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Karl O. Bayer

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## Federal Regulation of Emerging Genetic Technologies

Thomas O. McGarity\*  
Karl O. Bayer\*\*

*Over the past ten years scientists have perfected revolutionary techniques in the field of genetic engineering. Although this new technology promises to have enormous commercial and industrial value, some scientists fear that the risks accompanying genetic experimentation may outweigh its social benefits. In their Article Professor McGarity and Mr. Bayer examine the legal debate over how government should regulate this emerging technology. After describing various genetic engineering techniques and the risks underlying their use, Professor McGarity and Mr. Bayer discuss the elements of a regulatory framework adequate to handle the new technology and assess the existing regulatory structure in terms of a more appropriate framework. They conclude that the appropriate existing federal agencies immediately should undertake data collection and risk assessments to identify the dangers in the experimentation, manufacture, and practical use of genetically altered micro-organisms. Professor McGarity and Mr. Bayer recommend that Congress be prepared to enact new legislation if the existing regulatory framework fails to meet the challenge of this exciting new technology.*

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\* Professor of Law, University of Texas School of Law. B.A. 1971, Rice University; J.D. 1974, University of Texas.

\*\* Member of the Texas Bar, Pluymen & Bayer, Austin, Texas. B.A. 1971, Rice University; M.S. 1973, Massachusetts Institute of Technology; J.D. 1976, University of Texas.

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## I. INTRODUCTION

In the mid-1970's scientists perfected exciting and controversial techniques for researching the intricate genetic structure of micro-organisms.<sup>1</sup> Variouslly described as "recombinant DNA" (rDNA), "gene splicing," and "genetic engineering," these new techniques promised rapid growth in knowledge of genetic processes.<sup>2</sup> At the same time, many scientists were predicting that this research could pose serious risks to laboratory workers and to persons living near laboratory facilities.<sup>3</sup> Skeptics of the new technology conjured up hypothetical risk scenarios of pandemics spawned by the escape of hazardous micro-organisms from university and industrial laboratories.<sup>4</sup> Some scientists questioned any interference with "evolutionary wisdom" absent reliable information about the long range effects of the genetic technologies.<sup>5</sup> A broad scientific, ethical, and philosophical debate ensued in which participants from many disciplines argued the pros and cons of governmental regulation of scientific research risks.<sup>6</sup> The outcome of this debate, not surprisingly, was inconclusive. Nevertheless, the National Institutes of Health (NIH) attempted to quell public concerns by promulgating detailed guidelines for the conduct of rDNA

1. For general descriptions of the debate over recombinant DNA (rDNA) research in the mid-1970's, see J. GOODFIELD, *PLAYING GOD* (1977); M. ROGERS, *BIOHAZARD* (1977); N. WADE, *THE ULTIMATE EXPERIMENT* (1977); Swazey, Sorenson & Wong, *Risks and Benefits, Rights and Responsibilities: A History of the Recombinant DNA Research Controversy*, 51 S. CAL. L. REV. 1019 (1978).

2. See Cohen, *Recombinant DNA: Fact and Fiction*, 195 *SCIENCE* 654 (1977); Cohen, *Restriction of Research with Recombinant DNA: The Dangers of Inquiry and the Burden of Proof*, 51 S. CAL. L. REV. 1081 (1978); David, *Potential benefits are large, protective methods make risks small*, *CHEM. & ENG'G NEWS*, May 30, 1977, at 27; Nathan, *Potential Benefits of the Research*, in *RESEARCH WITH RECOMBINANT DNA: AN ACADEMY FORUM*, 49 (Nat'l Acad. of Sci. 1977) [hereinafter cited as *ACADEMY FORUM*]; Thomas, *Notes of a Biology Watcher: The Hazards of Science*, 296 *NEW ENG. J. MED.* 324 (1977).

3. See M. ROGERS, *supra* note 1, at 31-50; N. WADE, *supra* note 1, at 29-39.

4. See Cavalieri, *New strains of life—or death*, *N.Y. Times*, Aug. 22, 1976, § 9 (Magazine), at 62; *Fruits of gene-juggling: blessing or curse?*, 17 *MED. WORLD NEWS*, Oct. 4, 1976, at 45; *The Promise and Peril of Genetic Engineering*, *NRDC Newsletter*, Winter 1976, at 1.

5. See Chargaff, *On the Dangers of Genetic Meddling*, 192 *SCIENCE* 938 (1976); Sinsheimer, *Troubled dawn for genetic engineering*, 68 *NEW SCIENTIST* 148 (1975); Wade, *Recombinant DNA: A Critic Questions the Right to Free Inquiry*, 194 *SCIENCE* 303 (1976) (reporting views of Dr. Robert Sinsheimer).

6. See *ACADEMY FORUM*, *supra* note 2; Grobstein, *The Recombinant-DNA Debate*, *SCI. AM.*, July 1977, at 22; *Biotechnology and the Law: Recombinant DNA and the Control of Scientific Research*, 51 S. CAL. L. REV. 969 (1978).

research.<sup>7</sup> Although these guidelines were not binding on industrial research,<sup>8</sup> an institution in which a violation took place could lose governmental financial support.<sup>9</sup> With a few exceptions,<sup>10</sup> scientists have recognized that these guidelines place reasonable restraints on research and have attempted to adhere to them.<sup>11</sup>

As more thorough investigations began into the potential risks of rDNA research, many scientists concluded that the risks which the presence of altered DNA in numerous common experimental organisms posed were not nearly as great as some experts originally had suggested.<sup>12</sup> Risk assessments that scientists performed on selected experimental organisms revealed the low probability that the organisms would infect human beings or exchange DNA with an organism capable of infecting humans.<sup>13</sup> The NIH, therefore, gradually began to relax its guidelines and even entertained proposals to eliminate virtually all requirements for most kinds of

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7. National Institutes of Health, Recombinant DNA Research Guidelines, 41 Fed. Reg. 27,902 (1976) [hereinafter cited as NIH Guidelines]. NIH has amended these guidelines extensively. The Institute promulgated the most recent version of the guidelines in June 1981. National Institutes of Health, Guidelines for Research Involving Recombinant DNA Molecules, 46 Fed. Reg. 34,462 (1981) [hereinafter cited as NIH Guidelines—1981]; see Karny, *Biotechnology: the Regulatory and Legislative Environment*, 5 RECOMBINANT DNA TECHNICAL BULL. 127 (1982).

8. NIH Guidelines, 41 Fed. Reg. at 27,905. Several states and municipalities, however, have enacted restrictions similar to the NIH Guidelines that apply to privately sponsored rDNA research. See, e.g., MD. ANN. CODE art. 43, §§ 898-910 (Cum. Supp. 1977) (repealed 1982).

9. The NIH has invoked this sanction only once. See *Genetic Scientist Is Punished for Test Violations*, Wash. Post, March 23, 1981, at A1, col. 1.

10. Some exceptions do exist. See McGarity, *Contending Approaches to Regulating Laboratory Safety*, 28 U. KAN. L. REV. 183, 232-34 (1980).

11. See SUBCOMM. ON SCIENCE, TECHNOLOGY AND SPACE OF THE SENATE COMM. ON COMMERCE, SCIENCE, AND TRANSPORTATION, 95th CONG., 2D SESS., OVERSIGHT REPORT ON RECOMBINANT DNA RESEARCH AND ITS APPLICATIONS (Comm. Print 1978).

12. Dr. Roy Curtiss III made perhaps the most dramatic reassessment of rDNA risks. Dr. Curtiss was a former proponent of strict controls who changed his position because of research he performed on those risks. See Letter from Dr. Roy Curtiss III to Dr. Donald Fredrickson (April 12, 1977), reprinted in *Science Policy Implications of DNA Recombinant Molecule Research: Hearings Before the Subcomm. on Science, Research and Technology of the House Comm. on Science and Technology*, 95th Cong., 1st Sess. 1046-55 (1977); see also National Institutes of Health, Recombinant DNA Research; Final Plan for a Program to Assess the Risks of Recombinant DNA Research, 46 Fed. Reg. 30,772 (1981) (NIH director concurs "with most scientists that the perception of risk from this research is certainly less now than earlier," but recognizes that "there still remain selected areas where data are insufficient to determine risk.").

13. See National Institutes of Health, Program to Assess the Risks of Recombinant DNA Research: Proposed First Annual Update, 45 Fed. Reg. 61,874 (1980) (summarizing risk assessment research on rDNA hosts and vectors).

rDNA research.<sup>14</sup> In the face of strong public comment favoring retention of mandatory federal controls on gene-splicing research, NIH settled for a relaxation of the rules.<sup>15</sup>

At the same time that anxiety about the hazards of ordinary research was beginning to wane, researchers were demonstrating that this new breed of genetic engineering could have enormous commercial value. Genetically altered bacteria are capable of producing an extraordinary variety of marketable chemicals.<sup>16</sup> Industrial application of this research through fermentation technologies can be extremely profitable because the processes are relatively uncomplicated, utilize inexpensive raw materials, and are not labor intensive.<sup>17</sup> The new genetic research also will make available organisms capable of performing large-scale industrial jobs such as pollution control and mineral leaching.<sup>18</sup>

Although some biotechnology firms have encountered preliminary financial problems,<sup>19</sup> investors generally predict a rosy future for companies that successfully employ the newly emerging genetic technologies.<sup>20</sup> Nevertheless, doubts still linger about the risks that these technologies may pose to humans and the environment.<sup>21</sup>

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14. *Gene-Splicing Rules Should be Relaxed, Federal Panel States*, Wall St. J., September 14, 1981, at 8, col. 3; see *NIH Panel Moving to End Regulation of Gene Splicing*, Wash. Post, April 24, 1981, at A12, col. 1; *Deregulation of DNA Studies Sought; Seen as Boon to University Geneticists*, Chronicle of Higher Educ., September 23, 1981, at 1, col. 2.

15. See *NIH Unit Votes to Ease but Retain Federal Rules on Gene-Splicing*, Wash. Post, February 9, 1982, at A7, col. 4.

16. See OFFICE OF TECHNOLOGY ASSESSMENT, IMPACTS OF APPLIED GENETICS ch. 4-5 (1981) [hereinafter cited as OTA REPORT]; Aharonowitz & Cohen, *The Microbiological Production of Pharmaceuticals*, Sci. AM., Sept. 1981, at 140; Eveleigh, *The Microbiological Production of Industrial Chemicals*, Sci. AM., Sept. 1981, at 154.

17. See OTA REPORT, *supra* note 16, at 51; Bull, Ellwood, & Ratledge, *The Changing Scene in Microbial Technology*, in MICROBIAL TECHNOLOGY: CURRENT STATE, FUTURE PROSPECTS 1 (1979) [hereinafter cited as MICROBIAL TECHNOLOGY]; Demain & Solomon, *Industrial Microbiology*, Sci. AM., Sept. 1981, at 67.

18. See OTA REPORT, *supra* note 16, at 117-27; Demain & Solomon, *supra* note 17, at 74.

19. Two biotechnology firms have shut down operations during 1982 pending acquisition of new capital. Both corporations have filed for reorganization under Chapter 11 of the Bankruptcy Code. See *Lee Biomolecular Research Labs in Chapter 11 Proceedings*, 1 BIOTECHNOLOGY L. REP. 98 (1982); *Armos Corp. Becomes Third Major Biotech Casualty: Files Chapter 11*, 1 BIOTECHNOLOGY L. REP. 125 (1982).

20. See *Investors Dream of Genes*, TIME, Oct. 20, 1980, at 72; *How Pillsbury, Madison Took Genentech to Market*, Am. Law., Dec., 1982, at 22; *Genetic Engineers Create New Breed of Legal Practice*, Nat'l L.J., Sept. 21, 1981, at 1, col. 1; *Hutton Revives Gene Splicing Venture With Changes Reflecting New Tax Law*, Wall St. J., Sept. 4, 1981, at 4, col. 3; cf. *Genentech: Is its Glamor Gone?*, 211 SCIENCE 262 (1981).

21. See OTA REPORT, *supra* note 16, at 197-207; *Hearings on Industrial Applications of Recombinant DNA Techniques Before the Subcomm. on Science, Technology and Space*

Nuclear power was one highly touted technology that withered after its full socio-economic effects became apparent.<sup>22</sup> Cautious commentators have warned that society should not allow the new genetic technologies to blossom too rapidly before careful examination and control of all the potential risks have taken place.<sup>23</sup> Several federal statutes give various agencies authority to regulate conduct that poses unacceptable risks to humans and the environment, but the adequacy of any existing regulatory scheme depends upon the nature of the problem that the agency must address.

This Article examines the applicability of several federal statutes to the emerging genetic technologies. Part II describes some of the technologies and the risks that they pose. Part III sets out elements of an adequate regulatory regime for controlling these unique risks. Part IV measures existing statutory authorities against the criteria suggested in part III and assesses the extent to which existing federal agencies have adequate authority to regulate genetic technologies should this regulation become necessary. Part V examines whether Congress should enact a separate statute to address specifically the regulation of the new genetic engineering technologies. The Article concludes that (1) regulatory agencies should assess and regulate these new technologies before they come on line; (2) the Environmental Protection Agency (EPA) should assemble the expertise necessary to assess the risks and monitor the development of these technologies, and the courts and Congress should state expressly that EPA has regulatory authority in the biotechnology field; (3) if testing determines that these technologies pose risks to man or the environment, the EPA, the Federal Food and Drug Administration (FDA), and the Occupational

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of the Senate Comm. on Commerce, Science and Transportation, 96th Cong., 2d Sess. 11-13 (1980) (statement of Dr. Anthony Robbins, former director of the National Institute for Occupational Safety and Health (NIOSH)) [hereinafter cited as *1980 Senate Hearings*].

22. See, e.g., *Decommissioning Commercial Nuclear Power Plants*, Publication No. 80-6, 10, 14 (Center for Urban and Regional Affairs 1980).

23. See, e.g., Cripps, *A Legal Perspective on the Control of the Technology of Genetic Engineering*, 44 *MOD. L. REV.* 369 (1981); Holden, *Ethics Panel Looks at Human Gene Splicing*, 217 *SCIENCE* 516 (1982) (In testimony before the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, Nicholas Wade stated that one day scientists will come to a full understanding of the workings of life and will be in a position to alter the nature of man. Hence, the Commission should look into the far distant future and discuss setting some firm guidelines.); Karny, *Regulation of Genetic Engineering: Less Concern about Frankensteins but time for action on Commercial Production*, 12 *U. Tol. L. Rev.* 815, 836 (1981) ("In a situation in which there is uncertainty and even strong disagreement about the nature, scope and magnitude of the risk, it is difficult to conclude whether a given solution to the problem is a 'good' or 'poor' one.").

Safety and Health Administration (OSHA) should assert their regulatory authorities to ensure public safety; (4) Congress should allocate adequate resources to these agencies to ensure that they can monitor these developing technologies; and (5) if the prevailing regulatory framework fails to meet the challenge of genetic engineering, then Congress should enact a separate statute to address specifically the regulatory problems of this new technology.

## II. POSSIBLE HAZARDS OF NEWLY EMERGING GENETIC TECHNOLOGIES

Although predicting all the future uses of genetic technology is impossible, current and future technologies are divisible for purposes of analysis into three general categories: fermentation technologies, technologies such as mineral leaching that consist of the broad application of genetically altered micro-organisms to the environment, and technologies that use direct manipulation of human cells. This part of the Article describes the first two classes of technology and identifies some of the risks that each of them poses to man and the environment. The third class of technology—direct manipulation of human cells—raises a variety of interesting regulatory issues but is beyond the scope of this Article.<sup>24</sup>

### A. *Fermentation Technologies*

Fermentation technologies have served man for thousands of years.<sup>25</sup> During the fermentation process a micro-organism,<sup>26</sup> or an enzyme that a micro-organism produces, transforms one organic compound into another compound.<sup>27</sup> The process becomes commercially useful when an organism converts an inexpensive nutrient into a more valuable end product at a relatively low tempera-

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24. For a discussion of the regulatory issues that gene therapy raises, see McGarity & Shapiro, *Public Regulation of Recombinant DNA Gene Therapy*, 3 J. LEGAL MED. 185 (1982).

25. Before 6000 B.C. the Sumerians and Babylonians were using a simple fermentation process employing yeast, and the Egyptians used the carbon dioxide from yeast to leaven bread as early as 4000 B.C. Demain & Solomon, *supra* note 17, at 67.

26. The micro-organisms that industrial fermentation processes most commonly use are yeasts, molds, bacteria, and filamentous bacteria (actinomyces). See Phaff, *Industrial Micro-Organisms*, SCI. AM., Sept. 1981, at 77.

27. See Demain & Solomon, *supra* note 17, at 67. The micro-organism converts nutrients into proteins, which themselves can be commercially valuable. Some proteins, called enzymes, in turn can convert other raw materials into valuable products. OTA REPORT, *supra* note 16, at 50-51; Demain & Solomon, *supra* note 17, at 70-71. For an explanation of the whole process, see MICROBIAL TECHNOLOGY, *supra* note 17; Phaff, *supra* note 26, at 77-89.



ture. For example, certain yeasts can convert relatively inexpensive grains into a variety of valuable alcoholic beverages.<sup>28</sup> Other micro-organisms can convert inexpensive nutrients into more exotic, if less palatable, products such as glycerol,<sup>29</sup> methane, acetone, antibiotics, carbohydrates, lipids, and other organic compounds.<sup>30</sup>

Although the earliest fermentation technologies employed micro-organisms that spontaneously infected nutrients,<sup>31</sup> greater understanding of the fermentation process gradually gave rise in the twentieth century to the discovery and development of special strains of yeasts, bacteria, and molds that produce special proteins and other end products. Industrial researchers refined existing strains through selective mutation to produce organisms that more efficiently could convert nutrient into end product.<sup>32</sup> These researchers now believe that the new gene-splicing tools will increase dramatically the capacity of common industrial micro-organisms to produce commercially useful products.<sup>33</sup>

Practical implementation of gene-splicing research should follow a pattern similar to that used in the pharmaceutical and chemical industries. Two basic processes predominate in these industries: the "batch" method and the "continuous" approach.<sup>34</sup> Both processes require aseptic conditions. Foreign contaminants in the nutrient can interfere with or destroy the useful micro-organisms

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28. See Rose, *The Microbiological Production of Food and Drink*, SCI. AM., Sept. 1981, at 127, 133-36.

29. Demain & Solomon, *supra* note 17, at 68; see also OTA REPORT, *supra* note 16, at 92 ("In principle, virtually all organic compounds can be produced by biological systems.")

30. See OTA REPORT, *supra* note 16, at 50-51.

31. See Rose, *supra* note 28, at 127.

32. See MICROBIAL TECHNOLOGY, *supra* note 17, at 16-20; Demain & Solomon, *supra* note 17, at 67-70.

33. See OTA REPORT, *supra* note 16, at 54-55; Demain & Solomon, *supra* note 17, at 74.

34. By far the most widely used process in gene-splicing research is the "batch" method in which a laboratory worker places the micro-organisms, nutrients, and other starting materials in a large stainless steel vessel and stirs them during the fermentation process. After fermentation is complete, the worker empties the vessel, kills the organisms, and removes them through filtration or centrifugation. Then the worker separates the end product from the remaining liquids. See OTA REPORT, *supra* note 16, at 51-53; Gaden, *Production Methods in Industrial Microbiology*, SCI. AM., Sept. 1981, at 181. In the less commonly used "continuous" process, scientists immobilize the micro-organisms on a material such as alumina, charcoal, clay, or cellulose. Scientists then supply the nutrients and withdraw the liquids containing the end products in a steady, continuous stream. Next, they filter and purify the exhaust liquids as in the batch process. See 1980 Senate Hearings, *supra* note 21, at 38 (statement of Dr. Irving S. Johnson, Eli Lilly Corp.); Gaden, *supra*, at 181. Although the continuous process has several inherent advantages over the batch process, practical considerations limit its current use. See *id.* at 196.

or the end product. Moreover, unwanted organisms can introduce toxic impurities into the liquids that may survive the purification process and contaminate the end product. To avoid contamination, technicians sterilize the vessel and all starting materials to keep the micro-organisms scrupulously pure. Even the air entering the vessel usually is purified.<sup>35</sup> A manufacturer's desire to avoid contaminating the fermentation process thus provides a constant incentive to minimize the contact between workers and end products.<sup>36</sup>

While this natural incentive to avoid contamination operates in practice to protect workers from exposure to industrial micro-organisms, worker protection is not a primary goal, and, therefore, contamination routinely can occur. For example, no independent incentive exists to avoid worker exposure to micro-organisms after employees have completed a batch process, although the normal processing techniques usually ensure that such exposure does not occur until after the organisms are dead.<sup>37</sup> Adequate worker protection requires some mechanism for monitoring the micro-organism kills.<sup>38</sup> Exhaust gases from forced air fermentation vessels can expose workers and the environment to potentially pathogenic organisms. Manufacturers virtually can eliminate this risk of exposure by sterilizing exhaust gases with chemicals or steam.<sup>39</sup> Employees face possible contact with micro-organisms during the charging and inoculating process, centrifugation,<sup>40</sup> and the collec-

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35. Gaden, *supra* note 34, at 184.

36. See Letter from Mr. William Henderson to Dr. William Gartland, reprinted in 6 NATIONAL INSTITUTES OF HEALTH, U.S. DEP'T OF HEALTH AND HUMAN SERVICES, DOCUMENTS RELATING TO "NIH GUIDELINES FOR RESEARCH INVOLVING RECOMBINANT DNA MOLECULES" JANUARY 1980-DECEMBER 1980, at 271 (1981) [hereinafter cited as NIH DOCUMENTS]. Mr. Henderson states that "[t]he very high cost of mounting the commercial operation of large-scale biotechnology, e.g., the cost of the medium to fill an industrial-scale fermenter and the consequences of any contamination tend to ensure that the safety desirable for the growth of genetically manipulated organisms is likely to be achieved." *Id.*

37. See 1980 Senate Hearings, *supra* note 21, at 38-39 (testimony of Dr. Irving S. Johnson); 6 NIH DOCUMENTS, *supra* note 36, at 544-46 (NIOSH walk-through report on Genentech Corporation).

38. See 1980 Senate Hearings, *supra* note 21, at 39 (testimony of Dr. Irving S. Johnson); 6 NIH DOCUMENTS, *supra* note 36, at 443, 447 (statements of Dr. Irving S. Johnson); *id.* at 363 (statement of Dr. Anthony Robbins, NIOSH).

39. Large-scale fermenters that use organisms containing rDNA now are able to filter or incinerate exhaust gases. See 6 NIH DOCUMENTS, *supra* note 36, at 443 (statement of Dr. Irving S. Johnson).

40. Robert McKinney, Basic Practices and Procedures for Hazardous Biologic Operations—Regulatory Compliance Aspect, Paper presented at First Engineering Foundation Conference, "Advances in Fermentation Technology," in Boniff, Alberta, Canada (June 7-12, 1981) (copy on file with author).

tion of in-process samples,<sup>41</sup> even though the fermentator may be functioning properly.

Workers and the environment also risk exposure to micro-organisms during abnormal occurrences such as leaks, spills, and other breaches of the containment vessels.<sup>42</sup> Although companies employing fermentation technologies contend that major ruptures of containment vessels have not occurred,<sup>43</sup> small leaks have sprung in the vessels on rare occasions.<sup>44</sup> Technicians, of course, easily can sterilize leaked material,<sup>45</sup> but infection may occur prior to sterilization efforts. Personal protective devices such as rubber gloves and masks also can reduce exposure. While scientists have been unable to trace any major epidemics to exposure of workers to industrial micro-organisms, the general lack of employee health data in the fermentation industry precludes concluding that workers are free of micro-organism related infections.<sup>46</sup>

Exposure both to chemicals that the extraction process uses and to biologically active products and by-products of the fermentation process also can threaten worker safety.<sup>47</sup> For example, worker exposure to synthetic estrogens—products of a fermentation technology—resulted in numerous physical abnormalities in employees.<sup>48</sup> As companies continue to develop genetic technologies to produce compounds that are extremely rare in nature, the risks to workers from abnormally high exposure to end products may grow.<sup>49</sup> Appropriate adjustments in the physical plants and the protective devices that employees use, however, can reduce these risks to acceptable levels.

Most scientists probably would agree that the risks posed by

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41. See Memorandum from Dr. Seth Parker to Dr. William J. Gartland (Jan. 25, 1980), reprinted in 6 NIH DOCUMENTS, *supra* note 36, at 261.

42. See 6 NIH DOCUMENTS, *supra* note 36, at 63 (statement of Dr. LeRoy Walters); *id.* at 66 (statement of Dr. Christine Oliver).

43. See *id.* at 245 (comments of Eli Lilly Co.); *id.* at 266 (comments of Upjohn Co.); *id.* at 282 (comments of Genentech, Inc.).

44. See McKinney, *supra* note 41, at 9 ("The potential for exposure to aerosols is very real in large scale operations."); Telephone interview with Dr. David West, NIOSH, (September 21, 1981).

45. See 6 NIH DOCUMENTS, *supra* note 36, at 282 (comments of Genentech, Inc.).

46. See OTA REPORT, *supra* note 16, at 207; 1980 Senate Hearings, *supra* note 21, at 2-3 (statement of Dr. Anthony Robbins).

47. See OTA REPORT, *supra* note 16, at 204; 6 NIH DOCUMENTS, *supra* note 36, at 259 (comments of Coalition for Responsible Genetic Research); 1980 Senate Hearings, *supra* note 21, at 12 (statement of Dr. Anthony Robbins).

48. See 1980 Senate Hearings, *supra* note 21, at 11 (testimony of Dr. Anthony Robbins); Telephone interview with Dr. David West, *supra* note 44.

49. Telephone interview with Dr. David West, *supra* note 44.

fermentation technologies which employ micro-organisms containing well-characterized rDNA<sup>50</sup> will not be appreciably greater than the risks that current fermentation technologies create.<sup>51</sup> Companies are not likely to use highly infective organisms for fermentation, given the potential for substantial liability if any accidents occur and the relative ease of substituting noninfective organisms.<sup>52</sup> Moreover, existing risk assessments indicate that the presence of a recombinant molecule is not likely to increase the infectivity of a noninfective organism.<sup>53</sup> The risks, however, may increase if companies choose to take advantage of the greater flexibility of genetic engineering techniques and use fermentation technologies to produce more exotic, and perhaps more toxic, products and by-products. Because scientists have only limited experience with organisms containing recombinant DNA molecules, any unequivocal statements about the risks that these organisms pose to humans and the environment are premature.

*B. Technologies Consisting of Large-Scale Release of Micro-Organisms into the Environment*

Genetically engineered micro-organisms are capable of serving human beings beyond the confines of fermentation vessels. For centuries mining companies have used micro-organisms in leaching—a process that renders valuable metals more soluble and easily recoverable from low-grade ores. In this process one applies the micro-organisms directly to the mine spoils and waters them. With the aid of the bacteria, the metals dissolve and are recoverable later from the runoff. This technology has the potential to facilitate *in situ* mining of metals such as uranium.<sup>54</sup> Similarly, genetically engineered micro-organisms can be useful in enhancing oil recovery from wells in which primary and secondary techniques are no longer effective.<sup>55</sup>

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50. See *infra* text accompanying note 80.

51. Telephone interview with Dr. David Logan, OSHA, (Sept. 24, 1981); Telephone interview with Dr. Karim Ahmed, Natural Resources Defense Council, (Sept. 22, 1981); Telephone interview with Dr. David West, *supra* note 44; Telephone interview with Dr. Robert McKinney, NIH, (Sept. 18, 1981); see *infra* note 81 and accompanying text.

52. Interview with Dr. Karim Ahmed, *supra* note 51; see 1980 Senate Hearings, *supra* note 21, at 71 (statement of Dr. David Parkinson).

53. See *supra* note 13.

54. See OTA REPORT, *supra* note 16, at 117-19; Demain & Solomon, *supra* note 17, at 74.

55. Long-chain polymers, such as xanthan gum, can increase the viscosity of water and thereby improve the ability of injected water to displace oil in underground formations.

Industrial micro-organisms aid in pollution control. Bacteria already serve in sewage treatment plants to accelerate the process of oxidizing organic wastes. New genetic engineering technologies may yield organisms capable of breaking down harmful pollutants in the environment into relatively harmless substances. For example, the first micro-organism to receive a patent was a bacterium capable of breaking down chemicals found in oil spills.<sup>56</sup> Scientists also have undertaken to develop organisms that can alter highly toxic chemicals such as 2, 4, 5-T, and dioxin.<sup>57</sup>

In all these technologies, genetically engineered micro-organisms must enter the environment in large quantities. Widespread introduction of these organisms greatly reduces the amount of control over them. Monitoring for their presence is much more difficult in the natural environment than in relatively clean laboratories, and remedial action presents a greater challenge. Although the large-scale release of these micro-organisms apparently has not caused human or environmental harm,<sup>58</sup> the possibility exists that as genetic engineering techniques create exotic strains of potentially useful organisms, one or more of these strains will produce unwanted side effects. Ideally, scientists would test micro-organisms with the potential for large-scale application in the laboratory and in limited natural settings before releasing them in large quantities into the environment. Even adequate testing, however, may not prevent these organisms from acquiring a harmful trait in the environment or manifesting a deleterious characteristic once they find an ecological niche.<sup>59</sup> The performance of important industrial jobs through the widespread release of genetically engineered micro-organisms only very recently has become a realistic

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Scientists can produce these polymers by standard fermentation technologies and inject them into wells or, alternatively, produce them *in situ* by injecting an appropriate micro-organism and a suitable nutrient. See OTA REPORT, *supra* note 16, at 119-23. Although *in situ* methods have failed in the past, *id.* at 121, rising oil prices and further research may combine to yield a workable *in situ* mechanism.

56. See *Diamond v. Chakrabarty*, 447 U.S. 303, 305 (1980); OTA REPORT, *supra* note 16, at 126-27, 240-41.

57. OTA REPORT, *supra* note 16, at 126; 5 CHEM. REG. REP. (BNA) 1002 (1981).

58. See M. Levin, Understanding the Environmental Effects of Applied Genetics, Paper Presented at the International Symposium on Epidemiology and Molecular Biology of Plasmids (Jan. 6, 1981) (copy on file with author).

59. For example, some experts have suggested that an organism capable of digesting oil spills also might be able to digest oil in its beneficial state. Cf. *Diamond v. Chakrabarty*, 447 U.S. 303, 305 n.1 (1980). Similarly, using genetic engineering techniques to allow plants to fix nitrogen might alter the entire nitrogen cycle and cause irreversible climatic consequences. See Lovins, *Cost-Risk-Benefit Assessments in Energy Policy*, 45 GEO. WASH. L. REV. 911, 914 n.16 (1977); Lovins, *Nitrogen Fixation*, 255 NATURE 8, 8 (1975).

possibility, and the potential environmental effects of this new technology have received little thought.<sup>60</sup>

### III. ELEMENTS OF AN ADEQUATE REGULATORY REGIME

In the current deregulatory climate any argument for regulating business conduct must be justifiable as necessary to meet important societal goals.<sup>61</sup> Protecting the environment and the health and safety of workers and other citizens are, of course, worthy public objectives. The question, however, remains whether regulatory controls over the emerging genetic technologies are necessary to meet these goals and, if so, whether existing agencies possess sufficient statutory authority to implement appropriate controls. The brief examination of the risks that might arise from the extensive unmonitored use of the new genetic technologies<sup>62</sup> indicates the imprudence of assuming that genetic engineering always will prove benign. Past experience with other new technologies, such as railroads, automobiles, synthetic organic chemicals, and nuclear power, warns against the facile assumption that technological change is costless.

While current predictions concerning the hazards of new genetic technologies admittedly are speculative, caution suggests that society should examine its existing regulatory mechanisms and decide whether to take protective measures if genetic engineering proves more dangerous than it currently appears. At the same time policymakers should be sensitive to the need of a growing and potentially beneficial technology to be free of unnecessary regulatory constraints.

Society could decide to ignore the possible hazards of these technologies until evidence of actual harmful effects makes policymakers aware of those risks. If society, however, chooses not to ig-

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60. EPA currently is making some tentative efforts to study the possible environmental effects of large-scale applications of genetically engineered micro-organisms. See Levin, *supra* note 58; J. Johnson, Year End Report on the Genetic Engineering Planning Study, prepared for USEPA Advanced Environmental Control Technology Research Center at the University of Illinois (Dec. 20, 1980) (copy on file with author).

61. Breyer, *Analyzing Regulatory Failure: Mismatches, Less Restrictive Alternatives, and Reform*, 92 HARV. L. REV. 549, 552 (1979) ("[A]n unregulated marketplace is the norm and . . . those who advocate government intervention must justify it by showing that it is needed to achieve an important public objective that an unregulated marketplace cannot provide."); Crandall, *Environmental Control is out of Control*, CHEM. & ENG'G NEWS, Apr. 23, 1979, at 29-30; Sagoff, *Economic Theory and Environmental Law*, 79 MICH. L. REV. 1393, 1395 (1981).

62. See *supra* notes 35-52 and accompanying text.

nore genetic engineering technologies, a host of regulatory options is available, ranging from requiring companies to disclose information relevant to risk assessments to forcing firms to demonstrate product by product or process by process that the benefits of using genetically altered organisms exceed the risks. Society, of course, could select some intermediate regulatory policy, such as requiring firms to assess continuously the risks that their processes and products pose, and reporting the results of those assessments to an agency or the public. Society then would hold in abeyance a reserve regulatory capability for addressing problems as they arise.

#### A. *Data Collecting and Monitoring*

Perhaps the most important and least intrusive aspect of any mechanism for regulating human conduct is collecting information on the need for the regulation. The best way to determine whether regulation is necessary is to have a means of producing data that the agency can use to assess the risks present in the practical application of a technology. Risk assessments based upon this data can contribute to the decision whether to regulate and, if so, whether to impose controls upon the implementation of a particular technology. In addition, data collection should extend to the technology once it is in place to detect unexpected hazards and to determine whether the regulatory controls are functioning properly.

The data collection and monitoring mechanism for industrial applications of genetically engineered micro-organisms should be capable of compiling a central registry of hosts, vectors, industrially useful genetic sequences, and products and by-products from genetically engineered micro-organisms.<sup>63</sup> Without this basic information those persons within and outside of government who have an interest in evaluating the risks that genetic technologies pose, have nothing with which to begin their assessments. The data normally should be easily obtainable by an agency during the research and development phase of process and product development. Indeed, industrial firms are likely to generate this information irrespective of any regulatory requirement for the data. The crucial regulatory question concerns the authority of a regulatory agency

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63. Letter from Dr. Eula Bingham to Dr. Donald Fredricksen (Dec. 17, 1979), reprinted in 6 NIH DOCUMENTS, *supra* note 36, at 342, 343 ("A registry of all users of recombinant DNA material would be an important step in defining the scope and extent of use of recombinant DNA material and would facilitate continuing evaluation of any adverse health effects or toxicity.").

or independent "public interest" scientist to acquire the information and assemble it in a meaningful manner. This access, of course, would require some grant of power to a regulatory agency or interested member of the public.

The risk assessor also must have information on the extent to which humans and the environment are likely to come into contact with genetically altered micro-organisms before the assessor can engage in rational attempts to evaluate the risks of such exposure. Exposure estimates require knowledge about the potential use patterns for the organisms and about the kinds of interactions that will occur between the environment and the organisms, their products, and by-products as a result of these use patterns.

Regulatees probably will be reluctant to disclose information voluntarily on the nature of the micro-organisms, products, and by-products that they intend to use and market, because competitors could use this information to reduce or eliminate the regulatees' competitive advantage.<sup>64</sup> Preserving the competitive advantage of someone who has made a useful discovery can protect incentives to develop beneficial technologies.<sup>65</sup> A blanket legal requirement that all firms engaged in genetic engineering reveal information relevant to the risks of genetic technologies almost certainly would generate as many requests from competitors as from governmental agencies and public interest groups.<sup>66</sup> Hence, authority to require companies to disclose commercially sensitive information probably should lie within a regulatory agency, rather than with any member of the public. Since the public, however, has an obvious interest in the health and environmental aspects of the information, it should have some access to the data.

For many years the enigma of the "trade secret" status of health and safety information has plagued attempts by EPA and FDA to comply with the Freedom of Information Act's disclosure requirements.<sup>67</sup> Perhaps the best approach is a balancing process that weighs the public interest in disclosure of health and environment related information against the private interest in nondisclosure of data that incidentally might give other firms a competitive

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64. See generally McGarity & Shapiro, *The Trade Secret Status of Health and Safety Testing Information: Reforming Agency Disclosure Policies*, 93 HARV. L. REV. 837, 848-57 (1980) (innovator could lose substantial lead time by disclosure).

65. *Id.* at 848-56.

66. See *A Battle Over Pesticide Data*, 217 SCIENCE 515, 515 (1982).

67. See McGarity & Shapiro, *supra* note 64, at 867-82.



advantage.<sup>68</sup> Since innovative micro-organisms can be patented, however, the balance probably should weigh in favor of disclosure. The patent process requires disclosure of all innovative aspects of a new invention. In return, the holder of the patent receives exclusive use of the invention for seventeen years.<sup>69</sup> Since a firm can achieve this protection from its competitors, the government should require a company that desires to prevent the disclosure of information relevant to the health and environmental effects of its products and processes to sustain the burden of demonstrating that patent protection is insufficient to protect its proprietary interest.<sup>70</sup>

In addition to gathering information about the kinds of organisms that regulatees use industrially and about the expected interactions between these organisms and the environment, a regulatory mechanism should be able to monitor actual application of the technology for the improper presence of organisms.<sup>71</sup> Laboratories or firms should monitor the area around the fermentation tanks periodically to determine if the organism used in the fermentation process has escaped. In addition, waste flows should be checked periodically to validate micro-organism kills.<sup>72</sup> These monitoring tasks are relatively simple because scientists easily can detect

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68. *See id.* at 863-64.

69. 35 U.S.C. § 101 (1976); *see Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480-81 (1974).

70. *See McGarity & Shapiro, supra* note 64, at 885; *cf. Note, Trade Secrets and the NLRA; Employees' Right to Health and Safety Information*, 14 U.S.F.L. REV. 495, 514-15 (1980).

71. NIOSH has suggested the following elements of an adequate monitoring program:

- a. Registry of potentially exposed individuals.
- b. Work area monitoring program, including air and services, for viable recombinant DNA host-vector organisms.
- c. Direct personnel monitoring for host-vector organisms, and if colonization has occurred, further testing for the expression of the relevant gene product may be appropriate.
- d. Occupational and medical histories, which should include a determination of existing factors that might place workers at increased risks.

6 NIH DOCUMENTS, *supra* note 36, at 262-63; *see id.* at 355-56 (statement of Ms. Margaret Seminario, industrial hygienist, AFL-CIO); *id.* at 357 (statement of Dr. Christine Oliver, occupational physician, Oil, Chemical, and Atomic Workers Union).

72. *See* 6 NIH DOCUMENTS, *supra* note 36, at 260 (comments of Coalition for Responsible Genetic Research); *id.* at 443 (description of Eli Lilly Company validation procedures); *id.* at 546 (NIOSH report describing and critiquing validation procedure at Genentech Corporation); National Institutes of Health, Recombinant DNA Research; Physical Containment Recommendations for Large-Scale Uses of Organisms Containing Recombinant DNA Molecules, 45 Fed. Reg. 24,968, 24,969-70 (1980) (proposed sections VII-B-2; VII-C-2; and VII-D-2) [hereinafter cited as NIH Large-Scale Guidelines].

traces of micro-organisms in the environment by checking for their presence in nutrient solutions placed around the fermentation area.<sup>73</sup> Similarly, laboratories could monitor areas near the locations of large-scale micro-organism application to determine whether the organisms are spreading farther than expected. If policymakers impose regulatory controls upon a particular genetic technology, a monitoring mechanism would be useful for measuring the effectiveness of those controls.

Finally, a monitoring mechanism should be available to detect instances of actual human and environmental harm caused by exposure to genetically engineered micro-organisms, their products, and by-products. Without periodic surveillance of worker health and the environment surrounding genetic engineering sites, policymakers will be unable to tell if more intrusive regulatory controls are necessary. Even if premanufacture risk assessments indicate a potential for only minimal harm, a company nevertheless should monitor workers and others who might come into contact with the new technology to detect harm when risk assessments are overly optimistic. In addition to recording systematic and unplanned exposures due to spills and other accidents, a thorough monitoring program would include periodic medical surveillance of exposed persons and, in a large-scale release, periodic monitoring of the surrounding environment.<sup>74</sup>

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73. NIOSH has cautioned that air monitoring must be very thorough to be effective: Quantitative and qualitative sampling of air and surfaces in the production and laboratory areas can be an effective measure of sanitation, environmental conditions, and efficacy of control measures. Environmental sampling programs have been utilized in hospitals, the food industry, and containment laboratories for years and the principles of these programs are applicable to the operations at Genentech. The efficacy, sensitivity, and accuracy of environmental sampling and analytical techniques should, however, be considered and their validity must be established prior to utilization. The procedures analysis, sampling points and sampling schedules, thus established, should be formalized in writing.

6 NIH DOCUMENTS, *supra* note 36, at 549.

74. The NIH has proposed a monitoring program for large-scale activities that use organisms which require P3-LS containment at the laboratory level. "The program shall include: preassignment and periodic physical and medical examination; collection, maintenance and analysis of serum specimens for monitoring serologic changes that may result from the employee's work experience; and provisions for the investigation of any serious, unusual or extended illnesses of employees to determine possible occupational origin." NIH Large-Scale Guidelines, *supra* note 72, at 24,968.

The Eli Lilly Company voluntarily has adopted an employee medical surveillance program for its rDNA fermentation operations. This plan includes an annual physical examination and screen collection. See 6 NIH DOCUMENTS, *supra* note 36, at 64, 445-56, 507. See also *id.* at 545 (Genentech Corporation employees working with human growth hormone and interferon subject to fecal monitoring). The Cetus Corporation does not require annual

To avoid potential tort and workers' compensation claims regulatees may monitor voluntarily for the presence of genetically engineered micro-organisms in improper places and for illness and environmental damage caused by the organisms.<sup>75</sup> Without a legal requirement to monitor, however, some firms may choose blissful ignorance. A company may adopt the attitude that what the company does not know, the workers will not know, and what the workers do not know cannot hurt the company. Even if most firms do not adopt this short-sighted view, they may not be willing to share their data with regulatory agencies and the public when the monitoring could reveal possible health problems or violations of regulations or guidelines. The legislature, therefore, might consider giving a governmental agency the authority to command access to genetic engineering firms so that the agency can monitor for regular and irregular releases of genetically engineered micro-organisms. The legislature could go still further and require enforceable self-monitoring of micro-organism releases.<sup>76</sup> Finally, to ensure that the regulator discovers actual harm as soon as possible, the legislature could give the agency authority to require firms to report systematically on planned and unplanned exposures to the organisms and to engage in periodic medical and environmental surveillance of exposed humans and the environment.

### B. Risk Assessment

Like the common-law courts, which rarely invoke their authority until after a harm has occurred, the legislature may elect to assume an entirely passive stance with respect to the risks posed by newly emerging genetic technologies. Experience with other potentially dangerous technologies, however, repeatedly has demon-

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physical examinations, but all employees on sick leave must have clearance from a physician before returning to work. Furthermore, the company excludes employees with open wounds or on antibiotic therapy from rDNA areas. *Id.* at 559. NIOSH plans to develop guidelines for medical surveillance techniques for companies using genetically engineered micro-organisms. See Memorandum from Dr. Anthony Robbins to Dr. Gilbert S. Omenn (June 11, 1980), reprinted in 6 NIH DOCUMENTS, *supra* note 36, at 372-73; see also 6 NIH DOCUMENTS, *supra* note 36, at 494 (statement of Dr. Anthony Robbins).

75. Eli Lilly Company, for example, conducts periodic environmental monitoring around its 150-liter rDNA fermentor. The monitoring program measures the exhaust gases and the general room environment twice a week with both air samples and plate samples. See 6 NIH DOCUMENTS, *supra* note 36, at 64, 445, 507. See also *id.* at 544 (description of environmental monitoring at Genentech Corporation); *id.* at 260 (comments of Coalition for Responsible Genetic Research).

76. See Clean Water Act § 311(b)(5), 33 U.S.C. § 1321(b)(5) (1976 & Supp. V 1981) (requiring self-monitoring of spills on navigable waters).

strated the value of assessing the risks to man and the environment before the technologies attain widespread use.<sup>77</sup> A legislature, therefore, may choose to charge some governmental entity with the duty of regularly assessing the risks to society that may arise from industrial processes which utilize genetically engineered micro-organisms. Thorough risk assessments may demonstrate that no regulation is necessary beyond periodic monitoring for unexpected health and environmental effects. Moreover, risk assessments can guide decisionmakers to the most appropriate regulatory approaches, if the government deems that regulation is needed.<sup>78</sup> Absent adequate risk assessments, however, society will learn that a technology is malignant only after it has damaged—perhaps irreparably—human life or the environment.<sup>79</sup>

An appropriate risk assessment of the industrial use of genetically engineered micro-organisms would consist of at least three kinds of analyses. First, a genetically altered micro-organism should undergo a thorough characterization. This characterization should include analyses of the structure of the organism's DNA, the ability of the organism as altered to infect humans and other

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77. See The Technology Assessment Act of 1972, 86 Stat. 797 (codified at 2 U.S.C. §§ 471-481 (1976)); Danhof, *Assessment Informations Systems*, in *TECHNOLOGY ASSESSMENT 7*, 9-10 (R. Kaspar ed. 1969); Speth, *The Federal Role in Technology Assessment and Control*, in *FEDERAL ENVIRONMENTAL LAW 420* (E. Dolgin & T. Guilbert eds. 1974).

78. See R. LAVE & S. OMENN, *CLEARING THE AIR: REFORMING THE CLEAN AIR ACT 18* (1981). ("The approach of specifying the nature of the risks and analyzing the kinds of effects and numbers of people to be affected at each level of exposure allows a rational assessment of acceptable remaining risks in light of the feasibility of compliance with alternative standards."). See *Comparative Risk Assessment, Hearings Before the Subcomm. on Science, Research and Technology of the House Comm. on Science and Technology*, No. 129, 96th Cong., 2d Sess. (1980); *Risk Benefit Analysis in the Legislative Process, Joint Hearings Before the Subcomm. on Science, Research and Technology of the House Comm. on Science and Technology and the Subcomm. on Science, Technology and Space of the Senate Comm. on Commerce, Science and Transportation*, No. 71, 96th Cong., 1st Sess. (1979).

79. The FDA experience with Diethylstilbestrol (DES) is one example of inadequate risk assessment that resulted in unforeseen and widespread tragic effects. Doctors prescribed DES for years to women with estrogen deficiencies, to pregnant women to prevent miscarriage, and as a "morning after" contraceptive, before further analysis of the drug's long-term effects revealed its cancer-causing nature. S. HADDEN, *DES AND THE FDA: THE USES OF TECHNICAL ADVICE IN REGULATORY POLICY-MAKING 9-11* (Southern Center for Studies in Public Policy 1976). As many as 1.5 million American women took the synthetic hormone before Dr. Arthur Herbst discovered that the drug caused rare vaginal cancer, an increase in premature deliveries, pregnancy loss, and possible infertility among daughters of women who took the drug. *Miscarriages, Early Births Higher in 'DES Daughters,'* Wash. Post, Jan. 25, 1980, at A8, col. 1. See also HOUSE COMM. ON SCIENCE AND ASTRONAUTICS, 91ST CONG., 1ST SESS., *REPORT OF THE NATIONAL ACAD. OF SCIENCES: TECHNOLOGY, PROCESSES OF ASSESSMENT AND CHOICE 1* (Comm. Print 1969).

organisms, the pathogenicity of the organism, and the possible products and by-products of the organism.<sup>80</sup> Second, if the characterization of the organism reveals that it could infect humans or other organisms, the risk assessment should attempt to estimate the probability that human and environmental exposure to the organism would be of sufficient duration and concentration to create the potential for damage in the infected entity.<sup>81</sup> Last, the assessment should estimate the risks to humans and the environment attributable to exposure to the chemical products and by-products of the industrial process.<sup>82</sup>

The governmental entity that performs these risk assessments need not be a regulatory agency. Indeed, an independent governmental agency that has no regulatory role, such as NIH, could perform the analyses to ensure objectivity in the assessments. Risk assessment is by nature a highly speculative enterprise. Substantial uncertainties inevitably accompany any serious effort to assess the potential harm to society of a particular technology. The goals of public policy ultimately determine the extent of preventative regulatory controls on any industrial activity. Nevertheless, risk assessments can be very helpful to legislatures and agencies deciding whether to regulate and which regulatory options to adopt.

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80. Characterization of genetically altered micro-organisms is sufficiently important to the director of the NIH that the NIH Guidelines for Recombinant DNA Research prohibit experiments using more than 10 liters of culture "unless the recombinant DNAs are rigorously characterized and the absence of harmful sequences established." NIH Guidelines—1981, *supra* note 7, § I-D-6, at 34,463.

81. Several organizations already have undertaken to study the survivability of genetically altered organisms in animals and the environment. See National Institutes of Health, Program to Assess Risks of Recombinant DNA Research; Proposed First Annual Update, 45 Fed. Reg. 61,874 (1980) [hereinafter cited as NIH Program to Assess Risks]. These studies generally have concluded that the danger of pathogenic infection from commonly used micro-organisms is very low. See National Institutes of Health, Recombinant DNA Research; Final Plan for a Program To Assess the Risks, 46 Fed. Reg. 30,772 (1981); NIH Program to Assess Risks, *supra*, at 61,874. EPA also is planning studies to evaluate the potential hazards of industrial application of genetic engineering. See J. Johnson, *supra* note 60; M. Levin, *supra* note 58.

82. Methods for assessing the human and environmental risks due to exposure to chemicals in the environment are familiar, if occasionally controversial. See, e.g., NATIONAL ACADEMY OF SCIENCES—NATIONAL RESEARCH COUNCIL, EVALUATING THE SAFETY OF FOOD CHEMICALS (1970); NATIONAL ACADEMY OF SCIENCES—NATIONAL RESEARCH COUNCIL, PRINCIPLES FOR EVALUATING CHEMICALS IN THE ENVIRONMENT (1975); NATIONAL CANCER ADVISORY BOARD SUBCOMMITTEE ON ENVIRONMENTAL CARCINOGENS, GENERAL CRITERIA FOR ASSESSING THE EVIDENCE OF CARCINOGENICITY OF CHEMICAL SUBSTANCES (1976); Leape, *Quantitative Risk Assessment in Regulation of Environmental Carcinogens*, 4 HARV. ENVTL. L. REV. 86 (1980).

### C. Regulatory Controls

The risk assessments that scientists already have made on many micro-organisms indicate that industrial use of these organisms may pose very few risks to man and the environment. Most experimental strains of *E. coli*, for example, do not appear to be capable of infecting human beings or of exchanging genetic material with "wild" organisms that can infect humans.<sup>83</sup> The tests, however, are not conclusive and more experiments are necessary before scientists can say with confidence that genetically altered *E. coli* poses no threat to exposed humans.<sup>84</sup> Moreover, genetic engineers are experimenting with organisms, such as *bacillus subtilis*, *streptomyces*, and *saccharomyces*, which they must assess further for potential risks.<sup>85</sup> Different organisms may present a whole new set of environmental hazards.

If future risk assessments demonstrate that industrial application of genetically engineered micro-organisms poses little or no threat to society, erection of a specific regulatory structure capable of controlling risky aspects of that technology may be unnecessary. Scientists, however, are far from being able to draw this conclusion. Since genetic technologies presently appear relatively safe, policymakers may prefer to forego more intrusive regulatory mechanisms until risk assessment results indicate otherwise. Considering, however, how long Congress takes to react to serious health and environmental problems,<sup>86</sup> some speculation may be useful

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83. See Korwek, *OSHA Regulation of Industrial Applications of Recombinant DNA Technology*, 50 U. CIN. L. REV. 284, 289-90 (1981).

In general, it has been found that *E. coli* and yeast are not pathogenic, cannot be made pathological by insertion of rDNA sequences, and do not implant in the intestinal tracts of laboratory animals or humans. In addition, *E. coli* and yeast containing rDNA sequences are not easily transmitted to other microorganisms, nor are they likely to survive in a competitive environment.

*Id.* at 290.

84. STAFF OF SUBCOMM. ON SCIENCE, RESEARCH AND TECHNOLOGY OF THE HOUSE COMM. ON SCIENCE AND TECHNOLOGY, 96TH CONG., 2D SESS., GENETIC ENGINEERING, HUMAN GENETICS, AND CELL BIOLOGY, EVOLUTION OF TECHNOLOGICAL ISSUES, BIOTECHNOLOGY (SUPPLEMENTAL REPORT III) 9 (Comm. Print 1980).

While accepting the expert's assurances that it is virtually impossible to convert *E. coli* K-12 into a pathogen, there is no harm in recollecting that even totally defined, man made systems . . . occasionally produce surprises . . . [O]nly a third of the metabolic activities which take place in *E. coli* K-12 are known at present, and it may take another 20 to 25 years before we approach the state of knowing them thoroughly, according to James Watson.

*Id.* at 48-49 (citation omitted).

85. See 6 NIH DOCUMENTS, *supra* note 36, at 447 (statement of Dr. Irving S. Johnson).

86. Two examples of congressional delay are the enactments of the Toxic Substances

about what regulatory mechanisms would be appropriate if the dangers associated with genetic technologies were to increase.

A policymaker has several regulatory options from which to choose in addressing genetic technologies. The options exhibit varying degrees of intrusiveness, and range from performance standards to a requirement that the government license each technology. The purpose of this Article is to discuss broadly the kinds of options that are available to legislatures and regulatory agencies. An examination of four dimensions of health and environmental regulation is useful in gaining this overall view. A policymaker can focus upon (1) the nature of the regulatory statement that the agency articulates; (2) the nature of the immediate regulatory goal; (3) the addressee of the regulatory statement; and (4) the focus of the regulatory statement. These dimensions are not mutually exclusive. The particular regulatory strategy that the legislature or regulatory agency adopts will depend *inter alia* upon the nature of the regulatory problem, the degree of protection required, and the degree of intrusiveness that the policymaker desires.

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Control Act (TSCA), 15 U.S.C. §§ 2601-2629 (1976 & Supp. V. 1981), and the Surface Mining Control and Reclamation Act of 1977 (SMCRA), Pub. L. No. 95-87, 91 Stat. 445-532 (1977). Toxic control legislation originated in 1971 in response to a report by the Council on Environmental Quality emphasizing an increasing need for regulation. During the 92d and 93d Congresses, both the House and Senate separately passed legislation. Because of delay in passing the House bill and the inability of the Conference Committee to reach a compromise between the bills, however, all legislation died at the end of each session. The 94th Congress in 1976 finally enacted the current statute, which had its origin in an earlier Senate bill (S. 1478). Gaynor, *The Toxic Substances Control Act: A Regulatory Morass*, 30 VAND. L. REV. 1149, 1150 (1977).

The SMCRA took six years to enact. The 90th Congress held the first hearings in 1971 but neither the 90th nor the 91st Congress reported any legislation. During the 92d Congress, the Subcommittee on Minerals, Materials and Fuels unanimously reported a bill to the Senate (S. 630) and reserved the right to amend it on the floor. The House passed a similar bill (H.R. 6482) in October 1972, but the 92d Congress recessed before the Senate could consider either bill. During the 93d Congress the Senate drafted compromise legislation (S. 425) that met a pocket veto by the Ford Administration at the end of that Congress. On February 6, 1975, the President drafted suggested changes to the proposed bills; senators realized that eight of those changes were crucial for Administration approval. At the beginning of the 94th Congress, a joint bill incorporated a majority of the suggested changes. The changes were inadequate, however, and President Ford vetoed this bill May 20, 1975; the House almost overrode the veto on June 10, 1975, but failed to do so by three votes. Later in the same session, Congressmen introduced two bills that met Administration requirements, but both failed in Congress. President Carter finally signed the current act into law in 1977. Comment, *The Surface Mining Control and Reclamation Act of 1977*, 9 ST. MARY'S L.J. 863, 863 & n.1 (1978).

## 1. The Nature of the Regulatory Statement

The current occupational safety and pollution control statutes contain two approaches to health and environmental regulation: the "command and control" approach and the "incentive" approach.<sup>87</sup> The command and control approach is the regulatory technique best known to lawyers—the regulatory entity proscribes certain conduct, and anyone who engages in that activity can face a civil or criminal fine or perhaps even incarceration.<sup>88</sup> The command and control approach requires the standard-setter to be very familiar with the operations and vocabulary of the regulated enterprise and the nature of its unwanted effects so that the standards can proscribe "bad" conduct without unduly inhibiting "good" conduct.<sup>89</sup> The approach also requires that the standard-setter draw clear and definite lines between acceptable and unacceptable conduct because ambiguity can precipitate attempts to prevent acceptable conduct, particularly in the grey areas.<sup>90</sup> Since standards can have severely negative effects on the regulated entities, the command approach requires that these entities be able to participate in the promulgation of the rules and challenge those that are arbitrary or lack support.<sup>91</sup> Unfortunately, this aspect of the pro-

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87. Perhaps the most articulate description of this basic distinction appears in C. SCHULTZE, *THE PUBLIC USE OF PRIVATE INTEREST* (1977). The distinction, however, is common in the literature on the economics of regulation. See A. KNEESE & C. SCHULTZE, *POLLUTION, PRICES AND PUBLIC POLICY* 91 (1975); B. MITNICK, *THE POLITICAL ECONOMY OF REGULATION* 342-56 (1980).

88. See Toxic Substances Control Act § 17, 15 U.S.C. § 2616 (1976); Occupational Safety and Health Act § 10, 29 U.S.C. § 659 (1976); Clean Water Act § 309, 33 U.S.C. § 1319 (1976); Clean Air Act § 113, 42 U.S.C. § 7413 (Supp. V 1981); Resource Conservation and Recovery Act § 3008, 42 U.S.C. § 6928 (1976 & Supp. V 1981).

89. Hays, *Political Choice in Regulatory Administration*, in *REGULATION IN PERSPECTIVE, HISTORICAL ESSAYS* 124, 129 (T. McCraw ed. 1981) ("If one were to require that pollution control technology used by the 'best' firms be applied to all, one had to have a clear notion of the range of technology in place for existing firms so as to know which would serve as examples for others."). See F. ANDERSON, A. KNEESE, P. REED, R. STEVENSON, & S. TAYLOR, *ENVIRONMENTAL IMPROVEMENT THROUGH ECONOMIC INCENTIVES* 12 (1977) [hereinafter cited as *ENVIRONMENTAL IMPROVEMENT*]; C. SCHULTZE, *supra* note 87, at 20.

90. Spence & Weitzman, *Regulatory Strategies for Pollution Control*, in *APPROACHES TO CONTROLLING AIR POLLUTION* 199, 202 (A. Friedlaender ed. 1978) ("Frequent changes in regulations may create serious implementation problems for a well-intentioned business management.").

91. *ENVIRONMENTAL IMPROVEMENT*, *supra* note 89, at 12-15. "If an agency decides to be strict and impose standards that an industry thinks cannot be met, it must fight industry experts in administrative proceedings and in court." *Id.* at 14. See Henderson & Reason, *Implementing Federal Environmental Policies: The Limits of Aspirational Commands*, 78 *COLUM. L. REV.* 1429, 1438 (1978) (In some cases the agency will lack sufficient expertise and will have to "rely on those possessing the expertise—in most instances, the same firms



cess offers a recalcitrant regulatee numerous opportunities for obfuscation and delay. Moreover, the command approach requires an effective enforcement agency capable of monitoring the conduct of regulated entities to observe whether or not they are complying with the standard-setter's directives.<sup>92</sup>

The incentive approach attempts to guide rather than prescribe the regulatees' conduct. The regulator seeks to induce conduct indirectly by rewarding "good" conduct with grants or tax breaks and penalizing "bad" conduct with charges or other economic costs.<sup>93</sup> While the command approach generally requires the standard-setter to supersede the market,<sup>94</sup> under the incentive approach the intervening governmental entity must supplement the market by making undesirable conduct more costly.<sup>95</sup> Policymakers might devise an incentive-based scheme to allow individual firms the freedom to achieve a required goal, such as fewer workplace deaths or fewer dead fish in a nearby lake, through source- or receptor-oriented technologies.<sup>96</sup>

which are to be regulated—for substantial assistance in the rulemaking process.”).

92. ENVIRONMENTAL IMPROVEMENT, *supra* note 89, at 8 (“[A]ll programs require that discharges and ambient quality be monitored; there is no escaping this technological imperative.”).

93. Several distinct types of incentive-based regulatory regimes exist. The scheme that economists advocate most commonly for remedying “spillover” problems is the “tax” or “charge” system under which the regulatee must pay an agency a charge for each unit of undesirable conduct. *See id.* at 14-17; A. KNEESE & C. SCHULTZE, *supra* note 87, at 99-101. Under an alternative “marketable permit” approach, the regulatory entity identifies in advance—usually in accordance with some media quality-based standard—the quantity of undesirable conduct that is socially acceptable. The regulatory entity then auctions off the right to engage in this conduct to the highest bidders and prohibits anyone from engaging in that conduct except pursuant to a purchased right. After the initial auction the rights are freely transferable. *See* ENVIRONMENTAL IMPROVEMENT, *supra* note 89, at 21; Rose-Ackerman, *Effluent Charges: A Critique*, 6 CAN. J. ECON. 512 (1973); Rose-Ackerman, *Market Models for Water Pollution Control: Their Strengths and Weaknesses*, 25 PUB. POL’Y 385 (1977) [hereinafter cited as *Market Models*].

94. Breyer, *Analyzing Regulatory Failure: Mismatches, Less Restrictive Alternatives, and Reform*, 92 HARV. L. REV. 549, 561 (1979) (“[T]he relation between the regulator and the affected industries is often adversary, for the regulator is to lead the industry to perform in a manner different from that dictated by the unregulated market.”).

95. ENVIRONMENTAL IMPROVEMENT, *supra* note 89, at 29-30 (“[A] market approach] require[s] those wishing to discharge pollutants into the air or water . . . to pay for these uses of the common property resources.”); Kelman, *Economists and the Environmental Muddle*, 64 PUB. INTEREST 106 (Summer 1981).

96. Source-oriented regulatory schemes concentrate on companies whose waste emissions make them sources of pollution. Receptor-oriented approaches focus on the persons who might come in contact with the pollution. Most current suggestions for incentive-based regulatory approaches do not give the regulatory entity the authority to allow the regulated firms to choose between source- and receptor-oriented schemes. The proposals would levy pollution taxes upon units of pollution, not upon units of damage. Similarly, regulatees

Unless regulators are content to use incentives on an ad hoc experimental basis, they need information upon which to base predictions about the incentive's impact on the quality of the receiving media and/or its impact on the regulated firms.<sup>97</sup> Moreover, while the regulatory entity in an incentive system does not have to police individual regulatee compliance with detailed standards, nevertheless, it needs an enforcement mechanism capable of detecting "cheaters" who, in effect, attempt to "steal" a clean environment or safe workplaces from society.<sup>98</sup>

The primary advantage of the incentive approach to regulation is its efficiency. It allows regulated firms to achieve a given level of health and environmental protection in the most cost-effective manner.<sup>99</sup> Furthermore, the incentive theory gives regulated firms a great degree of freedom to mix "process" and "end of pipe" controls to meet the special circumstances of individual plants.<sup>100</sup> Genetic technology firms would fully realize these advantages. An incentive approach is an especially attractive means of regulating a new technology that requires the construction of new facilities because the regulated entity has the widest range of options when it is designing a facility from scratch. Furthermore, an innovative new industry that has not settled into established technologies desires flexibility to choose which control technologies are most suitable to its circumstances.

Despite the enthusiastic endorsement of economists and other policy analysts, the incentive approach has not proved attractive to policymaking bodies. Congress briefly flirted with the notion of a tax on sulfur emissions in the early 1970's but rejected the idea for a number of reasons—many of them probably unrelated to the proposal's merits.<sup>101</sup> Professor Kelman recently has reported that opposition to a "charge" approach remains strong, especially

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would receive pollution rights for units of pollution, not for units of health or environmental harm. If an agency could craft these techniques in units of environmental harm rather than in units of pollution, sources would be free to choose between source- and receptor-oriented techniques.

97. B. MITNICK, *supra* note 87, at 353; Solow, *The Economists' Approach to Pollution and Its Control*, 173 *SCIENCE* 498, 501 (1971).

98. ENVIRONMENTAL IMPROVEMENT, *supra* note 89, at 32-37; C. SCHULTZE, *supra* note 87, at 42; *Market Models*, *supra* note 93, at 395.

99. ENVIRONMENTAL IMPROVEMENT, *supra* note 89, at 9, 33, 151; B. MITNICK, *supra* note 87, at 376.

100. See ENVIRONMENTAL IMPROVEMENT, *supra* note 89, at 10, 34; A. KNEESE & C. SCHULTZE, *supra* note 87, at 87-91; B. MITNICK, *supra* note 87, at 376.

101. ENVIRONMENTAL IMPROVEMENT, *supra* note 89, at 52-53; A. KNEESE & C. SCHULTZE, *supra* note 87, at 100.

among industry representatives and liberal congressional staffers.<sup>102</sup> Environmentalists appear to be split on the issue.<sup>103</sup>

The general lack of enthusiasm for the incentive approach stems primarily from its three disadvantages. First, the incentive approach is difficult to enforce. Often the kind of conduct that threatens human health or the environment is not easily divisible into discrete units for convenient metering. Second, an incentive system requires the regulated firm to incur immediate and constant costs unrelated to the productivity of the target activity. While incentives give management greater flexibility than do commands, no opportunity exists under the incentive system for variances or other ameliorative measures. The firm immediately must absorb fees or the cost of marketable permits in its operating budget. Hence, while an incentive scheme might be more attractive to a firm in the long run, its immediate costs cause management to be wary of that approach. Last, the incentive approach is unsuitable to hazards of a catastrophic nature. When conduct entails a very small probability of a very high consequence accident, the regulatory entity must ensure that the accident never happens. Obviously, fines or fees make little sense when a firm's conduct has caused the death of 50,000 people. While conceivably the regulatory entity could adapt an incentive scheme to discrete units of risk, rather than to units of damage, the legal literature has not explored this option in detail.

The disadvantages of an incentive approach pertain directly to the regulation of genetic technologies. Agencies might have difficulty determining the units of worker health or environmental disruption attributable to infections by harmful organisms or damage from toxic products and by-products. If a particular organism or its by-products posed only a low risk of infection or other health effects, regulators might set a fee based upon the frequency of the micro-organism's release from the containment area.<sup>104</sup> This option would require continuous monitoring for the presence of organisms and by-products outside the area. The expense of monitoring might be prohibitively high. Although assessing firms a minimal fee based on the release of relatively harmless organisms and by-

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102. Kelman, *supra* note 95, at 109.

103. *Id.* at 111.

104. While this approach more easily is applied to enclosed systems such as fermenters, nevertheless, it is adaptable to large-scale release technologies. The difficulty with the latter application is in defining the containment area outside which the organism or its by-products should not spread.

products would encourage firms to minimize releases, this measure also would represent an acknowledgement of the inevitability of those releases. This option obviously would be inappropriate for organisms and by-products that posed a relatively high risk of serious harm to health or the environment.

Firms considering entry into the new field may object to the immediate costs that an incentive system imposes upon them. New firms should not have strong objections because they can avoid fees by designing controls into the new plants. Nevertheless, many of the newer firms entering the genetic engineering field must struggle for sufficient capital to begin scale-up activities. They are likely to oppose an incentive system just as vociferously as they would oppose any regulatory requirement that has no promise of increasing the ultimate profitability of their enterprise.

The incentive approach operating alone is inappropriate for a technology that uses hazardous organisms. Some scientists still paint scenarios of epidemics and devastating environmental degradation caused by industrial use of genetic technologies. Certainly the use of some hosts might result in great harm to health and the environment if the organisms escaped the confinement area. While no firms at present indicate any desire to utilize highly infective organisms in industrial genetic engineering, in the event that they choose to do so in the future, the government may decide to use an incentive approach reinforced by a more intrusive regulatory scheme.

## 2. The Nature of the Immediate Regulatory Goal

Almost every existing regulatory regime adopts either a media quality-based,<sup>105</sup> a technology-based,<sup>106</sup> or a balancing approach<sup>107</sup>

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105. A media quality-based approach focuses primarily upon the quality of the receiving medium. The first step is to articulate a general goal for the receiving medium. Policy-makers could specify this standard with great particularity—for example, no more than 150 dead fish or 100 cases of human cancer per year—but more often the goal is expressed in more hortatory terms, such as fishable/swimmable water. A regulatory entity then determines the level of pollutant—or other unit of unacceptable conduct—in the receiving medium to meet the goal. See, e.g., 1 EPA, Air Quality Criteria for Particulate Matter and Sulfur Oxides, External Review Draft No. 2 (Feb. 1981) (unreleased preliminary draft). The regulator probably will have to estimate the environmental and health effects of the pollutant in the receiving medium at various concentrations. *Id.* Using a model that relates discharges from individual facilities to media quality, the regulator calculates the pollution load for locations that meet the standard and the pollution reduction load for sites that exceed the permissible level. See *Texas v. EPA*, 499 F.2d 289, *cert. denied*, 427 U.S. 905 (1974); Clean Water Act § 303, 33 U.S.C. § 1313 (1976 & Supp. V 1981); cf. EPA 600/5-76-004, Evaluation of Water Quality Models: A Management Guide for Planners (July 1976).

to health and environmental regulation. The media quality and

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Finally, the regulating entity apportions the load among the existing sources and perhaps saves some portion of the available load for future sources. *See* Clean Air Act § 110, 42 U.S.C. § 7410 (Supp. V 1981); Clean Water Act § 303, 33 U.S.C. § 1313 (1976 & Supp. V. 1981); TEXAS AIR CONTROL BOARD—TEXAS STATE IMPLEMENTATION PLAN, CONTROL STRATEGIES (March 30, 1979). Of course, if the entire load in a relevant media quality region is attributable to a single source, as would happen with most detrimental aspects of genetic technologies, then allocation is not necessary and the regulatory entity simply can use its reduction model to work backwards from the desired level of media quality to an effluent or emission limitation for the source. The agency monitors the sources and the receiving media to detect violations of limitations and to determine whether the load reduction model functioned properly.

106. Under the technology-based approach the legislature specifies in broad terms, such as "best available technology," Clean Water Act § 301, 33 U.S.C. § 1311(b) (1976 & Supp. V. 1981), or "lowest achievable emission rate," Clean Air Act § 171, 42 U.S.C. § 7501(3) (Supp. V 1981), the degree of pollution control technology that it expects regulated industries to implement, regardless of the impact on the quality of the receiving media. Pollution control technology does not refer simply to end of pipe technologies. Changes in design, in the operation of the basic units of production, and in the way that employees perform their tasks can reduce pollution as effectively—and often more cheaply than—end of pipe methods. *See* A. KNEESE & C. SCHULTZE, *supra* note 87, at 24.

After the standard-setter has articulated its expectation regarding pollution control technology, it divides the various regulated industries into categories and subcategories according to the production processes they employ, the nature of the product and waste stream, the age of the facilities, the costs of pollution control, and other elements that appear relevant to the standard-setter and its engineers. The standard-setter next examines the pollution control technologies in use in the regulated industry and in industries with similar waste streams. The regulator also studies the technologies that may be at the pilot plant or at even less advanced stages of development. The regulator then picks a technology that best meets the statutory criteria. Since cost invariably is one criterion, the standard-setter must consider economic as well as technological feasibility. The standard-setter must specify the degree of effluent reduction attainable within each category and subcategory and write a standard, expressed as units of pollutant per unit of production, input, or discharge that mandates that degree of effluent or emissions reduction. 40 C.F.R. §§ 400-460 (1982).

Promulgation of a technology-based standard need not occur industry-wide or even subcategory-wide. In principle, each individual source of pollutant could have a technology-based standard. The standard-setter then would act very much like a court and adjudicate the economic and technological feasibility of various suggested pollution control alternatives for each source. The approach, however, would entail enormous administrative costs. Nevertheless, at least one circuit court interpreted the Clean Water Act to require case by case technology-based standard-setting by local permitting authorities before the Supreme Court in *E. I. Du Pont de Nemours & Co. v. Train*, 430 U.S. 112 (1976), held that EPA has the authority to promulgate national limitations. *See CPC Int'l, Inc. v. Train*, 540 F.2d 1329, 1331-32 n.1 (8th Cir. 1976), *cert. denied*, 430 U.S. 966 (1976). Although regulators more commonly associate incentive approaches with media quality standards, a technology-based regime could adopt a less direct approach and require the standard-setter to establish a charge of effluent or emissions tax, rather than an effluent or emissions limitation, to induce the regulatee to adopt the desired degree of technology.

Statutes nearly always give individual sources the freedom to meet the promulgated standard with any technology that they choose to adopt so long as it performs as well as the technology that the agency selected. The standard-setter rarely receives the authority to mandate the actual use of particular technologies. *See* Clean Air Act § 112, 42 U.S.C. § 7412 (Supp. V 1981). The Occupational Safety and Health Act (OSHA) gives OSHA the flex-

technology approaches represent two extremes on a continuum, and the balancing approach lies somewhere between them. The pure technology-based approach ignores media quality considerations and the pure media quality-based scheme fails to take account of economic and technological feasibility. In reality, regulatory agencies rarely apply either approach in its pure form. Agencies invariably consider feasibility in setting media quality-based standards, if only covertly to decide a satisfactory level of cleanliness. Similarly, media quality considerations intrude into the determination of technology-based standards when the application of the best possible technology clearly will bring about no health or environmental benefit.

The question where along the continuum the legislature ought to locate a regulatory strategy is the subject of sharp debate among students of the regulatory process.<sup>108</sup> While a thorough rehearsal of the debate is beyond the scope of this Article, the piece does discuss some of the primary advantages and disadvantages of various positions on the continuum in the context of regulating genetic technologies. The primary disadvantage of the media quality-based approach is the difficulty in determining what level of exposure to a substance creates too much risk. Some toxic and infectious agents appear to be harmless to most people and the environment below a certain threshold level. With an appropriate margin of safety, a regulatory entity can set media quality-based standards for these agents so that human and environmental exposure does not exceed this level. Identification of this safety level for other agents, however, is more difficult.<sup>109</sup> Determining the effects of low

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ibility to require the implementation of specific "practices, means, methods, operations or processes . . . ." Occupational Safety and Health Act § 3(8), 29 U.S.C. § 652(8) (1976 & Supp. V 1981).

107. The balancing approach, which falls between the media quality and technology theories on the regulatory continuum, measures the costs of greater controls against the predicted benefits of those controls. See Federal Insecticide, Fungicide and Rodenticide Act, as amended, 7 U.S.C. §§ 135-136 (1976); Toxic Substances Control Act, Pub. L. 94-469, 90 Stat. 2003 (1976) (codified at 15 U.S.C. §§ 2601-2629); Liroff, *Cost Benefit Analysis in Federal Environmental Programs*, in *COST BENEFIT ANALYSIS AND ENVIRONMENTAL REGULATION: POLITICS, ETHICS AND METHODS* 35, 47 (D. Swartzinan, R. Liroff, & K. Croke eds. 1982). The balancing approach thus requires the regulatory entity to consider both the harm that the discharge causes to the receiving medium and the economic and technological feasibility of reducing the discharge.

108. *Cost Benefit Analysis: The Potential of Conflict of Interest, Hearings Before the Subcomm. on Oversight and Investigations of the House Comm. on Interstate and Foreign Commerce*, 96th Cong., 2d Sess. (1980).

109. Most scientists would agree that establishment of a threshold level for most carcinogens is impossible. See McGarity, *Substantive and Procedural Discretion in Adminis-*

level or accidental exposure to toxic or infectious agents requires a substantial amount of expensive information derived from epidemiological studies and tests with laboratory animals.<sup>110</sup> Furthermore, most populations include sensitive individuals who may suffer harm from exposures that would be below the threshold level for the rest of the population. In genetic technologies, establishing an appropriate level of exposure would be especially difficult because the technology is new and rapidly changing. By the time the regulatory entity has assessed the effects of a particular genetically engineered organism and its products and by-products, the technology may have changed to a new organism. The manufacturer may have modified the organism intentionally to meet production needs or the organism could have changed spontaneously through mutation or other natural causes. Thus, the target of the regulation is constantly moving. This problem of shifting technology also has plagued attempts to assess the health effects of products of the rapidly evolving chemical industry.<sup>111</sup>

Another problem with media quality-based standards results from the uncertainties that are inherent in translating a level of

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*trative Resolution of Science Policy Questions: Regulating Carcinogens in EPA and OSHA*, 67 GEO. L.J. 729, 733-34 (1979).

110. The continuing controversy over the health effects of dioxin, a contaminant of the pesticide 2, 4, & 5-T, illustrates the difficulty in determining a threshold level for a potent teratogen. See Notice of Intent to Cancel the Forestry, Rights-of-Way and Pasture Registrations of Pesticide Products Containing 2, 4, 5-T, 44 Fed. Reg. 15,893, 15,894 (1979).

111. In *Environmental Defense Fund v. EPA*, 12 Env't Rep. Cas. (BNA) 1353 (D.C. Cir. Nov. 3, 1978), petitioners challenged the toxic effluent standards that EPA set for polychlorinated biphenyls (PCBs), an industrial chemical used widely in solvents, plasticizers, adhesives, and textile coatings, but principally in electrical equipment. PCBs may vary in the number of chlorine atoms per molecule and are separable into "more chlorinated" and "less chlorinated" categories. *Id.* at 1354. Use of less chlorinated PCBs increased rapidly in the early 1970's and created a "knowledge gap" about their effects. *Id.* at 1354 n.17. EPA faced this gap when it complied with a court-ordered regulation of toxic substances. *Natural Resources Defense Council v. Train*, 8 Env't Rep. Cas. (BNA) 2120, 2122 (D.C. Cir. June 8, 1976) (Flannery, J.), *rev'd in part on other grounds sub nom. Natural Resources Defense Council v. Costle*, 561 F.2d 904 (D.C. Cir. 1977). In response, EPA set the standards for all PCBs at the same level. Industry, however, objected that EPA could not extrapolate from studies done on more chlorinated PCBs to establish the health effects of less chlorinated PCBs. EPA insisted that the words of the statute allowed standards to err on the side of over-protection and that absent adequate knowledge about less chlorinated PCBs, evidence of risk from more chlorinated PCBs justified a general standard for all PCBs. The court in *Environmental Defense Fund* held that under a substantial evidence test EPA had sufficient data with which to make a decision and gave great deference to the expertise of the agency in interpreting the information. "[EPA's] policy decisions are subject to deferential review, and its factual conclusions are upheld although they may not be supported by all the evidence, or even by most of it." *Environmental Defense Fund v. EPA*, 12 Env't Rep. Cas. (BNA) at 1375.

media quality into an effluent or emissions limitation for an individual source. Difficulties often arise in relating a given discharge to a particular level of health or environmental harm. Lacking adequate risk assessment and dispersion models, the regulatory entity must resort to highly speculative guesswork when it attempts to set a standard, put a price on a discharge, or determine the appropriate number of saleable units. Although the regulator may correct mistakes by adjusting the standard, fee, or number of marketable rights, a proper cure may take a long time. This difficulty is not so debilitating in genetic technologies in which only a single source for a hazardous agent exists in a relevant media quality area.<sup>112</sup> Still, the regulatory entity must devise a "reduction" model to translate emissions into levels of media quality. This procedure could be especially difficult for infective agents that do not degrade but rather expand as they are carried from person to person. Regulators must establish a media-quality standard for these agents at such a level that infection of any individual would be impossible.

The media-quality approach is not especially useful for regulating technologies that pose a low probability of catastrophic harm for the same reasons that the incentive approach is inappropriate for these processes. The technology-based approach may be more effective for regulating genetic technologies that pose catastrophic risks. Technologies currently exist for confining micro-organisms, their products, and by-products to reduce human and environmental exposure within the context of the fermentation industry. Hence, a regulatory agency should not have too much difficulty choosing from among the existing technologies and prescribing an appropriate one. The most important considerations probably will be the capacity of a particular technology to avoid and contain accidents. In the context of the large-scale release of genetically engineered micro-organisms, containment technologies probably are not as well developed because the field is new and rapidly changing. Prescribing technology-based standards for these uses would be more difficult, and the agency likely would have to rely more heavily upon prototype projects and technology projections.

The technology-based approach also has disadvantages. The most troublesome drawback is its inefficiency. A regulatory agency

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112. To the extent that new biotechnologies produce conventional pollutants, such as biological oxygen demand and particulate emissions, the waste streams from biotechnology plants will intermingle with streams of other firms, and the agency must apportion the available load among existing sources.



has difficulty tailoring technology-based standards to individual circumstances. A technology that works well in one plant may be ineffective or excessively expensive in another plant. Even when the regulatory agency allows variances from general standards for individual circumstances, as usually happens, the technology-based approach gives management little flexibility in designing the most cost-effective solution to a technological problem. This situation is especially disadvantageous in the context of a rapidly developing technology such as genetic engineering in which production and clean-up processes are not standardized and, hence, one plant's experience is not especially relevant to another plant's problems. In these circumstances flexibility is especially important.

Another great disadvantage of technology-based standards is their tendency to freeze technology at the levels of the prescribed standards. Once a source has complied with a technology-based standard, it has little incentive to install more protective technologies as they develop. Indeed, it has positive disincentive to develop better technologies. Although technology-based standards can be effective in bringing the laggards up to the performance level of the exemplary plants in a given industry,<sup>113</sup> the standards are unlikely to inspire any major technological innovations.<sup>114</sup> This disadvantage is of limited significance for fermentation technologies because little innovation is necessary to achieve adequate containment of potentially hazardous micro-organisms.<sup>115</sup> The drawback is much more relevant to large-scale release technologies in which the containment problem has received little thought, and innovation, therefore, is highly desirable.

The balancing approach avoids many of the disadvantages of the technology-based theory. Since society can weigh benefits and costs against each other, the balancing approach is more globally efficient. Every regulation that meets a balancing test is cost-justified in that some health or environmental benefit justifies the cost of the requirement. The balancing approach is less likely to freeze technology because as new beneficial technologies become available regulators can require new plants to include them and old facilities to install them as the balancing equation indicates. The combination of a balancing approach and an incentive-based scheme can be

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113. See generally La Pierre, *Technology Forcing and Federal Environmental Protection Statutes*, 62 IOWA L. REV. 771 (1977) (technology-based standard provides no incentive for industry to exceed minimum standard).

114. *Id.* at 825-26.

115. See *supra* text accompanying note 53.

especially useful in achieving the optimal degree of technological innovation. In theory, the overall balancing approach will ensure that every firm pays its own way while the incentive approach encourages firms to develop breakthrough technologies that may shift the overall balance toward further clean up by all regulated firms.

The balancing approach does not avoid the major disadvantages of the media quality theory. Although a balancing approach does not focus upon threshold levels, the regulatory entity must estimate the effects of a toxic or infective agent at many different exposures before assessing the benefits of installing a control technology. These estimates contain substantial uncertainties, and good assessments require much expensive information gathering.<sup>116</sup> A balancing approach also requires the agency to employ a reduction model to relate levels of media quality to individual discharges. Similarly, a balancing approach is not easily adaptable to low probability-high consequence risks associated with catastrophic accidents. For example, balancing a \$100 safety expenditure against a minute probability that 50,000 people will die in a genetic engineering accident is extremely difficult. A further disadvantage of the balancing approach is the quantification dilemma that arises from comparing costs of regulatory requirements to benefits. A pure balancing approach would require a reduction in both costs and benefits to the same units of value. The decisionmaker thus would have to place a monetary value on environmental amenities, various degrees of human illness, and human life itself. Regulators may not be able to carry out this valuation process straightforwardly and objectively.<sup>117</sup>

The disadvantages of the balancing approach are all relevant to the regulation of genetic technologies. Regulatory entities will have difficulty estimating the value of the technologies themselves to assess the impact of regulatory controls on technological development. Similarly, any effort to quantify and place a monetary value on the risks posed by the new technologies inevitably will produce highly speculative estimates that are dependent upon un-

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116. For a discussion of the complex problems and policy-dominated nature of quantitative risk assessment, see OTA REPORT, *supra* note 16; Leape, *supra* note 82; McGarity, *supra* note 10.

117. See COST BENEFIT ANALYSIS, *supra* note 107; REFORMING REGULATION 105-23 (T. Clark, M. Kusters, & J. Miller III, eds. 1980); McGarity, *Media Quality, Technology and Cost-Benefit Balancing Strategies for Health and Environmental Regulation*, — LAW & CONTEMP. PROBS. — (1983) (forthcoming); Peskin, *Environmental Policy and the Distribution of Benefits and Costs* in CURRENT ISSUES IN U.S. ENVIRONMENTAL POLICY (Portney ed. 1978).

derlying assumptions. At best, the process will yield a conclusion about whether costs and benefits are in the same "ballpark." More information about the potential risks and benefits of newly emerging technologies is necessary before regulatory decisionmakers can use the balancing approach to ascertain whether to impose process and end of pipe requirements upon the firms that utilize the technologies.

### 3. The Addressee of the Regulatory Statement

Discussion of the appropriate techniques for health and environmental regulation usually focuses on the sources of the harmful substances. In general, society views the goal of a regulatory strategy as the reduction in the amount of dangerous substance that enters the environment or workplace. While most environmental and health statutes do address sources of dangerous substances in the environment, an alternative approach would be to subject the receptors of the substances to regulatory scrutiny.

Professor Coase has suggested that the pollution problem is equally a function of the receptor's sensitivities and the source's noxiousness.<sup>118</sup> In the value-neutral analysis of the economist, pollution is as much the "fault" of a stream's poor assimilative capacity as it is the "fault" of the polluter's discharge of oxygen demanding substances.<sup>119</sup> In the occupational safety and health context, employee illnesses due to toxic substances in the workplace are both the workers' fault for breathing the substances and the employer's fault for discharging the toxic materials. Therefore, a regulation that would require employees to wear respirators or other protective devices,<sup>120</sup> or that would force particularly susceptible workers to leave the workplace,<sup>121</sup> is as appropriate as a rule

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118. See Coase, *The Problem of Social Cost*, 3 J. LAW & ECON. 1 (1960).

119. Professor Coase illustrates his theory using *Cooke v. Forbes*, 5 L.R. Eq. 166 (1867). In *Cooke* a coconut fiber weaver brought a nuisance action against a manufacturer of sulfate ammonia. The emissions from defendant's ammonia plant discolored plaintiff's bleached mats. Defendant argued that plaintiff could avoid the problem if he used a different bleaching process. *Id.* at 167.

120. In the past OSHA has articulated a policy of requiring engineering controls on sources rather than respirators for employers. Occupational Exposure to Benzene, 43 Fed. Reg. 5918, 5952 (1978). OSHA, however, occasionally has prescribed respirators as an interim control. *Id.* at 5953. Employers strongly urge the adoption of respirators, which are normally much cheaper, albeit less comfortable, than design and engineering controls. *Id.* at 5952. Major controversy, however, exists over the efficiency of respirators in protecting workers. Occupational Exposure to Lead, 43 Fed. Reg. 52,952, 52,990 (1978).

121. See McGarity & Schroeder, *Risk-Oriented Employment Screening*, 59 TEX. L. REV. 999, 1065 (1981).

which would force the manufacturer to reduce the emissions level of toxic substances. Manufacturers of potentially dangerous consumer products such as drugs use the common receptor-oriented technique of a simple warning.

Source-oriented techniques usually are preferable to receptor-oriented approaches because their goal is to eliminate health and environmental hazards.<sup>122</sup> Sometimes, however, receptor-oriented techniques can achieve the same risk reductions as source-oriented methods at considerably lower costs.<sup>123</sup> For example, surgical masks, respirators, and good hygiene can be extremely effective methods of reducing the risks that infective organisms pose in fermentation technologies. Employees may object to the inconvenience of receptor-oriented requirements, but their complaints are unpersuasive given that infected employees themselves are sources for further spread of infective diseases. Thus, receptor-oriented hygiene requirements are really secondary source-oriented requirements. A company may combine receptor-oriented techniques with source-oriented requirements, such as directional air flows and air filtration, to produce an optimal degree of safety.

Public attention recently has focused on a receptor-oriented technique that supporters have dubbed the "worker right to know."<sup>124</sup> The concept is simple but its implementation has proved difficult. Advocates of worker right to know regulations contend that employees could avoid many injuries caused by chemical substances in the workplace if they knew the chemical names and hazards of the materials with which they have contact.<sup>125</sup> Scientific literature has reported extensively on the effects of many toxic substances, but this information often is useless to employees in

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122. While source-oriented techniques can remove health and environmental hazards from one medium, these techniques may cause the introduction of new hazards into a different medium. Sewage treatment plants, for example, clean up discharged water but create large quantities of sludge, which may contain dangerous concentrations of heavy metals, such as cadmium. Similarly, scrubbers installed in smokestacks remove sulfur oxides from the air but create large amounts of potentially toxic solid waste. See Kneese, *Pollution and a Better Environment*, 10 ARIZ. L. REV. 10, 11-16 (1968).

123. "The Council on Wage and Price stability and some industry representatives suggested a control strategy which would permit employers to place principal reliance on respiratory protection where employers determined that it was a 'less costly method of achieving the same level of worker health.'" Occupational Exposure to Lead, 43 Fed. Reg. 52,952, 52,990 (1978).

124. Conry, *The Right to Know: Not to be Denied*, Environmental Regulation Analyst 9 (1982); Grozuczak, *Poisons on the Job: The Reagan Administration and American Workers*, in SIERRA CLUB NATURAL HERITAGE REPORT No. 4 (October 1982).

125. Conry, *supra* note 124, at 9.

evaluating the hazards of products in the workplace. While scientists refer to hazards and toxic effects by the scientific name of the substance, products in the workplace are identified by thousands of trade and code names. Hence, workers may be ignorant of the potentially life-threatening exposures that they face.

Worker right to know advocates demand a free flow of information between the government, industry scientists, and workers.<sup>126</sup> Supporters maintain that this exchange of information is critical to the "voluntary" and "cooperative" approach to occupational safety and health that is currently popular among regulators. Some advocates would extend this concept to a "community right to know" in which industry with the assistance of government would inform the public of the identities and risks of chemical substances to which the public might suffer exposure.<sup>127</sup>

Receptor-oriented regulatory techniques are likely to prove less useful in genetic technologies involving large-scale releases. Once an organism or its by-products enter the environment, a receptor-oriented technology capable of reducing health and environmental risks becomes much more difficult to devise. Moreover, a receptor-oriented approach probably will encounter far greater resistance from citizens who expect a reasonably clean and healthy environment and question the right of any firm to "blame the victim" by insisting that receptors take steps to avoid risks.

#### 4. The Focus of the Regulatory Statement

A final distinction that may aid a policymaker in choosing among various health and environmental regulatory techniques concerns the difference between addressing regulatees as individuals and addressing them as members of a larger class.<sup>128</sup> In a perfect regulatory world every regulatee would be addressed on its own merits. For example, a regulator would promulgate media quality-based standards for very small airsheds, short segments of rivers, and individual workplaces, rather than for all airsheds, wa-

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126. Grozuczak, *supra* note 124, at 21-24.

127. Conry, *supra* note 124, at 10-11.

128. See Boyer, *Alternatives to Administrative Trial-Type Hearings for Resolving Complex, Scientific, Economic and Social Issues*, 71 MICH. L. REV. 111, 115-16 (1972); Robinson, *The Making of Administrative Policy: Another Look at Rulemaking and Adjudication and Administrative Procedure Reform*, 118 U. PA. L. REV. 485, 521-22 (1970). Although the distinction between generic and individual is relevant in an incentive-based approach to health and environmental regulation (investment-inducing charges could be calculable individually or generically), it is more commonly applicable to a command approach. See Boyer, *supra*, at 133.

tersheds, and workplaces in the nation. Similarly, technology-based standards would reflect a detailed examination of all idiosyncratic economic and technological aspects of each production process and regulatee. Unfortunately, in the real world these detailed examinations are extremely costly and in some cases impossible to perform. If the regulatory entity is to function at all, it must have the power to impose some generic regulations. Regulatory alternatives lie on a continuum between across the board standards and individualized permits. Generic standards generally are more intrusive than individual permits because they are less efficient and provide for less flexibility in the regulatory process. The legislature determines its location along the spectrum by balancing considerations of efficiency and administrative flexibility.<sup>129</sup>

The generic approach may be more appropriate for regulating the use of genetically engineered micro-organisms in fermentation technologies. Since several generic processes exist that reduce the risks posed by those technologies, broad technology-based requirements probably could address the risks of most hosts in almost every firm. The agency, however, might decide to be more individualistic and promulgate separate containment standards for each variety of micro-organism. The agency could individualize still further and set the requirements for every process that yields a separate product. Some processes undoubtedly are riskier than others. The crucial question, for which no satisfactory answer currently exists, is the extent to which these differences are likely to justify the added administrative costs of establishing individual standards.

In large-scale application of genetically engineered micro-organisms, scientific experience is insufficient to establish generic requirements. Hence, the best approach is probably a case by case permit requirement in which the relevant agency assesses technologies, predicts health and environmental effects, or balances these two elements against each other in individual permit proceedings.

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129. Another consideration that often enters the decision whether to use a generic or individual approach concerns intergovernmental comity. While a single national entity can promulgate, implement, and enforce generic requirements, administrative infeasibility often precludes national administration of an individual approach. State and local entities, therefore, must participate in implementing and administering federal permitting programs. *See, e.g., Clean Water Act § 402(b), 33 U.S.C. § 1342(b) (Supp. V 1981)*. Thus, a policymaker's choice between generic and individual approaches may depend upon the trust that it has for state and local governmental entities.

## 5. General Conclusions

Since the current information on the risks of newly emerging genetic technologies is insufficient to determine with any acceptable degree of confidence *whether* the government should impose regulatory controls, any suggestion of a particular regulatory regime would be extremely speculative. The preceding discussion has attempted to set out a wide range of options for policymakers if regulation becomes necessary. The discussion is also useful in deciding whether existing schemes will provide a sufficient framework for genetic technology regulation or whether the government will have to devise a new plan.

In formulating an appropriate regulatory strategy for the new genetic technologies, regulators should begin by distinguishing between the use of genetically engineered micro-organisms in traditional fermentation technologies and in large-scale applications. Using micro-organisms in fermentation is not at all unique. Technologies exist that are capable of isolating the organisms so that no human or environmental exposure will result. Furthermore, scientists can contain micro-organism products and by-products through the application of well-established technologies. Given that containment of most risks posed by fermentation technologies is possible and that these risks are likely to be low probability/high consequence risks,<sup>130</sup> technology-based commands probably are most appropriate. The incentive approach is less adaptable to a technology-based scheme, and the continuous monitoring necessary to enforce an incentive plan would entail great cost for very little benefit.<sup>131</sup> Technologies that are oriented toward protecting health and the environment are very similar to the technologies

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130. See *supra* note 51 and accompanying text. Although the use of genetically engineered micro-organisms in traditional fermentation technologies is different from the large-scale application of genetic technology, both uses present low probability/high consequence risks. In the fermentation setting the probability of an explosion and escape of an infectious organism is low, but if it were to occur, the results could be devastating. In large-scale application, the concern is that released micro-organisms could evolve into infectious and deadly organisms. Scientists assume that the probability that a benign organism could evolve into a deadly entity in the environment is low.

131. An incentive-based scheme for a fermentation facility presumably would rely upon escapes of micro-organisms, their products, or by-products as the incentive rather than upon human deaths or injuries. Hence, continuous monitoring of the surroundings of the fermentator would be necessary. Since existing technology, according to industry witnesses, is capable of reducing escapes to a rare event, most of the resources expended on monitoring would be wasted. A technology-based scheme using a command approach would require periodic monitoring to ensure that the technology was operating correctly, but this option probably would be less expensive than continuous monitoring.

appropriate for efficient production.<sup>132</sup> If efforts to attain these goals continue to coincide, little need exists for balancing health and environmental considerations against economic and technological feasibility in prescribing technology-based requirements. If, however, health and environmental technologies become more expensive than normal construction and operation costs, policymakers may want to gravitate toward a balancing approach.

The question whether regulators should apply technology-based commands generically or individually is difficult to answer. The commonplace nature of fermentation controls indicates that they should be generic, but the novel nature of genetic technology and the tenuous financial status of many new genetic engineering firms weigh in favor of an individualistic approach. The appropriate regulatory agency, rather than the legislative body, probably should resolve the issue.

A policymaker should retain authority to impose both source-oriented and receptor-oriented requirements for fermentation technologies. Existing source technologies seem reasonably effective for containing the current generation of fermentation microorganisms, products, and by-products. Future research and development efforts, however, may result in the creation of more dangerous processes. Without receptor-oriented controls, scientists may not discover these risks until actual harm results. Receptor-oriented controls, such as respirators and hygiene requirements, can provide a margin of safety by helping to ensure worker protection even if harmful agents escape from containment facilities.

A different regulatory strategy may be appropriate for technologies that require large-scale release of genetically engineered microorganisms. Since the risks of large-scale applications are likely to be low probability/high consequence risks, technology-based commands would be most suitable. This approach is preferable given the difficulty that a regulatory agency which applied a media quality-based theory would have in identifying unsafe levels of health or environmental harm caused by large-scale release of microorganisms. Moreover, the current primitive state of large-scale release technologies makes it extremely difficult to identify or predict the cause and effect relationships upon which to base individual source controls under the media quality approach. The regulatory entity initially should prescribe general technology-based requirements as the production technologies themselves evolve.

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132. See *supra* notes 35-36 and accompanying text.



Because protective technologies will not likely correspond to production technologies and will make a production process more expensive without adding to the "productivity" of the enterprise, regulators may want to apply a broad balancing approach.

As with fermentation technologies, an agency will have difficulty identifying a meterable unit of health or environmental harm to implement an incentive approach. On the other hand, since the production technology is so new and scientists have not yet developed controls for many processes, freezing control technologies through technology-based commands probably would be unwise. Any predictions about the adaptability of the incentive approach to large-scale release production technologies would be highly unreliable without more information about individual technologies. Perhaps the best strategy is to give the regulatory entity the authority to choose either the incentive or command approaches on a case by case basis, at least until clearer identification of the risks and further evolution of production and control technologies occur. Alternatively, policymakers may decide simply to prohibit large-scale release technologies case by case pending a more thorough study of the risks.

The foregoing analysis suggests that an individual approach is more suitable to large-scale release technologies. Indeed, the novel nature of many genetic technologies makes them ideal subjects for a permit system that gives the regulator and regulatee an opportunity to explore the risks that a technology might pose and to examine options for ensuring public safety. The major drawback to a permitting system concerns the political infeasibility of giving a single agency veto authority over a potentially wide range of production technologies, ranging from mining to farming. As this Article discussed previously,<sup>133</sup> the regulation of large-scale release production technologies is particularly unsuited to the receptor-oriented approach. For practical and political reasons manufacturers must direct whatever controls they place upon the interaction between the production technologies and the entities affected by those technologies toward the technologies themselves.

#### IV. CURRENTLY EXISTING REGULATORY REGIMES

After discussing the possible hazards of the new genetic technologies and the possible elements of an adequate regulatory scheme, an analysis of how policymakers could apply existing regu-

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133. See *supra* notes 118-27 and accompanying text.

latory regimes to the emerging technologies is appropriate. Part IV examines these regimes and addresses the question whether new rules and statutes are necessary to ensure human safety and environmental protection in the genetic engineering industry. Several sources of regulatory authority exist for addressing biotechnologies. The first section of part IV describes broadly the relevant statutes and administrative regulations that may be applicable to the risks posed by genetic technologies. The remainder of part IV measures particular statutory and regulatory provisions against the options suggested in part III.

#### A. Sources of Regulating Authority

##### 1. The National Institute of Health Guidelines

Following a vigorous public debate on the risks and benefits of conducting laboratory research with rDNA, NIH issued its "Guidelines for Research Involving Recombinant DNA Molecules" on July 1, 1976.<sup>134</sup> Although NIH has amended them several times,<sup>135</sup> the guidelines nevertheless, have received broad support and have served as a model for regulators throughout the world.<sup>136</sup> In the United States the guidelines are binding on all research conducted by federal agencies or sponsored by grants from federal agencies.<sup>137</sup> The guidelines require the establishment of Institutional Biosafety Committees, detail the responsibilities of these committees, categorize rDNA research, and prescribe varying levels of biological and physical containment for certain experiments.<sup>138</sup>

The NIH Guidelines address one type of genetic engineer-

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134. NIH Guidelines, *supra* note 7, at 27,902.

135. See *supra* note 7.

136. Other countries have similar regulations for rDNA research, although foreign standards historically have been less detailed and less stringent than NIH Guidelines. For excellent descriptions of the evolution of rDNA research regulation in countries other than the United States, see Henderson, *Japanese Regulation of Recombinant DNA Activities*, 12 U. Tol. L. Rev. 891 (1981); Tooze, *International and European Regulation of Recombinant DNA Research*, 12 U. Tol. L. Rev. 869 (1981).

137. Technically, the NIH Guidelines are binding only upon research sponsored by NIH. NIH Guidelines—1981, *supra* note 7, § IV-B, at 34,475. Virtually all other federal agencies, however, have agreed to make the NIH Guidelines binding on research that they support. See *Hearings Before the Subcomm. on Health and the Environment of the House Comm. on Interstate and Foreign Commerce*, 95th Cong., 1st Sess. 320, 327 (1977) (testimony of Dr. Donald B. Fredrickson, director, NIH).

138. See NIH Guidelines, *supra* note 7. Interestingly, the most recent version of the NIH Guidelines exempts research conducted with *E. coli* K12, the bacteria that probably will be the predominant organism used in early industrial applications of rDNA technologies. NIH Guidelines—1981, *supra* note 7, app., at 34,485.

ing—rDNA experimentation. They apply primarily to research using rDNA molecules and not to practical applications of rDNA technologies. The guidelines prohibit large-scale experiments that require more than ten liters of rDNA culture unless the researcher can show to the satisfaction of the director of NIH that the researcher has rigorously characterized the rDNA molecules used in the experiment and that no harmful sequences exist.<sup>139</sup>

This prohibition on large-scale experimentation could constitute a significant impediment to industrial use of rDNA technologies. The NIH Guidelines, however, are not binding on private entities that do not receive federal funding for rDNA research. The only sanction that NIH can impose upon a laboratory that violates the guidelines is the termination of NIH funding. Clearly, the only arguably relevant requirement for large-scale projects using rDNA technologies is not binding upon the corporate entities that are likely to be developing these projects. Although many corporations in the United States have agreed voluntarily to abide by the NIH Guidelines,<sup>140</sup> they have declined to adhere to the prohibition on large-scale use of rDNA organisms.

Recognizing the limitations of its regulatory authority, NIH in 1980 promulgated "Physical Containment Recommendations for Large-Scale Uses of Organisms Containing Recombinant DNA Molecules."<sup>141</sup> These recommendations merely serve as a guide to private laboratories embarking on large-scale rDNA experimentation. Like the NIH Guidelines, the recommendations attempt to categorize large-scale projects according to levels of expected risk. The recommendations prescribe three increasingly stringent levels of physical containment for large-scale projects. In addition, the NIH Recombinant DNA Advisory Committee offers to consult with companies attempting large-scale efforts and to review suggested safety precautions.<sup>142</sup> None of the NIH requirements is legally binding upon private companies that use large-scale applications of rDNA technologies, and these firms are free to ignore the

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139. NIH Guidelines—1981, *supra* note 7, § I-06, at 34,463.

140. See, e.g., *Hearings on Science Policy Implications of DNA Recombinant Molecule Research Before the Subcomm. on Science, Research and Technology of the House Comm. on Science and Technology*, 95th Cong., 1st Sess. 91,374 (1977) (testimony of Dr. Ronald E. Cape, president, Cetus Corporation and testimony of John G. Adams, vice president for scientific and professional relations, Pharmaceutical Manufacturers Association). Private companies in Japan and Europe also have cooperated voluntarily with their countries' guidelines. See Henderson, *supra* note 136, at 897; Tooze, *supra* note 136, at 879-80.

141. 45 Fed. Reg. 24,968 (1980).

142. *Id.*

guidelines and recommendations. Although the guidelines alone are not adequate to regulate any aspect of large-scale industrial biotechnology, the recommendations provide a convenient model for a regulatory entity with the authority to promulgate rules binding on experimentation. The remainder of part IV limits discussion of the guidelines and recommendations to their use in this capacity.

## 2. The Occupational Safety and Health Act

In enacting the Occupational Safety and Health Act of 1970 (OSHAct)<sup>143</sup> Congress intended to "assure so far as possible every working man and woman in the [United States] safe and healthful working conditions . . . ."<sup>144</sup> The statute created the Occupational Safety and Health Administration (OSHA) within the Department of Labor to establish and enforce occupational safety and health standards,<sup>145</sup> and an independent Occupational Safety and Health Review Commission (OSHRev) to adjudicate alleged violations of OSHA standards and of the statute's general duty clause.<sup>146</sup> The OSHAct also created a National Institute for Occupational Safety and Health (NIOSH) in the Department of Health and Human Services (HHS) to gather data, assess risks, and recommend occupational safety and health standards to OSHA.<sup>147</sup> The Act thus establishes a comprehensive scheme for protecting employees from workplace hazards.

## 3. The Federal Food, Drug and Cosmetic Act, the Fair Packaging and Labeling Act, and the Public Health Service Act<sup>148</sup>

FDA administers several statutes that could serve to regulate ge-

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143. 29 U.S.C. §§ 651-678 (1976).

144. *Id.* § 651.

145. *See id.* § 653.

146. *See id.* § 661.

147. *See id.* § 671.

148. This section focuses primarily on Food and Drug Administration (FDA) regulation of the microbiological production of pharmaceuticals. Although some questions unique to food and cosmetics will not be answered, drugs are likely to be the first commercially significant products of the new technologies and thus raise the immediately important regulatory issues. The discussion extensively draws upon the work of Dr. Edward L. Korwek. *See, e.g.,* Korwek, *The NIH Guidelines for Recombinant DNA Research and the Authority of FDA to Require Compliance with the Guidelines*, 35 FOOD DRUG COSM. L.J. 633 (1980), reprinted with modifications in 21 JURIMETRICS 264 (1981); Korwek & Trinker, *Perspectives on the FDA Status of Drug Products Manufactured by the Recombinant DNA Technique*, 36 FOOD DRUG COSM. L.J. 517 (1981).

netic technologies, such as the Federal Food, Drug and Cosmetic Act (FFDCA),<sup>149</sup> the Fair Packaging and Labeling Act (FPLA),<sup>150</sup> and sections of the Public Health Service Act (PHSA).<sup>151</sup> The primary purpose of these laws is to ensure that food is safe, pure, and wholesome; that human and animal drugs, and biological products, and therapeutic devices are safe and effective; and that all these products have honest labels.

For administrative convenience in achieving its goals, FDA has structured itself along product lines. Separate bureaus have responsibility for all regulatory activities regarding specific classes of products—for example, foods, drugs, and biological and medical devices. Although different products necessarily require different regulatory approaches, each bureau addresses many issues common to all products. The FFDCA prohibits distribution or importation of adulterated or misbranded articles. The term “adulterated” refers to products that are defective, unsafe, filthy, or were produced under unsanitary conditions.<sup>152</sup> The word “misbranded” pertains to statements, designs, or pictures in labeling that are false or misleading and to the failure to provide required information on labels.<sup>153</sup> The statute also prohibits distribution of any article that requires but has not received FDA approval.<sup>154</sup>

FDA must approve certain products for safety before their sale or use. For example, manufacturers must submit samples of production batches of antibiotics and insulin to FDA laboratories for testing. The agency then certifies the purity, potency, and safety of these products before it permits their shipment.<sup>155</sup> Similarly, the agency must approve new drugs and certain devices for safety and effectiveness.<sup>156</sup> Premarket controls also apply to biological products, such as serums or vaccines.<sup>157</sup> Pesticide residues in food commodities must not exceed safe tolerances that EPA establishes and FDA enforces.<sup>158</sup> FDA bases all premarketing clearances on scientific data that manufacturers provide. The information is subject to review and acceptance by FDA scientists for scope and

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149. 21 U.S.C. §§ 301-392 (1976 & Supp. V 1981).

150. 15 U.S.C. §§ 1451-1461 (1976 & Supp. V 1981).

151. 42 U.S.C. §§ 262-263 (1976 & Supp. V 1981).

152. 21 U.S.C. §§ 342, 351, 361 (1976).

153. *Id.* §§ 342, 352, 362.

154. *Id.* § 331a.

155. *Id.* §§ 356, 357.

156. *Id.* § 360e.

157. 42 U.S.C. § 262 (1976).

158. 21 U.S.C. § 346a (1976).

adequacy. Owners or operators of all establishments manufacturing or processing drugs and devices must register their facilities and products with FDA.<sup>159</sup>

In addition to its product licensing power under the FFDCA, FDA has broad authority under section 361 of the PHSA<sup>160</sup> to promulgate regulations in cooperation with the Center for Disease Control "to prevent the introduction, transmission, or spread of communicable diseases." The Surgeon General of the Public Health Service may provide for "inspection, fumigation, disinfection, sanitation . . . and other measures" to carry out these rules.<sup>161</sup>

#### 4. The Toxic Substances Control Act

Congress enacted the Toxic Substances Control Act (TSCA)<sup>162</sup> in 1976 to provide a comprehensive mechanism for gathering data on the health and environmental effects of chemical substances,<sup>163</sup> for assessing the risks of these substances,<sup>164</sup> and for ensuring that the manufacture, distribution, use, and disposal of toxic materials does not pose unreasonable risks to man and the environment.<sup>165</sup> Congress charged the EPA with administering and enforcing the statute.<sup>166</sup> To date, EPA's implementation efforts have been slow and halting and recent budgetary cuts ensure that the TSCA will remain a relatively ineffective regulatory tool. Nevertheless, the statute is a large repository of regulatory power that EPA may draw upon when necessary.

The TSCA regulates only chemical substances<sup>167</sup> and mixtures.<sup>168</sup> While the TSCA clearly is an appropriate vehicle for regu-

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159. *Id.* § 360.

160. 42 U.S.C. § 264 (1976).

161. *Id.* § 264a.

162. 15 U.S.C. §§ 2601-2629 (1976 & Supp. V 1981).

163. *Id.* § 2601(b)(1) (Supp. V 1981).

164. *Id.* § 2601(b)(2).

165. *Id.* § 2601(b)(3).

166. *Id.* § 2602(1).

167. *Id.* § 2602(2)(A). Section 3(2) of the TSCA defines the term "chemical substance" broadly to include "any organic or inorganic substance of a particular molecular identity, including . . . any combination of such substances occurring in nature, and . . . any uncombined radical." *Id.* The definition explicitly excludes mixtures, pesticides, tobacco, food, food additives, drugs and cosmetics, source material, special nuclear material, and by-product material. *Id.* § 2602(2)(B).

168. The statute defines a mixture broadly to include "any combination of two or more chemical substances if the combination does not occur in nature and is not, in whole or in part, the result of a chemical reaction." *Id.* § 2602(8).

lating chemical products and by-products of genetic engineering technologies, whether EPA can invoke the statute to protect the public against risks that the micro-organisms themselves create depends upon whether the organisms come within the broad definition of chemical substance. Although an entire micro-organism probably is not a chemical substance, the DNA molecule within a genetically engineered micro-organism would seem to fit the statutory definition of chemical substance. The molecule has a particular molecular identity even though that identity is not always ascertainable. Indeed, the presence of DNA within the micro-organism allows the "microbial factory" to be industrially useful.<sup>169</sup> Even if the combination of genes does not "occur in nature," the DNA might come within the definition of mixture. Clearly, this question is ripe for litigation if EPA decides to regulate the DNA of genetically engineered industrial micro-organisms. If the courts refuse to find that the DNA within a micro-organism is a chemical substance or a mixture, then the TSCA will be unavailable to regulate the industrial use of genetic technologies.

##### 5. The Federal Insecticide, Fungicide, and Rodenticide Act

Conceivably, researchers might use rDNA technologies to create organisms, such as insect or plant pathogens, for use as pesticides. If scientists developed rDNA-based pesticides, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)<sup>170</sup> would be another source of authority for regulating some genetic engineering. The statute provides that no pesticide may be sold, distributed, or used within the United States unless it is registered with EPA.<sup>171</sup> The FIFRA defines the word "pesticide" very broadly to include "any substance or mixture of substances intended for

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169. The author uses the term "microbial factory" to analogize the production capacity of micro-organisms to the production capacity of a traditional industrial factory. See *supra* part II.

170. 7 U.S.C. §§ 136-136y (1976 & Supp. V 1981).

171. *Id.* § 136a. An applicant for registration must demonstrate that:

- (A) its composition is such as to warrant the proposed claims for it;
- (B) its labeling and other material required to be submitted to comply with the requirements of [the Act];
- (C) it will perform its intended function without unreasonable adverse effects on the environment; and
- (D) when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment.

*Id.* § 136a(c)(5). The applicant must make these showings using scientific studies that it has performed on the efficacy and safety of the pesticide.

preventing, destroying, repelling, or mitigating any pest.”<sup>172</sup> EPA has promulgated extensive registration guidelines that describe the kinds of studies it will accept to show that a pesticide is safe and effective.<sup>173</sup> The guidelines, however, do not apply to biological pesticides, which EPA regulates case by case.<sup>174</sup>

## 6. The Clean Air Act, the Clean Water Act, and Other Federal Statutes

### a. *The Clean Air Act*

If the industrial process that uses genetic technologies causes the release into the atmosphere of “criteria” pollutants or currently listed hazardous air pollutants, the firm must comply with Parts A, C, and D of Title I of the Clean Air Act.<sup>175</sup> In the normal operation of a fermentation plant or large-scale release process the chances are remote that significant emissions of current criteria or hazardous pollutants will result unless a laboratory decides to dry liquid wastes and incinerate them.<sup>176</sup> Furthermore, organisms containing rDNA molecules probably will not qualify as new criteria pollutants because plants will not release them from “numerous or diverse mobile or stationary sources”—a necessary precondition.<sup>177</sup> Therefore, before these organisms can be subject to regulation under the Clean Air Act, EPA must list them as hazardous pollutants.<sup>178</sup>

### b. *The Clean Water Act*

Under sections 301, 304, and 306 of the Clean Water Act,<sup>179</sup> EPA may promulgate technology-based effluent limitations and guidelines for categories and subcategories of new and existing dis-

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172. *Id.* § 136(u).

173. *See* 40 C.F.R. § 162.5 (1982).

174. 43 Fed. Reg. 29,696 (1978).

175. 42 U.S.C. §§ 7401-7508, 7521-7574, 7601-7626 (Supp. V 1981). The currently listed criteria pollutants are sulfur dioxide, particulate matter, carbon monoxide, ozone, hydrocarbons, nitrogen dioxide, and lead. 40 C.F.R. § 50 (1982). The currently listed hazardous air pollutants are asbestos, beryllium, mercury, and vinyl chloride. 40 C.F.R. § 61 (1982).

176. *See* UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, DEVELOPMENT DOCUMENT FOR INTERIM FINAL EFFLUENT LIMITATIONS GUIDELINES AND PROPOSED NEW SOURCE PERFORMANCE STANDARDS FOR THE PHARMACEUTICAL MANUFACTURING POINT SOURCE CATEGORY 91-94 (1976).

177. 42 U.S.C. § 7408(a)(1)(B) (Supp. V 1981).

178. *Id.* § 7412.

179. 33 U.S.C. §§ 1311, 1314, 1316 (1976 & Supp. V 1981).



chargers of "conventional pollutants"<sup>180</sup> into the navigable waters of the United States.<sup>181</sup> Effluent limitations and guidelines for various categories and subcategories of industries specify the "best practical control technology" for these conventional pollutants, and future limitations and guidelines will specify the "best conventional control technology."<sup>182</sup> If a source does not belong to a category for which EPA has promulgated effluent limitations and guidelines, that source still must obtain a National Pollution Discharge Elimination System (NPDES) permit under section 402.<sup>183</sup>

*c. The Solid Waste Disposal Act, the Resources Conservation and Recovery Act, and the Marine Protection, Research, and Sanctuaries Act*

EPA may regulate the disposal of solid wastes that genetic technologies generate under the same statutory authority that permits the agency to regulate disposal of solid waste from any laboratory or manufacturing process. Like the Clean Air and the Clean Water Acts, the Solid Waste Disposal Act (SWDA),<sup>184</sup> as amended by the Resource Conservation and Recovery Act of 1976 (RCRA),<sup>185</sup> focuses more directly upon the pollutants than on the processes that generated them. The RCRA amendments to the SWDA considerably have advanced federal involvement in the regulation of solid waste disposal and management, particularly in the area of hazardous waste management. Despite these substantial advances, however, federal regulation of solid waste falls short of the federal government's participation in air and water pollution control.

Although the disposal of solid wastes into the ocean hitherto has posed only a minor environmental problem, in 1972 Congress enacted the Marine Protection, Research, and Sanctuaries Act of 1972, commonly known as the "Federal Ocean Dumping Act."<sup>186</sup>

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180. Conventional pollutants include biological oxygen demand (BOD), pH, fecal coliform, and suspended solids. *Id.* § 1314(a)(4) (Supp. V 1981).

181. The statute defines the term "navigable waters" broadly to include every stream in the United States. *Id.* § 1362 (1976). See *United States v. Phelps Dodge Corp.*, 391 F. Supp. 1181 (D. Ariz. 1975); *United States v. Holland*, 373 F. Supp. 665 (M.D. Fla. 1974).

182. 33 U.S.C. §§ 1311(b), 1314(b) (1976 & Supp. V 1981). EPA will prescribe the best conventional control technology case by case during the permitting process. *Id.*

183. *Id.* § 1342.

184. 42 U.S.C. §§ 3251-3259 (1976).

185. *Id.* §§ 6901-6987 (1976).

186. 33 U.S.C. §§ 1401-1444 (1976). Congress also enacted the Water Pollution Control Act Amendments in 1972. 33 U.S.C. §§ 1251-1265 (1976).

Congress subsequently amended the Act in 1974 to make the law conform with United States treaty responsibilities under the Convention of the Prevention of Marine Pollution by Dumping of Wastes and Other Matter.<sup>187</sup> Although the prohibition against ocean dumping pertains primarily to international protection of the waters of the sea, the dumping issue is also relevant to domestic waste disposal.<sup>188</sup> The purpose of the statute is to regulate the ocean dumping of materials transported from the United States and of materials transported from outside the United States if the dumping occurs in ocean waters over which the United States has jurisdiction or may exercise control.<sup>189</sup>

The foregoing survey of relevant statutes reveals that at least three agencies possess overlapping regulatory authority. Clearly, each statute gives its agency limited power over certain aspects of a complete technology. The food and drug and pesticides statutes focus primarily on end products. The air, water, and waste disposal statutes address unwanted by-products. The OSHA Act is aimed at the manufacturing process. Only the TSCA adopts a holistic approach to a given technology, provided the technology results in the production or use of a chemical substance. Measuring the previously identified options for an adequate regulatory regime against the existing statutes will reveal which options current law will authorize and which areas may require interagency cooperation or new statutory authority.

## B. Data Collecting and Monitoring

### 1. A Central Registry

This Article has concluded that a data collecting and monitoring system is a prerequisite to an adequate regulatory scheme and,

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187. *Id.* §§ 1283, 1285, 1371, 1375. See Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter, Dec. 29, 1972, 26 U.S.T. 2403, T.I.A.S. No. 8165.

188. Ocean dumping generally refers to dumping on the open sea. The Federal Ocean Dumping Act prohibits dumping of

matter of any kind or description, including, but not limited to, dredged material, *solid waste*, incinerator residue, garbage, sewage, *sewage sludge*, munitions, radiological, *chemical and biological warfare agents*, radioactive materials, *chemicals, biological and laboratory waste*, wreck [sic] or discarded equipment; rock, sand, excavation debris, and industrial, municipal, agricultural, and other waste.

*Id.* § 1402(c) (emphasis added). The statute parallels closely the Federal Water Pollution Control Act in its approach and in its reliance on a permit system.

189. *Id.* § 1401(c).

indeed, is crucial to a decision whether to regulate at all.<sup>190</sup> One useful element of a data collection and monitoring system would be a central registry of hosts, vectors, industrially useful genetic sequences, products, and by-products.<sup>191</sup> The TSCA arguably gives EPA authority to require firms using genetically engineered micro-organisms to submit information necessary to compile an adequate registry, provided the organism's DNA is a chemical substance.<sup>192</sup> Under section 5 of the TSCA<sup>193</sup> the manufacturer of a new chemical substance must submit to EPA a notice of its intention to manufacture or process the substance.<sup>194</sup>

Section 5 thus appears to give EPA sufficient authority to require companies to notify the agency of any new chemical products or by-products that result from fermentation or other large-scale use of genetically engineered micro-organisms. This section does not necessarily give EPA power to require companies to disclose what solvents or other existing chemicals they use in the fermentation extraction process.<sup>195</sup> Nor does section 5 appear to permit the agency to force companies to give it premanufacture notification of hosts and vectors because these materials generally would not meet the definitions of chemical substance or mixture.<sup>196</sup> On the other hand, since DNA may be a chemical substance or mixture, section 5 may give EPA authority to require that companies notify the agency of the identity of the genetically manipulated DNA that is within the host cell.

The information that EPA could generate under section 5 probably would be sufficient for a comprehensive registry of new products, by-products, hosts, and vectors. The data bank would

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190. See *supra* part III(A).

191. The Interagency Committee on Recombinant DNA Research, chaired by Dr. Donald Fredrickson, director of the National Institutes of Health, reached a consensus that registration was an "important element of regulation" and should occur before the use or production of rDNA molecules. See 2 NIH DOCUMENT, *supra* note 36, at 268.

192. 15 U.S.C. §§ 2602(2), 2602(9), 2605, 2607(b)(1) (1976).

193. *Id.* § 2604.

194. The statute defines the term "manufacture" circularly as "to import . . . produce, or manufacture." *Id.* § 2602(7). Notice must include the following: (1) Name, chemical identity and chemical structure; (2) categories or proposed categories of use; (3) estimates of total amounts to be manufactured, processed or used; (4) description of byproducts; (5) existing health and safety data; (6) estimates of the number of people who will be exposed to the substance; and (7) manner of disposal. *Id.* § 2604(d).

195. EPA's inventory of existing chemical substances, however, should list these chemicals. See *id.* § 2607(b).

196. See *supra* notes 158-59 and accompanying text. Arguably, a small viral or plasmid vector would be a chemical substance within the meaning of section 3(2) of the TSCA, 15 U.S.C. § 2602(2) (1976).

grow automatically as firms developed new products, hosts, and vectors. The broad reading of section 5 that this Article suggests may impose an excessive burden on biotechnology companies. Section 5(h)(4), however, allows EPA to exempt the manufacture of any new chemical substance from all or part of the section 5 requirements if EPA determines that the manufacture, processing, distribution, use, or disposal of the chemical will not present an unreasonable risk of injury to health or the environment.<sup>197</sup> In addition, section 5(h)(5) permits the agency to exempt from section 5 notification and test data submission requirements "any chemical substance (A) which exists temporarily as a result of a chemical reaction in the manufacturing or processing of a mixture or another chemical substance, and (B) to which there is no, and will not be, human or environmental exposure."<sup>198</sup> Section 5(h)(5) apparently would apply to the DNA that is within organisms used in the fermentation process if the organisms are destroyed when the fermentation is complete. Moreover, EPA may grant exemptions under section 5(h)(4) for fermentation processes and certain unenclosed technologies that the agency determines are free of unreasonable risks. The exemption provisions may be one way for the agency to handle the expected flood of premanufacture notification filings that otherwise will result as manufacturers begin to "fine tune" organisms to achieve maximum output.

Section 5 of the TSCA thus appears to provide EPA with a flexible authority to compile an adequate registry of products, by-products, and sequences. The agency probably does not have the power to require firms to report hosts and vectors per se, but it may be able to require the reporting of sequences, which will convey essentially the same information. Although few host-vector systems currently exist, as the number increases, EPA's inability to require entities to report hosts and vectors may become a significant informational impediment.

Like most regulatory statutes, the TSCA provides that the agency may not disclose trade secret information that is otherwise exempt from disclosure under subsection 552(b)(4) of the Freedom of Information Act.<sup>199</sup> This prohibition almost surely would include

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197. 15 U.S.C. § 2604(h)(4) (1976). EPA recently has exempted certain chemicals used in enclosed photographic processes. See 40 C.F.R. § 710.4(d)(5) (1982).

198. 15 U.S.C. § 2604(h)(5) (1976).

199. *Id.* § 2613(a). The contents of health and safety studies, however, do not fall within the definition of trade secret so long as the agency does not disclose "processes used in the manufacturing or processing of a chemical substance or mixture or, in the case of a

the identity of products, by-products, hosts, and vectors; hence the public could not inspect the registry.<sup>200</sup> To avoid total nondisclosure of newly developed chemical products, the TSCA requires that EPA provide the public with at least a generic description of new chemicals as entities report them to the agency.<sup>201</sup> The agency could attempt to implement a similar disclosure scheme for the products and by-products of a biotechnology.

FDA has significant authority under the FFDCA to require a report of products, by-products, hosts, vectors, and technologies used to manufacture drugs.<sup>202</sup> FDA can require firms to give the agency this information at the time of a new drug application. In addition, the agency can require companies to report significant aspects of manufacturing technologies during early developmental stages as a condition to later new drug approval.<sup>203</sup> The FIFRA gives EPA similar authority to require reporting of processes used to manufacture pesticides.<sup>204</sup> The government could use both authorities to compile limited registries of products, by-products, hosts, and vectors used in the production of pesticides and of products subject to FDA's licensing authority. At present, however, neither agency has indicated whether it intends to devote any special attention to biotechnologies that use genetically engineered micro-organisms.<sup>205</sup>

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mixture, . . . the portion of the mixture comprised by any of the chemical substances in the mixture." *Id.* § 2613(b).

200. The agency, however, must disclose information on the identity of products and by-products if the information is in a health and safety study. *Id.* Since health and safety studies generally are not complete until long after development and marketing of the chemicals, this provision will not be useful in compelling public disclosure of the registry.

201. *Id.* § 2604(d)(2).

202. 21 U.S.C. § 360 (1976).

203. FDA uses its product licensing authority to require companies to comply with its rules on human experimentation during clinical trials for drugs. *See* 21 C.F.R. [§ 58.1]-58.219 (1982); *id.* § 312.1(a); *cf.* Protection of Human Subjects: Standards for Institutional Review Boards for Clinical Investigations, 46 Fed. Reg. 8958 (1981).

204. 7 U.S.C. § 136a (1976 & Supp. V 1981).

205. *See infra* text accompanying notes 223-24. FDA has acknowledged that although it has not worked out the details for assuring compliance with the NIH Guidelines, it is considering a registration requirement for all rDNA research conducted for submission to FDA. 43 Fed. Reg. 60, 134 (1978). In evaluating this research FDA would utilize the expertise of NIH as necessary and might refer specific applications to NIH to determine their compliance with the NIH Guidelines. *Id.*

EPA recently has requested that the Administrator's Toxic Substances Advisory Committee examine the possibility of regulating the newly emerging biotechnologies under the TSCA and other environmental laws. *See EPA Official Asks Committee to Examine TSCA's Application to Genetic Engineering*, 6 CHEM. REG. REP. (BNA) 735 (Sept. 17, 1982).

Clearly, neither the FFDCA nor the FIFRA gives regulatory agencies adequate authority to compile a central registry of all genetically engineered hosts and vectors and their by-products. The TSCA grants the only comprehensive authority to perform this function. Hence, EPA must take the lead and address biotechnologies by promulgating regulations pursuant to section 5 of the TSCA. Once biotechnology firms are on notice that EPA considers the DNA in genetically altered micro-organisms to be a chemical substance, the firms either will provide the information requested or will litigate EPA's authority to regulate. If companies choose to comply, then EPA may begin compiling an adequate registry. If the firms contest the regulations, resolution of the scope of the agency's authority will occur early in the development of the new biotechnologies. EPA's authority to demand information is only meaningful if the agency exercises its power to assemble a registry. EPA's past and current unwillingness to do so is unfortunate because the agency may lose the opportunity to regulate and monitor unintrusively this important emerging technology. If the new technology does prove hazardous, EPA once again will have to implement a regulatory scheme hastily and reactively.

## 2. Surveillance of Technologies in Operation

Even if EPA cannot compile a central registry, some agency may be able to gather information on the potential risks of the biotechnology industry by monitoring, conducting inspections, and requiring regulatees to keep adequate records. This surveillance function would be essential for the enforcement of any regulatory controls that the agency promulgates. Ideally, the regulatory agency should have authority to place the burden of monitoring and data gathering upon the regulatee. The agency might require the regulatee to monitor the workplace and the environment for the presence of genetically altered micro-organisms, to validate micro-organism kills in fermentation technologies, to monitor for any ill effects in employees and the surrounding environment, and to test products, by-products, and micro-organisms for toxicity and other undesirable characteristics.

Section 8(a) of the TSCA gives EPA authority to require companies, other than small manufacturers,<sup>206</sup> to "maintain such

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206. The statute defines small manufacturers according to standards prescribed by EPA after consultation with the Small Business Administration. See 15 U.S.C. § 2607(a)(3)(B) (1976); 40 C.F.R. §§ 710, 712 (1982).

records and . . . submit . . . such reports as [EPA] may reasonably require."<sup>207</sup> The statute appears to give the agency adequate authority to require firms to inform it of potential systematic employee and environmental exposure to genetically engineered micro-organisms, their products, and by-products in the fermentation industry and in other large-scale applications.<sup>208</sup> In addition to EPA's recordkeeping authority, section 8(a)(2)(E) of the TSCA gives EPA the power to require manufacturers to submit "all existing data concerning the environmental and health effects of such substance or mixture" insofar as the data are known or reasonably ascertainable.<sup>209</sup> This requirement could provide EPA with existing studies on the survivability of host organisms in human and other environmental systems. Moreover, EPA could demand that companies make available relevant reports that characterize genetically engineered organisms and any existing risk assessments performed on these organisms.

Section 8(c) of the TSCA independently requires the manufacturer, processor, and distributor of a chemical substance to "maintain records of significant adverse reactions to health or the environment . . . alleged to have been caused by the substance,"<sup>210</sup> and section 8(e) requires manufacturers, processors, and distributors who obtain information "which reasonably supports the conclusion

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207. 15 U.S.C. § 2607(a)(1)(A) (1976). Such records and reports may include:

- (1) The common or trade name, the chemical identity, and the molecular structure of each chemical substance or mixture for which such a report is required.
- (2) The categories or proposed categories of use of each such substance or mixture.
- (3) The total amount of each such substance and mixture manufactured or processed, reasonable estimates of the total amount to be manufactured or processed for each of its categories of use, and reasonable estimates of the amount to be manufactured or processed for each of its categories of use or proposed categories of use.
- (4) A description of the by-products resulting from the manufacture, processing, use, or disposal of each such substance or mixture.
- (5) All existing data concerning the environmental and health effects of such substance or mixture.
- (6) The number of individuals exposed, and reasonable estimates of the number who will be exposed, to such substance or mixture in their places of employment and the duration of such exposure.
- (7) In the initial report under paragraph (1) on such substance or mixture, the manner or method of its disposal, and in any subsequent report on such substance or mixture, any change in such manner or method.

*Id.* § 2607(a)(2).

208. The Clean Air Act, the Clean Water Act, and the RCRA give EPA similar recordkeeping authority. *See* 33 U.S.C. § 1318 (1976 & Supp. V 1981); 42 U.S.C. §§ 6922(1), 6923(a)(1), 6924(1), 6925(b) (1976); 42 U.S.C. § 7414 (Supp. V 1981).

209. 15 U.S.C. § 2607(a)(2)(E) (1976).

210. *Id.* § 2607(c).

that such substance or mixture presents a substantial risk of injury to health or the environment" to inform the EPA immediately of that information.<sup>211</sup> These statutory sections appear to provide sufficient authority to require biotechnology firms to report diseases caused by exposure to products and by-products of genetic technologies. Whether the provisions give EPA power to compel information about diseases that result from genetically engineered pathogenic *organisms* depends upon whether the DNA within the organisms caused the diseases.<sup>212</sup> Similarly, whether the DNA presents a substantial risk of injury determines whether the substantial risk notice requirement applies to pathogenic organisms.

Section 11 of the TSCA<sup>213</sup> allows a duly designated representative of EPA to inspect any establishment that engages in manufacturing or processing of chemical substances or mixtures.<sup>214</sup> This provision appears to grant EPA sufficient authority to require firms to allow agency employees or designated representatives to monitor facilities for human and environmental exposure to microorganisms and for possible diseases resulting from these organisms. Although section 11 does not grant EPA authority to require firms to self-monitor, section 6(a)(4)<sup>215</sup> of the TSCA provides that EPA by rule may require manufacturers and processors of a chemical substance to "monitor or conduct tests which are reasonable and necessary to assure compliance with the . . . rule."<sup>216</sup> Before the agency may promulgate a section 6 rule, however, it first must make the threshold determination that the manufacture or processing of the chemical substance "presents or will present an unreasonable risk of injury to health or the environment."<sup>217</sup> This limitation will preclude section 6(a)(4) from serving as a useful mechanism for acquiring information during the initial stages of

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211. *Id.* § 2607(e).

212. This statement assumes that DNA is a chemical substance or mixture. *See supra* notes 162-69 and accompanying text.

213. 15 U.S.C. § 2610 (1976).

214. The Clean Air Act, the Clean Water Act, and the RCRA give EPA similar authority to inspect regulatees' facilities. *See* 33 U.S.C. § 1318 (1976 & Supp. V 1981); 42 U.S.C. § 6927 (1976); 42 U.S.C. § 7414 (Supp. V 1981). Section 6 of the TSCA empowers EPA to require monitoring. 15 U.S.C. § 2605 (1976). EPA, however, only may exercise this authority pursuant to a § 6 rule that requires a threshold determination of unreasonable risk. As previously discussed, this finding is difficult to make during the early stages of the development of industrial biotechnologies. *See supra* part III(B).

215. 15 U.S.C. § 2605(a)(4) (1976).

216. *Id.*

217. *Id.* § 2605(a).



the development of genetic technologies.<sup>218</sup>

Section 4 of the TSCA<sup>219</sup> supplements EPA's extensive data gathering authority. This provision allows the agency to order companies to conduct testing in accordance with specified standards on a substance or mixture to develop data about its health and environmental effects.<sup>220</sup> The determination whether a substance poses an unreasonable risk will be difficult for the agency to make in the abstract. Conceivably, some forms of altered DNA in certain kinds of micro-organisms could produce substances that are harmful to humans and the environment. Existing risk assessments on a few industrially useful micro-organisms, however, indicate that human or environmental exposure to these organisms will pose no unreasonable risks regardless of the organisms' genetic alterations. Hence, EPA justifiably might decline to require testing for whole strains of genetically altered bacteria once the agency has established the safety of the bacteria itself. On the other hand, EPA might require testing on the effects of DNA in micro-organisms that it has not yet fully characterized and determined to be sufficiently safe.

Even if EPA cannot determine that genetically altered DNA within a micro-organism may pose unreasonable risks, as section 4 of the TSCA requires, the agency may order testing if a company produces the substance in large quantities that will enter the environment or result in substantial human exposure.<sup>221</sup> While enclosed fermentation processes probably do not meet this test, large-scale industrial use of genetically altered micro-organisms in the environment—for example, for leaching minerals or digesting oil spills—easily could satisfy the requirement.<sup>222</sup>

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218. See *supra* note 199.

219. 15 U.S.C. § 2603 (1976).

220. *Id.* § 2603(a). Before EPA may order testing, it first must determine that:

(i) the manufacture, distribution in commerce, processing, use, or disposal of a chemical substance or mixture, or that any combination of such activities, may present an unreasonable risk of injury to health or the environment, and (ii) there are insufficient data and experience to predict the effects of the substance on health or the environment, and (iii) testing is necessary to develop adequate data.

*Id.* The TSCA establishes a committee to make recommendations to the Administrator of EPA concerning which chemical substances or mixtures should receive priority testing. *Id.* § 2603(e) (1976).

221. *Id.* § 2603(a)(B)(i).

222. Section 3013 of the RCRA authorizes EPA to require the owner or operator of a facility to conduct monitoring, testing, or analysis when the agency determines that the presence of any hazardous waste at the facility, or the release of any such waste from the facility, may present a substantial hazard to human health or the environment. 42 U.S.C. § 6934 (Supp. V 1981). Section 3013 is highly significant because it provides the Administra-

The OSHAct gives OSHA and NIOSH extensive authority to acquire and analyze data on possible diseases attributable to newly emerging genetic technologies. Section 20 of the OSHAct empowers NIOSH to gather information on workplace safety and "conduct (directly or by grants or contracts) research, experiments, and demonstrations relating to occupational safety and health . . . ." <sup>223</sup> In particular, section 20(a)(4) authorizes NIOSH to "conduct special research, experiments and demonstrations relating to occupational safety and health as are necessary to explore new problems, including those created by new technology in occupational safety and health, which may require ameliorative action beyond that which is otherwise provided for in the operating provisions of this Act." <sup>224</sup> Pursuant to this authority NIOSH currently is conducting a study of risks that the fermentation industry poses to workers. The agency intends ultimately to make a general assessment of those risks. <sup>225</sup>

Under section 8(a) of the OSHAct, <sup>226</sup> NIOSH and OSHA officials have authority to enter workplaces at reasonable hours to conduct reasonable investigations of conditions therein. <sup>227</sup> In addition, section 8(c)(1) of the OSHAct requires employers to "make, keep and preserve" such records as the Secretary of Labor, in cooperation with the Secretary of HHS, prescribes by regulation as "necessary or appropriate for the enforcement of [the OSHAct] or for developing information regarding the causes and prevention of occupational accidents and illnesses." <sup>228</sup> These regulations may "include provisions requiring employers to conduct periodic inspections." <sup>229</sup> They appear to provide adequate authority for

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tor of EPA with the necessary power to order continuous monitoring and to obtain information from both inactive and active disposal sites. *Id.*

223. 29 U.S.C. § 669 (1976 & Supp. V 1981).

224. *Id.* § 669(a)(4).

225. See Division of Surveillance, Hazard Evaluations and Field Studies, National Institute for Occupational Safety and Health, *Medical Surveillance of Biotechnology Workers: Report of the CDC/NIOSH Ad Hoc Working Group on Medical Surveillance for Industrial Applications of Biotechnology*, 5 NIH RECOMBINANT DNA TECHNICAL BULL. 133 (1982).

226. 29 U.S.C. § 657 (1976 & Supp. V 1981).

227. See *id.* Section 20 gives NIOSH the power to enter and investigate workplaces. *Id.* § 669. If an employer refuses to allow inspection of his premises, OSHA must obtain a warrant before entry. *Marshall v. Barlow's Inc.*, 436 U.S. 307, 321-22 (1978). A showing of probable cause in the strict criminal law sense, however, is not a prerequisite to obtaining a warrant. An agency may establish probable cause merely by showing that its inspection is part of a general administrative plan for enforcing the Act. *Id.* at 321.

228. 29 U.S.C. § 657(c)(1) (1976 & Supp. V 1981).

229. *Id.*

OSHA to require employers to monitor periodically the workplace environment near physical containment facilities for escaped micro-organisms. Arguably, section 8(c)(1) also permits OSHA to demand that employers convey to the agency the identities of hosts, vectors, genetic sequences, products, and by-products of particular genetic engineering technologies. OSHA, however, must establish whether these reporting requirements would be "necessary or appropriate" to "developing information regarding the causes and prevention of occupational accidents and illnesses."<sup>230</sup>

Section 8(c)(2) of the OSHAct<sup>231</sup> requires the Secretary of Labor, in cooperation with the Secretary of HHS, to prescribe regulations "requiring employers to maintain accurate records of, and to make periodic reports on, work-related deaths, injuries, and illnesses other than minor injuries."<sup>232</sup> In addition, section 8(c)(3) provides that OSHA must issue regulations instructing employers to maintain accurate records of employees' exposures to potentially toxic materials or harmful physical agents that are subject to the monitoring requirements of section 6 of the OSHAct.<sup>233</sup> These provisions apparently permit OSHA to establish a registry of diseases that cause serious injuries to workers. Whether OSHA may require reporting of worker exposures to genetically engineered micro-organisms absent a clearly demonstrated serious injury depends upon whether the organisms fall within section 6.<sup>234</sup>

Although the OSHAct clearly authorizes OSHA and NIOSH to compile information on the risks that new biotechnologies pose to workers, the agencies' ability to acquire data concerning hazards to the environment is much less clear. Since workers often are on the front line when the new technological risks emerge, the existing authority may be sufficient for most purposes<sup>235</sup> provided the agencies exercise it.<sup>236</sup>

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230. *Id.*

231. *Id.* § 657(c)(2).

232. *Id.*

233. *Id.* § 657(c)(3); *see id.* § 655.

234. *See id.* § 655; *infra* text accompanying notes 247-55.

235. Certain limitations exist on OSHA's regulatory authority. For example, federal agency employees and state and local government workers are exempt from OSHAct's coverage. 29 U.S.C. § 652(5) (1976 & Supp. V 1981). In addition, the Act covers only employers engaged in a business "affecting commerce." *Id.* The courts, however, have given this phrase a rather expansive meaning. For a general discussion of these issues, see G. NOTHSTEIN, *THE LAW OF OCCUPATIONAL SAFETY AND HEALTH* 32-55 (1981).

236. NIOSH has exhibited a commendable interest in the emerging biotechnologies and has conducted several site inspections of plants that use genetically engineered biotechnologies. While governmental budgetary cutbacks may curtail the work of this program, the

The FDCA<sup>237</sup> gives the FDA extensive monitoring and data gathering authority, depending upon how "new" the agency believes a product might be.<sup>238</sup> Except for a generic or so-called "me-too" version of a previously approved drug,<sup>239</sup> a manufacturer whose drug is subject to FDA's jurisdiction must submit a New Drug Application (NDA) containing the results of a full range of preclinical and clinical testing; a complete list of the raw materials used to manufacture the drug; the drug's composition; a full description of the methods employed in manufacturing, processing, and packaging the drug; and specimens of the proposed labeling.<sup>240</sup> This "full NDA" procedure,<sup>241</sup> which Congress and the Reagan Administration recently have criticized, typically requires years of testing and major financial expenditures.<sup>242</sup>

FDA has not announced an official policy for regulating genetic technologies. At one time it proposed incorporating the NIH Guidelines<sup>243</sup> into its regulatory plans, but recently FDA seems to have retreated from this position.<sup>244</sup> Agency officials commenting in scholarly publications are the best sources of current FDA policy.<sup>245</sup> For example, Dr. Henry Miller has written that when consistent with individual bureau policy<sup>246</sup> FDA should require an NDA for every product that uses rDNA technology, even if the product

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public interest requires that these inspections continue. Constant monitoring can identify potential problems before they grow into significant health risks.

237. EPA has similar power under the FIFRA to require health and safety testing for pesticides. See 7 U.S.C. § 136a (1976 & Supp. V 1981). Since the two laws are very similar on this issue, this Article will not discuss in detail the FIFRA's data gathering requirements.

238. 21 U.S.C. §§ 301-392 (1976 & Supp. V 1981).

239. See 21 C.F.R. § 314.1(f) (1982). One commentator has argued that genetically engineered "me-too" drugs should get full NDA treatment. See Miller, *The Impact of New Technology on Regulation by the FDA: Recombinant DNA Technology*, 36 FOOD DRUG COSM. L.J. 348, 351-52 (1981).

240. 21 C.F.R. § 314.1 (1982).

241. See *Oversight—The Food and Drug Administration's Process for Approving New Drugs: Hearings Before the Subcomm. on Science, Research, and Technology of the House Comm. on Science and Technology*, 96th Cong., 1st Sess. (1980); Korwek & Trinker, *supra* note 148, at 521.

242. For example, because genetically engineered human growth hormone is not chemically identical to the native hormone—which already is the subject of an NDA—FDA has stated that it will require preclinical testing as well as full human clinical trials.

243. 41 Fed. Reg. 27,902 (1976); see *supra* part IV(A)(1).

244. See 43 Fed. Reg. 60,134 (1978) (to be codified at 21 C.F.R. § 59).

245. Personal communication from Dr. Henry Miller, medical officer, Bureau of Drugs, FDA, to Mr. K. Bayer (1983).

246. Each bureau within FDA functions autonomously. Thus, FDA's notion of requiring an NDA when consistent with bureau policy could create substantial internal variation in the regulation of different products. Data requirements almost certainly would vary from product to product. See Miller, *supra* note 239, at 351.

is identical to a previously approved product or a natural substance.<sup>247</sup> Moreover, Dr. Miller reports that FDA does not plan to promulgate any additional "Good Manufacturing Practices"<sup>248</sup> for drugs or to extend its control over genetic technology through NEPA<sup>249</sup> or section 361 of PHSA.<sup>250</sup>

### C. Risk Assessment

EPA, FDA, OSHA, and NIOSH have authority to use information that they acquire on their own or from regulatees to assess the risks of newly emerging biotechnologies. Whether the agencies can perform risk assessments as information becomes available to them depends upon whether they develop and use the data aggressively. Although EPA, OSHA, and NIOSH have little, if any, expertise in assessing microbiological risks, they do have substantial skill in evaluating the hazards of the chemical products and by-products of biotechnologies. The Center for Disease Control, on the other hand, is the nation's chief repository for determining the risks of infective organisms. An interagency effort best might accomplish a holistic assessment of all the dangers posed by a particular biotechnology. The Interagency Regulatory Liaison Group, which consisted of representatives from EPA, FDA, OSHA, the Consumer Product Safety Commission, and the Department of Agriculture offered an ideal vehicle for initiating cooperative risk assessment efforts.<sup>251</sup> The Reagan Administration, however, has disbanded that organization. Another vehicle for ensuring the performance of complete risk analyses for emerging biotechnologies is an interagency memorandum of understanding that would divide up responsibility for performing risk assessments as information becomes available.

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247. MILLER, PROCEEDINGS OF BANBURY CONFERENCE ON MEDICAL APPLICATION OF RECOMBINANT DNA (1983) (forthcoming).

248. See *infra* notes 253-64 and accompanying text.

249. 42 U.S.C. §§ 4321, 4331-4335, 4341-4347 (1976).

250. Miller, *supra* note 247, at \_\_\_\_\_ (forthcoming). Section 361 gives FDA broad authority to regulate dangerous micro-organisms. The provision, however, is unclear whether that authority could extend to surveillance for latent or potential problems. The relatively small staff of the Center for Disease Control, which presumably would perform the actual surveillance, probably is incapable of adequately monitoring the new biotechnologies at its present size.

251. See Draft Work Plans of the Interagency Regulatory Liaison Group, 1 CHEM. REG. REP. (BNA) 1426-34 (1977).

### D. Regulatory Controls

The existing statutes provide the administering agencies with a large arsenal of regulatory requirements. Most product licensing statutes give the agency broad authority to condition a license on virtually any reasonable requirement. Other statutes, such as the TSCA and the OSHA Act, empower the agency to intervene into the manufacturing and distribution process. The Clean Air Act, the Clean Water Act, and the RCRA give the agency power to control only unwanted by-products of the manufacturing process. Each statute provides sanctions for violations of validly promulgated regulatory requirements.<sup>252</sup> An important distinction exists between the regulatory tools available in fermentation technologies and the measures available in large-scale release technologies. A regulatory mechanism that is adequate for one kind of technology may be entirely inappropriate for another kind.

#### 1. Product Licensing

Section 501(a)(1) of the FFDCA provides that the agency shall deem a drug adulterated if it "consists in whole or in part of any filthy, putrid, or decomposed substance . . . ." <sup>253</sup> According to section 501(a)(2)(A), a drug is adulterated "if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health . . . ." <sup>254</sup> Subsection (a)(2)(B) requires the agency to establish drug "good manufacturing practices" (GMPs).<sup>255</sup> The agency must find a drug adulterated if "the methods used in, or the facilities . . . used for, its manufacture, processing, packing, or holding do not conform to or are not operated . . . in conformity with current good manufacturing practice . . . ." <sup>256</sup> FDA rarely invokes these two subsections to seize drug products. According to Dr. Korwek, the drug GMP Regulations, promulgated

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252. The statutes provide for sanctions that may include, *inter alia*, the imposition of civil and criminal penalties, revocation of permits or licenses, and imprisonment for specific violations. In addition, agencies may secure compliance with the applicable regulations by issuing administrative orders or obtaining injunctive relief in federal district courts. For example, a violation of certain requirements of the TSCA can result in civil penalties of up to \$25,000 per day. 15 U.S.C. § 2615(a)(1) (1976). A knowing or willful violation can result in an additional fine of up to \$25,000 per day and imprisonment for up to one year. *Id.* § 2615(b). Section 7 of the TSCA authorizes injunctive relief. *Id.* § 2616.

253. 21 U.S.C.A. § 351(a)(1) (West Supp. 1982).

254. *Id.* § 351(a)(2)(A).

255. *Id.* § 351(a)(2)(B).

256. *Id.*

under section 501(a)(2)(B), "provide more objective standards for enforcement than do the subjective lack of cleanliness requirements. . . ." <sup>257</sup> Therefore, although an agency could use subsections (a)(1) and (a)(2)(A) to support requirements that protect humans and the environment from genetically engineered microorganisms and their by-products, FDA is unlikely to rely on those provisions given the authority available in subsection (a)(2)(B). <sup>258</sup>

While it could be argued that the extremely broad GMPs might be beyond FDA's authority under section 501(a)(2)(B), <sup>259</sup> the cases have been limited to constitutional claims that section 501(a)(2)(B) is void for vagueness. According to Dr. Korwek, these challenges generally have failed. The courts have held that the GMP Regulations "properly elaborate upon the Act," <sup>260</sup> meaningfully "refer to business practice and usage," <sup>261</sup> and "have been promulgated with active participation by industry." <sup>262</sup> These cases, as Dr. Korwek notes, have cited the general health protection purposes of the FFDCa, the strong presumption of statutory validity in upholding the Regulations, and FDA's statutory authority under the FFDCa. <sup>263</sup> A number of courts have stated that in public

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257. Korwek, *The NIH Guidelines for Recombinant DNA Research and the Authority of FDA to Require Compliance with the Guidelines*, *supra* note 148, at 641; *see also* 21 C.F.R. §§ 210-226 (1982); *see generally* *United States v. Article of Drug Labeled "White Quadrisect,"* 484 F.2d 748 (7th Cir. 1973) ("good manufacturing practices" not unconstitutionally vague).

258. Korwek, *The NIH Guidelines for Recombinant DNA Research and the Authority of FDA to Require Compliance with the Guidelines*, *supra* note 148, at 641. FDA has stated that drug GMPs will be the vehicle for incorporating the NIH Guidelines into FDA's regulatory regime. *Id.*

259. *See id.* Section 501(a)(2)(B) applies to "drugs." 21 U.S.C.A. § 351(a)(2)(B) (West Supp. 1982). Although the GMP Regulations do not define explicitly good manufacturing practices, they do specify criteria for buildings, equipment, components, product containers, laboratory controls, personnel, packaging, labeling, records, and reports used in the manufacture, processing, packaging, or holding of drug products. 21 C.F.R. §§ 210-226 (1982).

260. Korwek, *The NIH Guidelines for Recombinant DNA Research and the Authority of FDA to Require Compliance with the Guidelines*, *supra* note 148, at 641-42; *see, e.g., United States v. Article of Drug Labeled "White Quadrisect,"* 484 F.2d 748 (7th Cir. 1973).

261. Korwek, *The NIH Guidelines for Recombinant DNA Research and the Authority of FDA to Require Compliance with the Guidelines*, *supra* note 148, at 641-42; *see, e.g., United States v. Bel-Mar Laboratories, Inc.*, 284 F. Supp. 875 (E.D.N.Y. 1968).

262. Korwek, *The NIH Guidelines for Recombinant DNA Research and the Authority of FDA to Require Compliance with the Guidelines*, *supra* note 148, at 641-42; *see, e.g., United States v. Bel-mar Laboratories, Inc.*, 284 F. Supp. 875, 883 (E.D.N.Y. 1968).

263. Korwek, *The NIH Guidelines for Recombinant DNA Research and the Authority of FDA to Require Compliance with the Guidelines*, *supra* note 148, at 642. The decisions addressing the validity of the food GMPs, which are similar in scope and authority to drug GMPs, have affirmed the broad authority of FDA under the FFDCa to issue such regulations. *See, e.g., National Confectioners Ass'n v. Califano*, 569 F.2d 690, 692 (D.C. Cir.

health matters judges should construe liberally the FFDCA.<sup>264</sup>

FDA could amend its GMP Regulations to encompass any additional risks posed by genetically engineered micro-organisms.<sup>265</sup> The GMP Regulations adopt a technology-based approach that is consistent with the regulatory needs for newly emerging fermentation technologies. The Regulations are generic but amendments could prescribe case by case controls when necessary. Although worker protection is not expressly within FDA's authority, the GMPs do contain receptor-oriented requirements that protect employees as well as product purity. FDA, however, could amend its GMP Regulations to reflect a receptor-oriented approach only to the extent that the worker protection effort coincided with the agency's authority to regulate product quality.

FDA would have considerable difficulty amending the GMPs to protect the environment. The National Environmental Policy Act (NEPA), however, may bolster FDA's legal authority to demand compliance with regulations aimed at protecting health and the environment. Although the NEPA requires that federal agencies consider environmental effects "to the fullest extent possible" in their planning and decisionmaking,<sup>266</sup> the statute may not give FDA the authority to force companies to comply with environmentally protective GMPs. FDA has promulgated regulations implementing section 102(2)(c) of the NEPA,<sup>267</sup> which provides that an Environmental Impact Statement (EIS) must accompany any proposal for federal action affecting the quality of the human environment.<sup>268</sup> Exemptions, however, are available for whole categories of

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1978); *United States v. Nova Scotia Food Prods. Corp.*, 568 F.2d 240, 246 (2d Cir. 1977); *Golden Grain Macaroni Co. v. United States*, 209 F.2d 166, 168 (9th Cir. 1953); *Berger v. United States*, 200 F.2d 818, 822 (8th Cir. 1952).

264. See *supra* note 263 and authorities cited therein.

265. On December 22, 1978, FDA announced its intention "to propose regulations to require that any firm seeking approval of a product requiring the use of recombinant DNA methods in its development or manufacture demonstrate the firm's compliance with the requirements of the NIH Guidelines . . . with any work it has done or will do relating to that product." 43 Fed. Reg. 60,134 (1978) (to be codified at 21 C.F.R. § 59). In particular, FDA announced that it would require this assurance "in notices of claimed investigational exemption of new drugs (INB's) . . . , NDA's . . . , license applications for biologic products, requests for certification for antibiotics, feed additive petitions, and new animal drug applications (NADA's)." *Id.* Further, FDA intends to propose incorporation of the NIH guidelines in GMP Regulations if an applicant proposes rDNA techniques for manufacturing commercially distributed products. *Id.*

266. National Environmental Policy Act § 102, 42 U.S.C. § 4332 (1976).

267. National Environmental Policy Act § 102(2)(c), 42 U.S.C. § 4332(2)(C) (1976).

268. See *generally* 21 C.F.R. § 25 (1982) (environmental impact considerations).



drugs, animal drugs, and food additives<sup>269</sup> because FDA approvals normally do not significantly affect environmental quality. Furthermore, FDA can avoid filing an EIS in individual cases by making a "finding of no significant impact" (FONSI).

Arguably, the NEPA alone does not give the agency sufficient substantive authority to withhold its approval of a drug *solely* because of the environmental effects of the manufacturing process. Little litigation has arisen over the extent to which the NEPA imposes a duty upon each federal official to protect the environment. Nonetheless, in three important cases courts have upheld the authority and responsibility of agencies to protect the environment under the NEPA.<sup>270</sup> In *Environmental Defense Fund, Inc. v. Mathews*<sup>271</sup> the court held that FDA has authority under the NEPA to evaluate the environmental effects of its decisions. Whether FDA may base its action exclusively on environmental considerations remains an open question.<sup>272</sup> Clearly, however, a reviewing court may not *require* FDA to elevate environmental issues over other appropriate concerns. The United States Supreme Court in *Strycker's Bay Neighborhood Council, Inc. v. Karlen*<sup>273</sup> held that once an agency has made a decision pursuant to the NEPA's procedural requirements, the only role for a court is to ensure that the agency considered the environmental consequences.<sup>274</sup>

According to Dr. Miller,<sup>275</sup> environmental impact is an integral consideration in FDA's regulatory process.

FDA regulations provide that applicants seeking premarket approval file an Environmental Impact Analysis Report (EIAR). If . . . the data in the assessment leads [FDA to find] that a proposed action will have a significant impact upon the quality of the human environment, the Agency [must] prepare an . . . (EIS) to ensure that environmental consequences are considered in

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269. See *id.* § 25.1(f).

270. See *Calvert Cliffs' Coordinating Comm., Inc. v. United States Atomic Energy Comm'n*, 449 F.2d 1109, 1112 (D.C. Cir. 1971); *Zabel v. Tabb*, 430 F.2d 199, 209-14 (5th Cir. 1970); *Environmental Defense Fund, Inc. v. Mathews*, 410 F. Supp. 336, 337-38 (D.D.C. 1976); see also McGarity, *The Courts, the Agencies, and NEPA Threshold Issues*, 55 *Tex. L. Rev.* 801, 864-67 (1977) (discussion of cited cases).

271. 410 F. Supp. 336 (D.D.C. 1976).

272. Language in *Mathews* indicates that FDA probably must consider other elements: "NEPA requires FDA to *consider* environmental factors in its decision-making process and supplements its existing authority to permit it to act on those considerations." *Id.* at 338 (emphasis in original). "It permits FDA to base a decision upon environmental factors, *when balanced with other relevant considerations.*" *Id.* at 338 (emphasis added).

273. 444 U.S. 223 (1980).

274. *Id.* at 228.

275. See Miller, *supra* note 239, at 352.

the decision-making.<sup>276</sup>

Relying on the NEPA, FDA could take the position that its approval of products manufactured in compliance with environmentally protective GMPs, as amended, will not "significantly affect" the environment and, hence, FDA need not develop an EIS for these products. Alternatively, FDA could threaten to initiate the time-consuming full-scale EIS process unless an applicant demonstrated that it manufactured the product in accordance with the amended GMPs.<sup>277</sup>

Despite the lack of an official FDA position and the heated theoretical debate on the extent of FDA's authority, FDA currently is regulating genetic technologies.<sup>278</sup> Anticipating the submission of INDs and NDAs for substances produced by genetic technologies, FDA added to its staff several medical doctors and Ph.Ds with recent laboratory experience in the science and technology of rDNA. With this new expertise and the agency's lengthy experience in premarket approval procedures and the GMP Regulations, FDA believes that it can accommodate the new manufacturing technology.<sup>279</sup> FDA, however, will not apply a uniform regulatory scheme because it has different statutory requirements for different product classes—drugs, food additives, biologics, and devices. Rather, the agency intends to regulate product by product through its bureaus.<sup>280</sup>

EPA, like FDA, has authority to condition its grant of a pesti-

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276. *Id.*

277. FDA is considering informing industry that "a manufacturer's compliance with . . . NIH Guidelines [will mitigate] potential adverse effects to the environment from [the] new technology." *Id.* After making these assurances, FDA usually "would not seek . . . further environmental review in the form of an EIS, with regard to those particular aspects of the technology." *Id.* FDA easily could expand this approach to include compliance with amended GMPs that focus on technological application as well as on research.

278. FDA's own assessment of the pharmaceuticals that are made using genetic engineering techniques includes the following regulated products: (1) *Drugs*—Human Insulin; Human Growth Hormone (or Analogs); Thymosin; ACTH; Endorphins; DNA; (2) *Biologics*—Interferons; Vaccines, including Hepatitis B and Influenza; Serum Albumin; Urokinase; DNA; (3) *Foods*—Certain enzymes used in food processing; and (4) *Medical Devices*—*in vitro* diagnostic tests (e.g., Glucose Oxidase); specific *in utero* diagnostic tests (e.g., Thalassemia, Sickle-cell Anemia). See Miller, *supra* note 239, at 350.

279. *Id.* at 351.

280. Recently, the FDA commissioner established the rDNA Coordinating Committee. The deputy associate commissioner for health affairs and science chairs the Committee, which "has representatives from the Bureaus, the Office of Regulatory Affairs, Executive Director for Regional Operations (EDRO) and General Counsel. The Committee will serve as the focus of Recombinant DNA policy issues, coordinating, advising and interacting with FDA's various organizational units." *Id.* at 353.

cide registration upon the assurance that the product and its production processes are not environmentally harmful.<sup>281</sup> Although EPA has no special guidelines for genetically engineered pesticidal micro-organisms, the agency must approve new genetically engineered organisms before a company may market them.<sup>282</sup> Therefore, a company would be wise to follow EPA's guidelines in testing the product. The testing process itself can be very expensive; some cost estimates range as high as seven million dollars.<sup>283</sup> Unlike FDA's GMPs, the testing guidelines do not address health hazards in the workplace. Instead, they focus exclusively on providing information for the evaluation of the risks and benefits of pesticide products.<sup>284</sup> EPA generally has little concern for the impurities and other pesticidally inactive by-products that the product which reaches the public may contain. Thus, EPA probably will not use its FIFRA authority to erect a regulatory structure for the manufacturing process. The TSCA is probably the better vehicle for process requirements.

Clearly, existing product licensing statutes offer some authority to regulate genetic technologies. FDA's GMP Regulations offer an especially convenient vehicle for comprehensive regulation should the agency deem it necessary. The FFDCA and the FIFRA, however, at best can address only the health and environmental effects of specific products and their manufacturing technologies. Neither statute would be appropriate for regulating large-scale application of genetically altered micro-organisms other than those used for pesticides. Furthermore, both statutes only give the agencies authority to regulate products or processes that require licensing. Thus, even a combination of both statutes provides an inadequate regulatory framework.

## 2. Production Processes

The government could construct its most comprehensive regulatory scheme for genetic technology around one or more of the statutes that give agencies authority over production processes. These statutes require an agency to intervene in a firm's decision-making process once the agency has made a threshold showing of

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281. 7 U.S.C. § 136w(a)(1) (1976).

282. Persons cannot sell pesticides that are not registered with the administrator. *Id.* § 136a(a). If the agency does not approve the pesticide, the administrator may deny registration. *Id.* §§ 136a(c)(5)-(6).

283. See S. REP. NO. 334, 95th Cong., 1st Sess. 30 (1977).

284. 7 U.S.C. § 136a(c)(1)(D) (1976).

danger.

Section 6(b)(1) of the OSHA Act gives OSHA authority to promulgate "occupational safety and health standard[s] . . . in order to serve the objectives of this [Act]. . . ." <sup>285</sup> Section 3(8) defines the term "occupational safety and health standard" to mean "a standard which requires conditions, or the adoption or use of one or more practices, means, methods, operations, or processes, reasonably necessary or appropriate to provide safe or healthful employment and places of employment." <sup>286</sup> Section 6(b)(5) further elaborates on occupational safety and health standards for "toxic materials or harmful physical agents." For these substances, OSHA must

set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if such employee has regular exposure to the hazard dealt with by such standard for the period of his working life. <sup>287</sup>

The Supreme Court recently has wrestled with the meaning of these three interrelated phrases in cases concerning OSHA's attempts to set standards for workplace exposure to benzene and cotton dust. In *Industrial Union Department AFL-CIO v. American Petroleum Institute* <sup>288</sup> a plurality of the Court held that OSHA may not promulgate a standard requiring reduced exposure to a toxic substance or harmful physical agent unless this reduced exposure is "reasonably necessary and appropriate to remedy a significant risk of material health impairment." <sup>289</sup> OSHA was not at liberty to assume that a substance that causes leukemia in workers at ten parts per million poses a significant risk to employees subject to current exposure levels of one part per million or less. In *American Textile Manufacturers Institute, Inc. v. Donovan*, <sup>290</sup> however, the Court held that OSHA need not weigh a standard's costs against its benefits prior to imposing the requirement upon employers. As long as a standard is necessary to reduce or elimi-

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285. 29 U.S.C. §§ 655(b)-(b)(1) (1976). In addition, every employer under section 5(a)(1) of the Act has a "general duty" to "furnish to each of his employees employment and a place of employment which are free from recognized hazards that are causing or are likely to cause death or serious physical harm to his employees." *Id.* § 654(a)(1). OSHA can enforce this general duty clause at its own discretion. *United States Steelworkers of Am. v. Marshall*, 647 F.2d 1189 (D.C. Cir.), *cert. denied*, 453 U.S. 913 (1980).

286. 29 U.S.C. § 652(8) (1976).

287. *Id.* § 655(b)(5).

288. 448 U.S. 607 (1980).

289. *Id.* at 639.

290. 452 U.S. 490 (1981).

nate a significant risk, OSHA may require employers to implement all feasible control devices, even over objections that the costs of implementing the controls far exceed the projected benefits. Indeed, the Court strongly suggested that the statute does not *allow* the agency to use a balancing approach when it stated that "cost-benefit analysis by OSHA is not required by the statute because feasibility (technology-based) analysis is."<sup>291</sup>

Although genetically engineered micro-organisms arguably are not "toxic materials or harmful physical agents," Congress apparently intended the terms to be sufficiently inclusive to reach organisms that posed a significant risk to workers.<sup>292</sup> Even if genetically engineered industrial micro-organisms do not fit this definition, OSHA still could promulgate standards under section 6(b)(1) provided the standard was "reasonably necessary . . . to provide safe or healthful employment and places of employment."<sup>293</sup> Section 6(b)(5) appears to provide adequate authority for setting standards for physical containment of organisms that pose a significant risk of harm to workers. OSHA might specify a media quality-based ambient exposure level for the relevant micro-organisms, products, and by-products. Alternatively, it might specify technology-based requirements for containment vessels or receptor-oriented technology-based standards for personal protective gear.<sup>294</sup>

Any occupational health standard promulgated under section 6 must "prescribe the use of labels or other appropriate forms of warning as are necessary to insure that employees are apprised of all hazards to which they are exposed, relevant symptoms and appropriate emergency treatment, and proper conditions and precautions of safe use or exposure."<sup>295</sup> This provision would allow OSHA to require manufacturers to educate employees about the risks of substances that the agency regulates under section 6. In addition, OSHA has proposed pursuant to section 6(b)(7) of the OSHAct generic labeling regulations requiring employers to inform employees of risks of hazardous materials in the workplace.<sup>296</sup> Finally, when appropriate, a section 6 occupational health standard must "pro-

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291. *Id.* at 509.

292. *Synthetic Organic Chem. Mfrs. Ass'n v. Brennan*, 503 F.2d 1155, 1160 (3d Cir. 1974).

293. 29 U.S.C. § 652(8) (1976).

294. In the past OSHA has preferred engineering and design controls over personal protective devices, although it may be changing its position on this issue.

295. 29 U.S.C. § 655(b)(7) (1976).

296. Hazard Communication, Notice of Proposed Rulemaking and Public Hearings, 47 Fed. Reg. 12,092 (1982) (to be codified at 29 C.F.R. § 1910).

vide for monitoring or measuring employee exposure at such locations and intervals, and in such manner as may be necessary for the protection of employees."<sup>297</sup> This standard may prescribe the type and frequency of medical examinations or other tests that the employer shall make available to exposed employees. This section of the statute gives adequate authority to require monitoring of employee exposure and health but only after the Secretary has determined that sufficient danger exists to warrant the promulgation of an occupational health standard. Nevertheless, this monitoring should be valuable in assessing the efficacy of the standard in operation.

OSHA, like FDA, has no clear authority to protect the environment. The limitation on environmental protection authority may not be especially significant for the infective risks of fermentation technologies because worker protection standards probably will have the effect of protecting other humans and the environment. For technologies that use large-scale application of genetically engineered micro-organisms, however, measures designed to protect workers alone may not be adequate to safeguard the environment.<sup>298</sup> To the extent that OSHA's authority is insufficient to protect the environment, the TSCA grants EPA authority to fill the gaps. If EPA determines that it has a "reasonable basis to conclude that the manufacture, processing, distribution, use, or disposal of a chemical substance . . . will present an 'unreasonable risk of injury to health or the environment,'" it may apply any of several requirements set forth in the statute.<sup>299</sup> In addition, if EPA has a "reasonable basis to conclude" that a particular manufacturer or processor is making a chemical substance or mixture in a

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297. 29 U.S.C. § 655(b)(7) (1976).

298. OSHA may rely on the NEPA for authority to allow it to promulgate environmental protection regulations. See *supra* notes 266-77 and accompanying text. OSHA, like other agencies, must consider the environmental effects of its actions and prepare EISs for major federal actions significantly affecting the quality of the human environment. See *Dry Color Mfrs. Ass'n v. Department of Labor*, 486 F.2d 98 (3d Cir. 1973).

299. 15 U.S.C. § 2605(a) (1976). EPA may apply:

(1) A requirement *prohibiting* the manufacture, processing, and distribution of the substance entirely or for a particular use; (2) A requirement *limiting* the amount of the substance which may be manufactured, processed, and distributed; (3) A *labelling* or *warning* requirement; (4) A *recordkeeping* requirement; (5) A *monitoring* requirement; (6) A requirement *prohibiting* or otherwise *regulating* any manner or method of *commercial use* of the substance; (7) A requirement *prohibiting* or otherwise *regulating* any manner or method of *disposal* of the substance; (8) A requirement directing manufacturers or processors to give *notice* to the public and to distributors of such unreasonable risks and to *replace* or *repurchase* such substances as elected by the recipient of the notice. *Id.*; see *supra* notes 162-69 and accompanying text.

manner that unintentionally creates an unreasonable risk, EPA may require the manufacturer or processor to submit a description of its quality control procedures.<sup>300</sup> If EPA determines that the quality control procedures are inadequate to prevent the substance from posing an unreasonable risk, the agency may order the manufacturer to revise its quality control procedures as necessary to remedy the inadequacy.<sup>301</sup>

Assuming that the substance meets the "unreasonable risk" threshold and that the DNA in micro-organisms is a chemical substance or mixture, sufficient authority exists in section 6 for EPA to require technology-based commands for the physical containment of these organisms. Moreover, section 6(a)(5) may provide EPA with adequate authority to demand the use of only "safe" hosts.<sup>302</sup> In addition, EPA may have the power to specify hosts under its section 6(b) authority to revise quality control procedures.<sup>303</sup> Section 6(b), however, presumably would require a showing that a less risky host could produce the same end product. The labeling and warning provisions of sections 6(a)(3) and 6(a)(7) authorize the agency to educate and inform workers and others who suffer exposure to genetically engineered micro-organisms, their products, or by-products.<sup>304</sup>

Section 6 of the TSCA envisions primarily source-oriented commands. EPA, however, could promulgate receptor-oriented requirements pursuant to its authority under section 6(a)(5) to regulate any manner or method of commercial use of a chemical sub-

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300. 15 U.S.C. § 2605(b)(1) (1976).

301. *Id.* § 2605(b)(2).

302. Specifying appropriate hosts arguably regulates the commercial use of the DNA, as permitted under § 6(a)(5). *See id.* § 2605(a)(5).

303. *Id.* § 2605(b).

304. *See id.* §§ 2605(a)(3), (7). Note, however, that Congress in § 6(c)(1) of the TSCA indicated that EPA should use regulatory tools other than § 6(a) when feasible. Section 6(c)(1) provides:

If the Administrator determines that a risk of injury to health or the environment could be eliminated or reduced to a sufficient extent by actions taken under another Federal law (or laws) administered in whole or in part by the Administrator, the Administrator may not promulgate a rule under subsection (a) of this section to protect against such risk of injury unless the Administrator finds, in the Administrator's discretion, that it is in the public interest to protect against such risk under this chapter. In making such a finding the Administrator shall consider (i) all relevant aspects of the risk, as determined by the Administrator in the Administrator's discretion, (ii) a comparison of the estimated costs of complying with actions taken under this chapter and under such law (or laws), and (iii) the relative efficiency of actions under this chapter and under.

*Id.* § 2605(c)(1).

stance. Section 6 also seems to provide for technology-based commands or outright prohibitions rather than media quality-based requirements or incentives. EPA is powerless to invoke section 6 if it cannot make a threshold showing of unreasonable risk. This test connotes a balancing of risks against benefits, and the command that EPA select the "least burdensome" of its regulatory options indicates that Congress intended EPA to strike that balance in favor of allowing the use of the substance if at all possible.

The preceding analysis suggests that EPA alone or in cooperation with OSHA probably has authority to implement an appropriate regulatory strategy for genetic technologies. Although the statutes do not explicitly authorize incentives, such an approach probably would be premature anyway at this stage in the development of genetic engineering technologies.<sup>305</sup>

If the courts hold that genetically altered DNA in a host cell is not a chemical substance, OSHA may have to turn to FDA for assistance in protecting nonworkers and the environment. Section 361 of the PHSA is available for regulators to prevent the spread of communicable disease. Although this provision does not give FDA authority to regulate products and by-products of biotechnologies, it permits promulgation of rules to protect humans and perhaps other living entities from the risks of infection caused by genetic engineering operations.

The Public Health Service and FDA have used the "unusually broad delegation of authority [under section 361] in a variety of ways to regulate drinking water, milk and animal products, shellfish and pet turtles that might pose a danger to public health."<sup>306</sup> The agencies even have regulated noninfectious materials. This aggressive regulatory posture shows a clear "preference for prevention of the occurrence of any risk, rather than control of the spread of infection."<sup>307</sup> Because of the unusually broad scope of section 361 and its use to regulate a wide variety of products and activities, conceivably the provision could serve to protect workers in fermentation facilities and to regulate large-scale applications of

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305. See *supra* notes 93-104 and accompanying text.

306. See SUBCOMMITTEE ON SCIENCE, TECHNOLOGY AND SPACE, SENATE COMM. ON COMMERCE, SCIENCE AND TRANSPORTATION, 95TH CONG., 2D SESS., OVERSIGHT REPORT: RECOMBINANT DNA RESEARCH AND ITS APPLICATIONS 24-25 (Comm. Print 1978) [hereinafter cited as OVERSIGHT REPORT]; 3 NIH DOCUMENTS, *supra* note 32, at A-258-59.

307. OVERSIGHT REPORT, *supra* note 306, at 25 (quoting Mr. Frank Press, Office of Science and Technology Policy Director).



genetically engineered micro-organisms.<sup>308</sup> The courts have upheld broad interpretations of section 361 "based primarily on the need to prevent exposing the public to contagious diseases."<sup>309</sup> In addition, although a Senate subcommittee and an interagency committee organized by the Secretary of HHS—then Health, Education, and Welfare—discovered policy problems with the use of section 361, they did not find any fatal legal flaws in the section as it applied to the regulation of rDNA research.<sup>310</sup>

On the other hand, section 361 refers only to communicable diseases affecting human beings. Presumably, some genetic engineering technologies could pose a risk of injury to plants, animals, or the environment, but not to humans. While damage to the environment often manifests itself in the form of public health problems, other ecological spoilage, such as the destruction of wildlife habitats or wilderness, has at best only a tenuous link to the public health. Arguably, however, once an agency has established jurisdiction over a substance it should have authority under the NEPA also to protect the environment.<sup>311</sup> Furthermore, the government might be able to protect nonhuman animals and plants through cooperation with the Secretary of Agriculture, who could intervene under the animal quarantine laws<sup>312</sup> and the Federal Plant Pest Act.<sup>313</sup> These statutes are both similar in purpose and structure to section 361.

Of greater concern than the existence of statutory authority is the government's ability to construct an effective regulatory system for genetic technologies using the PHSA. Its use by agencies to prescribe health and environmental standards, certify research facilities, or register technologies would be unprecedented. The statute would not limit the power of state and local governments to impose standards at variance with the federal requirements. The

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308. If FDA did exercise its authority under § 361 to protect workers, it thereby might divest OSHA of jurisdiction to regulate in that area. See *Organized Migrants in Community Action, Inc. v. Brennan*, 520 F.2d 1161 (D.C. Cir. 1975); 29 U.S.C. § 653(b)(1) (1976). For commentary on this subject, see Comment, *Farmworkers in Jeopardy: OSHA, EPA and the Pesticide Hazard*, 5 *ECOLOGY L.Q.* 69 (1975); Comment, *Interpreting OSHA's Pre-emption Clause: Farmworkers as a Case Study*, 128 *U. PA. L. REV.* 1509 (1980).

309. Korwek, *The NIH Guidelines for Recombinant DNA Research and the Authority of FDA to Require Compliance with the Guidelines*, *supra* note 148, at 647; see *Louisiana v. Matthews*, 427 F. Supp. 174 (E.D. La. 1977).

310. See *OVERSIGHT REPORT*, *supra* note 306, at 23-24.

311. See *id.* at 43; McGarity, *supra* note 270; *supra* notes 268-77 & 298 and accompanying text.

312. See 21 U.S.C. §§ 111, 114, 114b, 123, 134a (1976).

313. See 7 U.S.C. §§ 150bb, 150dd (1976).

criminal penalties in section 361, which are its exclusive remedies, generally would be inappropriate for all but the most serious willful violations. Nevertheless, HHS may contain the greatest reservoir of expertise for regulating the infective risks of genetic engineering technologies. Moreover, the Secretary or Surgeon General would not be encumbered by specific statutory requirements in promulgating, revising, or rescinding regulations. These officials would have maximum flexibility under section 361 to select the most appropriate regulatory strategies for various genetic engineering technologies.

### 3. Wastes

Numerous statutes give EPA authority to regulate virtually all aspects of the processing, discharge, and disposal of waste materials that result from biotechnologies.<sup>314</sup> Except for the potentially infective nature of some biotechnology wastes, this aspect of the newly developing industry poses few unique regulatory problems.

Section 112 of the Clean Air Act authorizes EPA to promulgate emission standards for hazardous air pollutants.<sup>315</sup> Before EPA can regulate genetically engineered micro-organisms under this section, it first must determine that a micro-organism, its products, or by-products are hazardous air pollutants. Although the burden on EPA is not exceptionally heavy, the agency still must produce some evidence that the waste disposal into the environment creates a health risk.<sup>316</sup> If EPA were to discover that a firm was using a micro-organism that the agency could characterize as a hazardous pollutant, EPA probably could ensure adequate physical containment through a media quality-based ambient air standard or a technology-based design equipment or operational standard because these requirements all include an "ample margin of safety."<sup>317</sup> Although an organism that escaped a fermentation

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314. See *supra* notes 175-89 and accompanying text.

315. 42 U.S.C. § 7412 (Supp. V 1981). Hazardous air pollutants are those noncriteria pollutants that EPA determines "may reasonably be anticipated to result in an increase in mortality or an increase in serious irreversible, or incapacitating reversible, illness." *Id.* § 7412(a)(1). If prescription or enforcement of an emissions standard is infeasible for a particular pollutant, EPA instead may promulgate a design, equipment, work practice, operational standard, or combination thereof. *Id.* § 7412(e).

316. The procedures for promulgating a hazardous air pollutant standard, however, are tedious and time consuming, and EPA is reluctant to employ them. The more likely alternative is for EPA to regulate potentially hazardous genetically engineered micro-organisms under the TSCA. See *supra* notes 175-78 and accompanying text.

317. 42 U.S.C. § 7412(b)(1)(B) (Supp. V 1981).

vessel probably would not travel very far in the air, it would qualify as an air pollutant, which consists of "any air pollution agent . . . [including any] biological . . . substance or matter which is emitted into or otherwise enters the ambient air."<sup>318</sup> Since airborne exposure to hazardous micro-organisms probably would effect workers first, the OSHAct may be the more appropriate vehicle for this regulation.<sup>319</sup>

Relying on the Clean Water Act, EPA has promulgated effluent limitations and new source performance standards for the pharmaceutical industry that specify the amounts of conventional pollutants (BOD, COD, and pH) a company may emit into the navigable waters by new and existing fermentation processes.<sup>320</sup> These limitations would not apply to new sources and modified existing sources that employ genetically engineered micro-organisms to produce products other than pharmaceuticals, although EPA could promulgate limits for these processes in the future. Since any source that discharges pollutants into the navigable waters must have a permit under section 402 of the Clean Water Act,<sup>321</sup> state or federal authorities can prescribe technology-based effluent limitations for individual sources for all pollutants discharged from facilities employing genetic engineering technologies.

While industrial fermentation technologies likely will produce conventional water pollutants, EPA's regulation of these effluents does not address directly an organism's toxicity. Section 301(b)(2), however, does require EPA to prescribe technology-based effluent limitations and guidelines for designated *toxic* substances reflecting the "best available technology" including zero discharge.<sup>322</sup> At present, the list of designated chemicals does not contain any organisms with genetically engineered molecules, but EPA may add to that list if it so desires. In determining whether to list a substance, EPA must take into account the toxicity of the pollutant, its persistence, and its degradability.<sup>323</sup>

Section 307 of the Clean Water Act also empowers EPA to promulgate toxic effluent standards, which are more stringent than

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318. *Id.* § 7602(g).

319. If EPA does decide to regulate emissions of micro-organisms under any of its statutory authorities with the object of protecting workers, then OSHA probably would have no power to address that subject matter. *See supra* note 308.

320. *See supra* notes 179-83 and accompanying text.

321. 33 U.S.C. § 1342 (1976); *see supra* text accompanying note 183.

322. 33 U.S.C. § 1311 (1976).

323. *See id.* § 1317(a)(1).

toxic effluent limitations.<sup>324</sup> These standards are water quality-based and must provide an ample margin of safety.<sup>325</sup> The essential difference between toxic effluent limitations and toxic effluent standards is that limitations are technology-based whereas standards are media quality-based. Either approach effectively could regulate the discharge of micro-organisms containing rDNA molecules, their products, and by-products should EPA determine that these organisms constitute toxic pollutants.

The solid wastes that genetic technology firms and laboratories generate, store, transport, treat, and dispose of could face stringent EPA regulation under the RCRA if the agency were to label them hazardous.<sup>326</sup> To regulate all the wastes that could fit within the broad hazardous waste definition, EPA has promulgated detailed regulations that became effective beginning in November 1980.<sup>327</sup> Although the regulations do not address specifically wastes from laboratories or industries engaged in genetic engineering activities, the rules easily could apply to the disposal of much of the solid wastes that both research and commercial applications of the new technology generate.

EPA designed the regulations to track hazardous wastes from the point of generation to ultimate storage, treatment, or disposal, and to render accountable all parties that have any significant role in waste generation or management.<sup>328</sup> The most important characteristics of a hazardous waste are ignitability, corrosivity, reactivity, and "extraction procedure" (EP) toxicity.<sup>329</sup> EPA establishes standards for generators, transporters, and disposers of hazardous

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324. *Id.* ] 131]7(a)(2).

325. *See generally* Environmental Defense Fund v. EPA, 598 F.2d 62, 73 (D.C. Cir. 1978) ("ample margin of safety" is "guiding principle"); Hercules, Inc. v. EPA, 598 F.2d 91, 110-11 (D.C. Cir. 1978) (economic impact and technical feasibility not a condition to safety standard). Before promulgating toxic effluent standards, EPA must consider the extent to which effective control is achievable under other regulatory authority. 33 U.S.C. § 1317(a)(2) (1976).

326. Section 1004(5) of subtitle C of the RCRA defines hazardous waste as a solid waste or combination of solid wastes, which because of its quantity, concentration, or physical, chemical, or infectious characteristics may—(A) cause, or significantly contribute to an increase in mortality or an increase in serious irreversible, or incapacitating reversible, illness; or (B) pose a substantial present or potential hazard to human health or the environment when improperly treated, stored, transported, or disposed of, or otherwise managed.

42 U.S.C. § 6903(5) (1976). *See supra* notes 184-85 and accompanying text.

327. *See* 49 C.F.R. §§ 171-175, 177 (1982); 40 C.F.R. §§ 122-125, 260-267 (1982).

328. *See* 42 U.S.C. § 6902 (1976); 40 C.F.R. § 264.1 (1982).

329. EP toxicity is a procedure in which components are extracted from wastes in the same way that leaching action occurs in landfills. *See* 40 C.F.R. §§ 261.21-24 (1982).

wastes.<sup>330</sup> Hazardous waste handlers must comply with an extensive manifest system and file annual reports.<sup>331</sup> EPA must approve all storage, treatment, and disposal facilities,<sup>332</sup> and regulations require packaging, labeling, marking, and placarding of the waste in accordance with EPA regulations.<sup>333</sup>

Although EPA has failed to propose any RCRA regulations that directly affect the solid waste products of genetic engineering research or manufacturing, the rules do address several other issues that might be important in the disposal of solid wastes associated with genetic technologies. The open dumping regulations<sup>334</sup> require disposal facilities to minimize the "on-site population of disease vectors . . . through periodic application of cover material or other techniques as appropriate so as to protect public health."<sup>335</sup> Arguably, this regulation is applicable to genetically engineered micro-organisms used in research, manufacturing, or waste water treatment, because the organisms could be disease vectors and disposed of at a landfill. EPA, however, currently has limited the definition of disease vector to "rodents, flies, and mosquitos capable of transmitting disease to humans."<sup>336</sup> EPA, of course, could extend this definition to include micro-organisms, but it does not presently intend to do so.

EPA has proposed listing as hazardous wastes infectious wastes that health care facilities, laboratories handling etiologic agents, and sewage treatment facilities generate, unless the wastes are sterilized or incinerated pursuant to EPA requirements.<sup>337</sup> When the agency initiated this proposal, EPA did not have a criterion for determining whether a waste was infectious. EPA claims that it now has developed a criterion but is deferring action on infectious wastes until it can identify the treatment methods that could exempt wastes from the regulation.<sup>338</sup> The agency could attempt to include in the definition of infectious wastes those wastes from facilities employing genetic engineering technologies. EPA, however, has not given any indication that it intends to regulate

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330. See 40 C.F.R. § 262 (1982).

331. *Id.* § 263.20-.22.

332. *Id.* §§ 264, 265.

333. See 49 C.F.R. §§ 172, 173, 178, 179 (1982).

334. Section 4005(c) of the RCRA prohibits open dumping. 42 U.S.C. § 6945(c) (1976).

335. 40 C.F.R. § 257.3-.6(a) (1982).

336. *Id.* § 257.3-.6(c)(2).

337. See 45 Fed. Reg. 33,087 (1980).

338. *Id.* at 33,086.

rDNA waste disposal activities in this manner.<sup>339</sup>

The foregoing description of existing statutes demonstrates that EPA has more than adequate authority to regulate wastes from industrial uses of genetic engineering. The primary task for the agency will be to monitor the emerging technologies to determine whether their wastes pose any unique regulatory problems that the EPA best can address using a case by case approach.

#### V. THE NEED FOR A SEPARATE STATUTE

The foregoing examination of the wide variety of relevant statutory authority demonstrates that federal agencies probably have sufficient regulatory power to acquire information relevant to the risks posed by industrial use of genetic engineering technologies and to protect the public health and the environment if risk assessments demonstrate that regulation is necessary. The current statutory arsenal, however, is not without its weaknesses. Some of the most effective statutes, such as the FFDCFA and the FIFRA, apply only to risks associated with the manufacture, distribution, and use of particular products. Other more comprehensive statutes—the Clean Air Act, the Clean Water Act, the RCRA, section 361 of the PHSA, and the OSHA Act, for example—relate to particular stages of the production process or to particular risks. Only the TSCA provides a comprehensive weapon that can target all risks and all stages of production. Section 5 of the TSCA provides a vehicle for a comprehensive registry of products, by-products, and perhaps hosts and vectors. Section 4 gives EPA the authority to require the health and safety testing that is essential to any ade-

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339. The ocean dumping law unconditionally prohibits the dumping of any radiological, chemical, or biological warfare agents, or of any high-level radioactive wastes. 33 U.S.C. § 1411(b) (1976); *see supra* notes 186-89 and accompanying text. The statute also prohibits the dumping of any other kinds of material, although EPA may issue permits to dump materials, including some solid waste, after notice and opportunity for public hearing, if it determines that such dumping will not “unreasonably degrade or endanger human health, welfare, or amenities, or the marine environment, ecological systems, or economic potentialities.” 33 U.S.C. § 1412(a) (1976). EPA must consider the need for the proposed dumping, the effects of such dumping on health and on economic, esthetic, and recreational values, the effect of dumping on fisheries, fishing resources, as well as on plankton, fish, shellfish, wildlife, shorelines, beaches, and on marine ecosystems generally. The administrator must also evaluate the persistence of the effects, and the impact of dumping particular volumes and concentrations of materials. *See id.*

Violations of the law or of the regulations that EPA has promulgated are punishable by a civil penalty of not more than \$50,000 for each violation, which the administrator shall assess. *Id.* § 1415(a). The administrator may revoke or suspend any dumping permit upon violation of the law, following notice and opportunity for a hearing. *Id.* § 1415(C).

quate risk assessment.

The linchpin of a regulatory strategy that relies on the TSCA is the validity of the assumption that the DNA in a micro-organism is a chemical substance or mixture.<sup>340</sup> The argument for regulating micro-organisms through their DNA is convincing, albeit risky.<sup>341</sup> Hence, the only way to ensure adequate monitoring and regulation of the emerging biotechnologies may be to enact a statute that specifically addresses those technologies. A separate statute would give Congress or a state legislature the opportunity to craft reporting, testing, and regulatory requirements to the precise needs of the new technology, rather than force an agency to attempt to fit the issues into an unsatisfactory statutory mold. By enacting new legislation, Congress also could choose the appropriate regulatory agency or create a new one. Because it would focus exclusively upon a single technology, the agency or subagency unit rapidly could acquire expertise in the technology and its risks.

Strong arguments, however, exist against creating a new regulatory regime. Since the relevant technologies are new and rapidly evolving, disagreement undoubtedly will arise over what constitutes the appropriate elements for the statute. A changing legislative problem is not always conducive to intelligent draftsmanship. Although precedent abounds for aiming regulatory regimes at particular technologies—for example, nuclear power and radio and television communications—the technique has important disadvantages. The close interaction between the agency or subagency unit and the regulated industry could breed a familiarity that ultimately could mature into captivity.<sup>342</sup> On the other hand, the regulatory program, to justify its existence, might feel pressure to regulate unnecessarily. Finally, absent some crisis or other incident that would bring the potential risks of new biotechnologies forcefully to the attention of the public, the issue probably would not generate enough enthusiasm to propel a bill through Congress.

Existing agencies should not view the possibility that a new statutory authority better could perform the monitoring and, if

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340. See *supra* notes 162-68 and accompanying text.

341. A court that faces the *reductio ad absurdum* argument that the TSCA is a substitute for Title 18 of the United States Code because we are all the slaves of our DNA well might refuse to allow EPA to extend its authority over toxic substances to control over organisms that produce toxic substances.

342. See R. FELLMETH, *THE INTERSTATE COMMERCE OMISSION* (1972); Cameron, *Federal Regulatory Agencies—The Need for a Broader Constituency*, 4 ENVTL. L. REP. (ENVTL. L. INST.) 50,132 (1974); Cramton, *The Why, Where and How of Broadened Public Participation in the Administrative Process*, 60 GEO. L.J. 525, 528 (1972).

necessary, the regulatory functions as an excuse to forego using their own existing power. As the technologies grow and mature, the probability of undetected risk increases and the agencies may find themselves in their all-too-familiar reactive postures. Ultimately, the wisest policy may be for Congress to enact a special statute. Until it does, however, the relevant agencies, especially NIOSH and EPA, should use their authority to monitor the new technology in operation. If this power later proves insufficient, then the agencies may petition Congress for new or expanded authority.

## VI. CONCLUSION

The rapid development of genetic engineering technology provides a rare opportunity to assess the risks of an emerging technology and to determine the extent to which that activity should be subject to governmental regulation. In the past society often has failed to anticipate the problems of a new technology. Federal agencies whose purpose is to protect the public health and environment have allowed entrepreneurs to develop processes and market products until data generated by independent sources—university scientists or, more recently, public interest group “watch-dogs”—have revealed the hazards that the technology and its products pose to society. Speculation about the dangers then receives widespread publicity as the public urges regulators to use their authority to protect society.

Existing agencies probably already have the power to avoid this reactive posture and require firms to generate information concerning the hazards of these new technologies before they come on line. EPA in particular can assemble a large repository of information on the emerging biotechnologies by using its TSCA testing and monitoring powers. FDA has similar authority for biotechnologies aimed at producing drugs and other products subject to its jurisdiction. To prepare adequately for the almost inevitable detrimental side effects of these new technologies, EPA should begin immediately to assemble the expertise that it needs to assess risks and monitor these technologies. If EPA does not take the lead in this effort, FDA should do so, and if neither agency begins to monitor in place technologies for risks, then Congress specifically should empower EPA to monitor and require testing for biotechnologies.

If the risk assessments that result from testing and monitoring reveal that these technologies pose unreasonable risks to human beings and the environment, EPA, OSHA, and FDA have a wide



array of regulatory authorities available to address those potential dangers. A court, however, may limit EPA's authority by determining that the genetically altered DNA in a micro-organism is not a chemical substance. To ensure against this possibility, Congress could amend the TSCA to give EPA explicit authority to address the infective risks of new biotechnologies. Congress also should appropriate to the relevant agencies adequate resources to implement their data gathering and risk assessment functions. Without monetary and personnel resources, the regulatory agencies simply will not accomplish these important objectives, and they will have lost the opportunity to oversee the unfolding of the dramatic new genetic engineering technologies.