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BIOTECHNOLOGY—A PROPOSAL FOR REGULATORY REFORM

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INTRODUCTION

Advances in biotechnology,[1] particularly those in recombinant DNA techniques, have created the potential for revolutionary change in a number of fields, including the well-publicized advances in human reproductive technology and pharmaceutical production. A less-publicized fact is that genetic engineering is also beginning to change the face of modern agriculture. The development of genetic transfers between a variety of plant, animal, and even insect species through biotechnology, as well as the production of mutant microbial pesticides and other plant-altering organisms, has already led some experts to claim that the advances in biotechnology constitute one of the major productivity revolutions in American agricultural history.[2]

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1. Biotechnology has traditionally been understood to include any technique that uses living organisms to make a product, improve plants or animals, or develop microorganisms for specific uses. These techniques have included the use of industrial microorganisms in the bread-baking process, the application of biological fermentation to produce alcoholic and drug products, and the breeding of hybrid plants and animals.

Over the past twenty to thirty years, however, the development of new techniques has led to a narrower definition of biotechnology. Today, biotechnology is understood to mean the development of new living organisms through such techniques as cell fusion and the manipulation of the genetic component of a cell (DNA) to produce a specific protein molecule. *See* Russell, *Rush to Market*, 9 AMICUS J. 16, 19 (1987).

2. Recently, the Congressional Office of Technology Assessment (OTA) surveyed about 300 leading public and private scientists and research administrators on the effect of biotechnology on agriculture. Based on these surveys, the OTA identified 28 areas where emerging technologies are likely to develop before the year 2000 and have major impacts on the agricultural sector. According to the OTA report:

> Many of the technologies examined for this study, such as growth hormones, monoclonal antibodies, superovulation, and embryo

These technological developments in agriculture create complex and troubling issues involving environmental risk, social and economic dislocation in farm communities, and the ethical limits of our power to manipulate the genetic traits of the biotic community.

Remarkably, the important public policy questions raised by the use of biotechnology, both in general and as applied to agriculture, have received little attention from the public and no specific legislation from Congress.[3] In the absence of such specific legislation, biotechnology is being regulated by a network of federal agencies acting under statutes promulgated before the advent of genetic engineering.[4] This regulatory scheme has been controversial, fragmented, and inadequate.[5]

This article describes the problems and the limits of the current regulatory system in dealing with the historical, environmental, socio-economical, and ethical questions created by the developments in biotechnology, with particular emphasis on its application to agriculture. Additionally, this article outlines an alternative regulatory system for biotechnology in order to address the panoply of public policy questions presented by this technology.

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transfers, are already in the marketplace, while others are still in the laboratory and will not become available for commercial introduction until 2000.

OFFICE OF TECHNOLOGY ASSESSMENT, U.S. CONG., TECHNOLOGY, PUBLIC POLICY, AND THE CHANGING STRUCTURE OF AMERICAN AGRICULTURE 31 (1986) [hereinafter OTA STUDY].

3. Two bills—S.1967, 99th Cong., 2d Sess. (1986), introduced by Senator David Darenberger (R-MN), and H.R. 4452, 99th Cong., 2d Sess. (1986), introduced by Representative Don Fugua (D-FL)—were introduced in the 99th Congress. Both bills attempted to extend the jurisdiction of the Environmental Protection Agency (EPA) under the Toxic Substances Control Act, 90 Stat. 2003 (1976) (codified as amended at 15 U.S.C. §§ 2601-29) (1982) by changing the statute from an information gathering statute to a "permit" statute. Neither bill had received full committee consideration when the 99th Congress ended, and no similar bills have been introduced in the current Congress.

4. The following statutes are illustrative: the Federal Food, Drug and Cosmetic Act, ch. 675, 52 Stat. 1040 (1938) (codified as amended at 21 U.S.C. §§ 301-392) (1982); the Federal Insecticide, Fungicide, and Rodenticide Act, ch. 125, 61 Stat. 163 (1947) (codified as amended at 7 U.S.C. §§ 121 *et. seq.*; the Toxic Substances Control Act, *supra* note 3; and the Occupational Safety and Health Act of 1970, 84 Stat. 1590 (codified as ammended at various sections of 5, 15, 29, 42 and 49 U.S.C.).

5. *See* Doyle, *Biotechnology Needs a "Predictive Ecology,"* ENVTL. POL'Y INST. PERSP. (Special Annual Edition, 1985); *A Novel Strain of Recklessness*, N.Y. Times, Apr. 6, 1986, §D, at 22, col. 1.

I. ENVIRONMENTAL RISKS

A central question that must be answered prior to large scale use and/or release of biotechnological products is what risk such products pose to human health and the general environment.

Scientists concerned with this question have labeled biotechnology a low probability-high risk problem. Dr. Martin Alexander, Chairman of the Environmental Protection Agency Study Group on Biotechnology, explains the low probability-high risk threat of biotechnology in the following way:

> The probability of a deleterious effect is the mathematical product of the probability of release, survival, multiplication, dissemination, and actual harm. Hence, the risk of genetic engineering is probably small . . . . Nevertheless, even if the risk is small, the consequences of an unlikely event could be enormous.[6]

The high risk potential of biotechnology is based on the fact that each time a genetically-engineered organism is released, it is released into a complex environment. This environment consists of a web of highly synchronized relationships which have developed over millions of years. Each release of a genetically-engineered organism or other product into the environment threatens to disrupt these delicately balanced relationships. In effect, each release is another pull of the trigger in a game of ecological roulette. In its 1984 statement of interim policy on small scale field testing of microbial pesticides, the Environmental Protection Agency (EPA) wrote:

> At present, there is a higher degree of uncertainty in predicting the ecological impacts of introducing certain microbial pesticides into the environment than with conventional pesticides. For example, microbial pesticides that are not native to the area of use or are genetically altered or manipulated could exhibit increased competitiveness, a greater ability to survive, a broader host range, production of a new toxin, or enhanced virulence, compared to indigenous microbes, or its introduction could lead to ecological perturbations. Moreover, because microorganisms can reproduce and be disseminated by a number of different

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6. Alexander, *Ecological Consequences: Reducing the Uncertainties*, 1 ISSUES IN SCIENCE AND TECHNOLOGY, 57, 64 (1985).

> mechanisms, they may be difficult to control or eradicate after being introduced. Finally, the genetic material in some genetically modified microbes may be unstable or transferable to other organisms.[7]

In a recent survey, one hundred of the top scientists in the United States acknowledged the potential benefits of genetic engineering, but warned that "its imprudent or careless use . . . could lead to irreversible, devastating damage to [the] ecology [of the planet]."[8]

Environmental scientists compare the risk of releasing biotechnological products to those we have encountered in introducing exotic organisms to North American habitats. While most of these organisms have adapted to our ecosystems, several, such as Chestnut Blight, Kudzu vine, Dutch Elm disease, and the Gypsy moth, have wreaked considerable havoc on the environment.[9]

In the future, industry and agriculture are expected to introduce thousands of new genetically engineered products into the environment each year[10]—just as they have introduced thousands of new petro-chemical products each year. As Dr. Alexander has written, our experience with petrochemicals should be instructive. When only a few chemicals were in daily use, the threat to the ecosystem was relatively small. But now that annual chemical production exceeds one billion pounds per year, the possibility of exposure and contamination are widespread.[11] In the same way, as the scope of genetic engineering expands, so too will the risk of catastrophe.

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7. Microbial Pesticides: Interim Policy on Small Scale Field Testing, 49 Fed. Reg. 40,659, 40,660 (1984).

8. Gilbert, *The Minds Behind the Top 100: Who They Are, What They Think, What the Future Holds*, 93 SCIENCE DIGEST, 64, 65 (1985).

9. Note, for example, that since its introduction into the United States in the early 1980s, Dutch Elm disease has killed more than one half of the nation's elm trees. Mansfield, *Elm Street Blues*, 37 AM. HERITAGE 96, 99 (1986). The U.S. Department of Agriculture reported that in 1981 the Gypsy moth caused $764 million in property damage nationwide, with 10 percent of the damage occurring in forests and 90 percent occurring in recreational and residential areas. Jackson, *Gypsy Invaders Seize New Ground in their War Against our Trees*, 15 SMITHSONIAN 47, 51 (1984). In 1986, Gypsy moths defoliated 2.5 million acres of forest from Maine to Virginia, damaging 40 percent more acreage than in the year before. WALL ST. J., Sept. 30, 1986, at 35, col. 1.

10. *See, e.g., supra* note 2.

11. Alexander, *supra* note 6, at 64.

Indeed, the long-term impact of thousands upon thousands of genetically-modified organisms could well eclipse the damage that has resulted from the wholesale release of petro-chemical products into the earth's ecosystems.[12] A chemical which is found to be hazardous does not reproduce itself, and though it might spread, its concentration will become increasingly dilute. Thus, the damage caused by petrochemicals is localized and dissipates with time. Biotechnological organisms, however, spread and reproduce themselves, with the disturbance to the ecosystem increasing and intensifying as the organisms multiply. The problem will not remain localized, but will expand in a potentially irreversible manner.

Given this hazardous scenario, some scientists have recommended a moratorium on the release of biotechnological products until a "predictive ecology" on the risks presented by these products has been developed.[13] The EPA Study Group on Biotechnology has also suggested immediate research and development of such a predictive method.[14] The EPA Study Group suggests that at least five questions must be answered in order to assess the safety of biotechnological products:

1) Will it survive?
2) Will it multiply?
3) Will it transfer its inserted genetic traits to other species?
4) Will it be transported to other sites?, and
5) Will it have a deleterious effect?[15]

Remarkably, the regulatory agencies, especially those involved in agricultural research, have repeatedly shirked their responsibility to assess the health and environmental risks of biotechnology.[16] A recent report by the General Accounting

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12. *Id.* at 64-65.

13. *E.g.*, Doyle, *supra* note 5.

14. In a 1986 report, the Study Group wrote: "The EPA should mount a research effort to assess possible perturbations in natural communities related to genetically engineered microorganisms. Research also should be conducted on the use of microcosms as models for natural communities, using the microcosms to evaluate effects of viable agents, as has been done for chemicals." SCIENCE ADVISORY BOARD, U.S. ENVIRONMENTAL PROTECTION AGENCY, ASSESSING EPA'S BIOTECHNOLOGY RESEARCH AND INFORMATION NEEDS: REPORT OF THE STUDY GROUP ON BIOTECHNOLOGY 4 (1986) [hereinafter REPORT OF THE STUDY GROUP ON BIOTECHNOLOGY].

15. *See id.* at 2-5; Alexander, *supra* note 6, at 61-64.

16. Bennett, *GAO Report Finds Federal Agencies' Risk Assessment Procedures Lacking*, GENETIC ENGINEERING NEWS, Nov.-Dec. 1986 at 3.

Office (GAO) showed that the United States Department of Agriculture's (USDA's) Agricultural Research Service is spending close to thirty million dollars on agricultural biotechnology research, and yet only 2-4% of this research is devoted to risk assessment.[17] The USDA's Cooperative State Research Service is spending close to fifty million dollars on biotechnology research, and yet at most only 15-20% of this research is directly aimed at risk assessment.[18] By its own admission, the EPA has "essentially no program" to assess the environmental effects of the release of biotechnological products.[19]

In addition to their failure to conduct risk assessment research, two recent actions, one involving the EPA and the other the USDA, revealed the inadequacy and outright blundering apparent in the present regulation of agricultural biotechnological products by the federal government.

In the first instance, the EPA suspended the field-testing permit of a California biotechnology company, Advanced Genetic Sciences, claiming that the company deliberately falsified data on the pathogenicity tests of a genetically-engineered microbe designed to prevent frost from forming on plants.[20] The company injected the chemical into 45 fruit and nut trees growing on a roof in Oakland, but told the EPA that the injections had been made inside a greenhouse.[21] After the Foundation on Economic Trends reported these violations, the EPA suspended the company's license.[22] A subsequent Congressional investigation criticized both the company and the regulation of biotechnology by the EPA.[23]

In another incident, the Foundation on Economic Trends discovered that the USDA and its Animal and Plant Inspection Service had run roughshod over the entire regula-

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17. UNITED STATES GENERAL ACCOUNTING OFFICE, BIOTECHNOLOGY: ANALYSIS OF FEDERALLY FUNDED RESEARCH 5-6 (1986).

18. *Id.*

19. REPORT OF THE STUDY GROUP ON BIOTECHNOLOGY, *supra* note 14, at 4.

20. *Field-Testing Permit for Genetic Concern Lifted for False Data*, N.Y. Times, Mar. 25, 1986, §A, at 1, col. 1.

21. *Id.*

22. *Id.*

23. *Issues in the Federal Regulation of Biotechnology: From Research to Release: Hearings before the Subcomm. on Investigations and Oversight of the House Comm. on Energy and Commerce*, 99th Cong., 2d Sess. 29-36 (1986) (statements of Dr. John Bedbrook, Advanced Genetic Sciences, and Dr. Ropert Colwell, Scientific Advisory Panel, U.S. Environmental Protection Agency) [hereinafter *Hearings*].

tory process by authorizing the release of a genetically engineered vaccine into the open environment.[24] This was the first time a genetically-altered virus had been released into the environment, and yet, far from exercising the caution such an initial release would require, the USDA neglected to require the license applicant, the Biologics Corporation, to comply with the National Institute of Health (NIH) Guidelines on Research Involving Recombinant DNA molecules, as required by its own directives.[25] The USDA also failed to subject the deliberate release of the recombinant vaccine to the required intra-agency review procedures.[26]

Top officials at the USDA acknowledged the Agency's errors in this incident, and one senior official stated that the Agency had "violated . . . the public's trust."[27] In response to the Foundation's disclosures, the USDA temporarily suspended the vaccine license, only to reinstate it after a brief period.[28] A Congressional investigation of the matter revealed substantial violations by the researchers and glaring inadequacies in the USDA regulatory scheme.[29] Finally, the NIH investigated the matter and censured the researcher,[30] while also criticizing ambiguities in its own Recombinant DNA Guidelines.[31]

Over the past few decades, federal policy has focused on the narrow question of the potential short-term economic benefits of new scientific and technological breakthroughs, with little or no attention paid to the long term environmental costs of the new technologies. It is now apparent that at the beginning of the nuclear technology and petro-chemical revolutions, the government failed to address the "hard" environmental questions concerning the long term effects of these technologies on the ecosystem. As a result, this generation, and succeeding ones, is, and will continue to be, forced to deal with a mounting environmental bill that includes nu-

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24. *See U.S. Quietly Approved the Sale of Genetically Altered Vaccine*, N.Y. Times, Apr. 4, 1986, §A, at A1, col. 3.

25. *Id.*

26. *Id.*

27. *Id.*

28. *Release of a Gene-Altered Virus is Halted by U.S. After Challenge*, N.Y. Times, Apr. 9, 1986, §A, at 1, col. 2.

29. *Hearings*, *supra* note 23, at 47-48 (statement of Alan Tracy, Acting Secretary of Marketing & Inspection, U.S. Department of Agriculture).

30. *Unauthorized Genetic Field Tests Criticized*, N.Y. Times, Oct. 22, 1986, §A, at 23, col. 1.

31. *Id.*

clear waste, acid rain, toxic waste dumps, erosion, clean water depletion, and the depletion of ozone in the atmosphere.

With the emergence of the genetic engineering revolution, the federal government is once again without a coherent and enforceable risk assessment framework to assure that proper regard is taken for the long term health of the environment. Until government agencies conduct adequate risk assessment and show the will and ability to enforce such a protocol, the release of genetically-engineered microorganisms into the environment should not be permitted.

II. Socio-Economic Dislocation

The use of biotechnology, especially in agriculture, creates the potential for considerable social and economic dislocation in the American farming community.

For example, the USDA's Agricultural Research Service (ARS) has made significant investments in biotechnology.[32] The ARS, through its comprehensive information dissemination program, effects virtually every American agricultural practice. The ARS's investment in, and dissemination of, agricultural genetic engineering and animal husbandry practices, with their high capital costs and high yields, favors large, well-capitalized farms over smaller farms; high density animal husbandry over more humane methods; the increased use of artificial foods, pesticides and disease control methods over more organic approaches; and the more intensive use of crop fields resulting in adverse impacts on soil and water.

Large technology transfers such as those sponsored by the ARS are not the only source of social and economic dislocation in agriculture caused by biotechnology. Even a single biotechnological product can have significant adverse effects. A timely illustration is the recent research and development of bovine growth hormone (BGH). This genetically-produced growth hormone can increase milk production by at least 30 percent per dairy cow.[33] Besides the ethical questions raised by the massive use of this hormone on dairy cows,[34] BGH

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32. *See* United States General Accounting Office, *supra* note 17, at 6.

33. *See* Russell, *supra* note 1, at 19.

34. Preliminary research has indicated that dairy cows receiving higher doses of BGH appear to have more reproductive problems and mastitis. *See, e.g.*, Soderholm, Otterby, Linn, Momont, Romagnoli, Hansen and Annexstad, Efficacy of Recombinant Bovine Somatotropin (rbSTH) for Lactating Cows (unpublished paper, University of Minnesota, St. Paul).

poses a serious threat to the economic well-being of many dairy farmers. Professor Robert Kalter, an agricultural economist at Cornell University, estimates that milk prices may fall 10-15 percent within the first three years of the introduction of BGH.[35] He further estimates that the number of dairy farms may have to be reduced 25-30 percent to restore market equilibrium.[36] A report by the Congressional Office of Technology Assessment concluded that BGH will cause a shift in production from the smaller, traditional dairies in the Great Lakes and Northeast regions to the larger, newer operations in the Southwest and West.[37] These adjustments will almost certainly have dramatic social, economic, and cultural effects.

Neither the EPA nor the USDA are authorized by statute, or institutionally capable, of making the public policy choices that the introduction of even one biotechnological product presents. Decisions affecting the economic and social welfare of such a large segment of the populace should be made by the public through the political process, and not by government bureaucrats.

III. Ethical Considerations

The profound effects of biotechnology raise difficult ethical questions. Its potential in human reproduction raises new concerns over the morality of eugenics,[38] and the current use of the technology to create new biological weapons further threatens human life. Unfortunately, the ethical dilemmas posed by the "advances" in biotechnology are seldom considered.

The use of biotechnology in agriculture is creating ethical questions no less important than those created in other areas. For example, the USDA has developed the "Animal Productivity Research Program" conducted under the auspices of the ARS. For decades this program has devoted itself to the production of larger, faster reproducing livestock. Recently, the program has focused on genetic engineering experiments, including the introduction of human growth hormones into livestock.[39] In a recent law suit, the Foundation

35. *Will Growth Hormone Swell Milk Surplus?* 233 Science 151 (1986).
36. *Id.*
37. *See* Russell, *supra* note 1, at 18.
38. *See, e.g.*, T. Howard & J. Rifkin, Who Should Play God? (1977).
39. *See, e.g.*, McDonald, *Rapid-Growth Genes Could Yield 'Super Livestock'*, 27 The Chronicle of Higher Education 1 (1984).

on Economic Trends challenged this program for its failure to comply with the National Environmental Policy Act (NEPA).[40] The Foundation also challenged the program as violative of the "biological integrity" of the species being genetically altered.[41] Subsequent to the suit many further experiments were performed, as genetic material was transferred between species. One of the most bizarre experiments involved the recent transfer of firefly genetic material into tobacco plants to create "glowing" plants.[42]

These experiments bring up several historical, ethical, and philosophical questions. What is wrong with a cow the size of an elephant, or a sheep the size of a horse, or "glowing" tobacco plants? Is there any meaning in the morphology of animals or plants, both internally and externally? Should we alter or mutate, perhaps permanently, the forms and shapes of the biotic community so that they better conform to our agricultural or industrial needs? Do plants and animals have any right to be treated as sufficient "ends" in themselves, and not merely as "means" in a system of production? What are the ethical implications of the likely proposal to engineer plant or animal genetic material into humans? Finally, who is to decide these issues: Congress? Scientists? Corporations? Theologians? The public? Federal agencies?

Right now, bureaucrats, often under significant pressure from industry and the executive branch, are deciding these issues.[43] These civil servants are ill-equipped and lack the statutory authority to make such decisions. Nonetheless, the EPA and the USDA are actually implementing policy involving such problems as the meaning of the forms and structures of the biotic world, the ethical limits of our destruction and manipulation of nature, and the rights of our fellow creatures and ourselves. These questions will take much time and interdisciplinary consideration to resolve. The time for such analysis will not be available if crucial decision-making on the im-

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40. Foundation on Economic Trends v. Block, Civil Action No. 84-3045 (D.D.C. 1986).

41. *Id.*

42. One hummorist has written:

> Just think of the enormous commercial potential. Tobacco growers will love it. No need to give migrant workers the night off: they can pick the stuff in the dark. Inveterate nocturnal smokers would no longer have to grope for the pack about 2 a.m.

Byrne, *A Fly-By-Light Discovery*, THE SCIENTIST, Dec. 15, 1986, at 12.

43. *See, e.g., A Test: Do Microbes and Politics Mix?*, N.Y. Times, Nov. 12, 1986, §B, at 6, col. 4.

plementation of this technology is left to agency bureaucrats under pressure from commercial and scientific special interest groups.

IV. A New Regulatory Statute for Biotechnology

The current regulation of biotechnology has been shown to be inadequate and incompetent in assessing the environmental risks of this technology. It is apparent that the federal agencies, acting under their present statutory authorization, are ill-suited and not empowered to decide the epic social, ethical, and economical questions which genetic engineering presents. Yet, even as the various federal agencies become further enmeshed and confused in the regulatory tangle of biotechnology, the industry continues to grow exponentially, as government infuses hundreds of millions of dollars into research.[44] Given this chaotic and dangerous situation, it is imperative that Congress pass a comprehensive regulatory statute governing the development and implementation of biotechnology. As the noted environmental author and attorney Thomas O. McGarity has written, such a statute "would give Congress the opportunity to craft reporting, testing, and regulatory requirements to the precise needs of biotechnology, instead of requiring existing agencies to force new regulatory issues into as unsatisfactory statutory mold."[45]

A threshold question to any Congressional or public debate over biotechnology is whether capability must always be identified with desirability; that is, we must decide if the fundamental ethical, socio-economical, and environmental interests of society are, at critical points, antithetical to the unimpeded development of biotechnology. In the agricultural area, this includes decisions on the desirability of government programs funding the permanent altering of the internal and external structures of animals and plants, the benefits of ever larger, more capitalized, high-technology farms, with the attendant dislocation of farm communities and culture, and our readiness to face the deliberate release of thousands of genetically-engineered organisms into the environment—a few with at least potentially catastrophic results.

In short, as a polity, we must decide whether technology must always alter society, or whether society, in pursuit of its

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44. *See, e.g.*, Crawford, *Biotech Market Changing Rapidly*, 231 Science, 12-14 (1986). *Going for the Gene Green*, Time, Nov. 4, 1985, at 56; *Biotechnology: the New Growth Industry*, USA Today, Mar. 12, 1985, at 38, col. 3.

45. McGarity, *Regulating Biotechnology*, 1 Issues in Science and Technology, 40, 51-52 (1985).

public policy goals, may limit or curtail technology. Have we not reached a juncture at which a "free" society and a "directed" genetic engineer might be preferable to "free" genetic engineering and a society "directed" by its technology?

V. A Proposed Regulatory Framework

Given this background, a legislature's first duty is not to regulate a technology, but rather to decide what parts, if any, of a new technology are compatible with societal goals and ethical standards. The choice cannot be avoided. Should the legislature fail to decide, these decisions will be made nonetheless. These decisions will not be made by the general population through the political process, but by a small coterie of scientists, venture capitalists, and government bureaucrats, all individuals with a vested interest in a smooth road to expansion and implementation of genetic engineering.

Only after the areas of public interest in biotechnology are identified and articulated should the legislature construct a regulatory procedure to govern those areas of biotechnology that are being implemented. Above all, such a regulatory scheme must provide for the comprehensive analysis of all future genetically-engineered products in biotechnology programs.

This analysis should include the preparation of a comprehensive environmental, social, and cultural impact statement for each new biotechnology proposal. Such a comprehensive impact statement is the only regulatory measure which could adequately provide decision-makers with the full range of information required to make the choice as to the ultimate costs and benefits of a biotechnology project.

In order to implement this new policy initiative, there should be two advisory committees connected with each federal agency: a scientific committee; and a broader based review committee.

The scientific committee would identify and evaluate the potential hazards involved in initiating genetic engineering experiments or introducing products in order to determine what additional research, if any, would be necessary to assure adequate consideration and minimization of substantial risks. In addition to the scientific committee, it is also important that each federal agency establish a review committee with the appropriate expertise to evaluate the "total impact" of each new genetic engineering proposal.

These governmental committees should be composed of experts from a wide range of disciplines, including economists, sociologists, anthropologists, philosophers, theologians, ethicists, political scientists, and ecologists—in other words, public representatives as well as scientific specialists. Such a reasonable balance of the relevant disciplines would be important to ensure that public concerns are articulated. In this way, each genetic engineering proposal would be assessed in terms of its total impact on society. It is essential that we begin to evaluate genetic engineering proposals in light of the overall context in which they will be introduced to properly judge the short-term and long-term costs and benefits.

While the scientific and review committees would make recommendations rather than decisions, those recommendations would be given great weight in the final agency decision. Accordingly, it would be important that each of the committee experts be voting members, rather than outside consultants, even though specialized experts might have to be retained occasionally as consultants.

The agency review committees would also be free from the conflicts of interest which stem from the linkage of committee members to biotechnology companies.

To ensure public participation in decisions regarding genetic engineering research and its commercial application, the Foundation on Economic Trends suggests that all agency reviews be made available for public comment and discussion prior to any agency decision. This means that adequate public access to the internal deliberations of the agency review committee is necessary.

In evaluating proposals involving scientific uncertainties and/or the lack of data, the same type of "worst case" analysis required by the NEPA for environmental impact statements should be conducted by the agency.[46]

After the advisory committees issue their recommendation to the agency decision-maker, a detailed proposal, including a description of the safeguards to be required if the decision is to grant the application, would be issued, with adequate time for public review and comment before a final decision is made.

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46. Under the NEPA, federal agencies are required to evaluate the reasonably foreseeable significant adverse impacts associated with their actions. Such evaluation is to include "impacts which have catastrophic consequences, even if their probability of occurrence is low." 40 C.F.R. §1502-22(b) (1986).

In addition to satisfying the specific data requirements specified by the agency for a particular proposal, the burden of persuasion would be on the applicant to demonstrate that the proposed release meets the applicable substantive standard. The standard should probably be that the release will not present a significant risk to either public health or the environment, and no permit should be issued unless that burden is satisfied.

A central registry, accessible to all interested federal regulatory agencies, would be established to contain data on the proposed, approved, and completed deliberate releases, to benefit the regulating agencies in evaluating proposals pending before them. A public version of the same registry would also be maintained, with the appropriate excision of confidential business information.

The agencies would develop generic requirements for particular classes of proposed releases as promptly as possible after an opportunity for public discussion and review. Where proponents could demonstrate that their proposals satisfied such requirements, individual permit proceedings, which are expensive and time-consuming, would be unnecessary.

Finally, Congress should enact legislation mandating that every government agency involved with regulation in this area prepare a total impact statement and adhere to the regulatory procedures described above.

Conclusion

Biotechnology, especially as applied to agriculture, cannot be responsibly regulated without proper regard for the full range of long-term environmental, social, and ethical concerns which the technology presents. Experience with the petro-chemical and nuclear industries teaches us that unless such long-term concerns are addressed, technology will develop without social constraint, resulting in enormous cost to the environment and to society.

Because biotechnology is still in its early stages, society, for the first time, has the opportunity to significantly regulate a new technology before its major adverse impacts have occurred. We ignore this opportunity at our peril. The regulatory proposal described above will create the potential for society to govern the future of technology rather than allowing technology to govern the future of society and the fate of the natural world.