considerations, such as, whether the modified plant has wild relatives in the new environment, how the modified plant is affected by factors such as climate, what selective pressures (*e.g.*, viruses or other pathogens that normally keep the plant population in check) exist in the new environment, and how the modified plant interacts with the native species of the importing country. It appears to be unreasonable to require such a site-specific risk assessment for every country that imports U.S. pesticides.

194. Section 17(a) of FIFRA provides:

(a) *Pesticides and Devices Intended for Export.* Notwithstanding any other

ning cancellation or suspension actions taken by the EPA (section 17(b)).¹⁹⁵ Beyond these notification provisions, FIFRA does not provide the EPA with the authority to regulate exports.

The Convention of Biological Diversity also contains a provision that requires consideration for an international biosafety protocol. Article 19 requires, among other things, that the parties consider the need for a protocol setting out appropriate procedures, including advance informed agreement, for the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity.¹⁹⁶ However, while the EPA certainly has the authority to comply with some form of an international biosafety protocol, FIFRA may not provide sufficient authority for the EPA

provision of this Act, no pesticide or device or active ingredient used in producing a pesticide intended solely for export to any foreign country shall be deemed in violation of this [Act]

(1) when prepared or packed according to the specifications or directions of the foreign purchaser . . . ; and

(2) in the case of any pesticide other than a pesticide registered under section 136a or sold under section 136(a)(1) of this [Act], if, prior to export, the foreign purchaser has signed a statement acknowledging that such pesticide is not registered for use in the United States and cannot be not sold in the United States under this [Act].

A copy of that statement shall be transmitted to an appropriate official of the government of the importing country.

7 U.S.C. § 136o(a) (1994).

195. Section 17(b) provides:

(b) *Cancellation Notices Furnished to Foreign Governments.* Whenever a registration, or cancellation or suspension of the registration of a pesticide becomes effective, or ceases to be effective, the Administrator shall transmit through the State Department notification thereof to the governments of other countries and to appropriate international agencies. Such notification shall, upon request, include all information related to the cancellation or suspension of the registration of the pesticide and information concerning other pesticides that are registered under section 136(a) of this [Act] and that could be used in lieu of such pesticide.

7 U.S.C. § 136o(b) (1994).

196. Article 19 of the Convention provides that:

3. The Parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity.

4. Each Contracting Party shall, directly or by requiring any natural or legal person under its jurisdiction providing the organisms referred to in paragraph 3 above, provide any available information about the use and safety regulations required by that Contracting Party in handling such organisms, as well as any available information on the potential adverse impact of the specific organisms concerned to the Contracting Party into which those organisms are to be introduced.

31 I.L.M. 830 at art. 19.

to require advance informed consent from an importing country prior to exporting a plant pesticide. Section 17(b) FIFRA merely authorizes the EPA to provide information related to the cancellation or suspension of pesticides to foreign governments. Information on pesticides that have not been cancelled or suspended is not required to be provided to foreign governments. On the other hand, exporters of pesticides that are not registered in the United States must ensure that foreign purchasers sign a statement acknowledging that the purchaser understands that the pesticide is not registered, and must submit a copy of such a statement to the proper government official.¹⁹⁷ Nothing in FIFRA, however, provides clear authority for the EPA to require pesticide exporters to obtain the "advanced informed agreement" of the importing country for all pesticide imports, as contemplated by Article 19 of the Convention.

One solution to this problem is new legislation that would authorize the EPA, at a minimum, to require exporting companies to obtain advanced informed consent from importing governments prior to exporting plant pesticides or other biotechnology products. Another perhaps more workable option for sharing information may be to require the government of the exporting country, rather than the exporting company, to provide information to the importing country. This approach would be similar to the EPA's existing policy under section 17(b) of FIFRA, under which the EPA is required to provide notice to importing countries when a pesticide registration is cancelled or suspended. This approach would operate in a similar fashion as the United Nations Prior Informed Consent (PIC) program, which applies to pesticides, including biological pesticides. The PIC program establishes a system whereby governments inform each other of control actions taken to ban or severely restrict chemical substances in order to protect health and the environment.¹⁹⁸ Within ninety days after receipt of a notification that a chemical has been banned or severely restricted, the importing country is

197. 7 U.S.C. § 136o(a)(2) (1994).

198. In 1985, the United Nations Food and Agriculture Organization (FAO) adopted a Code of Conduct on the Distribution and Use of Pesticides. U.N. Doc. M/R8130, E/8.86/1/5000 (1986). In 1987, the United Nations Environmental Programme (UNEP) adopted the London Guidelines for the Exchange of Information on Chemicals in International Trade. U.N. Doc. UNEP/GC, 14/17, Annex IV (1987). The PIC concept was developed and incorporated into both the FAO Code and the UNEP London Guidelines in 1987. U.N. GAOR, 42d Sess., No. 25, Supp. at 79, U.N. Doc. A/42/25 (1987). The PIC procedure in the London Guidelines was amended in 1989. U.N. Doc. UNEP/PIC/WG.2/4 app. (1989). These instruments make the PIC program voluntary. This voluntary program is administered jointly by UNEP and FAO. See *London Guidelines for the Exchange of Information on Chemicals in International Trade* (United Nations Environmental Programme 1989) U.N. GAOR, 44th Sess., Supp. No. 25, at 157, U.N. Doc. A/44/25 (1989); *International Code of Conduct on the Distribution and Use of Pesticides* (United Nations Food and Agriculture Organization 1987) U.N. GAOR, 42d Sess., No.25, Supp. at 79, U.N. Doc. A/42/25 (1987).

expected to make a decision whether to allow the import of the substance, allow it under certain specified conditions, or not to allow the import. This approach also is consistent with section 17(d) of FIFRA, which contemplates the EPA playing an active role in international efforts to regulate pesticides.¹⁹⁹

Another potential approach would be to make the advanced informed agreement provisions of Article 19 voluntary rather than mandatory. Again, FIFRA does not clearly authorize the EPA to require exporting companies to supply information of the type identified in Article 19 to importing countries. There does not appear to be any legal impediment, however, to establishing a voluntary system for exporting companies to participate in information sharing efforts with importing countries. The United Nations PIC program also is a voluntary program.

VI. CONCLUSION

The biotechnology industry is making rapid advances in developing plant-pesticide products. While these products have the potential to benefit the agricultural industry, the environment, and society as a whole, they also have potential environmental and human health risks. Moreover, many members of the public are apprehensive about the use of genetically engineered organisms and the uncertainties surrounding the new technologies that are used to create these organisms. The EPA's new policy and regulations on plant pesticides, when final, will be a significant first step in developing a regulatory scheme that strikes a proper balance between the potential risks and benefits of plant pesticides. Nevertheless, to have a truly effective regulatory system, the EPA must continue to tailor its existing regulations to address issues related to plant pesticides. Moreover, because of the limitations inherent in the risk-management of plant pesticides, the EPA must exercise caution in approving new plant-pesticide registrations. The EPA must continue to study and monitor plant pesticides and must be prepared to repeal exemptions for plant pesticides that are found to present significantly higher risks than previously believed. New legislation may be necessary to provide the EPA with the regulatory tools to accomplish quickly such a repeal without being required to engage in lengthy notice and comment rulemaking. The EPA should take a leading role in addressing the international implications of the use and trade of plant pesticides, both to implement the Convention on Biological Diversity and to assist other countries in addressing the potential risks from these products. Finally, it is

199. 7 U.S.C. § 136o(d) (1994) (providing that the Administrator "in cooperation with the Department of State and any other appropriate federal agency, participate and cooperate in any international efforts to develop improved pesticide research and regulations").

important to keep in mind that, although plant pesticides and other biotechnology products may be less risky substitutes for traditional chemical pesticides, the EPA should not concentrate its efforts on encouraging biotechnology at the expense of discouraging other reduced risk pesticides or pest control methods.

