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## Federal Regulation of Agricultural Biotechnologies

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# FEDERAL REGULATION OF AGRICULTURAL BIOTECHNOLOGIES

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Thomas O. McGarity\*

The scientific community in the United States, barely a decade ago, witnessed a great public debate about a new kind of scientific research using "recombinant DNA" techniques.<sup>1</sup> In the intervening years, the controversy over the possible hazards of that research has dimmed,<sup>2</sup> but we have launched into another full-scale debate over the risks and benefits of the technologies that have grown out of that research. Perhaps the most intense controversy has centered on agricultural uses of newly emerging biotechnologies.<sup>3</sup> Although agricultural biotechnologies will un-

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1. See J. GOODFIELD, *PLAYING GOD* (1977); M. ROGERS, *BIOHAZARD* (1973); N. WADE, *THE ULTIMATE EXPERIMENT* (1977).

2. See Levin, *Changing Views of the Hazards of Recombinant DNA Manipulation and the Regulation of these Procedures*, 7 *RECOMBINANT DNA TECHNICAL BULL.* 107 (1984).

3. See *Coordinated Framework for Regulation of Biotechnology: Hearing Before the Subcomm. on Investigations and Oversight and the Subcomm. on Natural Resources, Agriculture Research and Environment and the Subcomm. on Science, Research and Technology of the House Comm. on Science and Technology*, 99th Cong., 2d Sess. 135 (1986) [hereinafter *Coordinated Framework Hearing*]; *Planned Releases of Genetically-Altered Organisms: The Status of Government Research and Regulation: Hearing Before the Subcomm. on Investigations and Oversight of the House Comm. on Science and Technology*, 99th Cong., 1st Sess. 72 (1985) [hereinafter *Planned Release Hearing*]; *Biotechnology Regulation: Hearing Before the Subcomm. on Oversight and Investigations of the House Comm. on Energy and Commerce*, 98th Cong., 2d Sess. 98-193 (1984) [hereinafter *Biotechnology Regulation Hearing*]; *Environmental Implications of Genetic Engineering: Hearing Before the Subcomm. on Investigations and Oversight and the Subcomm. on Science, Research and Technology of the House Comm. on Science and Technology*, 98th Cong., 1st Sess. 36 (1983) [hereinafter *Environmental Implications Hearing*]; STAFF OF SUBCOMM. ON INVESTIGATIONS AND OVERSIGHT OF THE HOUSE COMM. ON SCIENCE AND TECHNOLOGY, 99TH CONG., 2D SESS., *REPORT ON ISSUES IN THE FEDERAL REGULATION OF BIOTECHNOLOGY: FROM RESEARCH TO RELEASE* (Comm. Print 1986) [hereinafter *ISSUES IN FEDERAL REGULATION REPORT*]; STAFF OF SUBCOMM. ON INVESTIGATIONS AND OVERSIGHT OF THE HOUSE COMM. ON SCIENCE AND TECHNOLOGY, 99TH CONG., 2D

questionably provide large benefits to farmers, food processors, agricultural supply companies, and consumers, they may also cause unanticipated harm. The environmental risks of highly touted chemical pesticides that emerged after World War II did not become apparent until long after those pesticides had become an almost indispensable component of modern agriculture. The data base assembled during the 1950's and 1960's on the risks of pesticides was not nearly up to the task of evaluating their risks, and regulatory agencies are still playing catch-up in the 1980's. Ironically, one of the most highly proclaimed benefits of agricultural biotechnology is its potential to reduce or eliminate the need for the chemical pesticides and fertilizers that only thirty years ago promised a "green revolution" in agriculture.

If we can implement an effective process for assessing and managing the risks of agricultural biotechnologies, we may perhaps avoid the unpleasant history of chemical pesticides. The United States Department of Agriculture (USDA) and the Environmental Protection Agency (EPA) have recently established policies and proposed regulations aimed at implementing an effective regulatory process under existing statutes. Although their efforts represent a sound beginning, the existing regulatory regime is still inadequate. Additional administrative action can fill some of the gaps, but a fully effective regulatory regime may require congressional attention.

Part I of this Article describes some of the risks and benefits of newly emerging agricultural biotechnologies. After discussing, in Part II, the role of federal agencies in regulating agricultural biotechnologies, Part III of the Article proposes elements for an adequate regulatory regime. Part IV then measures the existing legal authorities, as implemented by the USDA and the EPA, against the ideal elements. Part V examines the willingness of these agencies to regulate. Finally, Part VI suggests changes that can be made in the current regulatory regime to bring about more effective regulation and to enhance public trust in regulatory decisions.

## I. THE BENEFITS AND RISKS OF AGRICULTURAL BIOTECHNOLOGY<sup>4</sup>

Agricultural biotechnology encompasses a bewildering variety of agricultural applications of genetic engineering to agriculture, including biological pesticides, animal biologics, genetically engineered crops, and microorganisms designed to produce soil nutrients. All of these possible uses for biotechnology may have numerous benefits to society, but many pose potential risks as well.

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4. I will use the term "biotechnology" here in a very simplistic way to denote the use of modern or "novel" techniques, such as recombinant DNA, for modifying genetic material in plants or microorganisms to achieve socially desirable results. I will use the term "agricultural biotechnology" to refer to modern genetic engineering technologies that are directly applicable to agriculture, and I will confine my attention to genetically engineered microorganisms and plants.

The standard definitions of biotechnology are generally drawn in a broader fashion than this to include traditional fermentation and breeding technologies. *See, e.g.*, U.S. GEN. ACCOUNTING OFFICE, BIOTECHNOLOGY: AGRICULTURE'S REGULATORY SYSTEM NEEDS CLARIFICATION 8-9 (1986) [hereinafter GAO USDA REPORT]. I have narrowed the scope of the definition for purposes of this Article to facilitate the discussion of the risks and benefits of modern biotechnologies. I do not mean to imply that modern biotechnologies are necessarily more hazardous (or even more useful) than traditional biotechnologies; nor do I mean to imply that the use of modern techniques to produce an agriculturally useful product will necessarily have any impact on the regulatory approach taken to the product. It may well be that an adequate regulatory regime for organisms using novel biotechnologies is likewise appropriate for organisms using traditional biotechnologies.

I mean to exclude from the discussion traditional animal and plant breeding techniques, including those fairly recent technologies that use radiation or chemicals to induce mutations in tissue cells. For the most part, I will focus on technologies that are capable of inserting a gene from one organism into another. Although modern biotechnologies may someday be used to genetically engineer farm animals, I will not focus on genetically engineered higher animals in this Article. Finally, I will not discuss fermentation technologies that might be used to produce agriculturally useful chemical products such as animal hormones, fertilizers, and animal drugs.

One further limitation is required to keep this Article manageable. I will not analyze the regulation of agricultural biotechnologies by the Food and Drug Administration (FDA). The clearest application of the FDA's authority to agricultural biotechnology is the production of pest and disease resistant plants. Pest and disease resistance is usually induced by breeding the plant to synthesize toxic chemicals. In large enough quantities such chemicals can be toxic to humans and livestock who eat the crops. There is, of course, a natural incentive for a plant breeder not to breed a crop that is toxic to the intended consumers of the crop. Although using modern genetic engineering techniques to breed pest and disease resistant crops clearly comes within my definition of "agricultural biotechnology," I will not address the applicability of the FDA's authority to this problem. *See generally* McNamara, *FDA Regulation of Food Substances Produced by New Techniques of Biotechnology*, 42 FOOD DRUG COSM. L.J. 50 (1987).

### A. *Benefits of Agricultural Biotechnology*

Agricultural biotechnology can produce biological pesticides that are highly selective and therefore not as likely to cause adverse environmental side effects as chemical pesticides.<sup>5</sup> Similarly, microorganisms might be designed to control soil pH and salinity, thus effectively increasing the geographical range of many crops.<sup>6</sup> Modified bacteria may someday replace chemical fertilizers. Nitrogen fixing bacteria coexist symbiotically with certain legumes, such as soybeans, and genetic engineering techniques may enhance their nitrogen fixing capabilities. Indeed, a company has very recently given the EPA notice of its intent to field test such a microorganism.<sup>7</sup> It may even be possible to modify nitrogen fixing bacteria and algae to provide nitrogen for plants that lack a symbiotic relationship with currently existing nitrogen fixing bacteria.<sup>8</sup>

Genetic engineering techniques can help protect farm animals from disease. For example, scientists are attempting to design "subunit" vaccines to prevent viral animal diseases (such as foot and mouth disease and rabies) without placing the animal at risk of contracting the disease against which it is vaccinated.<sup>9</sup> Biotechnology is already beginning to yield suitable vaccines for bacterial animal diseases (such as scours and swine dysentery) which cause millions of dollars of damage annually.<sup>10</sup>

Genetic engineering techniques can also be applied directly to plants to improve yields.<sup>11</sup> Traditional plant breeding biotech-

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5. OFFICE OF TECHNOLOGY ASSESSMENT, *COMMERCIAL BIOTECHNOLOGY* 183-84 (1984) [hereinafter *OTA COMMERCIAL BIOTECHNOLOGY REPORT*].

6. *Id.* at 180.

7. See Crawford, *BioTechnica Tests EPA Review Process*, 235 *SCIENCE* 840 (1987); U.S. Env'tl. Protection Agency, Fact Sheet: EPA Receives First Notice for a Microorganism Subject to Section 5 of the Toxic Substances Control Act (Feb. 6, 1987) [hereinafter *EPA Fact Sheet*].

8. *OTA COMMERCIAL BIOTECHNOLOGY REPORT*, *supra* note 5, at 181-82; *GENETIC ENGINEERING*, *supra* note 3.

9. See *OTA COMMERCIAL BIOTECHNOLOGY REPORT*, *supra* note 5, at 162-67; *GAO USDA REPORT*, *supra* note 4, at 12. Subunit vaccines use only a few components of an infective organism to elicit antibodies. These components are incapable of infecting the host organism.

10. *OTA COMMERCIAL BIOTECHNOLOGY REPORT*, *supra* note 5, at 162-67. The USDA has already licensed 17 products resulting from modern biotechnologies, including five bacterins and bacterin-toxoids to prevent scours in swine and one modified live virus vaccine to prevent pseudorabies in swine. Comments of David Espeseth, Animal and Plant Health Inspection Service, USDA (Apr. 9, 1987) (commenting on an earlier draft of this Article) [hereinafter *Espeseth Comments*].

11. Doyle, *Biotechnology Research and Agricultural Stability*, 2 *ISSUES IN SCI. & TECH.* 111, 114 (1985).

nologies have greatly increased yields of commercially useful crops by selecting for plants that produce more of the commercially useful plant part (e.g., tubers in the case of potatoes; seeds in the case of sunflowers).<sup>12</sup> Similarly, traditional technologies have allowed seed companies to develop breeds that are much easier to harvest and process, thus reducing the ultimate expense of putting food on the table of the consumer.<sup>13</sup> Finally, traditional plant breeders have been able to select for plants that have a higher resistance to insects, disease, and drought.<sup>14</sup> Although modern biotechnologies will not replace traditional plant breeding, they can be used together to "speed up and perfect the process of genetic refinement."<sup>15</sup>

In addition, modern biotechnologies may be capable of achieving results that are unattainable with traditional biotechnologies. For example, genetic engineers may be able to devise new herbicide resistant strains of crops that facilitate minimum tillage agriculture.<sup>16</sup> Moreover, scientists can insert into plants genes from bacteria that cause the plants to produce proteins that are toxic to insects.<sup>17</sup> Finally, scientists may soon be able to improve plant biological processes, such as photosynthesis.<sup>18</sup>

### B. Risks of Agricultural Biotechnologies

Although most genetically engineered microorganisms will probably not be dangerous, most scientists agree that some deliberate releases may pose health and environmental risks under some conditions.<sup>19</sup> Unlike chemicals, microorganisms proliferate

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12. OFFICE OF TECHNOLOGY ASSESSMENT, *IMPACTS OF APPLIED GENETICS* 137-39 (1981) [hereinafter *OTA IMPACTS REPORT*].

13. J. DOYLE, *ALTERED HARVEST* 58-59 (1985). It is not clear that the consumer receives the full benefit of the reduced expense. Some would argue that a great deal of the savings is absorbed by food processors. *Id.* at 352-53.

14. *GENETIC ENGINEERING*, *supra* note 3, at 14; J. DOYLE, *supra* note 13, at 187; GAO *USDA REPORT*, *supra* note 4, at 12-13.

15. *OTA IMPACTS REPORT*, *supra* note 12, at 141.

16. See Birenbaum, *Pesticide and Herbicide Chemists Advised to Utilize Biotech Techniques*, *Genetic Engineering News*, Nov./Dec. 1986, at 12, col. 1. The USDA recently approved a request to field test a tobacco plant that had been genetically engineered to be resistant to the herbicide atrazine. Sun, *Biotech Guidelines Challenged by Rifkin*, 233 *SCIENCE* 516 (1986).

17. See Doyle, *supra* note 11, at 117-19; Rigi, *Field Test of Gene Altered Pest Resistant Plant Begins*, *Genetic Engineering News*, Oct. 1986, at 1, col. 1.

18. Doyle, *supra* note 11, at 114.

19. A House Committee Staff report identifies the following kinds of risks posed by large-scale release of biotechnologies: "(1) ecological disruption due to lack of natural enemies; (2) infectivity, pathogenicity, or toxicity to nontarget organisms . . . and (3)

when released into the environment. Unless the scope and conditions of initial releases of genetically engineered microorganisms are carefully limited, they can upset delicate ecological balances.

If genetically engineered pesticides, for example, are not selective for particular pests, or if they mutate so as to lose that selectivity, they can become hazardous to beneficial species or even to humans. One of the first genetically engineered pesticides is a bacterium that lives on the roots of corn plants. A chemical company engineered the bacterium to secrete a chemical that kills cutworms.<sup>20</sup> In reality, the bacterium is a pesticide *applicator*, and it apparently applies its pesticide continuously, whether or not the crop damaging insects are present in the field. Clearly, this pesticide has the potential to disrupt ecological systems.<sup>21</sup> Moreover, constant exposure of insects to the toxin will no doubt induce resistance among target insect species over time.

Microorganisms designed to modify soil pH and to add nutrients to the soil could cause environmental damage if they found a niche in soils not used for crops or if they modified the pH or increased the nutrient content of lakes and waterways. Such microorganisms would have to be carefully engineered to remain where they were most useful.<sup>22</sup>

Even though genetically engineered vaccines are likely to be safer for the host animals than current vaccines, things can go wrong. Live vaccines can mutate in the host into harmful organisms.<sup>23</sup> Two benign viruses can recombine within animal hosts to produce a deadly virus, although this is normally quite rare. It is also possible that live genetically engineered microorganisms that are harmless to domestic livestock pose risks to wildlife.

Any genetically engineered microorganism may be capable (either as designed or through mutation) of attacking other micro-

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exchange of genetic material with other organisms." GENETIC ENGINEERING, *supra* note 3, at 16.

20. See Doyle, *supra* note 11, at 118; Sun, *Monsanto May Bypass NIH in Microbe Test*, 227 SCIENCE 153 (1985).

21. Doyle, *supra* note 11, at 118.

22. See generally GENETIC ENGINEERING, *supra* note 3, at 15.

23. For example, when two nonpathogenic fungi were combined in an effort to enhance the nitrogen fixing capability of a species of pine tree, the combination was pathogenic and killed seedlings to which it was applied. GENETIC ENGINEERING, *supra* note 3, at 19 (citing Giles & Whitehead, *Reassociation of a Modified Mycorrhiza with the Host Plant Roots (Pinus Radiata) and the Transfer of Acetylene Reduction Activity*, 48 PLANT & SOIL 143-52 (1977)).

organisms, plants, and animals in unanticipated ways.<sup>24</sup> For example, even a nonpathogenic genetically engineered microorganism might outcompete beneficial species for available food supplies, thereby reducing populations of beneficial species.<sup>25</sup> As novel genetic engineering techniques begin to produce exotic strains of microorganisms, it is always possible that one strain will find an ecological niche and cause harm to the environment.<sup>26</sup> Microorganisms can be quite unpredictable in complex ecosystems, and the histories of the introduction of exotic organisms into new ecosystems clearly demonstrate that novel species are capable of upsetting delicate ecological balances.<sup>27</sup> Indeed, the introduction of a genetically engineered microorganism into a new environment may pose greater risks than the introduction of an existing exotic species because so little is known about novel organisms.<sup>28</sup> Some microorganisms are "promiscuous," sharing DNA with one another.<sup>29</sup> A genetically engineered bacterium that was designed to secrete an enzyme under carefully limited conditions might exchange the gene coding for that enzyme with a "wild" bacterium that would then secrete the enzyme under different conditions and cause environmental damage.

Genetically engineered plants can also cause economic and ecological harm if they proliferate in places where they are not wanted. One person's flower is another person's weed. For example, corn is regarded as a weed in a sorghum field. The kudzu vine, which was imported from Japan for soil conservation purposes, took over nearly every embankment in the Southeast United States, and then marched on to conquer trees and telephone poles.<sup>30</sup> It is remotely possible that genes in a genetically

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24. GAO USDA REPORT, *supra* note 4, at 13.

25. See *Coordinated Framework Hearing*, *supra* note 3, at 83 (testimony of Elliott A. Norse, Director, Public Affairs Office, Ecological Soc'y of Am.).

26. See GENETIC ENGINEERING, *supra* note 3, at 5. The microorganisms that cause dutch elm disease and chestnut blight thrived in the United States after they entered the country in wood imported from Asia. *Environmental Implications Hearing*, *supra* note 3, at 25 (testimony of Frances E. Sharples, Oak Ridge Nat'l Laboratory, Oak Ridge, Tenn.).

27. *Coordinated Framework Hearing*, *supra* note 3, at 79-81 (testimony of Elliott A. Norse, Director, Public Affairs Office, Ecological Soc'y of Am.); *Environmental Implications Hearing*, *supra* note 3, at 22-28 (testimony of Frances E. Sharples, Oak Ridge Nat'l Laboratory, Oak Ridge, Tenn.).

28. See generally *Environmental Implications Hearing*, *supra* note 3, at 5 (testimony of Martin Alexander, Professor of Agronomy, Cornell Univ.).

29. OFFICE OF TECHNOLOGY ASSESSMENT, GENETIC ISSUES IN ENVIRONMENTAL APPLICATIONS OF GENETICALLY ALTERED ORGANISMS 10-11 (1986) [hereinafter OTA GENETIC ISSUES REPORT].

30. See GENETIC ENGINEERING, *supra* note 3, at 19.



engineered crop species will move into weeds or other noncultivated vegetation, thereby bestowing on the weed the advantage that the gene gave the crop species.<sup>31</sup>

Traditional plant breeding techniques attempt to select for disease and pest resistance. In many cases this is simply a matter of breeding plants that best synthesize chemicals that are toxic to disease-producing microorganisms and other pests.<sup>32</sup> Modern genetic engineering techniques may produce crops that synthesize much larger quantities of such toxic substances and thereby render them toxic to wildlife.<sup>33</sup> Yet many ecologists would probably agree that the potential for unanticipated harm is less for genetically engineered plants than for genetically engineered microorganisms.<sup>34</sup>

Finally, agricultural biotechnologies may have an indirect impact on the environment not immediately attributable to the modified plants or organisms. For example, at least one scientist has suggested that rather than designing weed-specific herbicides, seed companies should use genetic engineering techniques to make several beneficial plant species resistant to herbicides.<sup>35</sup> Broad-spectrum herbicides could then be used to eliminate a wide variety of potential weed species, leaving the economically useful species intact. Such an approach might encourage the overuse of herbicides, resulting in damage to wildlife, water supplies, and ultimately human beings.<sup>36</sup> On the other hand, it might encourage use of more benign herbicides that currently do not adequately differentiate between weeds and crops.<sup>37</sup>

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31. *Planned Release Hearing*, *supra* note 3, at 54 (prepared statement of Robert M. Goodman, Vice President, Research & Dev., Calgene, Inc.). Several species that are normally considered weeds, such as wild sunflowers and Johnson grass, are used as sources of genetic variation in plant breeding programs. *Id.* at 59, 63. Because crops can interbreed with related species of weeds, the genetic material of crops can become incorporated into weeds.

32. *See, e.g.*, Balandrin, Klocke, Wurtele & Bollinger, *Natural Plant Chemicals: Sources of Industrial and Medicinal Materials*, 228 *SCIENCE* 1154 (1985).

33. Seed companies would probably not develop disease and pest resistant crops that were intended for human or animal consumption. That would, of course, be self-defeating. But many crops, such as ornamental species, are not directly consumed by humans, and many that are consumed by humans and livestock have uses other than human or livestock consumption. For example, if energy prices return to the 1970's levels, much corn will be grown to produce alcohol for fuel.

34. *OTA GENETIC ISSUES REPORT*, *supra* note 29, at 11; *Planned Release Hearing*, *supra* note 3, at 54, 91 (prepared statement and testimony of Robert M. Goodman, Vice President, Research & Dev., Calgene, Inc.).

35. *See* Birenbaum, *supra* note 16.

36. *See* Doyle, *supra* note 11, at 119-20.

37. Comments of Margaret Mellon, Staff Attorney, National Wildlife Federation (Mar. 23, 1987) (commenting on an earlier draft of this Article) [hereinafter Mellon Comments].

In sum, although the potential risks of modern agricultural biotechnologies are highly speculative, they are quite real.<sup>38</sup> If problems do occur, they may be severe. Thus, like nuclear power and some synthetic chemicals, agricultural biotechnologies pose low-probability, high-consequence risks, the magnitude of which will continue to be highly uncertain.<sup>39</sup>

## II. THE ROLE OF FEDERAL AGENCIES IN REGULATING AGRICULTURAL BIOTECHNOLOGIES

In the past, the USDA has played a significant role in promoting agricultural biotechnologies, and it will play an increasingly prominent role in regulating them. The Agricultural Research Service devotes approximately \$450 million per year to agricultural research, including \$24.5 million in fiscal year 1986 for projects using modern biotechnologies.<sup>40</sup> The Animal and Plant Health Inspection Service (APHIS) administers several statutes aimed at protecting agricultural crops and livestock, consumers of food, and the general environment from harmful plants and microorganisms.

Under the Virus-Serum-Toxin Act,<sup>41</sup> it is unlawful to transport or import a "worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product intended for use in the treatment of domestic animals."<sup>42</sup> Establishments that manufacture veterinary biological products must be licensed, and importers must have permits.<sup>43</sup> The USDA has issued regulations banning the shipment within the United States of individual products unless the manufacturer has satisfied USDA requirements for purity, safety, potency, and efficacy.<sup>44</sup> In effect,

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38. *Planned Release Hearing*, *supra* note 3, at 40 (prepared statement of Martin Alexander, Professor of Agronomy, Cornell Univ.).

39. *Environmental Implications Hearing*, *supra* note 3, at 9 (prepared statement by Martin Alexander, Professor of Agronomy, Cornell Univ.); Harlow, *The EPA and Biotechnology Regulation: Coping with Scientific Uncertainty*, 95 *YALE L.J.* 553, 559 (1986); McGarity & Bayer, *Federal Regulation of Emerging Genetic Technologies*, 36 *VAND. L. REV.* 461, 486 (1983).

40. U.S. GEN. ACCOUNTING OFFICE, *BIOTECHNOLOGY: ANALYSIS OF FEDERALLY FUNDED RESEARCH* 14 (1986).

41. 21 U.S.C. §§ 151-158 (1982 & Supp. III 1985).

42. *Id.* § 151. The original statute barred only the interstate shipment of harmful products, but the Food Security Act of 1985 expanded the USDA's authority to include intrastate shipments. Pub. L. No. 99-198, § 1768, 99 Stat. 1654 (codified at 21 U.S.C. §§ 151, 154-154a, 157, 159 (1982 & Supp. III 1985)).

43. 21 U.S.C. §§ 154-155 (1982 & Supp. III 1985).

44. 9 C.F.R. § 113 (1987).

the USDA has established a licensing regime for manufacturing establishments, imports, and individual products.

The Act of February 2, 1903, empowers the USDA to issue regulations and to take appropriate measures against the import or interstate transport of animal diseases.<sup>45</sup> The USDA has interpreted this statute to give it authority to require a permit for any import or interstate shipment of contagious or infectious diseases of animals.<sup>46</sup>

The Federal Plant Pest Act (FPPA)<sup>47</sup> empowers the USDA to regulate imports and movement within the United States of plant pests, which may be microorganisms, plants, or insects. Any import or shipment within the United States of designated plant pests must have a permit.<sup>48</sup> In addition, the Noxious Weed Act<sup>49</sup> requires a permit for the importation or interstate shipment of noxious weeds that have been listed by the USDA pursuant to somewhat cumbersome procedures.<sup>50</sup>

Finally, the recently enacted Food Security Act<sup>51</sup> gives the USDA very broad authority to "establish appropriate controls with respect to the development and use of the application of biotechnology to agriculture."<sup>52</sup> Although this extremely broad grant of authority was probably intended merely to give the USDA authority to protect the environment from USDA-sponsored research, the statute is not by its terms so limited,<sup>53</sup> and the USDA has not decided whether it will rely on the statute to bolster its other authorities.<sup>54</sup> However, because the quoted sec-

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45. 21 U.S.C. § 111 (1982).

46. 9 C.F.R. § 122 (1987).

47. 7 U.S.C. §§ 150aa-150jj (1982).

48. 7 C.F.R. § 330.200 (1987).

49. 7 U.S.C. §§ 2801-2813 (1982).

50. *Id.* § 2803. The term "noxious weed" is defined broadly to include any living stage of any plant that is "of foreign origin, is new to or not widely prevalent in the United States, and can directly or indirectly injure" crops or other "interests of agriculture, including . . . fish and wildlife resources." *Id.* § 2802(c). Because the USDA believes that it has adequate authority to regulate plants that pose risks to agricultural crops under the Federal Plant Pest Act, *Id.* §§ 150aa-150jj, and the Plant Quarantine Act, *Id.* §§ 151-167, and because the Noxious Weed Act is limited to weeds "of foreign origin," the agency has not relied heavily on the Noxious Weed Act in asserting its authority over agricultural biotechnologies.

51. *Id.* §§ 3121-3150 (1982 & Supp. IV 1986).

52. *Id.* § 3121(12).

53. This narrower reading of the Act is supported by the fact that it does not establish any of the normal elements of a regulatory program, such as hearing procedures, permit requirements, penalties, and inspection authority. Telephone interview with Terry Medley, Director, Biotechnology and Environmental Coordination Staff, Animal and Plant Health Inspection Service, USDA (Feb. 10, 1987) [hereinafter Medley Interview].

54. *Id.*

tion of the Food Security Act amended only the National Agricultural Research, Extension, and Teaching Policy Act of 1977,<sup>55</sup> it probably does not go beyond USDA-sponsored research and associated regulatory programs.<sup>56</sup>

Until very recently, the USDA did not actively exercise the foregoing powers because there were no proposals for large-scale use of modern agricultural biotechnologies.<sup>57</sup> Recognizing that it will soon play a major role in regulating agricultural biotechnologies, the Department has established within the APHIS a Biotechnology Environmental Coordination Staff that is responsible for coordinating the Department's regulatory activities and for ensuring that they are consistent with departmental policies and with the National Environmental Policy Act.<sup>58</sup>

Congress transferred regulatory authority for pesticides from the USDA to the EPA in 1970. Under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA),<sup>59</sup> no person may distribute a pesticide unless it has been "registered" with the EPA. The Act defines the term "pesticide" very broadly to include any substance "intended for preventing, destroying, repelling, or mitigating any pest" or "intended for use as a plant regulator, defoliant, or desiccant."<sup>60</sup> To obtain a registration for a pesticide, the registrant must demonstrate that it will not pose an "unreasonable risk" to humans or the environment.

The EPA's authority to regulate chemical substances under the Toxic Substances Control Act (TSCA)<sup>61</sup> may also have a role in regulating agricultural biotechnology. Any manufacturer of ei-

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55. Pub. L. No. 95-113, tit. 14, 91 Stat. 913, 981 (1977) (codified as amended at 7 U.S.C. §§ 3101-3336 (1982 & Supp. IV (1986))).

56. A. Carr, A Critique of the U.S. Department of Agriculture's Policy on Biotechnology Research and Regulation 5 (Congressional Research Serv. May 30, 1986) (paper prepared at the request of the Subcomm. on Investigations and Oversight of the House Comm. on Science and Technology); Medley Interview, *supra* note 53.

57. The Department did, however, condition its research grants for projects involving recombinant DNA on compliance with the National Institutes of Health (NIH) Guidelines for Recombinant DNA Research. *Biotechnology Regulation Hearing, supra* note 3, at 136 (testimony of Orville G. Bentley, Assistant Secretary for Science and Educ., USDA). After receiving criticism from the General Accounting Office for relying upon the NIH guidelines, which were aimed more at biomedical than agricultural research, the USDA has recently issued an advance notice of proposed rulemaking suggesting its own guidelines for agricultural research. Advanced Notice of Proposed USDA Guidelines for Biotechnology Research, 51 Fed. Reg. 23,367 (1986).

58. 42 U.S.C. §§ 4321-4370 (1982 & Supp. III 1985); Medley Interview, *supra* note 53. When fully staffed, the Biotechnology Environmental Coordination Staff will consist of microbiologists, plant pathologists, environmental specialists, and a program analyst and regulatory specialist. *Id.*

59. 7 U.S.C. §§ 136-136y (1982 & Supp. IV 1986).

60. *Id.* § 136(u).

61. 15 U.S.C. §§ 2601-2629 (1982 & Supp. IV 1986).

ther a new chemical substance or a significant new use of an existing chemical substance must file a notice with the EPA. The EPA may then require that the substance be tested for adverse health and environmental effects, and it can prevent the manufacture and distribution of the substance during the testing period. Any time that the EPA finds that a chemical substance presents an "unreasonable risk" of injury to humans or to the environment, it may promulgate a rule regulating the manufacture, distribution, and use of the substance. The EPA has interpreted the broad definition of "chemical substance" in the TSCA to include genetically engineered microorganisms, but this reading is not free from controversy.<sup>62</sup>

By the early 1980's, it became clear that modern biotechnologies would play a major role in producing useful agricultural products. Unlike previous technologies such as the automobile or the video cassette recorder that were introduced into the market with little or no governmental interference, biotechnology already had a history of state and federal regulation at the research and development stage. Biotechnology proponents therefore expected regulation, and they sought out the appropriate agencies before attempting to introduce the technologies into commerce. They soon discovered, however, that no single statute was aimed specifically at the risks of biotechnology, and they were frustrated to find several overlapping authorities. Moreover, the relevant agencies had given little thought to how their statutes might apply to biotechnology, and they had undertaken few efforts to eliminate gaps in coverage or to reduce overlaps.

The Reagan administration soon formed an interagency working group, called the Domestic Policy Council Working Group on Biotechnology, charged with drafting an overall federal framework for regulating biotechnology. The working group finished its job in June 1986, when it published a "Coordinated Framework for Regulation of Biotechnology" and an associated group of agency policy statements and proposed rules.<sup>63</sup> Concluding that existing statutes gave the federal government adequate authority to regulate biotechnology, the working group recommended against any statutory change. This Article critically examines the working group's sanguine assessment in the context of agricultural biotechnologies.

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62. See *infra* text accompanying notes 122-28.

63. Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23,302 (1986) [hereinafter Coordinated Framework].

### III. ELEMENTS OF AN ADEQUATE REGULATORY REGIME

Before identifying the elements of an adequate regulatory regime, it is worth exploring why there should be any regulatory regime at all for agricultural biotechnology. Inevitably, any regulation of agricultural biotechnology will slow down its progress and thereby deprive society of its benefits. In our market-oriented society, it is often presumed that there must be good reasons for regulation, and those reasons can guide the search for the best regulatory tools.

The primary reason for regulating agricultural biotechnology is to reduce the risks that at least some agricultural biotechnologies pose to humans and to the general environment. Past experience with new technologies, such as agricultural pesticides and nuclear power, argue against assuming that agricultural biotechnologies will be entirely benign. Yet society could allow the market, through the indirect incentives of the tort system, to regulate agricultural biotechnology without interference from regulatory agencies.

The tort system, however, is not likely to provide adequate incentives for reducing the risks of large-scale releases of genetically engineered microorganisms.<sup>64</sup> As with synthetic chemicals, it may be difficult to establish cause-effect relationships between genetically engineered microorganisms and environmental damage. If experts would generally be unwilling to testify that the release of a microorganism "probably" caused a plaintiff's damage, there would be no recovery, and hence no incentive to reduce risks. Even if causation could be established, the tort system would not send an adequate message unless all injured persons sued and all responsible parties were subject to suit.<sup>65</sup> The tort system will not address harm to the environment at all unless the technology also causes economic damage. When the ecology is thrown out of balance, there may be no individual with a sufficient direct financial stake to finance a lawsuit. Perhaps more importantly, the tort system generally works only after the fact; it is not well adapted to preventing harm before it occurs.<sup>66</sup>

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64. For an assessment of the efficacy of the tort system in controlling chemical risks, see McGarity, *Media Quality, Technology, and Cost-Benefit Strategies for Health and Environmental Regulation*, 46 *LAW & CONTEMP. PROBS.* 159, 173-79 (1983).

65. See *id.* at 174-75. Many of the new agricultural biotechnology companies are small entities that are not highly capitalized. Bankruptcy laws effectively shield such companies from full responsibility for the harm caused by their products.

66. See *id.* at 175-76.

The case for regulation is not as clear with genetically engineered plants. Economic damage due to genetically engineered plants that become weeds is probably fairly easily established. Because scientists seem less concerned that genetically engineered plants will cause large-scale uncompensable harm,<sup>67</sup> the after the fact aspect of the tort system would be less objectionable. On the other hand, the tort system would still lack incentives to reduce ecological harm that did not cause economic loss.

Whether or not society erects a regulatory mechanism to prevent harm from genetically engineered plants and microorganisms is ultimately a policy question that must be informed by technical considerations, but not dominated by them.<sup>68</sup> Perceptions, more than scientific facts, are likely to dictate the choice. At this stage in the development of biotechnology, public perceptions are poorly informed and ill defined. The public will probably insist upon a regulatory regime for microorganisms. Although the question is closer, policymakers may desire to err on the side of safety and provide some sort of regulatory regime for genetically engineered plants as well. The following discussion assumes that the decision has been made to erect a regulatory regime beyond that provided by the tort system, but it recognizes that the scope and intrusiveness of that regime might vary depending upon whether plants or microorganisms are involved. The elements of an adequate regulatory regime for biotechnology set out below are not necessarily exhaustive, and an adequate regulatory regime need not include every one of them. Ultimately, what constitutes an adequate regulatory regime is a policy question that Congress must resolve.

### A. *Prerelease Notice*

A comprehensive regulatory regime would require manufacturers to inform the regulatory agency in advance of releasing a novel genetically engineered plant or microorganism into the environment. Such advance notification would give the agency an opportunity to decide whether to exercise its regulatory power.

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67. The slight possibility that genetic engineering will create a food plant that poisons people is probably best addressed through traditional statutes regulating adulterated food. Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 342 (1982). This topic is beyond the scope of this Article.

68. Harlow, *supra* note 39, at 560; McGarity, *Substantive and Procedural Discretion in Administrative Resolution of Science Policy Questions: Regulating Carcinogens in EPA and OSHA*, 67 GEO. L.J. 729 (1979).

Without prerelease notification, the agency can only assume a reactive mode, perhaps after harm has resulted from the release. The information included in prerelease notice might vary, depending upon the nature of the plant or organism. For example, an identification of the host organism and an accurate characterization of the inserted DNA would seem to be the minimum information necessary. The location and circumstances surrounding the release are also fundamental. Beyond that, the information required might depend upon the suspected hazard. As the agency acquired more experience with classes of plants or organisms, less information might be required, and in time the entire prerelease notice might be waived for whole classes of plants and microorganisms.

Beyond the obvious burden imposed by the prerelease filing requirements, the most significant disadvantage of prerelease notification is the potential that it has for revealing valuable trade secrets.<sup>69</sup> Although all federal agencies have the power to protect legitimate trade secrets from disclosure,<sup>70</sup> information is sometimes released inadvertently; additionally, the public interest often requires that the affected public be provided information that might otherwise be considered a trade secret.<sup>71</sup> Nevertheless, policymakers may decide that inconvenience to manufacturers from the risk of disclosing trade secrets is outweighed by the advantages of prerelease notification.

### *B. Data Collection, Data Evaluation, and Risk Assessment*

An adequate regulatory regime would have some mechanism for producing information relevant to the health and environmental effects of agricultural biotechnologies.<sup>72</sup> Either the regulated entity or the agency itself should conduct studies on surrogate systems in laboratories and greenhouses prior to deliberate

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69. The complicated and delicate subject of the secrecy of trade information that is germane to evaluating the environmental effects of new technologies is beyond the scope of this Article. See generally McGarity & Shapiro, *The Trade Secret Status of Health and Safety Testing Information: Reforming Agency Disclosure Policies*, 93 HARV. L. REV. 837 (1980). The inquiry here will simply focus on the authority and the ability of the agencies to protect legitimate trade secrets.

70. The Trade Secrets Act, 18 U.S.C. § 1905 (1982), prohibits federal employees from releasing trade secrets. The Supreme Court has held that the Trade Secrets Act provides authority for an agency to withhold trade secret information, absent an explicit congressional command to release it. *Chrysler Corp. v. Brown*, 441 U.S. 281 (1979).

71. See McGarity & Shapiro, *supra* note 69, at 840-48.

72. See McGarity & Bayer, *supra* note 39, at 474-75.



release of genetically engineered plants and microorganisms into the environment.<sup>73</sup> Dr. Martin Alexander, a microbial ecologist, has suggested that an adequate risk assessment would be based upon information addressed to the following four questions:

- (1) the possibility that the organism will survive following its release, (2) the likelihood that it will multiply in some natural environment or in farmed areas, (3) the possibility that it will be dispersed and make contact with species that it can injure, and (4) the chance that it will be harmful.<sup>74</sup>

Unfortunately, there are presently no standardized guidelines for evaluating the potential of microorganisms to cause ecological damage.<sup>75</sup> At least during the first few years, protocols for such studies should probably be determined on a case by case basis, and the studies should be undertaken in carefully controlled test plots.<sup>76</sup>

In addition to gathering data, the agency must have the capacity to evaluate the quality of those data, analyze them, and draw scientifically valid conclusions. These functions require

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73. *Planned Release Hearing*, *supra* note 3, at 55 (prepared statement of Robert M. Goodman, Vice President, Research & Dev., Calgene, Inc.) ("Introduction of new crop varieties requires testing in many different environments over a period of several years."); *id.* at 82 (testimony of Robert K. Colwell, Professor of Zoology, University of Cal., Berkeley, Cal.) (suggesting a series of questions that should be asked about genetically engineered microorganisms before they are released into the environment).

74. *Id.* at 40.

75. *Environmental Implications Hearing*, *supra* note 3, at 220 (statement of Frances E. Sharples, Oak Ridge Nat'l Laboratory, Oak Ridge, Tenn.). Dr. Alexander has concluded that we are lacking an adequate body of information upon which to base regulation:

What is needed, therefore, is information on the potential for survival, multiplication, dispersal, and deleterious effects of the range of species of present and future interest to specialists in biotechnology, as well as a series of generally accepted tests that evaluate these phenomena . . . . It is in these two areas—developing a data base and a series of generally accepted tests—that essentially nothing has happened within the past 30 months.

*Planned Release Hearing*, *supra* note 3, at 40-41.

76. A statutory requirement that manufacturers of genetically engineered agricultural products provide the results of health and safety testing to a regulatory agency raises the complex question of the trade secret status of this information. Clearly, potential competitors should not be allowed to use the original manufacturer's information to obtain a license or other governmental advantage. The regulatory regime should therefore provide some mechanism for protecting the original manufacturer's legitimate interest in recouping its financial investment in the information without at the same time depriving the appropriate regulatory agency and the public of access to data that may be essential for an appropriate evaluation of the safety of the product. *See* McGarity & Bayer, *supra* note 39, at 475-76; *see generally* McGarity & Shapiro, *supra* note 69. This Article will not discuss this question in detail.

both a mechanism for ensuring that the data are produced in accordance with sound scientific protocols and expertise in evaluating the quality of scientific information. Typically, regulatory agencies with data evaluation responsibilities hire a staff of qualified experts. In addition, many agencies establish advisory committees composed of prominent scientists to evaluate information and to provide advice on the soundness of the agency's conclusions. Some agencies also circulate important scientific data for peer review to scientists selected by the agency staff.

Finally, the regulatory agency should use the information that it gathers to assess the risks posed by deliberate releases of agricultural biotechnologies.<sup>77</sup> At present, the art of risk assessment for biotechnology is very primitive indeed.<sup>78</sup> The Ecological Society of America has testified that:

[T]here is currently no definitive way to predict . . . what an organism will do when modified and released into the environment, for two reasons. For one, because the genetic engineering processes are, to varying degrees, imprecise, we do not know precisely what the products will be . . . . The other reason is that even if genetic engineers always knew precisely the nature and function of the genes they were transferring, it does not follow that they—or anyone else at this point—could then predict with sufficient assurance the fate and effects of the modified organism when it is released.<sup>79</sup>

Because the risks are likely to be of the low probability, high consequence variety that plagues regulators in other areas, it may be most appropriate to assess the risks of agricultural biotechnologies at first on a case by case basis prior to deliberate release.<sup>80</sup> This would require information on the pathogenicity of

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77. See ISSUES IN FEDERAL REGULATION REPORT, *supra* note 3, at 29-36 (discussing Advanced Genetic Science's unauthorized experiments releasing into the environment the 'ice-minus' microbe and suggesting several factors to be implemented by EPA in reviewing proposals to release genetically engineered organisms into the environment); Harlow, *supra* note 39, at 563; McGarity & Bayer, *supra* note 39, at 478-80.

78. See *Planned Releases Hearing*, *supra* note 3, at 4-5; Harlow, *supra* note 39, at 560-63; Stotzky & Babich, *Fate of Genetically-Engineered Microbes in Natural Environments*, 7 RECOMBINANT DNA TECHNICAL BULL. 163 (1984).

79. *Coordinated Framework Hearing*, *supra* note 3, at 81; see also Harlow, *supra* note 39, at 560-63 (pointing out the science policy aspects of risk assessments for large-scale releases of genetically engineered microorganisms).

80. See *Coordinated Framework Hearing*, *supra* note 3, at 19 (testimony of David T. Kingsbury, National Science Found.); *id.* at 71 (testimony of Monica Riley, American Soc'y for Microbiology); *id.* at 82 (testimony of Elliott A. Norse, Director, Public Affairs

the organism, its infectivity, and other possible undesirable by-products. Next, an adequate risk assessment would apply some sort of model to predict the dispersion of the organism or plant into the environment and the potential human and environmental exposure to it. Finally, still more modelling might be necessary to relate exposure to predicted harm.

Because the early risk assessments will be highly speculative, the agencies should undertake to characterize the attendant uncertainties. An agency could, for example, predict a "worst case" scenario and compare it with a "best case" scenario and a "most likely case" scenario. As the technology evolves and as more information becomes available from monitoring the technologies in the environment, the uncertainties should diminish, and the agency might be able to base regulatory decisions on generic predictions that certain classes of agricultural biotechnologies pose negligible or excessive risks.<sup>81</sup>

Once the decision has been made to allow the widespread use of a genetically engineered plant or microorganism, the regulatory agency should retain the capacity to monitor for the presence of the organism in the environment to determine whether it has unanticipated effects. Most likely, the amenability of a microorganism or plant to environmental monitoring will have to be genetically engineered into it at the outset.<sup>82</sup> Hence, the agency must have the authority to require the proponent of the technology to install this susceptibility to monitoring into the plant or microorganism.

### C. Risk Management

When risk assessments suggest that particular agricultural biotechnologies pose unacceptable risks, an adequate regulatory

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Office, Ecological Soc'y of Am.); *Planned Release Hearing*, *supra* note 3, at 31 (testimony of Ronald Cape, Chairman of the Bd. & Chief Executive Officer, Cetus Corp.) (favoring a case by case approach solely as an "interim necessity"); Harlow, *supra* note 39, at 555-56. *But see Planned Release Hearing*, *supra* note 3, at 91 (testimony of Robert M. Goodman, Vice President, Research & Dev., Calgene, Inc.) (arguing that a case by case approach "would result in shallow and redundant studies rather than the coherent, broadly based academic study that is called for").

81. See *Coordinated Framework Hearing*, *supra* note 3, at 71 (testimony of Monica Riley, American Soc'y for Microbiology); Harlow, *supra* note 39, at 555-56.

82. Genetically engineering a microorganism to facilitate monitoring may itself cause undesirable traits. For example, one of the most common techniques for facilitating monitoring is to design antibiotic resistance into a bacterium. Obviously, this trait is of concern in its own right, because it may impede efforts to destroy the organism. Mellon Comments, *supra* note 37.

regime must be capable of reducing or eliminating those risks. A wide variety of regulatory approaches exists to address the risks posed by dangerous technologies, ranging from outright bans to positive economic incentives. The general options available for the regulation of biotechnology have been addressed elsewhere, and that analysis will not be repeated here.<sup>83</sup>

There seems to be an evolving consensus in the regulatory agencies, the regulated industry, and environmental groups that the most appropriate regulatory control for large-scale release biotechnology is a permit system designed to impose regulatory requirements on a case by case basis.<sup>84</sup> The permitting agency can attach such conditions upon the manufacture, distribution, and use of the technology as are necessary to render the risks acceptable. Moreover, because genetically engineered microorganisms and plants can proliferate once released into the environment, it is probably appropriate to require a permit even before small-scale testing of genetically engineered plants and microorganisms outside of greenhouses. There is a good deal of debate, however, over whether the acceptability of the risk should be determined by explicit reference to the technology's benefits, or whether it should be determined by broad reference to other risks that society deems acceptable.<sup>85</sup>

The permitting approach may have the significant disadvantage of "freezing" safety-oriented controls into standard categories. This inflexibility can hinder future development of potentially useful agricultural biotechnologies. "Performance" standards, under which proponents of a technology need only ensure that its uses do not violate broad indicia of health and environmental harm, give the proponents of technologies greater flexibility. But the risk assessment art is not currently sufficiently sophisticated to allow an agency to arrive at precise criteria for adequate performance. Even if the agency could somehow arrive at an "acceptable" concentration of a microorganism or plant in the general environment, it is not clear that current monitoring technologies are capable of detecting them in the environment at "unacceptable" concentrations. A case by case permitting approach is probably necessary until scientists under-

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83. See McGarity & Bayer, *supra* note 39, at 482-97.

84. See Coordinated Framework, *supra* note 63, at 23,309; McGarity & Bayer, *supra* note 39, at 499-500. Under this approach, the regulatory agency would require the proponent of a particular agricultural biotechnology to obtain a permit upon a showing that the risks of its use were not unacceptable.

85. See generally M. DOUGLAS & A. WILDAVSKY, *RISK AND CULTURE* (1982); L. LAVE, *THE STRATEGY OF SOCIAL REGULATION* (1981); W. LOWRANCE, *OF ACCEPTABLE RISK* (1976).

stand agricultural biotechnologies well enough to set performance based standards.

#### D. Public Participation

Given the controversial history of biotechnology in the laboratory,<sup>86</sup> any regulatory decisions that result in a deliberate release of genetically engineered plants or microorganisms into the environment should be made only with the broadest possible public participation. Opponents of agricultural biotechnologies can easily conjure up visions of pandemics and ecological catastrophes, and such images have played no small role in past debates over the use of recombinant DNA techniques in academic laboratories.<sup>87</sup> The not so distant memories of attempts to dismantle the EPA and other health and environmental agencies during the early 1980's suggest that we are not at a high point in public trust in regulatory agencies.<sup>88</sup> To some extent, the crippling of the nuclear power industry after Three Mile Island is attributable to a lack of public confidence in the decisions of the Nuclear Regulatory Commission.<sup>89</sup> To avoid a similar distrust of regulators of agricultural biotechnology, representatives of the public must be given a direct role in the regulatory decisions.

Public participation can be burdensome to regulatory agencies, and it can delay regulatory decisionmaking. If the technology develops uneventfully, public attention will no doubt wane and delays will not plague the process. But at least initially, the relevant regulatory agencies must make affirmative efforts to ensure that public interest groups and individual members of the public are informed well in advance of important decisions and are given sufficient time and opportunity to make their views known. If significant segments of the public are convinced that the regulatory process is closed to them, the technology may not survive in this highly pluralistic society, however vast its potential long-run benefits.

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86. N. WADE, *supra* note 1; Swazey, Sorenson & Wong, *Risks and Benefits, Rights and Responsibilities: A History of the Recombinant DNA Research Controversy*, 51 S. CAL. L. REV. 1019 (1978).

87. See M. ROGERS, *supra* note 1; N. WADE, *supra* note 1.

88. See J. CLAYBROOK, *RETREAT FROM SAFETY* (1984); J. LASH, K. GILLMAN & D. SHERIDAN, *A SEASON OF SPOILS* (1984); S. TOLCHIN & M. TOLCHIN, *DISMANTLING AMERICA* (1983).

89. See J. TOMAIN, *NUCLEAR POWER TRANSFORMATION* (1987).

## IV. ADEQUACY OF EXISTING REGULATORY AUTHORITIES

Having identified some important elements of an adequate regulatory regime for agricultural biotechnology, we shall now examine the existing statutory authorities to determine the extent to which they provide sufficient authority to implement an adequate regulatory program. At the same time, we shall examine the proposed regulatory programs for agricultural biotechnology and ask whether the USDA and the EPA are likely to have the resources and, more importantly, the institutional willingness to implement an effective regulatory program.

Most of the relevant statutes address particular uses of technologies or particular adverse end points. For example, the FIFRA<sup>90</sup> provides authority to regulate substances intended to mitigate pests, but vests no authority in the EPA to regulate the very same substances if they are not intended for pest control. Similarly, the Virus-Serum-Toxin Act (VSTA)<sup>91</sup> applies only to biologics and microorganisms intended for use in the treatment of domestic animals. The Act of February 2, 1903,<sup>92</sup> and the Federal Plant Pest Act<sup>93</sup> give the USDA somewhat broader authority to regulate microorganisms, plants, and other organisms that cause animal and plant diseases, or otherwise directly or indirectly damage or injure plants. It would be surprising if this patchwork of statutes, without the protective umbrella of a gap-filling statute like the TSCA,<sup>94</sup> provided adequate authority to protect the environment from all of the risks of agricultural biotechnologies. Therefore, we should not be surprised to discover that when measured against the aforementioned elements of an adequate regulatory regime, there are several significant gaps that must be filled by the TSCA.<sup>95</sup> Unfortunately, we shall also discover that the TSCA itself applies only ambiguously to agricultural biotechnologies, and even under the EPA's fairly ambitious interpretation of that Act, some elements of an adequate regulatory regime are still missing.

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90. 7 U.S.C. § 136 (1982 & Supp. IV 1986).

91. 21 U.S.C. §§ 151-158 (1982 & Supp. III 1985).

92. *Id.* § 111 (1982).

93. 7 U.S.C. §§ 150-150jj (1982).

94. 15 U.S.C. §§ 2601-2629 (1982 & Supp. IV 1986).

95. Of course, any existing statutory gaps need not be filled at all, if the policymaker believes that the risks posed by agricultural biotechnologies do not warrant a complete regulatory regime. For reasons identified in Part I(B) *supra*, however, the public will probably not knowingly accept an incomplete regulatory process for these new technologies.

### A. Prerelease Notification

1. *Genetically engineered microorganisms*— The current statutory authorities for regulating genetically engineered microorganisms vary somewhat from those that address genetically engineered plants. In addition, the risks posed by microorganisms may not be the same as those posed by plants. The following analysis will therefore distinguish between microorganisms and plants.

a. *Pesticides*— The FIFRA provides that a pesticide may not be sold, distributed, or received by any person unless the pesticide is registered with the EPA.<sup>96</sup> The EPA would necessarily be informed of any lawful uses of genetically engineered microorganisms that were intended to kill or mitigate pests. Even experimental uses of potential pesticides must have a permit from the EPA.<sup>97</sup> For example, the EPA has recently issued an experimental use permit for a genetically engineered organism intended to replace a bacterium that facilitates frost formation.<sup>98</sup>

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96. 7 U.S.C. § 136a(a) (1982).

97. *Id.* § 136a(b)(2). The EPA may issue an experimental use permit allowing a potential registrant to gather data sufficient to obtain a full registration. *Id.* § 136c (Supp. IV 1986). In theory, the EPA must be made aware of all experimental uses. The Agency, however, has in the past exempted uses of unregistered pesticides on less than 10 acres from the experimental use permit requirement. 40 C.F.R. § 172.3 (1987). Nevertheless, in light of the novelty of genetic engineering, the EPA has decided to make the exemption inapplicable to microorganisms deliberately formed to contain genetic material from dissimilar source organisms and microorganisms containing genetic material from a similar source if any source organism is a pathogen. With one exception (for combinations in which the genetic material added to the recipient microorganism consists only of well-characterized, non-coding regulatory regions), such organisms will be subject to EPA review prior to any release pursuant to an experimental use permit. A "well-characterized, non-coding regulatory region" is a region on the DNA molecule that has been studied in sufficient detail so that it is known with a high degree of certainty that the region does not code for the production of a protein, peptide, or functional RNA molecules. *See* U.S. Evtl. Protection Agency, Statement of Policy; Microbial Products Subject to the Federal Insecticide, Fungicide, and Rodenticide Act and the Toxic Substances Control Act, 51 Fed. Reg. 23,313, 23,332 (1986) [hereinafter EPA Policy Statement]. All other genetically engineered pesticides will be subject to an abbreviated review prior to the issuance of an experimental use permit. Nonengineered microorganisms that are not pathogens and that are not indigenous will likewise be subject to abbreviated review. Only indigenous nonengineered nonpathogens may be released without any review at all. *Id.* at 23,316. Depending upon the quality of the review, this approach may be sufficiently protective. *But see infra* text accompanying notes 130-31 (criticizing the exemption for intergeneric transfers of well-characterized, non-coding regulatory regions).

98. *See* Foundation on Economic Trends v. Thomas, 637 F. Supp. 25 (D.D.C. 1986); ISSUES IN FEDERAL REGULATION REPORT, *supra* note 3, at 29-36.

*b. Veterinary biological products*— Under the VSTA as amended by the Food Security Act of 1985,<sup>99</sup> the USDA has established a permit program for all viruses, serums, and toxins intended for use in the treatment of domestic animals.<sup>100</sup> A person may not import, distribute, or ship such “veterinary biologics” unless produced in a licensed establishment under a USDA product license. To obtain a license, the USDA must be satisfied that the product is safe for the treated animals, humans, and the environment. Thus, the USDA should obtain prerelease notification of all commercial uses of veterinary biologics.

The USDA has recently proposed regulations providing for prerelease notice of experimental releases of potential veterinary biologics as well. The USDA’s current regulations prohibit the unauthorized use of “experimental biological products”<sup>101</sup> in facilities that are licensed for the production of biological products,<sup>102</sup> and they prohibit the interstate shipment of experimental products without authorization,<sup>103</sup> but they do not currently regulate the experimental use of a potential product in a laboratory that is not a facility licensed to produce biologics.<sup>104</sup> The Department’s recently proposed rules prohibit intrastate shipment of any unlicensed biological product for experimental use in animals, except that the USDA may authorize such shipments for testing in a limited number of animals.<sup>105</sup>

Although old veterinary biologics must generally be prepared in a licensed facility, the recent amendments to the VSTA, which gave the USDA authority over intrastate shipment, also provide that the Department shall by regulation exempt from the licensing requirement biologics prepared by a person or cor-

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99. Pub. L. No. 99-198, § 1404, 99 Stat. 1544 (codified at 7 U.S.C. § 3121 (Supp. IV 1986)).

100. The USDA’s current regulations, 9 C.F.R. §§ 101-123 (1987), apply only to veterinary biologics that are intended for import or use in interstate commerce, but the Food Security Act of 1985 amended the Virus-Serum-Toxin Act to give it authority over veterinary biologics intended for use in intrastate commerce. The USDA has recently announced its intention to amend its regulations to reflect this new authority. Final Policy Statement for Research and Regulation of Biotechnology Processes and Products, 51 Fed. Reg. 23,339 (1986).

101. The term “experimental biological product” is defined as “a biological product which is being evaluated to substantiate an application for a product license or permit.” 9 C.F.R. § 101.3(b) (1987).

102. *Id.* § 103.1.

103. *Id.* § 103.3.

104. Telephone interview with David Espeseth, Animal and Plant Health Inspection Service, USDA (Feb. 19, 1987) [hereinafter Espeseth Interview].

105. 51 Fed. Reg. 41,975, 41,977 (1986) (proposed amendments to 7 C.F.R. § 103.3).



poration: (1) solely for administration to animals of that person or companies, (2) solely for administration to animals by a licensed veterinarian, or (3) solely for distribution pursuant to an approved state licensing program. The regulations still prevent the shipment of any worthless, contaminated, dangerous, or harmful product, and producers of products containing live organisms must still provide any information the Department may require to assess the product's safety and effects on the environment.<sup>106</sup> But the Department would not necessarily receive notice of shipments of exempted products in intrastate commerce.

Clearly, the first two exemptions leave a potentially large gap in the USDA's notice requirements. The USDA would not necessarily receive notice of the preparation and shipment of an unlicensed veterinary biological by a company for experiments in its own animals; nor would it receive notice of an unapproved shipment and use by a licensed veterinarian as part of a treatment for a diseased animal. These exemptions may well undermine the otherwise applicable notice requirement for intrastate shipment of genetically engineered biologicals for experimental purposes. Because the USDA has not promulgated implementing regulations for the first (and potentially most important) exemption, it remains to be seen whether the prerelease notice aspect of the regulatory regime for veterinary biologicals is adequate. Finally, there has been some ambiguity in the USDA's approach to testing veterinary biologics in animals outside the confines of a laboratory. Early statements by responsible officials indicated that the agency did not regard testing in an animal to be a "release" of a genetically engineered microorganism into the environment, even if the animal was not within an enclosed building.<sup>107</sup> The Department's recently proposed regulations for experimental uses of animal biologics<sup>108</sup> and more recent statements of agency officials,<sup>109</sup> however, indicate that the agency will receive notice and have an opportunity to disapprove of any unexempted shipment of animal biologics for experimental purposes.

*c. Animal diseases*— Under the Act of February 2, 1903, and the VSTA, the USDA has established a permit regime for the import and interstate transport of all organisms that "may introduce or disseminate any contagious or infectious disease of

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106. *Id.* at 41,975, 41,978 (proposed amendments to 9 C.F.R. § 107.1).

107. *Coordinated Framework Hearing*, *supra* note 3, at 267-68; A. Carr, *supra* note 56, at 13.

108. 51 Fed. Reg. 41,975 (1986).

109. Espeseth Comments, *supra* note 10.

animals (including poultry)."<sup>110</sup> Although this requirement could ensure that the USDA is made aware of all imports and interstate transports of genetically engineered microorganisms, three aspects of the permit program cast considerable doubt on its adequacy.

First, the permit requirement as written only applies to *interstate* transport of genetically engineered microorganisms or vectors of such microorganisms. The Department's authority under the Act of February 2, 1903 extends only to interstate commerce. Although the Department's authority under the Virus-Serum-Toxin Act has been extended to intrastate commerce, it is unclear whether that statute applies to organisms that are not intended to cure diseases in animals. Even if that statute could be read so broadly, the agency has not amended its regulations to require permits for intrastate transport of microorganisms that might cause animal diseases. Thus, for example, the USDA would not necessarily become aware of inoculations of cattle with a genetically engineered microorganism derived from some deadly human or animal virus, as long as the responsible person did not propose to take the microorganism across state lines.

Second, the permit requirement is limited to organisms that "may" cause animal diseases, and this important threshold finding may be difficult to make in the abstract. Apparently, no prerelease testing is required to determine whether an organism "may" cause an animal disease and therefore be subject to regulation. The Department has not attempted to assemble a list of animal pathogens as it has proposed for plant pests;<sup>111</sup> rather, it tends to focus exclusively upon particular diseases for which Congress has established quarantine programs.<sup>112</sup> The USDA would generally not be aware of the creation of a novel organism that could cause animal diseases, unless informed by the manufacturer.<sup>113</sup>

Third, the permit requirement is only tangentially relevant to microorganisms that may be dangerous to wildlife. A permit would probably not be required for a microorganism that caused an infectious disease only in reptiles. The regulations by their

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110. 9 C.F.R. § 122.1(e) (1987).

111. See *infra* text accompanying notes 119-22.

112. Telephone interview with William Ketter, Animal and Plant Health Inspection Service, USDA (Feb. 26, 1987) [hereinafter Ketter Interview]. These official programs typically are created at the behest of the affected industry. The USDA devotes the bulk of its attention to writing permits for the import of animals that might be diseased. *Id.*

113. *Id.*

terms apply to diseases of all "animals (including poultry),"<sup>114</sup> but the program's primary focus is clearly upon commercially valuable species.

*d. Plant pests*— Under the FPPA,<sup>115</sup> the USDA has established a permit regime for microorganisms, plants, and other organisms that "can directly or indirectly injure or cause disease or damage in any plants or parts thereof."<sup>116</sup> Such organisms cannot be imported into or transported in the United States without a permit.<sup>117</sup> The Department may refuse to issue a permit when "such movement would involve a danger of dissemination" of plant pests.<sup>118</sup>

As part of the Coordinated Framework for Regulation of Biotechnology, the USDA has promulgated regulations governing manufacturers and importers of genetically engineered microorganisms that may be plant pests.<sup>119</sup> The USDA has defined "regulated article" to include

[a]ny organism which has been altered or produced through genetic engineering, if the donor organism, recipient organism, or vector, or vector agent belongs to any genera or taxa designated in [a long list of designated organisms] and 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 organism or product altered or produced through genetic engineering which the Deputy Administrator determines is a plant pest or has reason to believe is a plant pest.<sup>120</sup>

114. 9 C.F.R. § 122.1(e) (1987).

115. 7 U.S.C. § 150aa-150jj (1982).

116. *Id.* § 150aa(c).

117. *Id.* § 150bb(a).

118. *Id.* § 150bb(b).

119. Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which are Plant Pests or Which There is Reason to Believe are Plant Pests, 52 Fed. Reg. 22,892 (1987) (to be codified at 7 C.F.R. pts. 330, 340) [hereinafter Introduction of Organisms].

120. *Id.* at 22,908. The definition explicitly excludes "recipient microorganisms which are not plant pests and which have resulted from the addition of genetic material from a donor organism where the material is well characterized and contains only non-coding regulatory regions." *Id.*

The list includes a large proportion of agriculturally oriented hosts and vectors.<sup>121</sup> A permit is required before "regulated articles" may be released into the environment.<sup>122</sup>

The quoted definition of "regulated article" represents a significant retrenchment from the definition that the USDA originally proposed in 1986.<sup>123</sup> Under the proposed definition, a genetically engineered organism or product would be a "regulated article" if the host or vector was on the list. The Agency assumed that such organisms and products "can directly or indirectly injure" plants. This broad, but quite reasonable, interpretation of the words "can directly or indirectly injure" would have included organisms that have not caused any harm in the past but that could injure crops in the future.<sup>124</sup> The USDA thus proposed a generic rule identifying a broad class of genetically engineered microorganisms that could injure plants in the future if appropriate conditions were not placed on their movement through the permit process.

The legislative history of the FPPA indicates that Congress did not mean to require a high degree of certainty before empowering the USDA to protect plants. The House Report stressed the need to supplement existing quarantine statutes, because they did not "provide authority to regulate the movement into or through the United States of insects that might later be found to be injurious to cultivated crops."<sup>125</sup> It is, therefore, unlikely that a court would have overturned the USDA's cautiously broad reading of its own statute. At least one company apparently acquiesced in the USDA's authority to require prerelease notice of genetically engineered organisms that are on its plant pest list,<sup>126</sup> and the Industrial Biotechnology Associa-

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121. Medley Interview, *supra* note 53. For example, most researchers use a plasmid from a listed organism to transfer genes to agriculturally related microorganisms in their recombinant DNA research. *Id.* In addition, the "reason to believe" catchall phrase is meant to encompass a broad variety of potentially harmful activities based on scientific information, such as biological data and toxonomic association. *Id.*

122. *Id.* The term "release into the environment" is defined very broadly to include "[t]he use of a regulated article outside the constraints of physical confinement that are found in a laboratory, contained greenhouse, or a fermenter or other contained structure." Introduction of Organisms, *supra* note 119, at 22,908-09.

123. Introduction of Organisms, *supra* note 119, at 22,896.

124. The USDA has adopted this broader reading in the past to require permits for microorganisms that might cause damage, even when they have not been proven to do so. See *Coordinated Framework Hearing*, *supra* note 3, at 145 (testimony of Karen Darling, Deputy Assistant Secretary for Mktg. & Inspection Servs., USDA).

125. H.R. REP. No. 289, 85th Cong., 1st Sess. 3 (1957).

126. A company has requested a permit to field-test a genetically engineered microorganism that may have an enhanced capacity to fix nitrogen for legumes. Crawford, *supra* note 7, at 840; EPA Fact Sheet, *supra* note 7.

tion suggested that "only an obtuse interpretation of the [FPPA] could lead one to conclude that USDA does not have the authority to determine whether a novel organism is a plant pest."<sup>127</sup>

Nevertheless, many companies objected that the USDA could not presume that a genetically engineered organism or product might be a plant pest simply because the host or vector came from the list. In their view, the USDA could not require a permit absent an independent determination that the organism or product met the statutory definition of plant pest. The USDA acquiesced in this narrower view of its authority, and in the final rule, it defined "regulated article" to include only organisms and products containing listed hosts and vectors that also met the statutory definition of "plant pest."

Although it is certainly true that the USDA has no authority under the FPPA to regulate organisms and products that do not meet the statutory definition of "plant pest," its proposed generic approach was a sensible and lawful tool for implementing the "can directly or indirectly injure" test of the statutory definition. The narrower definition of "regulated article" in the final regulations begs the critical question of *who* makes the independent "plant pest" determination. Because the USDA has no way of knowing whether a novel organism has been created until a permit has been requested, it is apparent that in virtually all cases, the creator of the new organism will be responsible for making the "plant pest" determination. And because the USDA has no authority to require testing for adverse health or environmental effects until someone has applied for a permit, the creator is apparently free to make the independent "plant pest" determination based on whatever data it deems appropriate. The long list of hosts and vectors is thus merely a guideline to manufacturers of genetically engineered organisms and products. The net result is that the USDA cannot be certain that it will receive prerelease notice of all genetically engineered organisms and products that might harm plants. As a practical matter, the USDA may discover the existence of a genetically engineered plant pest only after it has caused damage.<sup>128</sup>

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127. *Coordinated Framework Hearing, supra* note 3, at 163.

128. Another substantive weakness of the notification system is a relatively important exemption for "non-pathogenic" organisms that have resulted from the addition of genetic material that is "well characterized" and contains only "non-coding regulatory regions." *Introduction of Organisms, supra* note 119, at 22,908. This exemption appears to apply to such well-known hosts as *Bacillus subtilis* and some forms of *Escherichia coli*, two workhorses of recombinant DNA biotechnology. The Department would not necessa-

It should be noted, however, that the final rule does not necessarily leave a gap in authority to provide prerelease notification. To the extent that the USDA does not receive notification, the EPA should receive a premanufacture notification under the TSCA.<sup>129</sup> Hence, by narrowing its own jurisdiction, the USDA has simply broadened the EPA's jurisdiction. To the extent that the EPA has the scientific expertise to evaluate the potential of genetically engineered organisms and products to harm plants and to the extent that manufacturers who determine that their organisms and products do not meet the "plant pest" definition understand that they must still give prerelease notification to the EPA, this may be acceptable. Whether one applauds or condemns the USDA's final rule, therefore, depends upon one's faith in the relative abilities of the USDA and the EPA to protect the environment without unduly inhibiting new technologies.

*e. Other uses*— Genetically engineered microorganisms that would not be regulated under any of the foregoing authorities may be subject to regulation under the TSCA, which provides for premanufacture notification to the EPA of all new "chemical substances."<sup>130</sup> The EPA has taken the position that microorganisms, other than those specifically exempted by statute,<sup>131</sup> are chemical substances.<sup>132</sup> This author has argued elsewhere that although the DNA within microorganisms can reasonably be characterized as a chemical substance, the EPA may be going too far in calling the entire microorganism a chemical substance.<sup>133</sup> In any event, the EPA's position is subject to legal

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rily be made aware of the introduction of exempted organisms, unless the responsible person applied for a courtesy permit pursuant to the proposed regulations. *Id.* at 22,913. For a critique of the same exemption under the TSCA, see *infra* text accompanying notes 130-31.

129. See *infra* text accompanying notes 130-52. There is, however, a potential gap if manufacturers look only to the USDA list and do not realize that even if they do not employ hosts and vectors on the list, they are still subject to TSCA premanufacture notification.

130. 15 U.S.C. § 2604 (1982). A chemical substance is a "new" chemical substance if it is not on the inventory of chemical substances that the EPA has compiled under § 8(b) of the Act. *Id.* § 2607(b).

131. The statute exempts from the definition of "chemical substance" substances that are manufactured, processed, or distributed for use as pesticides, foods, food additives, drugs, cosmetics, and medical devices. *Id.* § 2602(2)(B)(ii), (vi). The intent here was clearly to prevent overlap with the FIFRA and the FDA's regulatory authorities.

132. EPA Policy Statement, *supra* note 97, at 23,324.

133. McGarity & Bayer, *supra* note 39, at 506; see also *Coordinated Framework Hearing*, *supra* note 3, at 66 (testimony of Monica Riley, American Soc'y for Microbiology) (describing the EPA's interpretation as "strained").

challenge.<sup>134</sup> Perhaps out of concern for what might replace the current regulatory regime if the TCSA were held to be inapplicable to genetically engineered microorganisms, the biotechnology industry has not objected to the EPA's expansive reading of its statute.

The EPA has adopted a system for prerelease notification under the TSCA that mirrors the system that it has adopted under the FIFRA. The EPA will require prerelease notification for all microorganisms resulting from intentional, intergeneric combinations of genetic material, except those in which the transferred material is only a well-characterized, non-coding regulatory region. Microorganisms resulting from intrageneric combinations of genetic material are not considered to be "new" chemical substances and are, therefore, not subject to the statute's premanufacture notification requirements.

The EPA's rationale for these distinctions does not coincide well with the statutory language, but one of the exemptions may be compelled by practical necessity. A "new" chemical substance is defined by statute to be a substance that is not on the inventory of existing substances that the EPA compiled pursuant to section 2607(b) of the TSCA.<sup>135</sup> The EPA has included on this inventory a generic category of all "unprocessed," naturally occurring substances.<sup>136</sup> "Naturally occurring" organisms are those that "(1) exist as a result of natural events or processes, or (2) have been developed as a result of limited manipulation of natural processes."<sup>137</sup> Hence, the EPA has historically taken the position that the products of traditional breeding techniques are not "new chemical substances," even though the DNA may never have existed before as a chemical substance. The Agency has extended this logic to conclude that the products of intrageneric gene transfers accomplished through modern biotechnologies are not "new" chemical substances. The rationale for this position is largely administrative practicality—the Agency might otherwise be overwhelmed with premanufacture notices for relatively trivial transfers that pose no known risks to humans or to the environment. The Agency believes that such microorganisms have a very low probability of exhibiting new combinations of traits.<sup>138</sup>

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134. McGarity & Bayer, *supra* note 39, at 506.

135. 15 U.S.C. § 2602(9) (1982).

136. 40 C.F.R. § 710.4(b)(1)(i) (1987).

137. Environmental Protection Agency, Proposed Policy Regarding Certain Microbial Products, 49 Fed. Reg. 50,880, 50,888 (1984) [hereinafter Microbial Products].

138. EPA Policy Statement, *supra* note 97, at 23,317-18.

The Agency does, however, have plans to deal with intrageneric transfers of genetic material when the host organism is a pathogen or the transferred material is from a pathogen. Even though the EPA has concluded that such an organism would not be a new chemical substance, it plans to issue a "significant new use rule" under section 5(a)(2)<sup>139</sup> that would require the manufacturer to make the EPA aware of any planned releases, even in small field tests, except to the extent that the microorganism would already be subject to USDA review as a plant pest or animal pathogen.<sup>140</sup> This accommodation should adequately address the most dangerous of the products of intrageneric transfers.

The EPA's exclusion of microorganisms resulting from intergeneric combinations in which the transferred material is only a well-characterized, non-coding, regulatory region is less comprehensible.<sup>141</sup> Having concluded that it would be administratively feasible to include most intergeneric combinations, it is not likely that the excluded combinations would substantially ease the administrative burden. The Agency argues that such transfers present a "special case," because "[w]here only regulatory material is transferred, no distinctly new combinations of traits are introduced; instead, existing traits in the receiving microorganisms are amplified or changed quantitatively."<sup>142</sup> For this reason, the EPA concludes that the microorganisms are not new, even though they contain DNA from an entirely different genus.

This explanation is entirely unconvincing. Amplifying existing traits can have a very large impact on the characteristics of an organism from the standpoint of the receiving environment. For example, a microorganism may secrete a material that is toxic to seeds only during the first six hours of its existence, when it is not likely to come into contact with seeds. Transferring regulatory material that makes the organism synthesize the material throughout its lifetime might cause economic and environmental damage if the organism did come into contact with seeds later in its life cycle. In addition, an organism can be quite "novel," even though it is the product of an intrageneric transfer of only a well-characterized, non-coding, regulatory region:

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139. 15 U.S.C. § 2604(a)(2) (1982).

140. EPA Policy Statement, *supra* note 97, at 23,328-29.

141. The following critique applies equally to the same exemption under the FIFRA, *supra* note 97, and the FPPA, *supra* note 128.

142. EPA Policy Statement, *supra* note 97, at 23,325-26.



The major concern about engineered organisms is their novelty. The manipulation of regulatory elements—start and stop signals and modulators of the rate at which genes are synthesized—could conceivably introduce a significant degree of novelty that is independent of dissimilarity of gene products or pathogenicity. Even though the genetic engineer in such circumstances is confined to the same set of structural genes, he can use the regulatory elements to turn those genes on and off in different sequences, and to produce gene products in different amounts and in combinations with other gene products. The result could be an organism with a high degree of novelty.<sup>143</sup>

The EPA has also taken steps to demand prerelease notification of experimental uses of genetically engineered microorganisms, despite statutory restrictions on its ability to intrude into research and development activities. Section 5(h)(3) of the TSCA exempts from the premanufacture notification requirements manufacturing and processing chemical substances “in small quantities (as defined by the Administrator by rule)” solely for the purpose of scientific experimentation or research and development. The EPA has proposed to avoid this limitation by determining that no small-scale release of a genetically engineered microorganism for experimental purposes would be a release of a “small quantity,” because microorganisms can proliferate in the environment.<sup>144</sup>

A more difficult hurdle is the fact that the premanufacture notification requirements apply only to manufacturing or processing substances for “commercial purposes.”<sup>145</sup> Purely academic experimentation with no commercial purpose is exempt. Although any academic research sponsored by the federal government would be subject to the NIH guidelines,<sup>146</sup> deliberate releases into the environment in connection with privately sponsored academic research apparently could proceed without the EPA’s knowledge. This is a potential gap in coverage,<sup>147</sup> the

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143. *Coordinated Framework Hearing*, *supra* note 3, at 53 (testimony of Margaret Mellon, Director, Toxic Substances Program, Environmental Law Inst.).

144. EPA Policy Statement, *supra* note 97, at 23,330.

145. See 15 U.S.C. § 2604(i) (1982).

146. National Insts. of Health, *Recombinant DNA Research: Proposed Revised Guidelines*, 46 Fed. Reg. 59,368 (1981); see *supra* note 57.

147. See Natural Resources Defense Council, Inc., *Comments on Proposal for a Coordinated Framework for Regulation of Biotechnology 22* (Apr. 15, 1985) [hereinafter NRDC Comments].

significance of which depends upon the extent to which academic researchers plan deliberate releases in the future.<sup>148</sup>

The EPA has attempted to avoid overlapping regulatory requirements by exempting from TSCA review genetically engineered microorganisms that will be adequately reviewed by the USDA.<sup>149</sup> Thus, microorganisms intended solely for use as animal biologics and those subject to the FPPA's permit requirements would be exclusively regulated by the USDA. The EPA does plan to use the TSCA as a gap-filling authority, and to the extent that no other agency claims authority over genetically engineered microorganisms, the manufacturer may have to file a premanufacture notice with the EPA.<sup>150</sup> To be on the safe side, it would probably be desirable at first for manufacturers to file notices with both the EPA and the USDA.<sup>151</sup> The EPA and the USDA plan to meet frequently to address questions of overlapping authority.<sup>152</sup>

2. *Genetically engineered plants*— The regulatory regime currently in place for plants that might pose risks to the environment is not extensive. On its face, it is limited to plants that are plant pests or noxious weeds. Whether these two categories encompass all genetically engineered plants that might pose environmental risks is debatable.

a. *Plant pests and noxious weeds*— As we have seen, the FPPA establishes a permitting regime for "plant pests." That term is defined to include, inter alia, "bacteria, fungi, other parasitic plants or reproductive parts thereof . . . or any organisms similar to or allied with any of the foregoing . . . which can directly or indirectly injure or cause disease or damage in any plants or parts thereof."<sup>153</sup> The Noxious Weed Act<sup>154</sup> also establishes a permit system for the movement of "noxious weeds," which are defined to include:

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148. For example, universities often establish privately sponsored research "institutes" that might well come within this gap in coverage, because the research would not necessarily be in pursuit of any particular commercialization plan. See M. KENNEY, *BIO-TECHNOLOGY* 42-54 (1986).

149. EPA Policy Statement, *supra* note 97, at 23,317.

150. See *id.* at 23,318; Medley Interview, *supra* note 53.

151. In a recent case, the manufacturer of the genetically engineered bacterium with enhanced nitrogen fixing capabilities filed both a premanufacture notice with the EPA and a request for a Plant Pest Act permit with the USDA. Crawford, *supra* note 7, at 840; see EPA Fact Sheet, *supra* note 7. See generally ISSUES IN FEDERAL REGULATION REPORT, *supra* note 3, at 79 (describing overlapping authority).

152. Medley Interview, *supra* note 53.

153. 7 U.S.C. § 150aa(c) (1982) (emphasis added).

154. *Id.* §§ 2801-2813.

any living stage . . . of any parasitic or other plant of a kind, or subdivision of a kind, which is of foreign origin, is new to or not widely prevalent in the United States, and can directly or indirectly injure crops, other useful plants, livestock, or poultry or other interests of agriculture . . . or the fish and wildlife resources of the United States or the public health.<sup>155</sup>

As we have seen, the USDA's regulatory regime under the FPPA would put the USDA on notice of any movement of "regulated articles" for commercial or experimental purposes.<sup>156</sup> The USDA's recent regulations define "regulated article" to include listed plants that have been genetically engineered, and any plants that have been genetically engineered through the use of a listed vector or that contain genes from a listed plant or micro-organism, as long as they independently meet the statutory definition of "plant pest." Because the listed vectors include virtually all of the vectors that are currently used in recombinant DNA biotechnologies, this very broad definition of "regulated article" potentially includes most genetically engineered plants.<sup>157</sup>

A large measure of the breadth of the definition of "regulated article," insofar as it applies to plants, is due to the inclusion of listed vectors. If other technologies for inserting foreign DNA into plant cells, such as micropipetting, become available, genetically engineered plants that are not listed and do not receive DNA from listed organisms may not come within the definition of "regulated article," and they will fall outside of the USDA's notice requirement.

More importantly, the definition of "plant pest" in the FPPA is limited to "*parasitic plants*" or other organisms similar to or allied with parasitic plants. The only reference to plants that are plant pests in the statute is a reference to parasitic plants. The USDA has tacitly acknowledged this limitation in its list of potential plant pests, which contains only parasitic plants. A manufacturer of a genetically engineered plant, who under the final regulation must make an independent "plant pest" determina-

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155. *Id.* § 2802(c).

156. *See supra* text accompanying notes 115-17.

157. Comments of Michael Lidsky, Regulatory Specialist, Biotechnology and Environmental Coordination Staff, Animal and Plant Health Inspection Service, USDA (Apr. 22, 1987) (commenting on an earlier draft of this Article) [hereinafter Lidsky Comments]; Comments of Edward Raleigh, Manager, Biotechnology Regulatory Affairs, E.I. DuPont de Nemours & Co. (Apr. 6, 1987) (commenting on an earlier draft of this Article) [hereinafter Raleigh Comments].

tion, could make a very persuasive case for the proposition that genetically engineered plants that are not parasites are not plant pests.<sup>158</sup>

The Noxious Weed Act establishes a similar regulatory regime for the importation and interstate transport of noxious weeds, but it requires the Department to promulgate a list of noxious weeds for which permits are required. There must be an opportunity for a public hearing before a plant is added to the list, and a plant may not be added unless the Department determines that the plant meets the definition of noxious weed *and* "that its dissemination in the United States may reasonably be expected to have, to a serious degree, any effect specified in [the definition of 'noxious weed']."<sup>159</sup> This latter limitation, which is contained in another section of the statute, may have the practical effect of precluding the Department from establishing a broad precatory permit system for nonparasitic plants that may cause damage to crops or wildlife.<sup>160</sup> The Department has not attempted to erect a regulatory program under its Noxious Weed Act authority for genetically engineered plants.<sup>161</sup> Acknowledging that it does not generally act to stop the spread of a noxious weed until the weed has done some economic damage, the Department has not stressed the Noxious Weed Act in describing its statutory authority.<sup>162</sup>

Absent any comprehensive permitting process, it seems clear that the Department will not receive prerelease notification of all genetically engineered plants; nor will it even receive prerelease notice of all genetically engineered plants that may turn out to be plant pests or noxious weeds.<sup>163</sup> The regulatory regime

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158. The USDA could perhaps argue that genetically engineered nonparasitic plants might come within the definition of "plant pest" because they are "similar to or allied with" parasitic plants. This argument is only plausible if there is some factual basis for concluding that genetically engineering a nonparasitic plant through a listed vector or by inserting DNA from a listed organism may turn the nonparasitic plant into a plant similar to or allied with a parasitic plant. The author is unaware of any factual information (or even reasoned speculation) that would support such an inference.

159. 7 U.S.C. § 2809 (1982).

160. See NRDC Comments, *supra* note 147, at 26.

161. The USDA has received and approved one application for a permit to release a genetically engineered tobacco plant into the environment for experimental purposes. GAO USDA REPORT, *supra* note 4, at 38. Because the tobacco plant was not likely to be a plant pest, the USDA issued an opinion letter under the FPPA indicating that field-testing the plant would not cause the introduction or dissemination of plant pests.

162. See *Coordinated Framework Hearing*, *supra* note 3, at 149 (testimony of Karen Darling, Deputy Assistant Secretary for Mktg. & Inspection Servs., USDA).

163. See *Planned Release Hearing*, *supra* note 3, at 177-79 (colloquy between Rep. Volkmer and John Patrick Jordan, Administrator, Cooperative State Research Serv.,

is, therefore, inadequate for this purpose.<sup>164</sup> Whether the potential risks of genetically engineered plants, which in the opinion of most experts are not as high as the risks of genetically engineered microorganisms, warrant a more thorough notice requirement is a matter for congressional attention.

*b. Applicability of the TSCA to plants*— The EPA has apparently recognized that it would have to stretch the words “chemical substance” beyond recognition to apply the TSCA to genetically engineered plants.<sup>165</sup> Hence, the EPA cannot provide the gap-filling role for genetically engineered plants that it proposes to play for genetically engineered microorganisms. Any gaps in the USDA’s authorities are likely to be gaps in all regulatory authority.

## *B. Data Collection, Data Evaluation, and Risk Assessment*

*1. Genetically engineered microorganisms*— Once again, it is appropriate to distinguish between genetically engineered microorganisms and genetically engineered plants in evaluating the adequacy of existing authorities for collecting and evaluating data and assessing risks.

*a. Pesticides*— To obtain a pesticide registration, the potential registrant must supply extensive information to the EPA on the pesticide’s identity, its environmental fate, its potential toxicity to humans and other animals, and its potential for ecological disruption.<sup>166</sup> Although the state of the risk assessment art for genetically engineered microorganisms is still too primitive to know definitively if the tests that the EPA requires will provide adequate data, they are a satisfactory starting point, and they should serve as a guide to other agencies.

The foregoing registration requirements do not apply to experimental uses of pesticides. Because even small-scale experimental uses of genetically engineered microorganisms might result in the proliferation of pathogenic organisms, however, a rudimentary risk assessment may be necessary before experimental uses are allowed. The Agency’s statute provides for “ex-

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USDA, in which Dr. Jordan admits that the USDA will not receive prerelease notification of all genetically engineered plants).

164. See NRDC Comments, *supra* note 147, at 26.

165. EPA Policy Statement, *supra* note 97, at 23,324.

166. The EPA has promulgated requirements for testing microbial pesticides, and these are constantly being reexamined to meet changing needs. 40 C.F.R. §§ 158.165, 158.170, 162.163 (1987).

perimental use permits" for this limited purpose.<sup>167</sup> Although the Agency has in the past exempted from the experimental use permit requirements applications of a pesticide to less than ten acres of land or one acre of water,<sup>168</sup> the Agency has determined that genetically engineered microorganisms should not have a complete exemption, even for such limited applications. The EPA has therefore decided to require potential registrants to submit at least some information prior to any experimental use of genetically engineered pesticides.<sup>169</sup> The Agency has, however, distinguished between one class of pesticides that the Agency believes warrants particularly close attention and all other genetically engineered pesticides.

Pesticides formed by deliberately combining genetic material from organisms of different genera, and genetically engineered pesticides derived from source organisms that are pathogens, must undergo so-called "Level II" review before the EPA decides whether to require an experimental use permit for small-scale releases. Level II review requires the submission of fairly extensive information on the identity of the microorganism, its genetic composition, the survivability of the host organism, its potential for genetic exchange with wild microorganisms, its pesticidal activity, the location of the test, and the differences between the test site and the natural habitat of the host organism.<sup>170</sup> Although it is difficult to tell whether the information that the EPA requires is sufficient for a preliminary determination of risk, it is an important first step.

All other genetically engineered pesticides must undergo only "Level I" review, which requires much less extensive information, prior to small-scale field testing. The EPA has only thirty days to review a Level I application. If it makes no objection within that time period, small-scale experimental use is permitted. The EPA has determined that genetically engineered microorganisms that do not involve the exchange of genetic information across genera are not sufficiently likely to result in new combinations of traits to warrant a high degree of attention. Therefore, it does not require the same amount of information for such pesticides. Indeed, the Agency has concluded that most potential registrants should have to go to no extra effort to secure the information necessary for Level I review.<sup>171</sup>

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167. 7 U.S.C. § 136c (1982).

168. 40 C.F.R. § 172.3(a) (1987).

169. See *Foundation on Economic Trends v. Thomas*, 637 F. Supp. 25 (D.D.C. 1986).

170. EPA Policy Statement, *supra* note 97, at 23,321-24.

171. *Id.* at 23,321.

In sum, it appears that the EPA has the ability to gather extensive information on all genetically engineered pesticides prior to sale or use in commerce and prior to large-scale testing. In addition, the Agency plans to gather fairly extensive data on most genetically engineered pesticides prior to small-scale testing. The only possible weakness in the scheme is the reduced data requirements for determining whether full experimental use permits will be required for Level I pesticides. It is not very likely, however, that this weakness will prove very important, because the vast majority of genetically engineered pesticides will probably be derived from some organisms that are pathogens.<sup>172</sup>

The EPA is slowly assembling a staff with expertise in evaluating the information that the companies will be submitting for registrations and experimental use permits. The EPA currently devotes approximately ten staff persons with training in microbial ecology, microbiology, and plant pathology to reviewing data on genetically engineered pesticides, and that number may well expand as demand for data reviews increases.<sup>173</sup>

Although the Agency will develop a full record for each decision to grant a full registration for a pesticide, it does not compile a full record for all experimental use permits. The Agency has, however, agreed to provide a written scientific position for each Level II proposal that identifies potential problems or significant unanswered questions after soliciting comments from a work group in the EPA and from other federal agencies.<sup>174</sup> Finally, if an application for an experimental use permit raises "complex or controversial scientific questions,"<sup>175</sup> the Agency will provide its notification package and its scientific evaluation to a group of independent scientists constituted as a subpanel of its existing Scientific Advisory Panel for pesticides, and some questions may, in turn, come under the scrutiny of the agency-wide Biotechnology Scientific Advisory Committee.<sup>176</sup> The thorough review that the EPA undertook in connection with its decision to approve an experimental use permit for the "ice minus" bacterial pesticide indicates that the EPA has the capacity to evaluate the scientific information that is necessary to an in-

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172. Raleigh Comments, *supra* note 157.

173. Telephone interview with Fred Betz, Supervisory Biologist, Hazard Evaluation Division, Office of Pesticides Programs, EPA (Nov. 25, 1987).

174. EPA Policy Statement, *supra* note 97, at 23,322.

175. *Id.* at 23,323.

176. Raleigh Comments, *supra* note 157.

formed decision.<sup>177</sup> Whether the Agency will subject future pesticides to such extensive review remains to be seen.

Although the EPA is currently sponsoring some research into risk assessments for genetically engineered pesticides, it has not developed satisfactory risk assessment models to use in evaluating permit applications. It is unclear how the EPA will determine the risks of a particular release. At present, the Agency has adopted a case by case approach to assessing the risks of individual permit applications, the critical elements of which are the scientific and policy judgments of the EPA's staff. Thus, whether or not an adequate regulatory regime exists for evaluating industry-submitted data and assessing risks for genetically engineered pesticides depends upon the confidence that one has in the scientific integrity and policy judgment of the EPA's personnel.

*b. Veterinary biological products*— The USDA has established fairly elaborate testing requirements for veterinary biologics to ensure that products meet the statutory criteria for purity, safety, potency, and efficacy.<sup>178</sup> In particular, "Master Seed" of bacteria, viruses, or other microorganisms must be approved by the USDA for use in the manufacture of veterinary biologics. Primary cell lines used for the production of Master Seed must be tested to demonstrate that they are free of bacteria, fungi, mycoplasma, viruses, and other extraneous agents. Tumorigenicity and oncogenicity tests must be conducted on cell lines if direct or indirect evidence indicates that the cell may induce malignancies in the species for which the product is intended.<sup>179</sup> The regulations do not explicitly require testing if there is no such evidence.<sup>180</sup> Most products must be tested in mice for seven days to detect any adverse effects,<sup>181</sup> and they must also undergo specific field tests.<sup>182</sup>

The USDA does not propose to treat genetically engineered veterinary biological products differently from products produced through other means. It has promised to evaluate each

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177. See *Foundation on Economic Trends v. Thomas*, 637 F. Supp. 25 (D.D.C. 1986).

178. 9 C.F.R. § 113 (1987); see *Coordinated Framework Hearing*, *supra* note 3, at 126 (testimony of Karen Darling, Deputy Assistant Secretary for Mktg. & Inspection Servs., USDA).

179. 9 C.F.R. § 113.52(h) (1987). Indirect evidence might come from required and host animal tests for other purposes. Espeseth Comments, *supra* note 10.

180. In practice, the Animal and Plant Health Inspection Service in the USDA refers biologics that might leave residues in beef or milk to the Food Safety and Inspection Service for further input. Espeseth Interview, *supra* note 104.

181. 9 C.F.R. § 113.33(b)(1) (1987); Espeseth Interview, *supra* note 104.

182. Espeseth Interview, *supra* note 104.



product on a case by case basis, and it may require additional tests when live microorganisms are present in the biological products.<sup>183</sup>

Although the USDA's regulations prohibit the shipment of experimental biologics without a license, the Department has not followed the EPA's lead in promulgating special regulations governing licenses for experimental uses of veterinary biologics. The Department proposes to deal with license applications on a case by case basis. Typically, the Department requires biologics to be tested in controlled field settings, subject to quarantines, prior to licensing a product.<sup>184</sup> Whether this approach is adequate depends almost entirely upon the degree of confidence one has in the officials in charge of experimental use licensing.

The USDA currently has a staff of seven veterinarians and one biometrician to evaluate biologic license applications. The staff also includes two persons with Ph.D.'s in microbiology, and one of these has had recombinant DNA research experience. Three of the veterinarians have Masters degrees in microbiology or related fields. The Department also hopes to employ an environmental scientist in the near future to prepare environmental assessments for license applications.<sup>185</sup> This staff currently handles a workload of approximately 150 license applications per year.<sup>186</sup>

The USDA has created no formal mechanism for peer review of information submitted in connection with license applications.<sup>187</sup> However, the USDA staff refers questions on licensing data to a separate staff at a USDA laboratory in Ames, Iowa. That laboratory performs separate tests to confirm the data prior to licensing new products.<sup>188</sup> Finally, data supporting any permit applications for live recombinant microorganisms and environmental assessments for such permits must be submitted to a recently established Veterinary Services Biotechnology Com-

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183. *Id.*; U.S. Department of Agriculture, Final Policy Statement for Research and Regulation of Biotechnology Processes and Products, 51 Fed. Reg. 23,336, 23,340 (1986) [hereinafter USDA Policy Statement].

184. Espeseth Interview, *supra* note 104. The Department's chief concern is that a modified live organism that is used to convey immunity to such organisms does not revert over several generations to the virulent form. So far, such a reversion to a virulent form has never been documented.

185. *Id.*

186. *Id.* The USDA has granted a total of 70 establishment licenses and approximately 1500 product licenses for veterinary biologics. *Coordinated Framework Hearing*, *supra* note 3, at 125 (testimony of Karen Darling, Deputy Assistant Secretary for Mktg. & Inspection Servs., USDA).

187. Espeseth Interview, *supra* note 104.

188. *Id.*

mittee,<sup>189</sup> but this committee is primarily engaged in reviewing broad policy questions, rather than individual data submissions.

The current data requirements for veterinary biologics seem adequate for products produced through conventional techniques. Whether they are adequate for genetically engineered biologics depends on the validity of the USDA's assumption that their risks do not differ significantly from those of conventional biologics and on the ability of USDA officials to detect individual instances where more testing is necessary.

The USDA has not developed generic risk assessment methodologies for veterinary biologics. In practice, the Department relies heavily upon small-scale field tests. If the biologic has any adverse effects on the test animals, it will probably not be licensed. The agency conducts periodic follow-up studies of treated animals to determine if a biologic causes side effects in sensitive subpopulations.<sup>190</sup>

The Department has devoted little attention to risks that veterinary biologics might pose to nontarget wildlife species. It believes that the host species is usually the most susceptible species to the microorganism that is the target of the vaccine, because most microorganisms have a limited host range. However, the Department will generally require data to evaluate host range for live genetically engineered vaccines before approving field trials.<sup>191</sup> Tests in laboratory rodents increase the Department's confidence in the results of the small-scale tests. Finally, even assuming that a nontarget species was affected by a biologic, the most likely outcome would be that the nontarget animal would be immunized against the target microorganism.<sup>192</sup> The Department does, however, plan to consider effects on nontarget species to some extent in preparing environmental assessments for genetically engineered biologics.<sup>193</sup>

c. *Animal diseases*— The USDA does not require applicants for permits for interstate transport of microorganisms causing animal diseases to undertake any particular testing regime;<sup>194</sup> nor has the USDA identified models for assessing the risks of particular microorganisms.<sup>195</sup> The USDA has not even published

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189. *Id.*

190. *Id.*

191. Espeseth Comments, *supra* note 10.

192. Espeseth Interview, *supra* note 104.

193. Lidsky Comments, *supra* note 157.

194. Ketter Interview, *supra* note 112.

195. The USDA does conduct its own tests for imported microorganisms and vectors of microorganisms at its Foreign Animal Disease Diagnostic Laboratory in Plum Island, New York. See USDA Policy Statement, *supra* note 183, at 23,341.

a list of microorganisms that are known to cause diseases in animals. Although such a list would not necessarily be definitive, it could aid genetic engineers by making them aware of hosts and vectors that might be suspect. As the regulations now read, it is apparently up to the manufacturer or transporter to determine whether its genetically engineered microorganism is capable of causing disease in animals, and the USDA's regulations do not prescribe any procedures for finding out whether a genetically engineered microorganism should be so characterized. To the extent that the manufacturer does not voluntarily produce data, it will not be forthcoming. This aspect of the USDA's regulatory regime is entirely inadequate as a mechanism for evaluating the capacity of genetically engineered microorganisms to cause diseases in animals. Once again, the EPA will have to use its TSCA powers to play a gap-filling role.

*d. Plant pests*— The current regulatory regime for ordinary plant pests does not contain any data-gathering requirements.<sup>196</sup> Agency scientists, in reviewing permit applications, rely primarily upon an extensive world literature on plant pests.<sup>197</sup> The literature is examined for pests of wild plants, as well as for pests of domestic crops.<sup>198</sup> Because the USDA has in the past authorized the movement of plant pests only for experimental purposes,<sup>199</sup> it is probably understandable that the Department has not specified particular data-gathering requirements for permits. The USDA's recent regulations requiring permits for "regulated articles,"<sup>200</sup> however, has required the Department to implement new information gathering requirements for genetically engineered microorganisms.

To obtain a permit under the proposed regulations, the applicant must submit descriptions of the expression of the modified organism, the purpose for its introduction into the environment, the country or locality of origin of the donor organism, and the processes, procedures, and safeguards that would be used to prevent contamination, release, and dissemination of donor or-

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196. The applicant for a permit must submit information about the nature of the pest, the method of shipment, and mitigation measures, but this information is usually readily available without additional data gathering efforts. 7 C.F.R. § 330,201 (1987).

197. Telephone interview with Arnold Foudin, Animal and Plant Health Inspection Service, USDA (Mar. 2, 1987) [hereinafter Foudin Interview].

198. *Id.*

199. See Microbial Products, *supra* note 137, at 50,901. The USDA does allow some movement of plant pests for nonexperimental purposes. For example, some beneficial biocontrol agents are also plant pests, but the Department still issues permits for them because their benefits outweigh the risks. Foudin Interview, *supra* note 197.

200. See *supra* text accompanying notes 115-24.

ganisms, recipient organisms, and vector or vector agents into the environment.<sup>201</sup> The proposed regulations do not, however, require any specific testing for potential damage to plants or animals. The Department will consult the world literature on the potential pathogenicity of the host organism and its ability to survive in particular environments, but there are no standard protocols for evaluating the potential pathogenicity of particular microorganisms, and the Department has no plans to design any protocols.<sup>202</sup>

The Department may require additional testing on a case by case basis. Although such testing requirements will focus primarily upon crop plants, such tests may well reveal risks to other wild plants.<sup>203</sup> The USDA will probably not, however, require specific tests to evaluate risks posed to wild plants, unless something in the current literature suggests a reason for doing so.<sup>204</sup>

The proposed regulations give no indication of the nature of the risk assessment that the agency will employ in issuing permits. Despite criticism for failing to support risk oriented research,<sup>205</sup> the Department has not developed any risk assessment models, and agency scientists are unaware of any models for predicting plant pathogenicity of genetically engineered microorganisms.<sup>206</sup> USDA scientists intend to apply their own experience on a case by case basis to determine the pathogenic potential of particular regulated articles.<sup>207</sup>

The USDA employs nine professionals to evaluate permit applications. Most are specialists in plant pathology, but the group also includes a microbiologist and a geneticist.<sup>208</sup> The staff evaluates between one and three applications per week, but most of the applications involve easily evaluated permits for movement of pests from one place to another, rather than for deliberate releases into the environment.<sup>209</sup> Because the agency expects a "tidal wave" of permit applications in the near future, it is at-

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201. Introduction of Organisms, *supra* note 119, at 22,911.

202. Foudin Interview, *supra* note 197.

203. *Id.*; Medley Interview, *supra* note 53.

204. Foudin Interview, *supra* note 197.

205. See *infra* text accompanying note 255.

206. Foudin Interview, *supra* note 197.

207. *Id.*

208. *Id.*; see also *Coordinated Framework Hearing*, *supra* note 3, at 126-27 (testimony of Karen Darling, Deputy Assistant Secretary for Mktg. & Inspections Servs., USDA) (describing overall resources available to the USDA for plant protection and quarantine).

209. Foudin Interview, *supra* note 197.

tempting to boost its staff to at least twenty-five professionals.<sup>210</sup> Whether that number will be sufficient remains to be seen.

If a permit application raises no questions that cannot easily be answered by USDA staff and if it raises no "controversial" scientific questions, the permit decision is made without peer review. When peer review is necessary, the question is referred to a "parent committee," composed of scientists drawn from across the Department, for advice.<sup>211</sup> The recently established Departmentwide Agriculture Biotechnology Recombinant DNA Advisory Committee is also available to offer scientific advice for genetically engineered plants and microorganisms.<sup>212</sup>

*e. Other uses*— The TSCA gives the EPA authority to require manufacturers of chemical substances to make information available to the Agency for risk assessments. The EPA has interpreted the premanufacture notification requirement, discussed previously,<sup>213</sup> to give it authority to require companies to submit a minimum data base to allow the Agency to determine whether it should object to the distribution of the substance during the ninety-day period that the Agency has to evaluate the premanufacture notice.<sup>214</sup> On the assumption that, in the absence of data to the contrary, all microorganisms may present a risk because of their potential to reproduce and exhibit new traits, the Agency requires general background information on the source organism and some limited test data on the organism indicating its potential for survival, replication, dissemination, and genetic exchange with other organisms.<sup>215</sup> In addition, man-

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210. *Id.*

211. *Id.*

212. See *Coordinated Framework Hearing, supra* note 3, at 111-17 (testimony of Orville Bentley, Assistant Secretary for Science & Educ., USDA); *Planned Release Hearing, supra* note 3, at 55 (testimony of Robert M. Goodman, Vice President, Research & Dev., Calgene, Inc.) (describing scientific resources available to the USDA).

213. See *supra* text accompanying notes 132-34.

214. To place genetically engineered microorganisms on its inventory, the EPA requires specific information on the organisms, including source organisms, methods used to manipulate source organisms, and the special functions obtained by the manipulation. In addition, the EPA requires manufacturers to submit information on deliberately released microorganisms relevant to risk assessment, including the purpose and intended effect of the application, site of application, numbers of microorganisms and methods of application, containment and mitigation measures, and monitoring. EPA Policy Statement, *supra* note 97, at 23,327.

215. *Id.*; see *Coordinated Framework Hearing, supra* note 3, at 133 (testimony of John Moore, Assistant Adm'r for Pesticides & Toxic Substances, EPA). The authority for this stance is 15 U.S.C. § 2604(b)(2) (1982), which requires manufacturers to submit with their premanufacture notices data that show that the substance will not present an unreasonable risk of injury to health or to the environment. The EPA plans to require similar data under a significant new use rule for microorganisms that are the products of

ufacturers have a duty, independent of any EPA request, to maintain records of "significant adverse reactions to health or the environment" alleged to have been caused by a chemical substance, and the EPA may inspect such records.<sup>216</sup>

Beyond acquiring this minimum data set, the Agency also has authority to prevent the distribution and use of a chemical substance that is the subject of a premanufacture notice, pending the development of additional information. The EPA may do so if it determines that "the information available to the [Agency] is insufficient to permit a reasoned evaluation" of its health and environmental effects, and either the substance may present an unreasonable risk of injury to health or the environment in the absence of such information, or the substance will be produced in substantial quantities and may reasonably be anticipated to enter the environment in substantial quantities or there may be significant human exposure to the substance.<sup>217</sup> It may be relatively easy for the Agency to make such determinations early in the evolution of agricultural biotechnologies because any significant release of a genetically engineered microorganism into the environment will ultimately be produced in substantial quantities and enter the environment in substantial quantities.

A major weakness in this data-gathering authority is the procedure that the Agency must use if a manufacturer is not cooperative. The order prohibiting or limiting the use of the substance pending required testing does not become effective for thirty days, during which time the manufacturer may file objections. If an objection is filed, the order does not go into effect, and the Agency must sue in a federal district court for an injunction to prohibit or limit the use of the substance, pending the submission of the required information.<sup>218</sup> This ponderous process provides a great disincentive to issuing data-gathering orders.<sup>219</sup>

Because the EPA's TSCA implementation program has in the past been exclusively devoted to regulating chemicals, the EPA

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intrageneric transfers of genes from a pathogen to a nonpathogen or of genes from a nonpathogen to a pathogen. EPA Policy Statement, *supra* note 97, at 23,330.

216. 15 U.S.C. § 2607(c) (1982).

217. *Id.* § 2604(e).

218. *Id.* § 2604(e)(B)-(C).

219. See NRDC Comments, *supra* note 147, at 21. The EPA also has broad authority to require testing of chemical substances under § 4 of the TSCA, 15 U.S.C. § 2603 (1982), but this authority has rarely been exercised, and it will not be available in any event until the microorganism is already out in the environment. Still, it does provide authority for the EPA to require follow-up data gathering after the microorganism has been released.

does not presently have a large staff of people trained in evaluating the risks of genetically engineered microorganisms. At this point the Office of Toxic Substances includes two microbial geneticists, two molecular biologists, two microbial ecologists, and one plant pathologist.<sup>220</sup> The Agency has established a Biotechnology Scientific Advisory Committee to provide technical advice, and it plans to supplement its staff with experts from other government agencies, academia, and other independent sources to help in evaluating the quality of health and safety data for genetically engineered microorganisms.<sup>221</sup>

The EPA has not crafted any particular risk assessment models for biotechnology. The Agency has suggested that some of the risk assessment approaches that it has found useful for nonengineered microbial pesticides will be relevant to genetically engineered microorganisms, but it acknowledges that these models may have to be adapted to address special problems.<sup>222</sup> Although it has developed a research plan to identify risk assessment models for biotechnology,<sup>223</sup> the Agency has adopted a case by case approach to risk assessment in the near term.<sup>224</sup>

2. *Genetically engineered plants*— The FPPA provides an adequate regime for plants that are plant parasites, with the caveats already mentioned in connection with microorganisms.<sup>225</sup> For other genetically engineered plants, only the Noxious Weed Act is available. Although that statute would allow the USDA to require information about a noxious weed prior to obtaining a permit to transport it, there is no vehicle for forcing the manufacturer of a genetically engineered plant to run tests to determine whether it is likely to be a noxious weed.<sup>226</sup> The Department has taken no action to require submission of information

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220. Telephone interview with Mark Segal, Senior Scientist, Chemical Review and Evaluation Branch, Health and Environmental Review Division, Office of Toxic Substances, EPA (Dec. 19, 1987); Telephone interview with Jane Rissler, Director, Biotechnology Division, Office of Toxic Substances, EPA (Mar. 10, 1987).

221. This built-in flexibility to change the scope of regulation as more knowledge is gained about genetically engineered plants and microorganisms is critical, but it must be exercised in a public forum. The matter is important enough to warrant notice and comment rulemaking procedures. EPA Policy Statement, *supra* note 97, at 23,328.

222. *Id.*

223. See *Planned Release Hearing*, *supra* note 3, at 160-61 (testimony of John Moore, Assistant Adm'r for Pesticides & Toxic Substances, EPA).

224. EPA Policy Statement, *supra* note 97, at 23,328.

225. See *supra* text accompanying notes 196-207. If the USDA is correct in interpreting "plant pest" broadly to include nonparasitic plants, see *supra* text accompanying note 158, then the regime comes much closer to the ideal for genetically engineered plants. As previously discussed, however, this ambitious interpretation is not likely to withstand judicial challenge.

226. See *supra* text accompanying notes 159-62.

about genetically engineered plants that are not on its existing list of noxious weeds except for those weeds that are parasitic plants. The current regulatory regime is, therefore, unable to regulate adequately nonparasitic plants.

### C. Risk Management

1. *Genetically engineered microorganisms*— Just as it is appropriate to distinguish between plants and microorganisms in assessing risks, it makes sense to draw the same distinction in deciding how society will manage those risks. Different technologies are available to reduce the risks of plants and microorganisms, and different techniques are available to avoid unnecessary exposures.

a. *Pesticides*— The licensing system for pesticides is the EPA's primary risk management tool. The operative legal document is the label on the licensed pesticide. The EPA manages pesticide risks primarily through its initial licensing decisions (and some fairly rare pesticide cancellation actions) and through conditions that are specified on the pesticide label.<sup>227</sup>

Less stringent regulatory controls apply to experimental use permits. Although the EPA must approve Level II small-scale testing, an applicant for a permit for a small-scale Level I test may commence testing after thirty days if the EPA does not object. The EPA has promulgated no specific regulatory criteria for granting experimental use permits for genetically engineered microorganisms, electing instead to deal with applications on a case by case basis.<sup>228</sup> As it acquires more experience with such permit applications, the Agency should attempt to identify generic criteria and attempt to make the process more standardized.

b. *Veterinary biological products*— Like the pesticide risk management regime, the statutory mechanism for veterinary biologics relies heavily upon a license system. The USDA has very few constraints on its authority to condition establishment and product permits on compliance with safety related requirements. The USDA also has in place a regime for authorizing experimental uses of veterinary biologics. Although the Department will license a biological product when it is shown that the benefits of

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227. For example, the EPA can specify on the label that a pesticide may only be used by applications that are certified by the EPA or the states. 7 U.S.C. § 136(b) (1982).

228. See NRDC Comments, *supra* note 147, at 18-19.



particular uses outweigh the risks,<sup>229</sup> it takes the position that any risk is unacceptable if a safer substitute exists.<sup>230</sup> In addition, the Department attempts to impose management practices that minimize any remaining risks.<sup>231</sup> Except for the previously discussed exemption for intrastate use of experimental biologics in nonlicensed facilities, the USDA regime seems to provide adequate risk management authority.

*c. Animal diseases*— The permit regime for animal diseases gives the USDA open-ended authority to condition permits upon safety precautions. The regime would therefore be adequate for agricultural biotechnologies if it were capable of defining the universe of microorganisms to which it applied. As we have seen,<sup>232</sup> however, the regulatory regime for animal diseases does not contain any prerelease testing requirements. Until the USDA becomes aware of the disease-causing propensities of a genetically engineered microorganism, the permit requirement is essentially irrelevant. As a practical matter, the USDA is not likely to discover that a genetically engineered microorganism is capable of causing animal disease until it has already caused some damage. Moreover, it is not clear that the Department will aggressively use its authority to protect noncommercially useful species, such as reptiles or insects.

*d. Plant pests*— The Department has adopted a permitting approach for managing the risks of genetically engineered microorganisms that are plant pests. Although the FPPA is not explicit as to the standard to be applied in awarding permits for the transport of plant pests, the Department has taken the position that no risks to plants should be allowed unless they can be adequately managed.<sup>233</sup> For example, even when benefits outweigh risks, the Department insists, to the extent possible, that risks be mitigated.<sup>234</sup> For example, the permitting officers attempt to ensure that microorganisms contain some kind of “switch” that allows them to be “turned off” if they are found to cause environmental harm.<sup>235</sup> Although the permit officers consider risks to noncrop species in meeting the Department’s obligations under the National Environmental Policy Act and the Endangered Species Act, they take a “realistic” anthropocentric

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229. Espeseth Interview, *supra* note 104.

230. *Id.*

231. *Id.*

232. See *supra* text accompanying notes 194-95.

233. Foudin Interview, *supra* note 197.

234. *Id.*

235. *Id.*

view.<sup>236</sup> In light of the Agency's excellent track record with respect to managing the risks involved in the importation of known plant pests, the approach should be adequate for microorganisms that come within the definition of "regulated article" in the new regulations.

The USDA's recently promulgated regulations, however, contain a provision that could potentially undermine the "gap-filling" function of the TSCA. The regulations allow the USDA to issue a "courtesy permit" for genetically engineered microorganisms "which are not subject to regulation under [the regulations] to facilitate movement when the movement might otherwise be impeded because of the similarity of the organisms to other organisms regulated under [the regulations]."<sup>237</sup> An application for a courtesy permit need not include any particular data; it need only include a "statement explaining why [the applicant] believes the organism or product does not come within the definition of regulated article."<sup>238</sup> Although the courtesy permit may be a reasonable technique for avoiding unnecessary review under the FPPA, it should not serve as a vehicle for avoiding premanufacture notification under the TSCA. Despite the EPA's commendable attempt to coordinate with the USDA, it should take the firm position that a "courtesy permit" issued by the USDA does not relieve a manufacturer of its obligation to file a premanufacture notification with the EPA under the TSCA and to comply with any testing requirements that the EPA imposes.

*e. Other uses*— The EPA can manage the risks of the remaining agricultural uses of genetically engineered microorganisms under its TSCA authority to protect the environment from unreasonable risks of chemical substances. Unlike the FIFRA and the agricultural statutes, however, the TSCA does not erect a permitting regime. After submitting a premanufacture notice and waiting ninety days, a company is free to manufacture, distribute, or use a chemical substance until the EPA promulgates a rule prohibiting, limiting, or otherwise regulating its use.

The Agency may at any time issue a rule under section 6 of the TSCA imposing the least burdensome of seven listed requirements if the Agency has a "reasonable basis to conclude"

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236. *Id.* For example, if a genetically engineered microorganism posed risks only to dandelions, the Department probably would not deny a permit. *Id.*

237. Introduction of Organisms, *supra* note 119, at 22,913.

238. *Id.*

that a chemical substance's manufacture, distribution, or use "will present an unreasonable risk of injury to health or the environment."<sup>239</sup> The listed requirements range from a prohibition on the manufacturing, distribution, or use of the substance to a requirement that it be labelled.<sup>240</sup> If the EPA's initial assessment of the information submitted with a premanufacture notification provides a "reasonable basis to conclude" that the sale, distribution, or use of a chemical substance "will present an unreasonable risk of injury to health or the environment" before a section 6 rule can be promulgated, the Agency may issue a rule imposing roughly the same requirements that could be imposed under section 6 prior to initial release of the substance. In either case, the burden is on the EPA to justify any conditions that it places on the distribution and use of the substance. As a practical matter, it is considerably more difficult for the EPA to justify the imposition of requirements upon a substance that has not yet been introduced into the environment under the TSCA than it is under the FIFRA or the agricultural statutes. Hence, the EPA has adequate risk management authority only to the extent that it vigorously polices premanufacture notifications and devotes considerable resources to seeking injunctions in district court when the information that accompanies a premanufacture notification is inadequate.<sup>241</sup> Nevertheless, the EPA has resisted suggestions that the TSCA be amended to give the Agency more complete authorization power.<sup>242</sup>

2. *Genetically engineered plants*— Parasitic genetically engineered plants come within the previously discussed regulatory regime for plant pests. The Noxious Weed Act establishes a permit process for plants determined to be "noxious weeds." As discussed, however, the current regulatory regime will not reach all genetically engineered plants, because it lacks a mechanism for prerelease testing.

#### D. Public Participation

1. *Genetically engineered microorganisms*— Although there is no obvious reason why the public should be less interested in genetically engineered plants than in genetically engineered mi-

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239. 15 U.S.C. § 2605 (1982).

240. *Id.* § 2605(a).

241. See *supra* text accompanying notes 213-24.

242. *Coordinated Framework Hearing, supra* note 3, at 132 (testimony of John Moore, Assistant Adm'r for Pesticides & Toxic Substances, EPA).

croorganisms, the current statutes generally provide for greater public participation in the regulation of microorganisms than plants.

a. *Pesticides*— Under the FIFRA, the EPA must publish notice in the Federal Register of each application to register new products or new uses of existing products. The public then has thirty days to comment on the application.<sup>243</sup> Although the statute does not provide for public participation in the experimental use permit process, the EPA has voluntarily allowed public participation in those applications for experimental use permits that may have “regional or national significance.”<sup>244</sup> Unfortunately, most of the information upon which the EPA bases its experimental use permit and registration decisions is shielded from public scrutiny until the EPA has completed its decision-making process. Potential registrants almost always claim that their health and safety data constitute “trade secrets” that are protected from public disclosure.<sup>245</sup> Although the statute requires the release of health and safety data to the public—despite trade secrecy claims—after the EPA has made a final registration decision,<sup>246</sup> the public can have access to such data prior to the registration decision only if the registrant is willing to share them with the public. Although some of the early applicants for experimental use permits have commendably forsworn their trade secrecy claims, there is no guarantee that they will continue to do so in the future. Insofar as registrants are unwilling to share safety related information with the public prior to registration, the public participation provision of the current regulatory scheme for pesticides is inadequate.

Once the EPA decides, perhaps on the basis of alleged trade secret information, to grant registration for a pesticide, there need be no public hearing before the product enters commerce.<sup>247</sup> Environmental groups seeking to challenge the factual or legal basis of a registration decision must appeal to a federal district court.<sup>248</sup>

b. *Veterinary biological products*— The current USDA regulations for licensing veterinary biological products and estab-

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243. 7 U.S.C. § 136a(c)(4) (1982).

244. EPA Policy Statement, *supra* note 97, at 23,323. Apparently the Agency, at its sole discretion, makes the determination whether an experimental use permit is of “regional or national significance.”

245. *See supra* note 76.

246. 7 U.S.C. § 136h(d)(2) (1982).

247. This contrasts starkly with the absolute right of the applicant for a pesticide registration to demand a hearing if the EPA denies registration. *Id.* § 136a(c)(6).

248. *Id.* § 136n(a).

ishments do not provide for any public participation in the licensing decisions, and the USDA's recent policy statements suggest no role for the public apart from the right to comment upon any environmental impact statements. The Agency, in fact, has no provision for making the public generally aware of applications for product licenses or for permits to conduct field tests.<sup>249</sup> Although most significant field tests will probably require an environmental assessment, the assessment will not necessarily reveal the test site,<sup>250</sup> or be available to the public in time for effective public comment prior to release.<sup>251</sup> The regime for animal biologics is therefore utterly inadequate with respect to public participation.

c. *Animal diseases*— There are no provisions for making the public aware of, or for allowing public participation in, USDA decisions to permit the interstate transport of animal diseases. Thus, the USDA regulatory regime is inadequate from the standpoint of public participation.

d. *Plant pests*— Neither the existing regulations for licensing the import and transport of ordinary plant pests nor the new regulations for "regulated articles" provide for any public awareness of, or participation in, licensing decisions beyond the opportunity to read and comment upon the Agency's environmental assessments.<sup>252</sup> Any other information relevant to the decision, such as any studies required of the permittee, may be requested under the Freedom of Information Act (subject to its exemption for confidential business information),<sup>253</sup> but will not routinely be made available to the public.<sup>254</sup> Reacting to several negative comments on its proposed rules,<sup>255</sup> however, the USDA has adopted a procedure for petitioning the Agency to include or

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249. Espeseth Interview, *supra* note 104.

250. *Id.*

251. The USDA plans to give the public 30 days to comment on environmental impact assessments. Espeseth Comments, *supra* note 10. It is not clear that 30 days is enough time for members of the public to provide written responses to environmental assessments. Much will depend upon the thoroughness of the assessments themselves.

252. Foudin Interview, *supra* note 197.

253. In the past, most biotechnology companies have claimed virtually all of the information submitted to be trade secrets. *Id.*

254. *Id.*; see Statement of Assemblyman Lloyd Connelly, Before the USDA, Sacramento, Cal. (July 29, 1986) (complaining that his staff was told by the USDA that he would have to file a Freedom of Information Act request to discover what genetically engineered products the Department had under review).

255. See Letter from Richard D. Godown, Executive Director, Industrial Biotechnology Association, to Dr. James Glosser, Associate Administrator, Animal and Plant Health Inspection Service 7 (Sept. 24, 1986) (copy on file with U. MICH. J.L. REF.).

remove a host or sector from its list of potential plant pathogens.<sup>256</sup>

*e. Other uses*— The EPA publishes public notice of each TSCA premanufacture notification that it receives.<sup>257</sup> In addition, the Agency must on a monthly basis publish a list of all premanufacture notices for which the ninety-day response period has not expired.<sup>258</sup> Chemical manufacturers, however, typically claim that virtually the entire contents of their premanufacture submissions and any required premanufacture testing constitute trade secrets. Although the EPA usually makes an effort to describe in generic terms the nature of the substance at issue and the results of health and safety testing, it is nevertheless often difficult for the public to decide on the basis of publicly available information whether it should be concerned about the product. The statute requires that health and safety data be made available to the public, despite trade secrecy claims,<sup>259</sup> but the Agency generally does not force the issue until a request has been filed under the Freedom of Information Act.

The TSCA makes no provision for a public hearing prior to the expiration of the ninety days during which the EPA may act to prevent the manufacture of the chemical. The EPA may nevertheless voluntarily conduct a hearing on a premanufacture notification, and it has recently done so with respect to the first notification for a genetically engineered microorganism.<sup>260</sup> Any member of the public may, however, comment in writing on the risks and benefits of any substance that is the subject of a premanufacture notification during the ninety-day period. In addition, the Agency must publish reasons for any decision not to take action with respect to a new chemical for which the Agency has made a generic finding that release into the environment “may present” an unreasonable risk of injury to health or to the environment.<sup>261</sup> There is, of course, no public participation with respect to substances that are released in connection with pri-

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256. 52 Fed. Reg. 22,913 (to be codified at 7 C.F.R. § 340.4).

257. 15 U.S.C. § 2604(d)(2) (1982).

258. *Id.* § 2604(d)(3).

259. *Id.* § 2613(b)-(c).

260. See Pesticide and Toxic Chemical News, Feb. 11, 1987, at 3; Mellon Comments, *supra* note 37.

261. 15 U.S.C. §§ 2604(g), 2604(b)(4)(A)(i) (1982). Although the Administrator is required to publish a statement of reasons prior to the expiration of the 90-day period, failure to publish the statement does not prevent the manufacturer from distributing the substance after the expiration of the 90-day period. *Id.* § 2604(g).

vately sponsored research and development that is not for commercial purposes.<sup>262</sup>

2. *Genetically engineered plants*— Neither the FPPA nor the Noxious Weed Act provides for public participation in decisions about the release of genetically engineered plants beyond the opportunity to read and comment upon the Agency's environmental assessment, and the USDA has not acted on its own to expand public participation in those decisions.<sup>263</sup>

## V. WILLINGNESS TO REGULATE

A regulatory regime based upon the most generous statutory authority will be inadequate if the agency administering the program is unwilling to regulate efficiently and effectively. The perceived willingness of a regulatory agency to regulate is critical to the trust that the public places in its decisions and, consequently, to the public's confidence in the regulated technology. The experience of nuclear power regulation in the United States is often cited as an example of how not to secure public trust in a regulatory agency and its regulated industry.<sup>264</sup> Part of the current debate over biotechnology is directed to the perceived willingness of the USDA and the EPA effectively to assess and manage its risks.

Although it is too early to tell how effective a regulator the USDA will be, there are disturbing indications that it may not function as an aggressive overseer. First, the Department finds itself in the same sort of "institutional conflict of interest" that characterized the old Atomic Energy Commission.<sup>265</sup> The same institutional entity that has the responsibility for regulating the technology to prevent unacceptable risks is also charged with promoting it. For example, the USDA has boasted that it "has been in the forefront in the development of modern biotechnol-

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262. See *supra* text accompanying notes 146-48.

263. The Noxious Weed Act does have a provision for a public hearing on the decision whether to list a plant as a noxious weed, see *supra* note 53, but there is no public participation in the decision whether or not to issue a permit for the interstate transport of a listed weed. The USDA has also adopted a process whereby a person may petition the agency to include a plant that is a plant pest on its long list of regulated articles. 52 Fed. Reg. 22,913 (to be codified at 7 C.F.R. § 340.4).

264. See generally, E. ROLPH, *NUCLEAR POWER AND THE PUBLIC SAFETY* (1979); K. SHRADER-FRECHETTE, *NUCLEAR POWER AND PUBLIC POLICY* (1980).

265. E. ROLPH, *supra* note 264; K. SHRADER-FRECHETTE, *supra* note 264.

ogy,"<sup>266</sup> and it has generally demonstrated an unrestrained enthusiasm for agricultural biotechnologies.<sup>267</sup> There are occasional signs of struggle between the promoters and the regulators within the Department.<sup>268</sup> The Department's research budget reflects an almost single-minded focus on the benefits of agricultural biotechnology and a relatively modest concern for exploring its potential risks.<sup>269</sup>

Perhaps the most disturbing indication of the USDA's "go-go" attitude toward the benefits of biotechnology is a recently held "Challenge Forum on Biotechnology," in which representatives from the USDA and the biotechnology industry extolled its virtues and belittled its risks. No representatives from public interest or environmental groups were invited to attend the Chal-

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266. Microbial Products, *supra* note 137, at 50,898; see also *Coordinated Framework Hearing*, *supra* note 3, at 119 (testimony of Orville Bentley, Assistant Secretary for Science & Educ., USDA) ("It is the policy of the USDA to encourage and support the responsible development and utilization of beneficial products of modern biotechnology consistent with the protection of public safety and the environment.").

267. See GAO USDA REPORT, *supra* note 4, at 60. Professor Robert Colwell, an ecologist who has advised the USDA on the environmental impacts of agricultural biotechnology has observed:

Traditionally, the U.S.D.A. has seen itself as not only an active promoter (and funder) of basic research, but also as a sort of travelling salesman of applied technology, working closely with seed companies, agrochemical firms, and farm machinery manufacturers to achieve the laudable goal of helping America's farmers and ranchers to maximize their productivity. I anticipate that in five years, Agricultural Extension agents will be promoting the use of genetically engineered crops, farm animals, and microbial inputs. Meanwhile, we are assured by unnamed "knowledgeable ARS [Agricultural Research Service] official[s]" and unnamed Assistant Administrators that approval to release genetically engineered organisms "would not be given without careful scrutiny."

*Planned Release Hearing*, *supra* note 3, at 80. He concluded: "In retrospect, I think we might have done well to have had the two roles of the U.S.D.A., as promoter and regulator, in separate and independent agencies." *Id.*

268. GAO USDA REPORT, *supra* note 4, at 52; Foudin Interview, *supra* note 197 (indicating that regulators received pressure from other offices not to undertake thorough reviews of genetically engineered microorganisms that might be plant pests).

269. See *Planned Release Hearing*, *supra* note 3, at 42 (testimony of Martin Alexander, Professor of Agronomy, Cornell Univ.) (complaining of the lack of USDA support for research into the risks of agricultural biotechnologies); *id.* at 80 (testimony of Robert K. Colwell, Professor of Zoology, University of Cal., Berkeley, Cal.) (expressing same concerns as Dr. Alexander); *id.* at 123 (testimony of Brian Crowley, Senior Assoc. Director, Resources, Community & Economic Dev. Div., U.S. Gen. Accounting Office). In 1984-1985, the USDA funded \$40.5 million in biotechnology research. Eighty-seven of 778 projects involved the possibility of large-scale release. Of those, only three addressed risk assessment as an integral part of the research plan. ISSUES IN FEDERAL REGULATION REPORT, *supra* note 3, at 34. From October 1, 1983 to September 30, 1984, USDA funding for activities identified as risk assessment for biotechnology totalled approximately \$700,000. *Planned Release Hearing*, *supra* note 3, at 124 (testimony of Brian Crowley, Senior Assoc. Director, Resources, Community & Economic Dev. Div., U.S. Gen. Accounting Office).



lenge Forum and none were listed on the long participant list. The USDA's summary of the proceedings, which can only be described as a glowing endorsement of modern agricultural biotechnology, contains the following exhortations:

New biotechnology techniques are extensions and refinements of *older techniques* for genetic manipulation. They are not technological disjunctions such as the advent of *nuclear fission*.

. . . .

. . . [Modern biotechnology is] a *quantum leap* in understanding . . . [It is] a bases-loaded home-run, a *masterful event* . . . we are witnessing the advent of a golden age in agriculture . . . a "Biological Age" with the potential to do for mankind in the *21st Century* what the Machine Age did for industrialization in the 19th Century.

. . . .

. . . One of the most profound challenges that we all face is to overcome the common misapprehensions, or *myths*, surrounding new biotechnology. Biotechnology myths can be damaging when they confuse or mislead the media, the Congress, and the public. Such myths can cost us dearly in *delaying* the fruits of new technology that may significantly improve the quality and duration of life.

. . . .

. . . Some think all biotech products are potentially too dangerous . . . others call for a *tight rein* on biotech research, making analogies to the introduction of kudzu, gypsy moth, and chestnut blight. That's *faulty*, said one speaker: Those introductions involved organisms totally unrelated to the ecosystem . . . new biotech products involve *modification* of organisms that are *indigenous* to the parent ecosystem.<sup>270</sup>

This one-sided view of biotechnology's benefits and risks does not inspire confidence in the USDA as a regulator of agricultural biotechnology.

The USDA has played the role of promoter and regulator of a technology once before, when it was given the inconsistent tasks

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270. USDA Biotechnology Challenge Forum, Highlight Summary, at 1-4 (Feb. 11, 1987).

of promoting and regulating pesticides.<sup>271</sup> While the USDA was playing both roles, it registered hundreds of pesticides, many on the basis of data that were later found to be wholly inadequate.<sup>272</sup> But it doggedly resisted all efforts to take proven "bad actors" such as DDT and Aldrin/Dieldrin off the market. This institutional conflict of interest was a major factor in the transfer of pesticide regulatory authority to the EPA in 1970. There is little reason to believe that the same entity that did such a poor job of regulating pesticides will do a better job of protecting society from the risks of agricultural biotechnologies.

The USDA's public statements indicate that it has firmly adopted the position that genetically engineered plants and microorganisms are presumed to be no different than normal plants and organisms.<sup>273</sup> This benign attitude stands in contrast to many of the cautious statements of independent scientists and other federal agencies.<sup>274</sup> Indeed, USDA scientists have been highly critical of the EPA's cautious approach toward allowing deliberate releases of genetically engineered microorganisms.<sup>275</sup> One scientist who has advised both the USDA and the EPA on the environmental effects of genetically engineered microorganisms notes two "distinctly different 'flavors'" in regulatory approach: the EPA's evaluation process "maintained an air of impartial judgment," while the USDA found certain National Institutes of Health guidelines in the agricultural arena to be "unnecessarily onerous."<sup>276</sup>

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271. The USDA regulated pesticides until 1970, when the function was transferred to the EPA. Reorg. Plan No. 3 of 1970, 35 Fed. Reg. 15,623, *reprinted* in 5 U.S.C. app. at 1132 (1982), and in 84 Stat. 2086, as amended by Act of Aug. 23, 1983, Pub. L. 98-80, § 2(a)(2), (b)(2), (c)(2)(C), 97 Stat. 485.

272. STAFF OF SUBCOMM. ON DEPARTMENT OPERATIONS, RESEARCH, AND FOREIGN AGRICULTURE OF THE HOUSE COMM. ON AGRICULTURE, 97TH CONG., 2D SESS., REPORT ON REGULATORY PROCEDURES AND PUBLIC HEALTH ISSUES IN THE EPA'S OFFICE OF PESTICIDE PROGRAMS (Comm. Print 1982); STAFF OF SUBCOMM. ON ADMINISTRATIVE PRACTICE AND PROCEDURE OF THE SENATE COMM. ON THE JUDICIARY, 94TH CONG., 2D SESS., REPORT ON THE ENVIRONMENTAL PROTECTION AGENCY AND THE REGULATION OF PESTICIDES (Comm. Print 1976) [hereinafter KENNEDY REPORT].

273. See *Planned Release Hearing*, *supra* note 3, at 168 (testimony of John Patrick Jordan, Administrator, Cooperative State Research Serv., USDA) ("[A]gricultural and forestry products developed through the use of biotechnology will not differ fundamentally in use and application from conventional products."); GAO USDA REPORT, *supra* note 4, at 27.

274. See A. Carr, *supra* note 56, at 3, 14.

275. See GAO USDA REPORT, *supra* note 4, at 47.

276. *Planned Release Hearing*, *supra* note 3, at 81 (testimony of Robert K. Colwell, Professor of Zoology, University of Cal., Berkeley, Cal.); see also *Coordinated Framework Hearing*, *supra* note 3, at 79 (testimony of Elliott A. Norse, Director, Public Affairs Office, The Ecological Soc'y of Am.) (complaining that the Coordinated Framework "is unbalanced, leaning too far toward allowing releases of engineered organisms without the

In its defense, the USDA points out that its promotional activities are segregated within the Department and are lodged under an entirely different Assistant Secretary.<sup>277</sup> The Department has also made a commendable effort to keep the two functions separate in its Coordinated Framework policy announcements.<sup>278</sup> Moreover, the National Environmental Policy Act, which did not exist during the days that the USDA regulated pesticides, may have made the Department more sensitive to environmental concerns,<sup>279</sup> especially because an inadequate environmental impact assessment for a major action can result in a burdensome lawsuit.<sup>280</sup> In addition, the USDA's past track record in protecting plants and animals from well known plant pests, noxious weeds, and infectious diseases is impressive.<sup>281</sup> Nevertheless, the evidence of the USDA's institutional attitude about modern biotechnology leaves a considerable lingering doubt about its commitment to protecting society from the risks of genetically engineered plants and microorganisms,<sup>282</sup> and some have suggested that the best institutional arrangement may be to place responsibility for regulating agricultural biotechnologies in another agency.<sup>283</sup>

The obvious candidate for transfer of authority is the EPA, which, in any event, will have a large role to play in regulating agricultural biotechnologies. Although the EPA is not plagued with the USDA's institutional conflict of interest, its effectiveness in regulating chemicals is far from exemplary. Its chemical

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safeguards that are appropriate at this stage of the technology's development"); GAO USDA REPORT, *supra* note 4, at 36 ("USDA officials did not want to impose cumbersome regulations that might stifle growth in biotechnology research or in the industries that have sprung from that research.").

277. *Planned Release Hearing*, *supra* note 3, at 174 (testimony of John Patrick Jordan, Administrator, Cooperative State Research Serv., USDA).

278. *See Coordinated Framework Hearing*, *supra* note 3, at 123 (testimony of Karen Darling, Deputy Assistant Secretary for Mktg. & Inspection Servs., USDA).

279. S. TAYLOR, *MAKING BUREAUCRACIES THINK* (1984).

280. *See GAO USDA REPORT*, *supra* note 4, at 36 (indicating that USDA is worried about lawsuits from opponents of biotechnology); *see also* *Foundation on Economic Trends v. Block*, No. Civ. A. 84-3045 (D.D.C. Apr. 29, 1986) (WESTLAW, Allfeds library, DCT file) (holding that animal productivity research is not major federal action requiring environmental assessment or environmental impact statement).

281. *See GAO USDA REPORT*, *supra* note 4, at 31.

282. For example, there are indications that the formal separation of promotional and regulatory functions is more illusory than real. The Associate Administrator of APHIS recently told a "Challenge Forum" that: "We in APHIS have been linked to . . . developments [in biotechnology] not only because of our regulatory responsibilities but also because USDA with the people it represents, and the programs it supports, is one of the biggest beneficiaries of this science." Remarks of James W. Glosser, Associate Adm'r, APHIS, USDA, at the Biotechnology Challenge Forum (Feb. 5, 1987).

283. NRDC Comments, *supra* note 147.

regulation program has promulgated fewer than a dozen major rules regulating toxic substances in its eleven year history.<sup>284</sup> Although the pesticide program in the EPA was very active in the mid-1970's, it too has been plagued by severe management and morale problems.<sup>285</sup> The EPA has also been criticized for failing to register new pesticides in an expeditious fashion, a problem that has plagued the newer biological pesticides even more severely than traditional chemical pesticides.<sup>286</sup> Thus, although environmental groups advocate giving the EPA exclusive authority to regulate agricultural biotechnologies, biotechnology companies are largely satisfied with the USDA's determination to play a major role.

It is very difficult to assess these arguments objectively. The USDA's history and its recent statements belittling risks of agricultural biotechnology justify a fair degree of skepticism about the willingness of that Department to be an effective regulator. The Department's unconstrained optimism about the benefits of agricultural biotechnology, exemplified in the recent "Secretary's Challenge Forum on Biotechnology," gives credence to the charge that the Department is likely to accentuate the benefits over the risks. On the other hand, the USDA's role in regulating biotechnology is not a very large one. Its role in regulating animal biologics is quite limited, and its regulatory program in that area seems very effective. Apparently by choice, its program for regulating animal diseases will be almost irrelevant to genetically engineered microorganisms. This regulatory function will go by default to the EPA under the TSCA, so long as the EPA does not erroneously assume that the USDA is in fact attempting to protect animals from new diseases resulting from genetically engineered microorganisms.

The only area in which USDA and EPA authorities overlap to any significant degree is in protecting plants from genetically engineered microorganisms. It is possible that the EPA would do a more effective job than the USDA in this area, but that is by no means certain. The USDA has proposed a comprehensive regulatory scheme under the FPPA to regulate genetically engineered microorganisms that may be plant pests. All indications are that the USDA is serious about this job, despite pressures from elsewhere within the Department. The EPA also has a role to play

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284. *See id.* at 31.

285. KENNEDY REPORT, *supra* note 272.

286. *Hearings Before the House Comm. on Agriculture on Federal Insecticide, Fungicide, and Rodenticide Act Extension*, 94th Cong., 1st Sess. 366 (1975) (testimony of Jack D. Early, Vice President, National Agricultural Chems. Ass'n).

under the TSCA in assessing the risks of genetically engineered microorganisms that are not on the USDA's list of plant pest hosts and vectors or that are not determined to be plant pests. The USDA and the EPA have recognized the possibility for overlap, and they have provided for coordinated reviews in these instances to ensure that data requests are not duplicated.<sup>287</sup> Perhaps an adequate check on any perceived tendency on the USDA's part to slight risks and accentuate benefits is to provide for dual review of all genetically engineered microorganisms that might be plant pests. The obvious inefficiency of dual review may be outweighed by the increased confidence that the public is likely to have in the ultimate product.

## VI. CONCLUSION AND RECOMMENDATIONS

When we piece together the patchwork of statutes and regulatory programs, it becomes apparent that nearly all modern agricultural biotechnologies are addressed to some extent. When measured against the elements of an adequate regulatory regime, however, there are some important gaps in coverage and some inadequacies in the programs that are covered. As previously suggested, this should not be surprising given the orientation of the applicable statutes, but it is somewhat disappointing that the EPA's gap-filling function under the TSCA has not provided a complete backstop.

### A. *Prerelease Notification*

Some large-scale releases of genetically engineered microorganisms that may be relevant to agriculture can take place under the existing regulatory regimes without any notification to any federal regulatory agency. Generally, the EPA must receive pre-release notification of all genetically engineered microorganisms, even if no other program requires prerelease notification.<sup>288</sup> Thus, even though the USDA does not require prerelease notification of experimental biological products when the experiments are undertaken in unlicensed facilities and there is no interstate transport, the EPA would have to be notified. And even though

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287. Introduction of Organisms, *supra* note 119, at 22,906.

288. There will be prerelease notification of all genetically engineered pesticides. See *supra* text accompanying note 142.

the USDA may not regard field testing of genetically engineered microorganisms in the environment to constitute a "release," the EPA probably considers it to be a release under the TSCA. The fact that the USDA's authority to require prerelease notification of interstate shipments of animal diseases and that even this requirement is largely applicable only to well-known diseases for which the USDA has established quarantine programs only mean that prerelease notification of microorganisms that might cause animal diseases will go to the EPA, rather than the USDA. Finally, to the extent that a person genetically engineers a product from the hosts and vectors on the USDA's list of potential plant pests but determines that the final product does not meet the definition of "plant pest," the EPA must be notified of the new "chemical substance."

Before we can confidently conclude, however, that the EPA will receive prerelease notification of all genetically engineered microorganisms, we must examine some of the weaknesses and gaps in the TSCA program. For example, the entire TSCA program may be inapplicable if the EPA's broad reading of the words "chemical substance" to include genetically engineered microorganisms is not upheld by the courts. To avoid the regulatory instability that would accompany a lawsuit challenging the EPA's authority to regulate biotechnology, Congress should enact a statute clarifying the EPA's gap-filling power in the context of biotechnology.

The TSCA's prerelease notification requirements do not reach privately sponsored noncommercial research and development, such as that undertaken in academic facilities without federal grants. When Congress included this exemption in the TSCA, it did not envision that the EPA would play a regulatory role with respect to potentially harmful organisms that might proliferate in the environment. Congress should now amend the TSCA to give the EPA authority to require prerelease notification of *any* deliberate releases of genetically engineered microorganisms, to the extent that notification is not already forthcoming under some other statute. Academic scientists are not immune from the kinds of pressures that cause people to make errors of judgment, and they should not be treated differently as a matter of principle.<sup>289</sup>

Finally, the EPA has voluntarily exempted organisms resulting from intragenetic gene transfers when the host organism is

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289. See generally McGarity, *Contending Approaches to Regulating Laboratory Safety*, 28 KAN. L. REV. 183 (1980).

nonpathogenic and organisms resulting from intergeneric transfers when the transferred material is only a well-characterized, non-coding, regulatory region.<sup>290</sup> The first exemption may be justified for reasons of administrative practicality and because it is possible to make a generic determination that such organisms are not likely to pose environmental risks. In any event, the exemption may not be very large, because the EPA has defined "pathogen" very broadly to include most current recombinant DNA activities.<sup>291</sup> The second exemption, which the USDA has followed under the FPPA,<sup>292</sup> is probably unwarranted, and both the EPA and the USDA should amend their regulations to repeal it.

Currently, there are virtually no legal requirements for pre-release notification of genetically engineered plants. Only the USDA requires prerelease notification of genetically engineered plants that are on the list of pathogenic organisms and vectors.<sup>293</sup> The TSCA does not give the EPA any gap-filling role whatsoever for plants. Thus, there can be no assurance that the harm producing potential of genetically engineered plants will come to the attention of any agency prior to actual damage. Because genetically engineered plants may not pose the same risks of widespread ecological damage as genetically engineered microorganisms, this may be deemed acceptable. If, however, Congress believes that prerelease notification of genetically engineered plants is desirable, it should amend the TSCA to give the EPA the same gap-filling authority for plants that it gives it for genetically engineered microorganisms.

### *B. Data Collection, Data Evaluation, and Risk Assessment*

The ability of the EPA and the USDA to require proponents of agricultural biotechnologies to submit health and safety data prior to release varies greatly from program to program. For pesticides and veterinary biologics, the EPA and the USDA have established data gathering and evaluation requirements that

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290. See *supra* note 120.

291. EPA Policy Statement, *supra* note 97, at 23,333-34; Mellon Comments, *supra* note 37.

292. See *supra* text accompanying notes 156-58.

293. The USDA's authority, however, probably only extends to parasitic plants. See *supra* text accompanying note 158.

seem adequate.<sup>294</sup> It is not clear at this point whether the USDA will require very extensive testing for adverse environmental effects prior to release.<sup>295</sup> The USDA has exercised its authority under the FPPA to require testing for organisms on its list of plant pathogens and vectors that are also plant pests, but it has not developed testing protocols. The USDA might usefully examine the EPA's protocols for conventional biological pesticides to provide guidance in its case by case evaluation of its data needs.

Testing for genetically engineered microorganisms that are not pesticides and not on the USDA's plant pest list will be required, if at all, by the EPA under its TSCA authority. Yet the EPA can only require a bare minimum data set with premanufacture notification, and it must be prepared to bear the burden of proving in district court the need to prohibit the release of an organism while additional data requirements are being met. Given the novelty of agricultural biotechnologies, Congress may conclude that this is not an adequate testing regime. If so, Congress could amend the TSCA to give the EPA the authority to prevent the release of genetically engineered microorganisms if it is unable to determine whether their deliberate release will cause unreasonable adverse effects on the environment without additional information. Congress could achieve the same result by establishing a permitting regime similar to that of the FIFRA and the FPPA.

There is currently no testing regime for genetically engineered plants other than those listed on the USDA's plant pest list that also meet the definition of "plant pest."<sup>296</sup> If Congress believes that testing of genetically engineered plants is desirable, it should amend the TSCA as suggested above to include plants as well as microorganisms.

### C. Risk Management

Assuming that a permitting regime is adequate, the risk management regimes for pesticides, veterinary biologics, and plant pests are adequate. Since the USDA's regulatory regime for animal diseases is extremely limited, the EPA's TSCA authori-

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294. The EPA's incomplete data requirements for its "Level I" evaluation of the need for an experimental use permit for small-scale testing casts some doubt upon this generally optimistic assessment.

295. See *supra* text accompanying notes 179-83.

296. Again, the USDA's authority probably does not extend beyond parasitic plants.



ties will govern virtually all other agricultural biotechnologies. Importantly, the TSCA does not establish a permitting regulatory regime. Manufacturers are free to distribute genetically engineered microorganisms ninety days after submitting a premanufacture notification to the EPA, unless the EPA assumes the affirmative burden of demonstrating that the manufacture, distribution, or use of the substance will present an unreasonable risk of injury to humans or to the environment. Under the current TSCA regime, inertia works in favor of the release of the microorganism. This will only be satisfactory if the EPA is given the resources to evaluate effectively the hundreds of premanufacture notifications that it can expect to receive in the near future. Otherwise, Congress should amend the TSCA to give the EPA permitting authority similar to that of the FIFRA.<sup>297</sup>

The only available regulatory regimes for genetically engineered plants are the FPPA, which is limited to parasitic plants, and the Noxious Weed Act, which is limited to interstate importation and transport of plants that are known to be weeds. Neither of these authorities provides much protection for nonparasitic plants until long after damage has occurred. If Congress determines that this is not an acceptable state of affairs, it should amend either the FPPA or the TSCA to give the USDA or the EPA authority to take action prior to the release of genetically engineered plants that might harm the environment.

#### *D. Public Participation*

All of the USDA-administered regulatory regimes are woefully inadequate from the perspective of public participation. None provide for public hearings prior to release of genetically engineered microorganisms, and none even provide for public notice of impending releases. The only public role is the very limited one of commenting upon environmental impact statements in cases in which they are prepared and commenting upon environmental assessments in the (perhaps) rare case in which a member of the public learns that an environmental assessment has been prepared. The USDA should remedy this inadequate situation by writing procedural regulations that provide for publica-

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297. *But see Coordinated Framework Hearing, supra* note 3, at 132 (testimony of John Moore, Assistant Adm'r for Pesticides & Toxic Substances, EPA) (arguing against amending the TSCA to establish a permitting regime).

tion of permit applications for genetically engineered plants and microorganisms and that allow for informed public comment.

The opportunities for public participation in the EPA's pesticide program are much more extensive, but they are still limited by the inaccessibility of health and safety data prior to the decision to grant a registration or an experimental use permit and the absence of a hearing prior to the registration decision. Although the EPA has commendably provided for an informal public hearing prior to making experimental use permit decisions of "regional or national" significance, it has not adequately explained why a public hearing would not be desirable for releases of only local significance. The Agency should allow public participation in all experimental use permit determinations, and it should attempt to facilitate citizen access to relevant health and safety data.

Public participation under the TSCA is even more extensive than under the FIFRA, but it too is plagued by the vexing problem of the trade secret status of health and safety testing data. Because the agency always gives the manufacturer an opportunity to sue in district court to prevent the release of information, manufacturers can as a practical matter delay providing health and safety data to the public until after the substance has been released, thereby effectively frustrating public participation in the decision to release. Although no companies have so far been this belligerent, the possibility still exists. Congress could remedy this problem by empowering the EPA to prevent the manufacture or distribution of a substance until all disputes over health and safety data have been resolved.

### *E. Willingness to Regulate*

Part V of this Article related several disturbing indications that the USDA may not be willing to regulate agricultural biotechnologies as effectively as the EPA would be. The USDA's institutional conflict of interest and its numerous public statements accentuating the benefits and belittling the risks of biotechnology certainly justify some skepticism about the Agency's desire to regulate agricultural biotechnologies. On the other hand, the EPA has not been an especially aggressive regulator of toxic substances and pesticides during the last several years, and it does not have the USDA's expertise in animal biologics and plant pests.

Biotechnology can get off to the running start that its proponents desire only if the public can trust the regulatory agencies that have been created to protect health and the environment. Without strong public confidence in the agencies, the technology may proceed, but it will face numerous delays and the possibility of a complete loss of public trust when, as is almost inevitable, something does go wrong. If the USDA's past activities and present pronouncements do not inspire the kind of public confidence that is necessary, at least three solutions are possible.

First, Congress can create an entirely new and independent agency. This solution would be expensive and time consuming, and it would no doubt be controversial at a time in which the public mood seems antagonistic to new federal agencies. In any event, it might well prove self-defeating, because the agency would no doubt be staffed with many of the same people who are currently running the programs in the USDA.

Second, Congress could transfer to the EPA all authority to regulate agricultural biotechnologies. Although the EPA could gear up to do the job and although the public may have marginally more confidence in the EPA's regulatory aggressiveness, this solution would also be time consuming and expensive. In addition, it would necessarily involve jurisdictional battles in both the House and the Senate where jurisdiction over agencies in the USDA is lodged in one committee and jurisdiction over the EPA is lodged in another committee. Finally, many of the same personnel would no doubt be transferred to the EPA as the USDA's pesticides regulatory staff was transferred to the EPA in 1970.

Third, Congress could simply provide for overlapping jurisdiction in both the USDA and the EPA for functions that are now assigned to the USDA alone. This could be accomplished with a minimum of effort by amending the TSCA. This solution is obviously burdensome for the regulated industry, because applications for permits and licenses would have to be cleared through both agencies. But this disadvantage may, in the long run, be outweighed by the ease with which permitting decisions could be made in a regulatory setting devoid of the suspicion that currently characterizes the public view of the USDA.

Even if Congress determines that no change in the institutional arrangements is desirable, the USDA could greatly enhance public confidence in its decisions by allowing the public to play a much greater role in its decisionmaking, as previously suggested. Providing notice to the public of pending license and permit requests and allowing informed public comment would be burdensome to the agency, and it might slow down the regu-

latory process somewhat, but enhanced public trust in the USDA's regulatory decisions may warrant these inconveniences.

### *F. Conclusion*

If current optimism about agricultural biotechnology is warranted, the USDA and the EPA should soon be flooded with applications for permits to test and market an astonishing variety of useful products. If the past is an appropriate indicator, some of these new products will pose risks to humans and to the environment. Both agencies have recognized the major roles that they will play in protecting the public from the risks of agricultural biotechnologies, and both have adjusted their traditional programs to meet their statutory obligations. Yet these efforts have not yielded an adequate regulatory regime for biotechnology, especially insofar as the public is to play a role in the regulatory process. With relatively minor changes to existing statutes, however, Congress can pave the way for the establishment of a regulatory regime that can give the public the protection that it deserves without depriving society of the enormous benefits of these exciting new products.

