

9-1-1993

Does Genetic Engineering Need Genetic Engineers?: Should the Regulation of Genetic Engineering Include a New Professional Discipline?

Stuart Auchincloss

Follow this and additional works at: <http://lawdigitalcommons.bc.edu/ealr>

 Part of the [Science and Technology Commons](#)

Recommended Citation

Stuart Auchincloss, *Does Genetic Engineering Need Genetic Engineers?: Should the Regulation of Genetic Engineering Include a New Professional Discipline?*, 20 B.C. Env'tl. Aff. L. Rev. 37 (1993), <http://lawdigitalcommons.bc.edu/ealr/vol20/iss1/3>

This Article is brought to you for free and open access by the Law Journals at Digital Commons @ Boston College Law School. It has been accepted for inclusion in Boston College Environmental Affairs Law Review by an authorized administrator of Digital Commons @ Boston College Law School. For more information, please contact nick.szydowski@bc.edu.

DOES GENETIC ENGINEERING NEED GENETIC ENGINEERS?: SHOULD THE REGULATION OF GENETIC ENGINEERING INCLUDE A NEW PROFESSIONAL DISCIPLINE?

*Stuart Auchincloss**

I. INTRODUCTION

Genetic Engineering, especially the change of inherited characteristics in living organisms by direct modification of the chemicals which transmit these characteristics, will soon be routine. Even though routine, these interventions in the processes of life will not thereby become fully understood nor free of unintended effects. Although genetic engineering is new, the phenomenon of unpredicted benefits and problems from new technology is surely as old as the intentional use of fire by our earliest ancestors.

This Article considers how genetic engineering and its products, are and should be regulated. For all introductions of new technology before now, from railroads to synthetic chemicals, the basic rule has been no regulation until there was a public outcry about the damage. For the first time, with biotechnology,¹ regulation of the technology is growing up with the new science itself; having begun almost as

* Special Counsel to the Czech Environmental Management Center; Advisor to the Federal Environment Ministry of Czechoslovakia. LL.M., 1991, George Washington University; J.D., 1977, University of Santa Clara. This Article is an adaptation of the author's thesis written in partial fulfillment of the requirements of an LL.M. in Environmental Law.

I wish to acknowledge my gratitude to all the people who provided comments, shared portions of their personal libraries, or introduced the author to the practice of biotechnology especially the following: Professor Arnold W. Reitze, Director of the Environmental Law Program; Margaret Mellon and Jane Rissler of the National Wildlife Federation; Johnathan Naimon of IRRC; Anne Barber of the National Cancer Institute of N.I.H.; Paul Tooley of the United States Department of Agriculture, Fort Detrick Research Station; Johnathan Wiener of the Land and Natural Resources Division, Department of Justice; and Edward Lee Rogers, Esq.

¹ In this Article, biotechnology is synonymous with genetic engineering.

soon as the early researchers perceived the potential dangers in their experiments.

These new regulations, this Article argues, must feature both technical and political aspects similar to urban land use law. Just as urban development requires a technical building code to protect consumers and the general public, genetic engineering requires a detailed technical regulation of its activities, particularly releases into the environment. At the public policy level, just as land use planning through zoning laws balances public taste and aesthetics with the market, genetic engineering requires a "public planning" type process to balance public opinion with the commercial uses of the technology.

The release of genetically modified organisms to the environment, however, differs from the introduction of other technologies. This new technology is burdened with the emerging sense among many people of nature's moral importance in addition to nature's aesthetic and utilitarian values.² The commercial interests' accommodations in biotechnology to the many public interests may be quite different from the societal accommodations obtained in other regulated enterprises, such as large scale real estate development.

Section II of this Article describes the new science of genetic engineering and some of its implications. In Section III, this Article provides a survey of some of the existing regulations governing releases of genetically modified organisms to the environment. A new regulatory scheme is proposed in Section IV featuring a licensed professional responsible for supervising all releases to the environment of genetically modified organisms. This licensed professional would have broad training in doing such releases safely and an ethical obligation to the public good.

II. BIOTECHNOLOGY TODAY

A. *What is Biotechnology?*

Biotechnology is the new alchemy; the science which turns an ordinary bacterium into a factory for making human insulin. Genetic engineers use biotechnology to create genetically modified organisms (GMOs)—organisms deliberately modified by the direct introduction

² See Mark Sagoff, "What is Environmentalism?", a paper delivered to the AAAS Conference in Washington, DC, February 16, 1991, at Footnote 30 with extensive references to public opinion research on these matters. (unpublished manuscript, on file with author).

or manipulation of genetic material in their genomes.³ When a scientist deliberately modifies an organism's genome through cross-breeding, intentional mutation, or other technique, the resulting organism is referred to as a "deliberately modified organism" (DMO).⁴

The breakthrough in molecular biology that allowed the field of genetic engineering to arise was the discovery that deoxyribonucleic acid (DNA), the complex chemical which carries the genetic blueprint from one generation to another, is identical for every class of organism.⁵ Because the genetic code is the same for bacteria and humans it is possible for scientists to insert into bacteria the fragment of human genetic material which codes for the production of insulin.⁶ The descendants of that bacterium will continue to carry this "human" trait. Insulin is then produced from these bacterium through a fermentation process.⁷

The terms "biotechnology" and "genetic engineering" refer to the study of genetic codes and the techniques necessary to transmit or modify genetic characteristics. Possible medical applications of this technology are very diverse. Besides allowing scientists to study the bodily processes of health and disease at the cellular and sub-cellular level, biotechnology has the potential for eliminating at conception certain genetic disorders that afflict human children.⁸ The same technology theoretically could allow parents to preselect their children's sex, hair color, eye color, or any other inherited characteristic.⁹

Scientists also use biotechnology to create laboratory animals which mimic human physiology in order to make the animals more useful analogs for medical research.¹⁰ The insertion of a human ge-

³ This article uses "genome" in the term's popular sense to refer to the complex chemical, deoxyribonucleic acid (DNA), which carries the genetic code of an organism's form and function, that is; the sum total of the organism's genes.

⁴ See 55 Fed. Reg. 31118.

⁵ For example, a gene that produces a protein in a human cell can be isolated and inserted into a bacteria. STEVE OLSEN, *BIOTECHNOLOGY: AN INDUSTRY COMES OF AGE* 15 (1986); see also JAMES D. WATSON & JOHN TOOZE, *THE DNA STORY*, 3 (1981).

⁶ See *id.*

⁷ See generally OLSON, *supra* note 6 at 4, 22-24 (describing the fermentation process).

⁸ See SHELDON KRIMSKY, *BIOTECHNICS AND SOCIETY: THE RISE OF INDUSTRIAL GENETICS* 172-73 (1991).

⁹ *Id.*; see also Malcolm Gladwell, *Gene-Defect Tests Planned*, WASH. POST, Dec. 31, 1990, page A1.

¹⁰ William Booth, *Mice Altered to Develop a Human Leukemia*, WASH. POST, Feb. 16, 1990, page A4; William Booth, *Scientists Advance Gene Implant Technique in Mice*, WASH. POST, April 19, 1990, page A22; R. Weiss, *Drug Resistance Gene Saves Mouse Marrow*, 137 SCIENCE NEWS 293, 293, May 12, 1990.

netic code into that of other organisms raises an important philosophical question: does it make any difference that a particular laboratory animal has human genetic material, or that animals slaughtered for meat have a human growth hormone? From a technical point of view, a bacterium does not become a human being just because the organism carries the human-derived genetic information for making insulin, but the question raises issues that scientific research alone cannot answer.¹¹

Scientists can also use biotechnology to make plants which are more resistant to drought or various diseases.¹² Biotechnology has the potential for augmenting the nutritional value of plants—for example, fortifying corn with amino acids.¹³ Biotechnology's first agricultural use, however, is making plants more resistant to chemical herbicides, thereby allowing heavier applications of toxic chemicals which often become environmental problems themselves.¹⁴

In addition to potential benefits, genetic engineering may also produce serious problems.¹⁵ Although most biotechnology research to date has taken place in enclosed laboratories, experiments which include releasing genetically modified organisms into nature raise difficult questions. What happens to the genetically modified organisms in the environment? Does the organism have a competitive advantage over natural organisms or will the genetically engineered organism run wild, filling an empty biological niche? Do the engineered genes in the organism transfer to wild relatives giving the wild organisms undesirable properties?

B. The Living Environment

Perhaps it is misleading to talk about "the environment" as if there were only one. Consider the question of scale. For a human observer it is easy to see that "the environment" changes within a few feet; here is a maple tree, a few feet away is a patch of grass,

¹¹ In 1988, the United Kingdom Advisory Committee on Genetic Manipulation produced detailed guidelines on the use of transgenic animals. Peter Newmark, *Guidelines Produced for the Use of Transgenic Animals in Research*, 337 NATURE 295, Jan. 26, 1989. The chair of the working party that drew up the guidelines said that it is inconceivable that approval would be given for the consumption of animals containing a human transgene. *Id.*

¹² Margaret Mellon, "Biotechnology and the Environment," National Biotechnology Policy Center, National Wildlife Federation, 1988, pages 24–25 (unpublished manuscript on file with author).

¹³ *Id.*

¹⁴ KRIMSKY, *supra* note 8, at 219 (1991).

¹⁵ See *infra* § II.B.

a few feet beyond that an oak tree, a few feet beyond that a stretch of pavement and so on. The change is even more rapid at the microscopic level, where typical agricultural soil contains ten to one hundred million bacteria per cubic centimeter.¹⁶

Despite this great diversity, the science of ecology has made certain observations about the environment that are relevant to the regulation of releases of genetically modified organisms to the environment. Barry Commoner has written a vivid description of some of these relationships.¹⁷

Commoner's first basic law of ecology is "everything is connected to everything else."¹⁸ Hence, any regulation of the release of genetically modified organisms to the environment must take into account the effect on the entire receiving ecosystem.

Another basic law of ecology is "everything has to go somewhere."¹⁹ Thus, in a closed ecosystem, organisms extract substances from the environment and use them, discarding portions in the form of waste which other organisms take up and use.²⁰ Because genetic engineering involves living organisms, which given the right circumstances, do not dissipate but multiply in the environment, the inter-relatedness of all life is particularly important.

Commoner's third basic law of ecology is "nature knows best"—a provocative way of describing nature's tendency to move toward stability.²¹ Just as "unnatural" organic compounds like dichlorodiphenyltrichloroethane (DDT) or dioxin have proven to be environmentally difficult to degrade, so genetically "unnatural" organisms may lead to similar problems.²²

Commoner's fourth rule of ecology is "there is no such thing as a free lunch."²³ In other words, any change in an ecological cycle, or intrusion by an incompatible component, inevitably leads to harmful effects.²⁴ What this means is that every action having an impact on an ecosystem has consequences which are inevitable and governed by the laws of nature. To the extent that these laws of nature are

¹⁶ COMMITTEE ON THE INTRODUCTION OF GENETICALLY MODIFIED ORGANISMS INTO THE ENVIRONMENT, INTRODUCTION OF RECOMBINANT DNA-ENGINEERED ORGANISMS INTO THE ENVIRONMENT: KEY ISSUES, 17 (1987). [hereinafter "KEY ISSUES"].

¹⁷ BARRY COMMONER, MAKING PEACE WITH THE PLANET, 6-7 (1990).

¹⁸ *Id.* at 8.

¹⁹ *Id.* at 9-10.

²⁰ *See id.*

²¹ *Id.* at 11-12.

²² *Id.*

²³ *Id.* at 14.

²⁴ *Id.*

known, the consequences of an intrusion are predictable and undesirable outcomes are preventable.²⁵ To the extent that the laws of nature are not known, the consequences of an intrusion will come as a surprise.²⁶

1. The Gypsy Moth Infestations

The danger of releasing genetically modified organisms is similar to the danger of introducing organisms from other parts of the world into new locations where the transplanted organisms do not have natural enemies.²⁷ The gypsy moth in the United States is a particularly vivid example of this class of threat because the infestation began from a small initial release. The origin of this pest is a model of how an experiment in genetic engineering, which does not adequately account for environmental problems, can go wrong.²⁸

In 1868 Leopold Trouvelot came to Medford, Massachusetts from France, as a visiting professor at Tufts University.²⁹ Trouvelot brought with him silk moths and gypsy moth larvae. Trouvelot's plan was to cross-breed these insects to create a hardy strain of silk moths for the French silk industry.

The gypsy moths Trouvelot brought to the United States were natives to Europe and North Africa, where, controlled by predators and disease, the insects seldom caused noticeable harm to the native plants. In the eastern United States, however, with ample food and no natural enemies, the gypsy moth prospered. In 1889, twenty years after Trouvelot's moths escaped, Medford experienced the first gypsy moth infestation in the United States. In the last hundred years the gypsy moth has survived the intentional introduction of a number of its natural enemies into the United States, the aerial application of DDT from C-47 transports, and the best eradication measures that modern pest control science has to offer.

2. The Southern Corn Leaf Blight

While it is true that genetic engineering did not create the gypsy moth, biotechnology has produced problems pointing to limitations of the science. The major failure of the United States corn crop in

²⁵ See *id.*

²⁶ See *id.*

²⁷ See KEY ISSUES, *supra* note 16 at 10-11.

²⁸ See *id.* at 10-11.

²⁹ This account is freely adapted from *Learning to Live with Gypsy Moths*, N.Y. TIMES, June 14, 1981, § 6 (magazine), at 36.

1972 resulted from almost universal use of hybrid seed and a lack of complete ecological understanding.³⁰

In creating hybrid corn seed,³¹ the American corn industry produced corn that was extremely susceptible to a particular race of a pathogenic fungus.³² Because this fungus seldom appeared on corn in the United States, corn breeders did not think resistance to the fungus was an important trait to select for in breeding seed corn.³³ In 1970 this fungus, under the name of Southern Corn Leaf Blight, wiped out about fifteen percent of the United States corn crop.³⁴ The blight caused a loss of about twenty million metric tons of corn worth about one billion dollars to the affected farmers.³⁵

The far-reaching tragedies resulting from Trouvelot's gypsy moth experiments and hybrid corn seed demonstrate the problems that can occur when biotechnology collides with Commoner's laws of ecology.³⁶ The Ecological Society of America has considered the ecological issues raised by the release to the environment of genetically modified organisms and has made some suggestions for regulating releases.³⁷ The ecologist's suggestions provide a different perspective on the release into the environment of genetically modified organisms than the suggestions of the scientists who plan and create the genetically modified organisms.³⁸ Both scientific perspectives, however, are important in the regulation of biotechnology.

C. *The Future for Farming*

Agriculture is one of the first industries biotechnology will revolutionize.³⁹ The power to insert specific traits into the hereditary material of crop plants will accelerate greatly the trial and error method of selective breeding.⁴⁰

³⁰ See CALESTOUS JUMA, *THE GENE HUNTERS*, 101 (1989).

³¹ Hybrid corn seed, produced by cross-pollinating two inbred lines, produces corn with a better yield than either of the parent strains.

³² *Helminthosporium maydis*, race T. JUMA *supra* note 30, at 101.

³³ See *id.* at 102.

³⁴ *Id.*

³⁵ *Id.*

³⁶ See *supra* notes 16-34 and accompanying text.

³⁷ See James M. Tiedje, *et al.*, *The Planned Introduction of Genetically Engineered Organisms: Ecological Considerations and Recommendations*, 70(2) *ECOLOGY* 298, 298-312 (1989).

³⁸ See *id.*

³⁹ See generally, KRIMSKY, *supra* note 8.

⁴⁰ See COMMITTEE ON SCIENTIFIC EVALUATION OF THE INTRODUCTION OF GENETICALLY MODIFIED MICROORGANISMS AND PLANTS INTO THE ENVIRONMENT, BOARD ON BIOLOGY, COMMISSION OF LIFE SCIENCES, NATIONAL RESEARCH COUNCIL, FIELD TESTING GENETI-

Scientists are using biotechnology to create agricultural crops that are resistant to herbicides, thus allowing an increase in the market for agricultural chemicals.⁴¹ Many of the chemical companies that manufacture herbicides and the other components of chemical agriculture now own the major agricultural seed companies and are in control of their research efforts.⁴² Some see this development as a betrayal of the promise of biotechnology for agriculture.⁴³

The big change in agriculture which genetic engineering will bring about, probably within the working lives of some scientists already in the field, will be the separation of agriculture from land. Presently there is not any theoretical scientific reason preventing genetically modified microorganisms from producing highly processed agricultural products—such as flour, cocoa powder, or even hamburger—in fermentation tanks as microorganisms produce beer and wine today.⁴⁴ These genetically modified organisms, operating on inputs as simple as sunlight, water, biomass, and trace minerals, should be able to produce the economically desirable portions of plants and animals without concern for “natural” problems like frost, drought, insects, or governmental changes in remote countries.⁴⁵ A major investor in this technology is the Hershey chocolate company.⁴⁶ Even though producing goods in a “brewery” makes commercial sense for a chocolate producer like the Hershey company, this technology spells economic disaster for farmers who produce and for national economies which are based on the production of cocoa.⁴⁷

D. A Case Study, Bovine Growth Hormone

Of further interest to agriculture is genetic engineering involving animals. For example, scientists can insert the human gene which codes for growth hormone into mouse cells in such a way that the

CALLY MODIFIED ORGANISMS: FRAMEWORK FOR DECISIONS, 30–31 (1989) (unpublished manuscript on file with author) [hereinafter “FIELD TESTING GMOs”].

⁴¹ JUMA, *supra* note 30, at 113.

⁴² See generally, Rebecca Goldberg, *et al.*, “Biotechnology’s Bitter Harvest, Herbicide Tolerant Crops and the Threat to Sustainable Agriculture” (1990) (unpublished manuscript, on file with author).

⁴³ *Id.*

⁴⁴ See, Mark Sagoff, *Biotechnology and the Environment: Ethical and Cultural Considerations*, 19 ELR 10520, 10523, n.23 (1989).

⁴⁵ See generally JUMA, *supra* note 30, at 136–40 (discussing problems besetting cocoa farming and biotechnology’s solutions).

⁴⁶ JUMA, *supra* note 30, at 139–40.

⁴⁷ *Id.* at 139–40.

mouse offspring inherit the gene.⁴⁸ Are there any ethical implications in such experiments with the transfer of "human" characteristics into animals?

Scientists have also isolated the gene for creating bovine growth hormone (BGH), which increases milk production when injected into cows.⁴⁹ To date, scientists have not determined how to increase cows' natural production of BGH, so scientists produce the hormone from genetically engineered bacteria in a pharmaceutical laboratory.⁵⁰

The production of BGH is a prime example of how the confusion between technical regulation and policy considerations has prevented regulatory actions on a product of biotechnology. In the last ten years pharmaceutical companies have genetically engineered bacteria to produce quantities of BGH sufficient for use in commercial dairies.⁵¹ When injected into productive cows, BGH has increased milk production by ten to forty percent.⁵² Technicians at the United States Food and Drug Administration Center for Veterinary Medicine (DVM) found there were no adverse effects on human health from consuming milk and meat from cows injected with BGH.⁵³

Despite the conclusions of the DVM reviewers, the Food and Drug Agency (FDA) delayed commercial marketing of BGH and requested a second opinion from the National Institutes of Health (NIH).⁵⁴ After hearing three days of testimony from BGH researchers and opponents of the drug, NIH concluded that the overall composition and nutritional quality of milk and meat from BGH treated cows is equal to the composition and nutritional quality of milk and meat from untreated cows.⁵⁵

Simultaneously with this technical discussion, there was also a policy debate. Small dairy farmers were concerned that they could not manage the detailed recordkeeping necessary to use BGH, and that the price the small dairy farmers received for their milk would

⁴⁸ William Booth, *Scientists Advance Gene-Implant Technique in Mice*, WASH. POST, Apr. 19, 1990, at A22.

⁴⁹ Judith C. Juskevich and C. Greg Guyer, *Bovine Growth Hormone: Human Food Safety Evaluation*, 249 SCIENCE, 875, 875 (1990).

⁵⁰ *Id.*

⁵¹ *Id.*

⁵² W. Stolzenburg, *Hormone-Boosted Milk Passes FDA Review*, 138 SCIENCE NEWS 116, 116 (1990).

⁵³ The technical basis for this conclusion is spelled out at some length in *Juskevich & Guyer*, supra note 49; see also R.N. Langreth, *Milk from Engineered Hormone: Udderly Safe*, 138 SCIENCE NEWS 372, 372 (1990).

⁵⁴ Guy Gugliotta, *A Wonder Drug or A Threat?*, WASH. POST, June 24, 1990, at A3.

⁵⁵ *Langreth*, supra note 52, at 372.

be lowered as BGH enabled the larger, more industrial dairy farmers to lower their production costs.⁵⁶ In addition, consumer advocacy groups opposed BGH based on skepticism of the human and bovine health data provided by the four chemical companies that manufacture BGH.⁵⁷

Adding to the political nature of this discussion, a nationally syndicated newspaper column criticized the BGH approval process, alleging that the FDA fired one animal safety expert because he had not approved BGH earlier.⁵⁸ The newspaper also reported studies indicating that BGH could harm cows and affect the quality of milk.⁵⁹

This brief history demonstrates that the BGH approval process was based only partly on the technology under consideration. The small dairy farmers who opposed the product may not have doubted BGH's efficacy, or even its safety, but were daunted by the management burden required to use the product.⁶⁰ From the newspaper accounts, it is impossible to tell whether the consumer advocate groups objected to BGH because of its danger, or the procedures the FDA used in the approval process, or the precedent those procedures set for future approvals of genetic engineering products.⁶¹ Splitting the approval process, as proposed in this paper, into technical and political components would allow each debate to remain focused on its own cluster of issues and thus improve both aspects of regulation.⁶²

A systematic poll conducted in 1986 by the Congressional Office of Technology Assessment (OTA) indicated that although Americans favor the end products of biotechnology, they believe strict regulation is necessary.⁶³ The study also found that in disputes over risk statements, the public is inclined to believe environmental groups rather than government agencies.⁶⁴ The strong implication here is that the public is ready for a comprehensive law regulating biotech-

⁵⁶ Gugliotta, *supra* note 54, at A3.

⁵⁷ *Id.*

⁵⁸ Jack Anderson and Dale Van Atta, *Bovine Hormone Treated as Sacred Cow*, WASH. POST, Nov. 27, 1990, at C12.

⁵⁹ *Id.*

⁶⁰ See *supra* notes 55–56 and accompanying text.

⁶¹ See *supra* notes 57–59 and accompanying text.

⁶² Such a law has been proposed in the European community, which is currently considering adding "socio-economic effects" to the list of criteria for approval of new medicines. Jeremy Chertas, *Europe: Bovine Growth Hormone in a Political Maze*, 249 SCIENCE 852, 852 (1990).

⁶³ OFFICE OF TECHNOLOGY ASSESSMENT (OTA), U.S. CONGRESS, NEW DEVELOPMENTS IN BIOTECHNOLOGY—BACKGROUND PAPER: PUBLIC PERCEPTIONS OF BIOTECHNOLOGY 5 (May, 1987) [hereinafter "OTA SURVEY"].

⁶⁴ *Id.*

nology, replacing the present regulatory patch-work and incorporating a cadre of professionals in whom the public may feel some confidence.⁶⁵

III. THE CURRENT REGULATION OF BIOTECHNOLOGY

A. *The Historical Roots*

When scientists in the early 1970s realized the power of biotechnology, they agreed on collective self-restraint in conducting experiments which might be hazardous.⁶⁶ When the scientists' concern became public, the safety of their work became a political issue. This Section describes those early actions and the political debate that took place as a result, showing that with the exception of the participation of a few non-governmental organizations, the scientists themselves have created all the federal regulation of biotechnology primarily on the basis of technical considerations, with only grudging acknowledgement of the existence of social issues.

1. The 1973 Gordon Research Conference

In 1973, Maxine Singer, a biochemist with NIH, was one of the two co-chairs of the Gordon Research Conference on Nucleic Acids, a meeting of professional molecular biologists.⁶⁷ On the last day of the conference, after the announcement of the powerful new technology of using restriction enzymes to combine the DNA of unrelated organisms, there was an unscheduled debate on the question of the potential hazards from dangerous synthetic mutant germs made possible by this process.⁶⁸ A large majority of those scientists who participated in this discussion favored expressing their concern to the National Academy of Sciences.⁶⁹ Just a little over half of these scientists also favored making their concerns known more widely in the scientific community.⁷⁰

Acting on this vote, Maxine Singer and her co-chair wrote to the president of the National Academy of Science and to the president of the National Institute of Medicine.⁷¹ The letter announced the

⁶⁵ See *supra* § IV.

⁶⁶ See *infra* note 72 and accompanying text.

⁶⁷ WATSON & TOOZE *supra* note 5, at 6.

⁶⁸ *Id.* at 3.

⁶⁹ *Id.*

⁷⁰ *Id.*

⁷¹ 181 SCIENCE 1114, 1114 (1973).

scientists' concern that certain hybrid molecules may be hazardous to laboratory workers and the public.⁷² The letter requested the National Academy of Sciences to establish a committee to consider the problem and recommend specific actions or guidelines.⁷³ As a result of the letter, the National Academy of Sciences established a committee of scientists to consider the matter in the Fall of 1973.

A year later, on July 26, 1974 *Science* published an open letter from the National Academy of Sciences Committee to all scientists throughout the world suggesting a voluntary moratorium on certain genetic engineering experiments because the experiments were too risky for currently available laboratory containment technology.⁷⁴ Although the concerned scientists intended only to encourage voluntary self-restraint among molecular biologists, the scientists' letter began to alert journalists and the general public to the potential dangers of genetic engineering.⁷⁵ Six months after the publication of the letter, an international conference of molecular biologists convened at Asilomar, California on February 24-27, 1975 to consider what the scientists themselves should do next.⁷⁶

2. The 1975 Asilomar Conference

Maxine Singer and four other concerned scientists organized the pivotal Asilomar Conference of molecular biologists in February 1975 to discuss the future of biotechnology.⁷⁷ The organizers proclaimed the following two principles to guide genetic engineering experiments: containment as an essential consideration in the design of experiments, and the containment's effectiveness equaling the experiment's estimated risk.⁷⁸ Even bearing these principles in mind, the conferees agreed that there were certain experiments which ought not to be conducted with the then available containment facilities.⁷⁹

Beginning at Asilomar, eminent molecular biologists disagreed among themselves about the risk of the genetic engineering exper-

⁷² *Id.* at 6.

⁷³ *Id.* at 6.

⁷⁴ Paul Berg *et al.*, *Potential Biohazards of Recombinant DNA Molecules*, 185 *SCIENCE* 303, 303 (1974).

⁷⁵ *See, e.g.*, WATSON & TOOZE, *supra* note 5, at 12.

⁷⁶ *Id.* at 25-27.

⁷⁷ *Id.*

⁷⁸ Paul Berg *et al.*, *Asilomar Conference on Recombinant DNA Molecules*, 188 *SCIENCE* 991, 992 (1975).

⁷⁹ *Id.* at 991.

iments.⁸⁰ While most molecular biologists believed that raising the issues and warning each other was enough, a few molecular biologists felt that the experiments should be halted altogether.⁸¹

B. *The Beginning of Federal Regulation*

1. The NIH Guidelines

On October 7, 1974, four months before the Asilomar conference, the NIH's director already had formed the Recombinant DNA Molecule Program Advisory Committee (RAC) to consider three aspects of the new genetic engineering technology: potential hazards, the spread of genetically modified organisms in the environment, and guidelines for scientists working with such organisms.⁸² After the Asilomar conference, however, RAC focused almost exclusively on its third task, preparing guidelines for researchers.⁸³

On June 23, 1976, the Director of the NIH formally issued the guidelines which effectively halted experiments using DNA from warm blooded animals and viruses.⁸⁴ NIH, the main source of federal funds for biotechnology research, required an institutional biosafety committee to review proposed experiments before the applicant could receive his or her grant to perform certain experiments.⁸⁵ The regulations also specified the degree of containment necessary for certain particularly dangerous genetic engineering experiments.⁸⁶

Despite their strict limitations on biotechnology experiments, the guidelines appear to apply only to entities receiving research grants from NIH.⁸⁷ In addition, the only sanction the guidelines imposed was cutting off funding for institutions that did not follow the guidelines.⁸⁸

As scientists around the world have carried out safely many laboratory experiments with genetic engineering, RAC steadily relaxed the guidelines until now most experiments require no more than

⁸⁰ See generally, Michael Rogers, *The Pandora's Box Congress*, 189 *ROLLING STONE* 36 (1975) (reprinted in WATSON & TOOZE, *supra* note 5 at 28).

⁸¹ See *id.* at 44.

⁸² See 41 Fed. Reg. 27903 (1976); Collin Norman, *Genetic Manipulation: Guidelines Issued*, 262 *NATURE* 2, July 1, 1976.

⁸³ *Id.*

⁸⁴ 41 Fed. Reg. 27,902-43 (1979); Norman, *supra* note 82, at 2.

⁸⁵ 41 Fed. Reg. 27,920-21 (1976); WATSON & TOOZE, *supra* note 5, at 63.

⁸⁶ See 41 Fed. Reg. 27,912-14 (1976).

⁸⁷ See generally 41 Fed. Reg. 27,920 (1976).

⁸⁸ *Id.*

local peer review.⁸⁹ Thus, early in the regulation of biotechnology, the NIH guidelines established the pattern of making compliance voluntary for laboratories operating without government funds, most notably industrial and commercial laboratories.⁹⁰

2. Congressional Study and Inaction

Two months after the Asilomar conference, on April 22, 1975, Senator Edward Kennedy, as Chairman of the Subcommittee on Health, held a hearing on the relationship of a free society to its scientific community.⁹¹ The hearing used genetic engineering as a case study to consider the public's role in both the direction of scientific research and the application of the research's results.⁹²

The April 22 hearing was followed by another hearing on September 22, 1976 on the same subject.⁹³ In his opening remarks, Senator Kennedy drew particular attention to the problem of industry's "voluntary" compliance with the NIH guidelines.⁹⁴ Senator Kennedy singled out General Electric for its unwillingness to participate in the hearing as an example of industry's unwillingness to follow the NIH guidelines.⁹⁵

Following these hearings, efforts to adopt a biotechnology control act continued in both the United States Senate and the House of Representatives until March 1978 when legislative action ceased.⁹⁶ Academic scientists opposed biotechnology regulation by taking the extreme position that the proposed government regulation was similar to the subjugation of Russian biological science to communist ideology during the middle of the Twentieth Century.⁹⁷

Congressional interest in a biotechnology bill disappeared in the Fall of 1978 for many reasons including a lack of support from the executive branch, NIH's relaxation of its guidelines thereby implying that the threat of biotechnology was less than feared, and the

⁸⁹ See, NIH Section of the Coordinated Framework, 55 Fed. Reg. 23,349 (1990).

⁹⁰ See *id.*

⁹¹ WATSON & TOOZE, *supra* note 5, at 63. The subcommittee on Health is part of the Senate Committee on Labor and Public Welfare.

⁹² *Id.*

⁹³ *Id.* at 144.

⁹⁴ See *id.* at 145.

⁹⁵ Opening Statement of Senator Edward M. Kennedy at a Hearing of the Senate Health Subcommittee on Recombinant DNA Research and the NIH Guidelines, Wednesday, Sept. 22, 1976, (reproduced in WATSON & TOOZE, *supra* note 5, at 144-45).

⁹⁶ For a summary of the legislative action see 43 Fed. Reg. 33,046-47 (1978).

⁹⁷ See, e.g., Nicholas Wade, *Gene Splicing: Senate Bill Draws Charges of Lysenkoism*, 197 SCIENCE 348, 348 (1977).

complexities of congressional politics.⁹⁸ At the same time, Secretary of Health, Education and Welfare (HEW), Joseph Califano stated that his agency, which controlled NIH, did not intend to invoke existing statutory authority to regulate DNA activities, preferring to continue with voluntary control of industry based on NIH's guidelines.⁹⁹ Over the next five years RAC steadily relaxed the NIH guidelines by determining that ever more classes of experiments posed no special hazard.¹⁰⁰

C. *The Coordinated Framework*

In the Spring of 1984 the Council on Natural Resources and the Environment formed a Working Group on Biotechnology.¹⁰¹ The Working Group prepared and published the Coordinated Framework as a proposal for the regulation of biotechnology by existing agencies, under existing statutes.¹⁰²

On October 31, 1985, the Domestic Policy Council formed the Biotechnical Science Coordinating Committee (BSCC),¹⁰³ to establish for all regulatory agencies common definitions of "intergeneric organism" and "pathogen," and to limit federal regulation to these entities.¹⁰⁴

The BSCC ruled that an intergeneric organism is a microorganism that is "deliberately formed to contain an intergeneric combination of genetic material."¹⁰⁵ Basing a regulatory definition on the location of microbes in the taxonomic system, however, is questionable because of the lack of scientific agreement on the taxonomic classifications and the categories' relation to each other.¹⁰⁶

Likewise, a pathogen is a "virus or microorganism . . . [broadly defined] that has the ability to cause disease in other living organisms."¹⁰⁷ This is followed by a long gloss stating, in effect, that an

⁹⁸ See Roger Lewin, *Recombinant DNA as a Political Pawn*, 79 NEW SCIENTIST 672, 672 (1978).

⁹⁹ *Id.* at 673.

¹⁰⁰ *Id.* at 674.

¹⁰¹ 49 Fed. Reg. 50,856 (1984).

¹⁰² 49 Fed. Reg. 50,856 (1985) (proposed Dec. 31, 1984).

¹⁰³ 50 Fed. Reg. 47,174 (1985); see also 51 Fed. Reg. 23302 (1986).

¹⁰⁴ The Coordinated Framework's definitions are intended to determine what organisms should be appropriate for certain types of review. 51 Fed. Reg. 23302 (1986).

¹⁰⁵ *Id.*

¹⁰⁶ See, "Principles for Federal Oversight of Biotechnology: Planned Introduction into the Environment of Organisms with Modified Hereditary Traits," 55 Fed. Reg. 31118, (1990) [hereinafter referred to as the "Proposed Refinement"] ". . . Taxonomy . . . is imprecise for microorganisms." *Id.* at 31119.

¹⁰⁷ 51 Fed. Reg. 23,302 (1986).

organism is a regulated pathogen when the organism is dangerous.¹⁰⁸ Up until July 31, 1990 the Coordinated Framework used these two definitions to describe reviewable genetically modified organisms.¹⁰⁹

After an eighteen month comment period, the Working Group published the final Coordinated Framework on June 26, 1986.¹¹⁰ The Coordinated Framework expressed the Executive Branch's opinion that the existing statutes provide a basic network of agency control over biotechnology's research and products sufficient for the regulation of the plants, animals, and microorganisms created by the new genetic engineering techniques.¹¹¹ The Coordinated Framework provides a chart which summarizes agency jurisdiction and authority over the approval of biotechnology products.¹¹²

Regulatory authority under the Framework, however, extends only to risks from the use or misuse of biotechnology products which are regulated already in the stream of commerce.¹¹³ As an example of the Framework's maintenance of the *status quo*, the Department of Labor declared that its regulations under the Occupational Safety and Health Act were adequate and that the new biology did not require new regulations to protect workers.¹¹⁴ Thus the Occupational Safety and Health Act does nothing to narrow the class of unregulated organisms or to regulate releases not covered by the Framework.

The Coordinated Framework does not cover animals which are not insects, plants which are not parasites, or insects which are not plant pests.¹¹⁵ Even though the FDA regulates the use of plants and animals for food and medicine,¹¹⁶ the FDA and United States Department of Agriculture regulate veterinary medicine,¹¹⁷ and the Public Health Service regulates the interstate movement of etiologic agents,¹¹⁸ a considerable range of transgenic plants and animals are still free of federal regulation.

¹⁰⁸ See, 51 Fed. Reg. 23,306-07 (1986).

¹⁰⁹ See 51 Fed. Reg. 23,307 (1986) (Coordinated Framework).

¹¹⁰ 51 Fed. Reg. 23,301 (1986).

¹¹¹ 51 Fed. Reg. 23,302-03 (1986) The White House Office of Science and Technology Policy (OSTP) reaffirmed this opinion when the agency issued its "Principles for Federal Oversight of Biotechnology." 55 Fed. Reg. 31,118 (1990).

¹¹² Chart 1, 51 Fed. Reg. 23,304 (1986).

¹¹³ 51 Fed. Reg. 23,304 (1986).

¹¹⁴ 51 Fed. Reg. 23,348 (1986).

¹¹⁵ See 7 C.F.R. § 340.1 (1990).

¹¹⁶ 21 U.S.C. §§ 301-393 (1988).

¹¹⁷ Food, Drug and Cosmetic Act, 21 U.S.C. §§ 351-360B (1988); Virus, Serum, Toxin Act, 21 U.S.C. §§ 151-159 (1989).

¹¹⁸ 42 U.S.C. § 264 (1991).

The residual class of life forms which are not regulated under any federal program will be referred to in this Article as "unregulated organisms." As examples of unregulated organisms, an industrial enterprise might engineer transgenic fish for weed and mosquito control, or oysters for pearl production and release them to the environment without any intent that people would use the organisms for food. If the genetic engineering work did not have government funding, the organisms' release would be unregulated even if the release occurred in the waters of the United States.¹¹⁹

Furthermore, the Coordinated Framework does not apply to a large amount of biotechnology work because research does not have a product.¹²⁰ Most genetically modified organisms that scientists release to the environment are experiments, not commercial products, therefore the Framework does not apply to the resulting organisms unless experimenters receive government funding,¹²¹ or come under the experimental use permit section of the laws.¹²² For experiments involving unregulated organisms and carried on without government funding, reporting and peer review are only voluntary.¹²³ While some such research on future commercial products might fall under the experiment provisions of, for example, Toxic Substance Control Act (TSCA)¹²⁴ and Federal Insecticide, Fungicide and Rodenticide Act (FIFRA),¹²⁵ one can imagine uses which might escape even these definitions.

D. The Proposed Refinement of the Coordinated Framework

In hopes of clarifying the Framework, the President's Office of Science and Technology Policy (OSTP), the parent body of the BSCC, referred the problem of what organisms the Coordinated Framework

¹¹⁹ See 7 C.F.R. § 340.1 (1990). No reported case or lawsuit has suggested that such a release might be covered by § 404 of the Clean Water Act (33 U.S.C. § 1344), § 10 of the Rivers and Harbors Appropriations Act of 1899 (33 U.S.C. § 403).

¹²⁰ That is, while some research may lead to a product, pure scientific research, especially as practiced in universities, does not by itself create a product *per se*.

¹²¹ 51 Fed. Reg. 23,305 (1986).

¹²² See, e.g., FIFRA § 5, (7 U.S.C. § 136c (1980)); TSCA § 5(h)(3), (15 U.S.C. § 2604(h) (1982)).

¹²³ See *supra* note 89 and accompanying text.

¹²⁴ See 15 U.S.C. § 2604(h). See generally, W. Schiffbauer, *Regulating Genetically Engineered Microbial Products Under the Toxic Substances Control Act*, 15 ELR 10279 (1985); Louis Sorell, Note, *Biotechnology Regulation Under the Toxic Substances Control Act*, PACE ENVTL. L. REV. 57 (1985).

¹²⁵ See 7 U.S.C. § 136c (1980); Michael Vandenberg, Note, *The Rutabaga That Ate Pittsburgh: Federal Regulation of Free Release Biotechnology*, 72 VA. L. REV. 1529 (1986).

covered to the White House Council on Competitiveness.¹²⁶ In late July 1990, on the basis of the Council on Competitiveness's recommendation, OSTP proposed a refinement of the Coordinated Framework for regulation of biotechnology.¹²⁷ As the refinement itself declares, the "Coordinated Framework was expected to evolve in accordance with the experience of the industry, and, thus, modifications to the framework were anticipated."¹²⁸ This modification, however, goes to the heart of the Coordinated Framework—the definition of organism and the need for government supervision of releases to the environment of genetically modified organisms.

The Coordinated Framework limited its application to two classes of organisms—organisms formed by the combination of genetic material from sources in different genera and microorganisms containing genetic material from pathogenic species—with each class having several exceptions.¹²⁹ The proposed 1990 refinement declares that the Coordinated Framework now applies to all "organisms with deliberately modified hereditary traits."¹³⁰ Because regulation under the refinement requires deliberate modification, regulation is limited to the products of genetic engineering and does not include the products of selective breeding and intentional mutation.¹³¹

For years scientists and representatives of industry have maintained that the regulation of biotechnology products should be no different from the regulation of hybrids because the risks from genetically modified organisms are comparable to the risks from organisms modified by conventional breeding techniques and possibly less risky because the genetic changes are so specific.¹³² Now, the refined Coordinated Framework reflects this view, and all such organisms will be brought within its purview.¹³³ The refined Framework discloses the principle that planned introductions "should not be subject to oversight . . . unless information concerning the risk posed by the introduction indicates that oversight is necessary."¹³⁴ The refinement thus has something for everyone—a broader defini-

¹²⁶ See 55 Fed. Reg. 3118 (1990).

¹²⁷ *Id.*

¹²⁸ *Id.*

¹²⁹ See *supra* notes 115–118 and accompanying text.

¹³⁰ 55 Fed. Reg. 31120 (1990).

¹³¹ See *id.* Because the Framework is based on risk rather than on strict classifications, only those organism introductions for which safety data already exist, or for which there are existing, adequate safety regulations will be excluded from oversight. See *id.*

¹³² See, e.g., FIELD TESTING GMOs, *supra* note 40, at 64.

¹³³ See 55 Fed. Reg. 31120 (1990).

¹³⁴ See *id.*

tion of genetically modified organisms and a vaguely worded prohibition on their regulation.

The refinement's definitions feature a no-oversight-until-risk-is-known approach, implying that the burden is on the regulator to demonstrate the risk and bear the cost of showing the risk's existence.¹³⁵ The problem is that regulation turns on the existence of "information concerning the risk posed," information which in most cases today does not exist yet.¹³⁶

E. State Regulation

Six states have their own biotechnology regulatory statutes.¹³⁷ The North Carolina statute requires a permit for any release into the environment of any, broadly defined, genetically modified organism.¹³⁸ The Oklahoma statute is similar to the North Carolina statute except that releases approved under federal law are exempt from regulation under Oklahoma law.¹³⁹ The Illinois and Wisconsin statutes provide for state commissions to intervene in the federal review of releases in their respective states, and to protect the states' interests in the federal review process.¹⁴⁰

1. The North Carolina Statute

The North Carolina statute is the only law in the United States, including the Coordinated Framework, that provides for comprehensive regulation of genetic engineering. For this reason it warrants a more complete description than the other state regulatory schemes.

The North Carolina permit process is the only state biotechnology statute totally separate from the complexities and ambiguities of the federal process; not relying on federal law even for definitions.¹⁴¹ The North Carolina statute applies to living organisms changed by "the introduction of new genetic material or the regrouping of [their]

¹³⁵ *See id.*

¹³⁶ *See generally* Tiedje, *supra* note 37.

¹³⁷ ILL. ANN. STAT. ch. 111 1/2, §§ 7601-7611 (Smith-Hurd Supp. 1992); ME. REV. STAT. ANN. tit. 7, §§ 231-236 (West 1989, Supp. 1991); MINN. STAT. ANN. § 116C.91-96 (West Supp. 1992); N.C. GEN. STAT. §§ 106-765-780 (Supp. 1991); OKLA. STAT. ANN. tit. 2, §§ 2011-2018 (West Supp. 1992); WIS. STAT. ANN. § 146.60 (West Supp. 1992).

¹³⁸ N.C. GEN. STAT. § 106-772 (Supp. 1991).

¹³⁹ OKLA. STAT. ANN. tit. 2, § 2016 (West Supp. 1992).

¹⁴⁰ ILL. ANN. STAT. ch. 111 1/2, § 7602 (Smith-Hurd Supp. 1992); WIS. STAT. ANN. § 146.60 (West Supp. 1992).

¹⁴¹ N.C. GEN. STAT. § 106-768 (Supp. 1991).

genes," except for organisms changed by traditional methods of selective breeding.¹⁴²

The statute requires a permit for any "release," defined simply as the placement of genetically modified organisms outside of a containing enclosure.¹⁴³ Although the statute allows the Genetic Engineering Review Board to request any information necessary in the permit application, the statute encourages the board to use applicable federal application information.¹⁴⁴ Fifteen days after the state's receipt of the application, the statute requires local notification and a public hearing in the county of the proposed release when there is "significant public interest."¹⁴⁵ The statute also provides for written notice to interested parties who request information concerning the release.¹⁴⁶

One of the North Carolina statute's most interesting provisions concerns the handling of confidential business information.¹⁴⁷ While permitting an applicant to designate parts of its application as confidential, the statute provides that any person may petition to see the information as long as the petition contains an affidavit from the petitioner stating that the petitioner does not have any commercial interest in the confidential information.¹⁴⁸ This petition triggers a required negotiating process between the petitioner and the applicant.¹⁴⁹ If the parties cannot reach an agreement on what information the petitioner will receive from the applicant, either party may appeal to the Board.¹⁵⁰ The Board can deny or grant the petition, and give the applicant the choice either to provide the information or withdraw its application.¹⁵¹ The statute also provides that the disclosure or use of confidential business information for the benefit of any person other than the applicant is punishable by the same daily penalties as those the statute established for any other violation of the act.¹⁵² This section does not apply to publicizing any information about adverse effects from a proposed release because the applicant knows in advance that it is accountable for such effects.¹⁵³

¹⁴² *Id.* § 106-768(6)-(8).

¹⁴³ *Id.* § 106-772(A); § 106-768(9).

¹⁴⁴ *Id.* § 106-772(b).

¹⁴⁵ *Id.* § 106-773(a-b).

¹⁴⁶ *Id.* § 106-773(a).

¹⁴⁷ *Id.* § 106-774.

¹⁴⁸ *Id.*

¹⁴⁹ *Id.* § 106-774(B).

¹⁵⁰ *Id.*

¹⁵¹ *Id.*

¹⁵² *Id.* § 106-774(C); § 106-776(C) (fine not less than \$250 nor more than \$1,000 for each offense with each day's violation constituting a separate offense).

¹⁵³ *Id.* § 106-774(D).

The statute was the outcome of an eighteen-month study of the regulation of biotechnology in North Carolina by a committee made up of manufacturers, users, universities, state government, and the environmental community.¹⁵⁴ During the process it appeared that the interests represented were not as divergent as most had at first expected, and the final law had the support of all factions.¹⁵⁵ This observation holds promise for the success of a more serious federal process to develop a national biotechnology law.

IV. A PROPOSAL FOR PROFESSIONAL RESPONSIBILITY

This article proposes another approach to the control of genetic engineering. In brief, the proposal is for a system which requires a routine permit for all releases to the environment of genetically modified organisms, deliberately modified organisms, and non-native organisms. All permit applications must be signed by a licensed professional scientist who accepts personal responsibility for the oversight of the release.

A. Replace the Coordinated Framework

The proposed system would replace the Coordinated Framework, although the present regulatory agencies would still regulate biotechnology products that fall under their jurisdiction. That is, pesticides would still have to comply with FIFRA,¹⁵⁶ food and medicine with the Food, Drug, and Cosmetic Act,¹⁵⁷ and plant pests with Federal Plant and Pests Act.¹⁵⁸

In order to gain the advantages of prompt responsive local processing of applications, the new regulatory system would require applicants to file their initial application in the state where the release was to take place.¹⁵⁹ To encourage further local response, the system would include provision for prompt public notice of the release proposal in the county of release.¹⁶⁰ States could further delegate the process to a more local level if they chose.

The initial review would quickly determine, on the basis of minimum criteria set forth in the law, whether the proposed release was

¹⁵⁴ Telephone Interview with Willard Dickerson, North Carolina Department of Agriculture (Jan. 3, 1990).

¹⁵⁵ *Id.*

¹⁵⁶ 7 U.S.C. §§ 136-136y.

¹⁵⁷ 21 U.S.C. §§ 301-393.

¹⁵⁸ 7 U.S.C. §§ 150aa-150jj.

¹⁵⁹ See *supra* notes 154-57 and accompanying text.

¹⁶⁰ See *supra* notes 156-57 and accompanying text.

routine—needing only local technical review and approval—or whether the release was novel—requiring review and possibly a hearing at a higher level. The criteria for routine treatment would evolve through time with increased knowledge of genetic engineering and the interaction of releases with the local ecology. For example, the planting of genetically modified corn where no potentially interbreeding relatives of the corn grow wild would require only routine treatment. A federal agency would determine whether there were public policy implications for projects such as increasing herbicide tolerance in crops or the release of deliberately modified organisms in National Parks or Wilderness Areas. After identifying any such implications, the agency would instruct the state hearing panels on factors to be considered in deciding whether or not to permit a specific release.¹⁶¹

The law also would provide for regional or state administrative hearings for review of the “novel” releases. This hearing would review both the technical considerations of the proposed release as well as the economic, social, and aesthetic considerations within limits set out in the law.¹⁶² The technical safety portion of the review of “novel” releases would be a detailed look at both the proposed organism and the ecological system into which the release was proposed. The review would require special studies to support the application. The permit would most likely have conditions attached to it when permission was granted. As in North Carolina, a public hearing would be an optional part of the review process.¹⁶³

At the present time, in biotechnology regulation, issues of safety and policy are totally entangled, resulting in regulatory gridlock.¹⁶⁴ This stagnation does not exist in building construction because the social questions raised by projects are decided in a political process which reviews the use proposed for the property. Only when the political process approves the proposed use does technical review of

¹⁶¹ For example, the state review would include economic, social, and aesthetic considerations but would not focus on the technical details of the release.

¹⁶² Congress should legislate in terms of general statements of objectives and procedures, with clear statement of the social values to be promoted. Then it should delegate the political decisions to the agencies' discretion, laying out only the circumstances when the discretion is to be exercised. This delegation would address the problems that arise when Congress becomes obsessed with the details of environmental legislation, the more elusive and erratic consensus becomes. Sanford E. Gaines, *Science, Politics, and the Management of Toxic Risks through Law*, 30 JURIMETRICS, J. OF LAW, SC. AND TECH., 271 (Spring 1990); see *infra* notes 283–86 and accompanying text.

¹⁶³ See *supra* note 145 and accompanying text.

¹⁶⁴ See *supra* note 136 and accompanying text.

the structure for compliance take place. The same process would be effective for review of releases to the environment.

B. Professional Supervision of Releases

This paper proposes that the federal law enacting the new system contain the following requirement:

Every release to the environment of organisms with deliberately modified hereditary traits must be supervised by a licensed professional who has personal responsibility that the release is conducted in accordance with good scientific practices.

The seven major elements of this proposal are considered in the following sections.

1. Every Release

This provision is different from the refinement,¹⁶⁵ in that this system requires professional supervision of every release, while the refinement limits governmental supervision to releases of demonstrable risk.¹⁶⁶ In addition, this proposal is not for governmental oversight, but rather oversight by individuals with ethical obligations, who are trained to look outside the normal bounds of their specialized fields.

This requirement applies to every release because although most releases will not have any dangerous implications for society or the environment, some releases will be dangerous. There is no way to tell which releases are dangerous without the consideration of someone trained to spot the few releases needing special review.

2. To the Environment

By this clause the statute is applicable only to releases to the environment. There is no requirement that a licensed professional supervise every bakery, brewery, or pharmaceutical factory using genetically modified organisms. This clause, however, in no way relieves responsible individuals from liability for accidental releases of genetically modified organisms which escape from the premises of such facilities.

The reason for regulating is that once genetically modified organisms are in the environment, they may be impossible to eradicate.

¹⁶⁵ See 55 Fed. Reg. 31,118 (1990), *see supra* notes 107–09 and accompanying text.

¹⁶⁶ 55 Fed. Reg. 31,118 (1990).

Despite the present concern with the extinction of species, it is very difficult to exterminate a specific species without doing serious collateral damage to the environment in which the species lives.¹⁶⁷

3. Organism with Deliberately Modified Hereditary Traits

This provision is the same as the language proposed in the refinement.¹⁶⁸ Any organism is a deliberately modified organism when human intervention has altered any of the organism's hereditary traits.¹⁶⁹ Unlike the refinement, however, the proposed law would not include any exceptions to the professional supervision of releases to the environment because the problem is not only from the organism's inherent danger but also from its interaction with a specific ecological context.¹⁷⁰

4. Supervised

This law proposes supervision similar to the supervision an architect exercises in designing a large building. Although an architect is not an expert in all the special disciplines required for the design and construction of safe structures, architects must know enough about buildings in general to coordinate their specialists' work to achieve the product the owner desires while satisfying the architect's professional duty to the general public's safety.¹⁷¹

Similarly, in biotechnology, this professional supervision would allow the coordination under one person's responsibility of the varied sciences which bear on releases to the environment. These varied sciences include the released organism's biology and molecular biology, as well as the release site's ecology. In addition, a professional scientist's expertise would include the knowledge of what other sciences are needed. This coordination of scientific specialties is necessary to manage the tremendous diversity and problems deliberately modified organism releases raise.

Because even a small release of a genetically modified organism can cause as much trouble as the gypsy moths have caused, profes-

¹⁶⁷ See generally, discussion *supra* parts II.B.

¹⁶⁸ See 55 Fed. Reg. 31,120 (1990).

¹⁶⁹ See *id.*

¹⁷⁰ See *supra* notes 16-26 and accompanying text.

¹⁷¹ See American Institute of Architects Code of Ethics and Professional Conduct.

sional supervision would be required even for small releases.¹⁷² This requirement applies to both academic and industrial research. Such supervision will not likely be a problem for industry because it already is accustomed to environmental regulation and reporting.¹⁷³ This mandatory supervision will be more of a change for academic researchers who are not used to any accountability beyond the peer review of the local biohazards safety committee, or RAC.¹⁷⁴ But to be fair, and to enhance public confidence, the rules must be the same for both kinds of research.

5. Licensed Professional

Certainly the release to the environment of genetically modified organisms requires competent professional judgment. Lawyers, for example, require a license to practice their profession, and all such practitioners must accept personal liability for their failure to live up to their profession's standards of competence.¹⁷⁵ Because the release of genetically modified organisms to the environment may have an even larger adverse impact than the actions of other professionals, assigning similar responsibility to an individual in charge of a release is a natural step.

The proposal is that a licensed professional scientist supervise and be personally responsible that the release is carried out in an ethical manner in accordance with the law. This does not mean that the professional scientist routinely would be personally liable for the unforeseeable consequences of a release. The professional scientist would be responsible only for conducting the release in a careful manner.

The new law could create a national license requirement. Professional designation would require knowledge of molecular biology and ecology, as well as the laws of genetic engineering. The key requirement is that the person supervising any release should have a sufficiently broad, general knowledge of the relevant sciences and law

¹⁷² Under the NIH Guidelines, as summarized in the Coordinated Framework at 55 Fed. Reg. 23,349 (1990), only four classes of experiments are brought to the RAC, including "Class III-A-2 deliberate releases to the environment of any organism containing recombinant DNA." All others require only approval of the local Institutional Biosafety Committee (IBC), (Class III-B), notice to the IBC (Class III-C) or the experiments are exempt (Class III-D) from the guidelines. *Id.*

¹⁷³ Howard Latin, *Good Science, Bad Regulation, and Toxic Risk Assessment*, 5 YALE J. ON REG. 89, 93 (1988).

¹⁷⁴ *Id.*

¹⁷⁵ See, e.g., American Bar Association Model Code of Professional Responsibility, Canon I.

to prevent mistakes arising from a failure to perceive risks outside an individual's specialty.¹⁷⁶

The cooperation of licensed professionals who have explicit obligations larger than their own interests is an important pillar in the structure of environmental law. The key to this regulatory system is personal professional accountability. Although there is no precedent for the legislative creation of licensed specialty practitioners, there are ample technically qualified candidates and adequate commercial incentives so that the creation of such a licensing law would not cause genetic engineering to cease.

6. Personal Responsibility

Personal responsibility means that professional scientists are personally liable if their review and planning of the release falls below the standard of care exercised by other professional genetic engineers in the community. This does not mean, however, that the professional engineer is responsible for damage done by a runaway deliberately modified organism if that damage was professionally unforeseeable.

Personal responsibility is important so that the general public knows there is an individual responsible for what happens, and ready to accept the consequences if anything goes wrong.¹⁷⁷ This responsibility helps allay the fear that specialists who lack concern for the wider implications of their work are releasing deliberately modified organisms.

7. Good Scientific Practices

Because the possibilities from harm from releasing deliberately modified organisms to the environment are very broad, the science itself has to be equally broad. The genetic engineer will receive training to think about the organism's movement by its own power,

¹⁷⁶ An example of how licensed professional status would be helpful in controlling risk from the release to the environment of genetically modified organisms is found as an incidental matter in the Federal District Court opinion in *Found. on Economic Trends v. Lyng*, 680 F. Supp. 10 (D.C. 1988). There the United States District Court for the District of Columbia allowed the USDA to use safety data on open air releases, even though the data had been obtained from an experiment that had not complied with USDA requirements for prior notice. *See id.* at 16. The court observed in a footnote that although the breach was serious it was simply not the issue under review in the case so it was disregarded. *Id.* at n.5. Had the researcher been a licensed professional, professional discipline would have been available to investigate and punish such a lapse.

¹⁷⁷ *See supra* notes 62-64 and accompanying text.

run-off, wind, or transport on some host or vector. The genetic engineer also will consider the possibility of the deliberately modified inheritable trait transferring genetically to other organisms in the vicinity, thereby allowing modified traits to escape despite physical control over the modified organism. The genetic engineer will also receive training to look for novel interactions—ecological trouble in the target environment from an organism which has not caused a problem in a different environment.

VII. CONCLUSION

Genetic engineering is only the latest manifestation of technical progress with Promethean potential for harm or good. It is not the last. Beyond the debate over the details of regulation, it is time for legislative control to evolve from seeking to prevent harm from each new technology to preventing harm from new technology in general. One useful tool in the construction of such a meta-system would be the early imposition of professional standards on new technologies as they arise, rather than waiting for guilds of practitioners to seek such status for their own benefit.