THE COMMISSION TO STUDY BIOTECHNOLOGY AND GENETIC ENGINEERING

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COMMISSION TO STUDY BIOTECHNOLOGY AND GENETIC ENGINEERING

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Executive Summary

Origin

In April, 1994, the 116th Legislature enacted LD 1361 (1994 Resolves chapter 47), authorizing the creation of the Commission to Study Biotechnology and Genetic Engineering Issues. Briefly the commission was charged with the following:

- Identifying and reviewing existing state statutes that provide authority for regulating products and activities.
- Advising the legislative and executive branches, on the adequacy of existing state and federal oversight frameworks and recommend needed action at state and federal levels.
- Assessing the adequacy of communication pathways.
- Considering mechanisms by which risks and benefits, including social or economic consequences to the public and the environment may be evaluated.
- Considering the role of research in the public sector. [1]

Background

The issue of biotechnology and genetic engineering was first addressed in Maine through the creation of the Commission on Biotechnology and Genetic Engineering, created by the 113th Legislature in 1988. The purpose of the Commission initially was to:

> *"...address the legitimate concerns of the public about the release of microorganisms into the environment as a result of increased use of biotechnology in agricultural and other industries. The Commission on Biotechnology and Genetic Engineering...would be charged with addressing this concern while at the same time providing an atmosphere which promotes this fast growing field of research."*

The Commission ran into difficulty on several fronts as it attempted to establish itself on matters involving genetically engineered products. First, the Attorney General's office advised that the Commission did not have clear authority to adopt rules, a cornerstone of the Commission's efforts. Secondly the BST issue, with which the Commission was involved in an advisory capacity, left many on the Commission disillusioned about the purposes and function of the Commission. Finally, the Commission was staffed and funded with only those resources that could be spared by the Department of Agriculture and had no direct funding. These issues, along with the rapid changes in the field of biotechnology and genetic engineering prompted the Legislation submitted to the 116th Legislature.

[1] See Appendix A for the complete text of the resolve.

The Study Commission Report; summary of recommendations

The current Commission on Biotechnology and Genetic Engineering.

- **The Commission recommends that the existing commission be repealed.** Existing agencies and resources devoted to biotechnology and a system of interagency cooperation, should be able to perform an appropriate state regulatory role.

- **The Commission recommends that the Governor create an ad hoc committee** for the purpose of establishing interagency cooperation in those areas in which biotechnology and genetic engineering issues are expected to see activity The committee should recommend procedures and protocols for State agencies and for working with private industry and the Federal government. Of specific concern to the Commission is the area of genetically engineered fish and shellfish, which is expected to see rapid growth with potential significant impact in Maine in the coming decade. It is important that this area be identified not only for safety related concerns but also for its economic development potential.

- **The commission supports the efforts already underway by the Maine Science and Technology Foundation to create the Maine Academy of Science and Engineering.** (See appendix B for the complete proposal). The purpose of the Academy is to provide the Maine State Legislature, the Executive Branch, and private organizations guidance on technical and social matters of science, engineering, and human and environmental health; and to promote Maine's scientific communities. Several members of the commission felt strongly that any effort made should be a regional approach, perhaps including New Hampshire and Vermont. The Academy would be an excellent resource for the state in the area of biotechnology and would provide additional benefits, as it would be able to address a much wider scope of science issues.

The adequacy of the existing federal oversight framework

- **The FDA should review and promulgate a regulation for the labeling of genetically engineered foods broad enough to protect the consumer's freedom of choice in the marketplace and ability to avoid health risks.** A labeling requirement, unique to the State of Maine, may limit the competitive ability of Maine companies by adding to the cost of doing business here. The additional expenses and potential liability may discourage non-Maine companies and corporations from shipping to Maine and may make it more difficult for Maine companies to compete in out-of-state markets. These economic consequences must be balanced by the protection of the public health through continuing assessments of health risks.

- **The FDA should establish an effective system of mandatory pre-market notification for genetically engineered foods.** Maine consumers and biotechnology industry representatives share an interest in seeing concerns about emergent biotechnology addressed by the federal and state government in a responsible, effective, and safe manner that encourages the growth of new and existing business in the State of Maine. One of the most basic ways the federal government can exercise responsible oversight is by keeping track of who is doing what in

the field, and what products of biotechnology are actually being marketed. The FDA has stated that it is working on a regulation for pre-market notification of genetically engineered foods.

- **The federal government should establish an effective system of oversight regarding genetically engineered fish and shellfish** . While the FDA claims responsibility for the ultimate safety to human consumers of fish and shellfish products, their statutory mandate to do so may be in question, and no agency has clear statutory authority to regulate and protect against environmental and ecological risks in the development and aquaculture of such organisms. As Maine is a primary site for the development of aquaculture industries, the Commission is concerned that the absence of effective regulation in this area may create ecological risks.

Education

Given the gap between public understanding and public perception of biotechnology, genetic engineering or gene mapping, it is unrealistic to expect the public to become engaged in a meaningful public policy debate regarding biotechnology and food. The task of providing such educational opportunities is a responsibility shared by all of those involved in biotechnology from educators, researchers, scientists to industry personnel whether they are associated with public or private institutions or companies.

- **The commission supports the recommendations in BIO-MAINE '93, which in its final report notes "...that if Maine's fledgling biotechnology/life science industry is to develop, a sustained, well coordinated, statewide "K-20+" science-education/training strategy must be established."** In addition, the report recommends the establishment of a common core of practical biotechnology/life science experience via a statewide certification mechanism, and the establishment of an adult education biotechnology/life science retraining programs. Models of how such educational process should be accomplished both in Maine and in other states are currently available.

Public perception issues

Biotechnology is expected to have significant impacts on food production and processing. Supporters predict a number of economic, social, and environmental benefits while opponents are concerned about the safety and ethics of biotechnology, including concerns about whether government is able to adequately regulate biotechnology now or in the future. One common theme throughout the different studies, and consistent with testimony provided at public hearings held in Maine on both rBST and the labeling issue, is that consumers are interested in being better informed. However, simply providing the information may not be sufficient as one study notes that there is a high level of skepticism many of the sources of information.

- **The Commission firmly believes that policy makers must accept and involve the public as a legitimate partner in the biotechnology debate.** The Commission recommends that policymakers consider the following when deliberating on issues involving biotechnology and genetic engineering.

- Public policy information, including who regulates and oversees the development and use of biotechnology, as well as how biotechnology is regulated.

- Information about the potential benefits and risks of using biotechnology, including effects on the environment and economy.

- Information on safety, including potential allergens, nutritional value, taste, cooking techniques, and storage properties.

- General information about the science behind the use of biotechnology.

The Existing Commission

History of the Commission on Biotechnology and Genetic Engineering

In 1988, the 113th Legislature enacted legislation creating the Commission of Biotechnology and Genetic Engineering. The legislation gave the Commission the responsibility:

- To assess potential risks of genetically engineered products to the public and the environment;
- To evaluate and determine the adequacy of federal regulations and state rules affecting biotechnology and genetic engineering and to adopt rules;
- To formulate and coordinate state policies affecting biotechnology and genetic engineering industries for biotechnology and genetic engineering research;
- To serve as a liaison between state and Federal agencies on matters affecting biotechnology and genetic engineering industries; and
- To serve as a resource and repository for expertise and information on biotechnology and genetic engineering.

In addition the Commission was directed to establish standards for the issuance of permits for the release of biotechnology products into the environment and was given broad rulemaking authority for this and other functions.

As required by law, the Commission submitted a work plan to the Legislature in January of 1990. The report included the Commission's interpretation of law, plans for action, comments and recommendations for statutory change. Also in the workplace, the Commission noted its dual role of simultaneously regulating and supporting the needs of biotechnology industries.

The initial focus of the Commission centered primarily on the needed regulatory mechanisms . To determine its role in the regulatory scheme, the Commission first reviewed federal regulation of biotechnology by the US Food and Drug Administration (FDA), the US Environmental Protection Agency (EPA) and the US Department of Agriculture (USDA). The federal government did not create laws to specifically regulate biotechnology and genetic engineering. Instead, federal law regulated the product (the food or other product created through biotechnology and genetic engineering), not the process of development.

The Commission decided that it should not duplicate federal regulation, but should instead fill in the gaps left by the federal government in its regulatory efforts. Those gaps appear to consist of:

- movement of a biotechnological or genetically engineered product into Maine or within the State;

- commercialization of genetically engineered products; and

- release of a biotechnological or genetically engineered product into the environment.

Prior to the change in federal law, the federal government had regulated movement into the state and release into the environment.

Concerns with the current Commission; LD 1361

The Commission ran into difficulty on several fronts as it attempted to establish itself on matters involving genetically engineered products. First, the Attorney General's office advised that the Commission did not have clear authority to adopt rules, a cornerstone of the Commission's efforts. Secondly the BST issue , with which the Commission was involved in an advisory capacity, left many on the Commission disillusioned about the purposes and function of the Commission. Finally, the Commission was staffed and funded with only those resources that could be spared by the Department of Agriculture and had no direct funding.

As a result, LD 1361 was submitted to the 116th Legislature for the purpose of clarifying the several outstanding issues. Essentially, LD 1361 would have clarified the mission of the Commission by adding

> *"The purpose of the commission is to allow the public access to the safe and proper use of biotechnology and genetic engineering products while safeguarding public health safety and welfare and protecting the natural resources of the State."*

In addition, LD 1361 would have redefined the powers and duties of the commission as well as granted specific authority for rulemaking.

At the public hearing on LD 1361 in the Committee on Housing and Economic Development, (Which in itself was unusual, as the issue had traditionally been handled in the Committee on Agriculture) committee members were inundated with testimony. The issue became less focused on the Commission and centered around the following: *The need for the public to be sufficiently informed, protected and heard with regard to biotechnology and genetic engineering and its effects on the food supply versus the desire of businesses both small and large to remain competitive and to nurture an industry with the potential for explosive growth here in Maine.* After the hearing Committee members discussed, generally, the following:

> 1. Should there be a Commission on Biotechnology and Genetic Engineering, and if so, what should be its mission and functions?
>
> 2. Should the Commission consider social, moral, ethical and economic factors in determining if a product should be allowed to move within the state, released into the environment or released as a commercial product?

3. Can the State regulate biotechnology and genetic engineering within existing legislative authority in the various executive branch agencies?

4. Can an Agency regulate and promote an industry simultaneously?

5. Would it be beneficial to broaden the scope of the Commission, moving it out of the Department of Agriculture?

The result, was to leave the existing Commission as is, which for all intents and purposes meant inactive, and return to the drawing board. LD 1361 was subsequently amended, creating this Commission which was charged with the following:

Identifying and reviewing existing state statutes *that provide authority for regulating products and activities, including statutes governing food and agriculture, health and safety, confidential business information and the environment;*

Advising the legislative and executive branches *including regulatory agencies, on the adequacy of existing state and federal oversight frameworks and recommend needed action at state and federal levels.*

Assessing the adequacy of communication pathways *among responsible state agencies, federal agencies and local communities and recommending a strategy for informing local community policy makers of state and federal oversight frameworks and the roles of local government in making regulations concerning biotechnology and genetic engineering and in communicating with the public on these issues, considering mechanisms for effective public involvement in the oversight process*

Considering mechanisms by which risks and benefits, *including social or economic consequences, to the public and the environment created by the use of biotechnology and genetic engineering products and waste products may be evaluated;.*

Considering the role of research *in the public sector and the need for oversight of research involving state resources; and*

Including the public, outside experts, state agencies and businesses *in the State involved in biotechnology and genetic engineering in the commission's deliberations.*

Short term recommendation

The Commission recommends that the existing commission be repealed. Existing agencies with resources devoted to biotechnology and a system of interagency cooperation, should be able to perform an appropriate state regulatory role.

Midterm recommendation

The Commission recommends that the Governor create an ad hoc committee for the purpose of establishing interagency cooperation in those areas in which biotechnology and genetic engineering issues are expected to see activity The committee should recommend procedures and protocols for State agencies and for working with private industry and the Federal government. Of specific concern to the Commission is the area of genetically engineered fish and shellfish, which is expected to see rapid growth with potential significant impact in Maine in the coming decade. It is important that this area be identified not only for safety related concerns but also for economic development potential.

Long term recommendation

*The commission supports the efforts already underway by the Maine Science and Technology Foundation to create the Maine Academy of Science and Engineering. (See **appendix B** for the complete proposal). Several members of the commission felt strongly that any effort to establish an Academy should be based on a regional approach, perhaps including New Hampshire and Vermont. It's purpose would be to provide, upon request, the Maine State Legislature, the Executive Branch, and private organizations guidance on technical and social matters of science, engineering, and human and environmental health; and to promote Maine's scientific communities. The Academy as planned would include some of the following:*

- *undertake studies of scientific or technical problems and associated-social and ethical implications related to public policy issues*
- *evaluate the scientific and technical content of reports and studies by others*
- *answer technical questions*
- *provide or suggest resource persons in Maine or elsewhere*
- *evaluate or design research and associated social and ethical issues related to public policy issues*

The Academy would be an excellent resource for the state in the area of biotechnology and would have additional benefit, as it would be able to address a much wider scope of science issues.

THE ADEQUACY OF EXISTING FEDERAL OVERSIGHT FRAMEWORK

The Commission began its task of reviewing the adequacy of the existing federal oversight framework by evaluating an article from the Maine Law Review by Dr. Christie C. Vito, entitled "Biotechnology Oversight: The Junction of Law and Public Policy" (Volume 45, Number 2, 1993). The Commission used this article as a vehicle for discussions with representatives of the FDA and the Environmental Defense Fund. An overview of the federal coordinated framework follows.

The initial federal effort to establish standards for working with genetically engineered organisms came in 1976, with the National Institute of Health's *Guidelines for Research Involving Recombinant DNA Molecules* (NIH Guidelines)[2]. These were drafted in response to requests by the community of scientists engaged in recombinant DNA research for the development of uniform federal safety standards to govern such research. The NIH *Guidelines* mandated different levels of physical and biological contaminants for all recombinant DNA research funded by the NIH in an effort to prevent the release of genetically engineered microorganisms into the environment. As confidence concerning DNA laboratory research grew, the *Guidelines* were revised to permit deliberate controlled environmental release of genetically engineered organisms, and to delegate oversight authority over research to local institutional peer-review committees known as Institutional Biosafety Committees. Because the *Guidelines* pertained only to recombinant DNA research "conducted at or sponsored by" the NIH, they generally allowed private commercial research to proceed unrestricted. In order, however, for a biotechnology company to receive its license for the manufacturing of pharmaceutical therapeutics and diagnostics, the federal Food and Drug Administration (FDA) requires certification of compliance with NIH *Guidelines,* in which the data is reviewed, and the samples are tested for the purpose of establishing the product's safety and efficacy. This testing process and cycle can take 3 - 5 years for a pharmaceutical producer.

In 1984, the White House Office of Science and Technology Policy published a proposal for an integrated regulatory scheme called the Coordinated Framework for Regulation of Biotechnology ("Coordinated Framework").[3] In proposing the Coordinated Framework, the Reagan Administration's Office of Science and Technology Policy adopted a fundamental policy position: that biotechnology and genetic engineering could be adequately regulated under existing legislative authority, and that no new legislation was necessary to protect the public or the environment. The Coordinated Framework has been adopted and further formalized by subsequent administrations, and accounts for the current system of federal oversight of testing and commercialization of biotechnology products. Under this system, three federal agencies regulate biotechnology under various statutes originally enacted by Congress prior to the need for consideration of scientific, ethical, or social issues specific to biotechnology. In some areas,

[2] Recombinant DNA Research; Guidelines, 41 Fed. Reg. 27,902 (1976); see also revisions at 43 Fed. Reg. 60, 101 (1978), 46 Fed. Reg. 59,735 1981); 48 Fed. Reg. 24,5567 (1983);51 Fed. Reg. 16,958 (1986).

[3] Proposal for a Coordinated Framework for Regulation of Biotechnology, 49 Fed. Reg. 50,856 (1984); see also revisions at 50 Fed. Reg. 47,174 (1985); 51 Fed. Reg. 23,302 (1986).

all three agencies have concurrent jurisdiction over a particular biotechnology product. In other areas, such as the genetic engineering of fish and shellfish in aquaculture, no agency has clear statutory authority at this time.[4]

The three agencies involved, the statutes under which they operate, and the principal areas of their responsibility for biotechnology are summarized as follows:

U.S. Department of Agriculture (USDA)

The USDA Food Safety Inspection Service regulates the inspection and labeling of meat and poultry, but to date has not proposed any regulations related specifically to genetically engineered products. More specifically involved in genetic engineering regulation is the USDA's Animal and Plant Health Inspection Service (APHIS), which claims jurisdiction over environmental releases of genetically engineered organisms from the federal Plant Pest Act[5] and the Plant Quarantine Act.[6] The Plant Pest Act grants authority to regulate the importation and interstate transportation of plant pests, defined as any invertebrate, parasitic plant, virus, or similar organism that "can directly or indirectly injure or cause disease or damage..."[7]

Under this authority, the USDA initially expanded existing regulations to require that any intentional release, importation, or movement across state lines of any genetically engineered plant pathogen must have a permit from the USDA.[8] The USDA has introduced a proposed rule which would create categories of exemptions applicable to certain transgenic plants, and allow developers of genetically engineered plants ready for commercialization to petition for non-regulated status under the Plant Pest Act.[9] Authority under the Plant Pest Act does not extend, however, to the majority of potentially genetically engineered host organisms which are not classified as plant pests, nor does it extend to vertebrate animals. The USDA is also responsible for the licensure and review of all animal diagnostic test systems. Through the Office of Veterinary Biologic and Biotechnology Analysis, the USDA evaluates the research and development data and the testing of the genetically engineered components of the test systems prior to the issuance of a license. All diagnostic test systems are reviewed under the Code of Federal Regulation prior to field use.

The U.S. Environmental Protection Agency (EPA)

According to the Coordinated Framework, the EPA regulates plants which have been genetically modified to resist pests and diseases, and hence are comparable in their proposed use to a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA).[10] Under FIFRA, EPA announced proposed regulations for the development and marketing of plant pesticides on November 21, 1994.[11]

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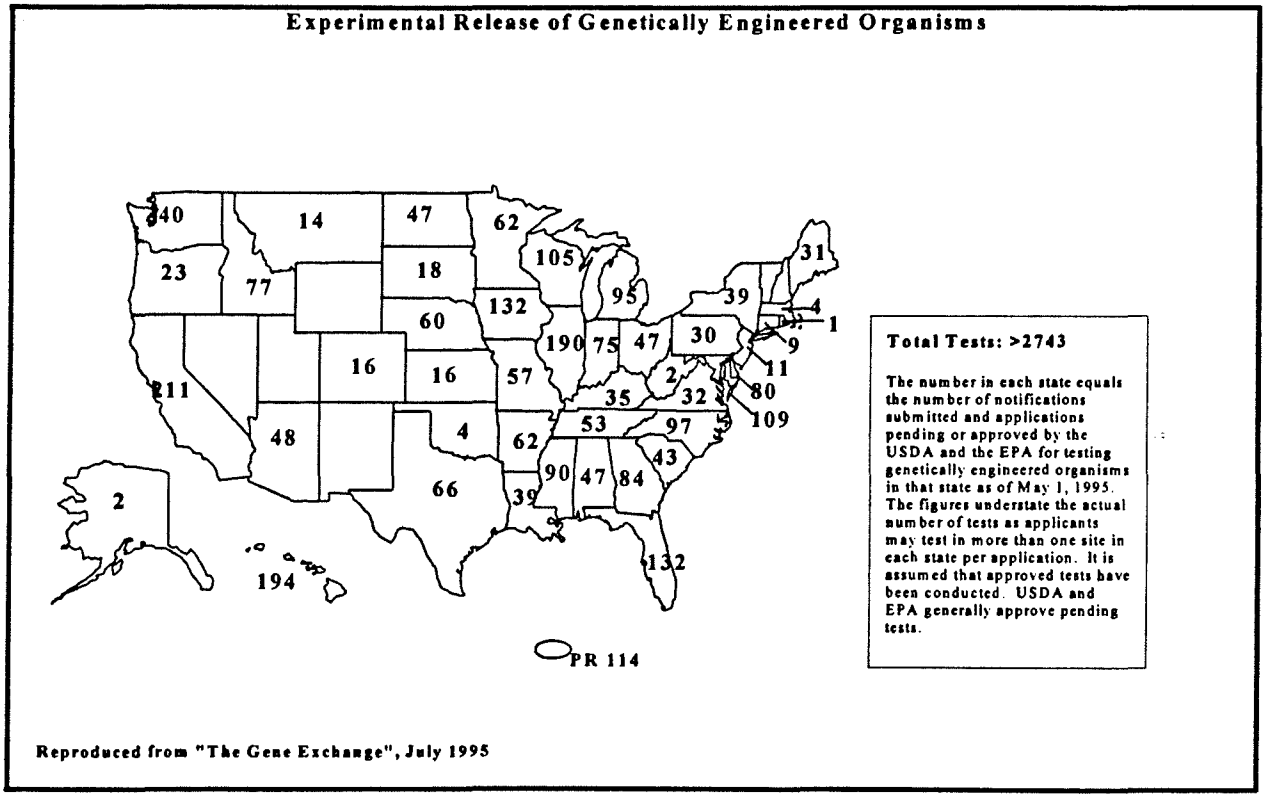
[4] See Generally, Christine Vito, *State Biotechnology Oversight: The Juncture of Technology, Law, and Public Policy*, 45 Maine L. Rev. 329, 336-354 (1993).
[5] 7 U.S.C. secs. 150aa - jj (1988).
[6] 7 U.S.C. secs. 151 - 64a, 166-67.
[7] 7 U.S.C. sec. 150 aa(c).
[8] 7 C.F.R. secs. 340.0, 340.1 (1992)
[9] 57 Fed. Reg. 53,036 (1992) (to be codified at 7 C.F.R. pt. 340).
[10] 7 U.S.C. secs. 136-136y (1988).
[11] 59 Fed. Reg. 60496 (1994) (to be codified at 40 CFR pt. 174)

Additionally, the EPA claims authority to regulate other genetically engineered microorganisms under the Toxic Substances Control Act (TSCA),[12] an act originally designed to regulate non-pesticidal toxic chemicals. The EPA has issued an interpretive policy defining "chemical substance" under TSCA to include living microorganisms, and has issued proposed regulations describing notification procedures and exemptions for new microbes formed by genetic engineering.[13]

Although the EPA is the federal agency given primary responsibility for protection of the environment, the EPA has no statutory authority to consider the environmental consequences of development, testing, or commercialization of genetically engineered plants or animals which are neither "plant pesticides" under FIFRA nor "microbes" regulated under TSCA.

The map below shows the total number of notifications submitted and applications pending or approved by the USDA and the EPA for testing genetically engineered organisms as of May 1, 1995



The Food and Drug Administration (FDA)

The FDA has authority under the Federal Food, Drug and Cosmetic Act to regulate all pharmaceuticals, medical devices, and non-meat and non-poultry foods. The FDA's primary activity to date with respect to genetic engineering used in food was the issuance in 1992 of a

[12] 15 U.S.C. sec. 2601 et. seq. (1986).
[13] Proposed Policy Regarding Certain Microbial Products, 49 Fed. Reg. 50,880, 50,886 (1984).

"Statement of Policy" intended to give developers of genetically engineered new food plant varieties guidance in determining when safety considerations might warrant FDA pre-market approval under food additive regulations and also publishing a request for data and information on labeling issues regarding genetically engineered foods.[14] The public relies on the FDA for assurance that foods are safe and wholesome. FDA has authority under the Act to ensure the safety of most domestic and imported foods in the US market, except meat and poultry which are regulated by the US Department of Agriculture (USDA). Pesticides used in or on foods are regulated primarily by the Environmental Protection Agency (EPA), which reviews safety and sets tolerances (or establishes exemptions from tolerance) for pesticides. FDA monitors foods to enforce the tolerances for pesticides set by EPA.

FDA regulates food and food ingredients developed by genetic engineering by the same provisions and regulations under the Act that it regulates other food products. The FDA takes the position that a food or food ingredient developed by genetic engineering must meet the same rigorous safety standards under the Act as other food products[15], and FDA has broad authority to take legal action against a substance that poses a hazard to the public.

One example of a food ingredient derived from biotechnology is Chymosin, the milk-clotting enzyme used to make cheese and other dairy products. FDA affirmed that chymosin was "generally recognized as safe" (GRAS), meaning that it is exempt from the pre-market approval requirements that apply to new food additives[16]. The source of the new enzyme was *E.Coli* K-12. To further explain how GRAS works, there were several important factors in the FDA's approval of fermentation produced chymosin:

> (1) The introduced chymosin gene that encoded the protein had the same structure and function as animal-derived chymosin;
>
> (2) The manufacturing process removes most impurities;
>
> (3) The production microorganisms were destroyed or removed during processing and were non-toxigenic and non-pathogenic ; and
>
> (4) Any antibiotic-resistance marker genes (e.g., ampicillin) are destroyed in the manufacturing process. The FDA approved this milk clotting enzyme and it is now widely used in the manufacture of cheese.

[14] 57 Fed. Reg. 22984 (1992)
[15] Although, as noted below, the Environmental Defense Fund contends that the FDA has relaxed standards for determining when a food additive is "generally recognized as safe" for genetically engineered products.
[16] 55 Fed. Reg. 10932

To date the FDA has reviewed safety and nutritional data provided by the developers of eight genetically engineered foods - four improved softening or delayed ripening tomatoes, a virus-resistant squash, an insect-resistant potato, and herbicide-tolerant cotton and soybean.[17] In each case, the provision of information to the FDA and request for approval was voluntary on the part of the developer and not required by any regulation. In each review the FDA found that the developer had addressed all relevant human food and animal feed safety issues.[18] With the exception of food additives not, under the FDA's interpretation, "Generally Recognized as Safe," the FDA has stated that its approach to genetically engineered food regulation, as with all other foods, is primarily based on its authority under section 402(a)(1) of the FDCA to seize and enjoin the production or marketing of "adulterated" or unsafe foods.[19] FDA will exercise post-market authority to remove from commerce foods determined to be unsafe, but will generally leave pre-market safety reviews and judgments to the food developer.

As explained by Dr. Maryanski, the centerpiece of the 1992 policy is a comprehensive "guidance to industry" section that discusses scientific issues for assuring safety and identifies scientific and regulatory questions for which firms should consult with FDA. The guidance to industry establishes a "standard of care" for developers to ensure food safety. In 1994, the FDA, in its publication, the FDA BACKGROUNDER, noted that safety assessments of foods derived from new plant varieties include evaluations of the following:

- Unexpected Effects (produces unexpected genetic effects)
- Known Toxicants (has significantly higher levels of toxicants than present in other edible varieties of the same species)
- Nutrients (significantly alters levels of important nutrients)
- New Substances (differs significantly in composition from such substances currently found in food)
- Allergenicity (contains proteins that cause an allergic response)
- Antibiotic Resistance Selectable Markers (contains markergenes that theoretically may reduce the therapeutic effects of clinically useful antibiotics)
- Plants Developed to Make Specialty Nonfood Substances (plants developed to make substances like pharmaceuticals or polymers that will also be used for food)
- Issues Specific to Animal Feeds (significant changes in nutrients or toxicants)

These principles are consistent with the principles for safety assessment discussed by various prestigious organizations, including the United States National Research Council, the

[17] One such product, the FLAVR SAVR tomato developed by Calgene, has already been marketed to consumers.in Maine and elsewhere.
[18] January 19, 1995 fax from James Maryanski to the Commission.
[19] 57 Fed Reg. 22984 (1992)

World Health Organization, the Food and Agriculture Organization of the United Nations, and the Organization for Economic Cooperation and Development. The burden of a lawsuit and loss of business in an adulterated or unsafe food situation is daunting at best and it is believed in the industry to be good policy to evaluate heavily the safety issues with regards to human food. Dr. Maryanski stressed that for rapidly evolving technologies such as recombinant DNA techniques, the policy should be sufficiently flexible to permit the necessary modifications as a result of innovations or modifications. He also stated that the FDA is continuing to consider issues raised in public comments regarding allergenicity, labeling, or pre-market notification. The FDA heavily regulates all pharmaceuticals (human and animal) and medical devices. The FDA requires testing data to establish safety and efficacy, pre-clinical data, and pre-market approval prior to licenser of and any new product

Vito and other commentators have characterized the federal Coordinated Framework as fundamentally flawed.[20] Vito argues that federal agencies leave themselves open to legal challenge when they stretch definitions under pre-existing statutes to cover new biotechnologies, that some potential biotechnology products do not fall within any of the regulatory initiatives under existing statutes, and that the Coordinated Framework "ignores the possibility that the new biotechnologies may pose previously unconsidered threats to the environment and to society."[21] She points out that TSCA, under which the EPA purports to regulate genetically engineered microorganisms, is a particularly weak environmental statute, since, unlike FIFRA, it places the burden on the EPA to demonstrate the existence of a risk before it can take regulatory action. Such an approach may be inappropriate in the regulation of organisms, which arguably pose greater risks than the chemicals TSCA was originally designed to regulate, because such organisms can, unlike chemicals, replicate and evolve in the environment.[22]

The Union of Concerned Scientists has raised a number of questions concerning federal oversight of field releases of genetically engineered plants,[23] and the Environmental Defense Fund has criticized the FDA's 1992 "Statement of Policy" as constituting a "decision to re-write well established law and policy so as to apply new definitions of 'food additive' and '[Generally Recognized as Safe]' when regulating genetically engineered foods.[24] The EDF notes that under the 1992 policy, developers may for the first time make self-determinations that a product is "Generally Recognized as Safe" and hence not subject to pre-market FDA food additive approval, based on internal and unpublished research. The EDF has also called for a stronger federal food labeling policy and system of mandatory pre-market notification for genetically engineered foods.[25]

Neither this Commission nor any similarly constituted commission is likely to be able to reach consensus regarding the overall risks and benefits of the rapid pace of development of

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[20] Vito, Christine, "Biotechnology Oversight: The Juncture of Technology, Law and Public Policy", 45 Maine Law Review 329, 336-354 (1993) and citations therein.

[21] 45 Maine Law Review at 348.

[22] Id. at 349-350.

[23] Union of Concerned Scientists, Perils Amidst the Promise: Ecological Risks of Transgenic Crops in a Global Market, December, 1993.

[24] October 15, 1992 letters from the Environmental Defense Fund to Dr. David Kessler.

[25] "A Mutable Feast: Assuring Food Safety in the Era of Genetic Engineering," Environmental Defense Fund, October 1, 1991.

biotechnology, [26] nor does this Commission have the expertise to second guess specific agency determinations with respect to the safety of a particular product. In the process of studying the federal regulatory framework, we repeatedly addressed the question of requiring specific labeling or permitting of genetically engineered products entering the state. The consensus of the commission is that medical and veterinary devices and pharmaceuticals are heavily evaluated under USDA and FDA regulations, and are used in a controlled manner by medical and veterinary professionals. That leaves the Commission with three areas of concern regarding the regulation of genetically modified products; these areas also reflect the highest level of public concern. Several members, although not a majority of the members of the Commission, believed that in the face of continuing federal inaction in the area of mandatory labeling for genetically engineered products, Maine should move ahead to impose a labeling law despite the potential for increased costs.

It was the consensus of the Commission, however, that the preferable alternative would be to encourage future Federal action on labeling. The Commission has also recommended federal action on mandatory pre-market notification of genetically engineered food, and a review of regulation of genetically engineered fish and shellfish in aquaculture.

OVERVIEW OF THREE KEY FOOD ISSUES

1. Labeling of Genetically Engineered Food

In each of the last two legislative sessions, consumer advocates have proposed bills in the Maine Legislature to require labeling of genetically engineered foods.[27] The proponents of these bills argued that the consumer's "right to know" that the food they were eating and feeding their family had been genetically engineered was fundamental. In an era when a tomato may be no longer exactly a tomato, though it appears to be no different to the naked eye, when a potato can and has been engineered to contain a waxmoth gene, corn to contain a firefly gene, and lettuce to contain a tobacco gene,[28] consumers argue a need to know from what diverse genetic components their food has been fabricated. Polls conducted suggested that as many as 85% of the American public want genetically engineered food to be labeled. The origin of this concern may stem from a variety of different sources: concerns about potential allergenicity, religious dietary laws and vegetarianism, and a desire to make informed choices about the economic systems which bring food to the table. As discussed earlier, industry representatives and state

[26] "The Cassandras talk darkly of Andromeda strains or developments that could change the ecology of the earth in a relatively short period of time. The Babbitts scoff at that gloom, dismissing past mistakes as minor laboratory accidents, explaining about the implications of thwarting innovation and suffocating the fledgling industry [of biotechnology] in an irrational overreaction to extremely remote events. Rational analysis of the science is somewhere between the two extremes." James J. Florio, Regulation in Biotechnology, Biotechnology: Implications for Public Policy 41 (S. Panem ed. 1985).

[27] 116th Maine Legislature, L.D. 1928: 117th Maine Legislature, L.D. 279.

[28] Information compiled from applications to the US Department of Agriculture to field test engineered plants, published in the Union of Concerned Scientists, Perils Amidst the Promise (1993) at 6.

agriculture officials argued, on the other hand, that a labeling requirement unique to the State of Maine would send a discouraging signal to Maine's emergent biotechnology industries, would significantly increase the costs of production and retailing of food, and may even keep some foods off the market shelves in Maine.

> *The Commission shares the view of industry representatives and the State Department of Agriculture that piecemeal state by state labeling requirements are at best an imperfect substitute for a carefully considered uniform federal labeling requirement.*

The FDA has twice formally indicated an intent to promulgate a labeling regulation[29] and James Maryanski, the FDA's Biotechnology Strategic Manager, affirmed that intent in his meeting with this Commission. However, such a regulation has been slow in coming.[30] Moreover, the philosophy expressed with respect to labeling in the FDA's 1992 "Statement of Policy", and reaffirmed in Mr. Maryanski's meeting with this Commission, may not go far enough to provide for consumers who are concerned about allergenicity, or about complying with religious dietary law or ethical dietary preferences.

The perspective of the food industry and the general consensus of the Commission is that a unique labeling requirement proposed by the State of Maine requiring specific state labeling for food would be a difficult, costly system to instigate and control. While protecting the safety of the public is the primary role of government, adverse economic effects of labelling could also cause considerable hardship on the people of Maine. Some of the main concerns are as follows:

- *Many corporations may choose not to ship their food products to Maine, if Maine has its own state-specific labeling law. They would do this in order to avoid adding the expense of certifying foods and creating labels increasing their manufacturing costs. In addition, they will have difficulty acquiring the data needed to comply with this law from their vendors and suppliers unless there is a national regulation to this effect. For small companies the added costs and complications of doing business in Maine may present even more of an economic burden. Perhaps to an even greater degree than with the larger companies, acquiring the appropriate certification documents from their vendors and suppliers without a national requirement may not be feasible.*

- *The companies and corporations that make their home in Maine may also face similar hardships. The majority of their vendors and suppliers may not be able to provide the necessary certification documents, and the few vendors and suppliers who will be able to provide certification will charge a premium for it. Without a national mandate, letters of certification may be questionable. Yet, the burden of proof (and the accompanying liability) will be placed on the Maine manufacturer, who will have had no control over the information provided. Additional label requirements may conflict with their mandate*

[29] See 57 Fed. Reg., 22984 (1992) and 58 Fed. Reg. 25837 (1993).

[30] Since the FDA's first expression of an intent to regulate labeling in 1992, one food developed with genetic engineering, Calgene's Flavr Savr tomato, has already been marketed, and at least seven others are close to commercialization. It is significant that the Calgene tomato (marketed in parts of Maine as the "MacGregor" tomato) comes to the market shelves fully labeled with both stickers on each tomato and an explanatory brochure, even though under FDA's current expressed position the agency would not require such labeling.

and definitions. As a result of this regulation, vendors and suppliers may simply choose not to do business in Maine.

- *And finally, the cost of Maine manufactured foods may be higher and this may make Maine companies less competitive. This is of particular concern because we already experience unique added costs. These include transportation expenses that result from our geography, workman's compensation rates, and high utility expenses.*

In summary, a labeling requirement unique to the State of Maine may limit the competitive ability of Maine companies by adding to the cost of doing business here. The additional expenses and potential liability may discourage non-Maine companies and corporations from shipping to Maine and may make it more difficult for Maine companies to compete in out-of-state markets. These economic consequences must be balanced by the protection of the public health through continuing assessments of health risks.

Allergenicity

Food allergies are a serious public health concern. Roughly one to two percent of the United States population, or 2.5 to 5 million people suffer from true food allergies --- reactions to substances in foods mediated by the immune system, in most cases by immunoglobin E (IgE) antibodies. [31]

Some allergy experts believe that severe allergic reactions to foods are becoming more common in this country, because of the increasing diversity of our diet, and because of increasing exposure to proteinaceous food additives.[32] Genetically engineered foods could lead to further increases in the incidence of allergic reactions to food. Most, if not all, natural food allergens that react with IgE-mediated antibodies are proteins or glycoproteins. [33] Because genes encode proteins, foods obtained from organisms genetically engineered to express new genes will in most cases contain proteins that were not previously found in the food. In one instance, allergenic properties have been demonstrated to be transferred from a donor organism to a host organism. The seed company Pioneer Hi-Bred International, Inc. recently dropped plans to commercialize soybeans genetically engineered with a gene from Brazil nuts because the engineered beans produced antibodies in blood serum samples from Brazil nut-allergic

[31] Butkus, S.N. and K. Mahan, "Food allergies: Immunological reactions to food," Journal of the American Dietetic Association 86: 601 - 607 (1986); Sampson, H.A., R.H. Buckley, and D.D. Metcalfe, "Food Allergy", Journal of the American Medical Association 258: 2886-2890 (1987).

[32] Sampson, et. al, supra nt. 36; Breneman, J.C., Basics of Food Allergy, 2nd edition, Springfield, IL: Charles C. Thomas Publishing (1984).

[33] Aas, K., The Biochemistry of Food Allergens: What is Essential for Future Research? Pages 1 - 11 in Food Allergy, Eberhardt Schmidt ed., NY, NY: Vesey / Raven Press, Ltd. (1988)..

individuals. Thus, it is entirely possible that future availability of genetically engineered foods could lead susceptible individuals to be allergic to foods they previously could safely consume.[34]

The FDA's 1992 Policy Statement acknowledges that genetically encoded proteins could move via genetic engineering from an allergenic food to a new food, and may sometimes cause the recipient food to become newly allergenic: "FDA's principal concern regarding allergenicity is that proteins transferred from one food source to another might confer food from the host plant the allergenic properties of the food from the donor plant."[35] The FDA's response to this risk is a policy that will require pre-market approval as a food additives for proteins (or other added substances such as fatty acids and carbohydrates) produced by introduced genes if the protein differs substantially in structure and function from the many proteins that comprise our foods. Conversely, the FDA will presume that proteins that are derived from foods and proteins that are substantially similar to such proteins are GRAS, and therefore, the FDA will not require pre-market review for such substances. Based on present knowledge of developments in agricultural research, the FDA believe that most of the substances that are being introduced into food by genetic modification have been safely consumed as food or are substantially similar to such substances. Therefore, the FDA does not anticipate that most foods developed by recombinant DNA methods will contain substances that require pre-market approval as new food additives.

The FDA believes that particular attention should be given to proteins that are derived from foods to which individuals in the US population are commonly allergic, such as milk, eggs, wheat, fish, tree nuts, and legumes. In such cases, the developer should demonstrate scientifically that the allergenic substance is not present in the new food, or FDA would require some form of labeling to alert sensitive consumers.

The FDA <u>does not</u> appear to presently contemplate any labeling requirement which would apply to genetic use of foods that are allergenic to smaller numbers of individuals. Watermelon, celery, banana, pears, and potatoes, and spices such as aniseed, cumin, and coriander are among the many foods that have been found to be allergenic to some individuals, but are not considered "common" allergens.[36]

Nor, more fundamentally, would a labeling requirement limited to genetic material from "common" allergens address the potential that entirely new proteins not previously found in the food system would create new allergic responses. As observed in the FDA's 1992 "Statement of Policy": "A separate issue is whether any new protein food has the potential to be allergenic to a segment of the population. At this time, the FDA is unaware of any practical method of predict or assess [sic] the potential for new proteins in food to induce allergenicity and requests

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[34] Norlee, J.A., Taylor, S.L., Townsend, J.A. Thomas, L.A., Bush, R.K. "Identification of a Brazil Nut Allergen in Transgenic Soy Bean," <u>The New England Journal of Medicine</u>, vol. 334, No.11 at 688 (March 14, 1996). See also editorial in same issue "Allergy in Transgenic Foods - Questions of Policy".

[35] 57 Fed. Reg. 22987.

[36] Ortolani, C.M., et.al., "Comparison of results of shin prick test (with fresh foods and commercial food extracts) and RAST in 100 patients with oral allergy syndrome." Journal of Allergy and Clinical Immunology 83:683-690 (1989);Stager, J., et.al., "Spice Allergy in celery-sensitive patients," Allergy 46:475-478 (1991).

comments on these issues."[37] *A broad labeling requirement for genetically engineered foods would give consumers the options to avoid this risk when choosing the foods they consume.*

> *In sum, the FDA should review and promulgate a regulation for labeling of genetically engineered foods broad enough to protect the consumer's freedom of choice in the marketplace and ability to avoid health risks.*

2. Mandatory Pre-market Notification for Genetically Engineered Foods

Maine consumers and biotechnology industry representatives share an interest in seeing concerns about emergent biotechnologies addressed by the federal and state government in a responsible, effective, and safe manner that encourages the growth of new and existing business in the State of Maine. One of the most basic ways the federal government can exercise responsible oversight is by keeping track of who is doing what in the field, and what products of biotechnology are actually being marketed. The FDA has stated that it is working on a regulation for pre-market notification of genetically engineered foods.

The FDA to date relied upon a system of voluntary notice by companies intending to market genetically engineered products, and appears confident that such a system is working effectively. The Environmental Defense Fund has raised concerns that as the number of companies involved in genetic engineering proliferates, and the novelty of producing such products wears off, there is a risk that voluntary notice will be less effective. Without a system of mandatory pre-market notification, the FDA will not necessarily know what genetically engineered foods are on the market. A pre-market notification would enhance the FDA's ability to comply with its statutory responsibility to remove a hazardous food from the market, or warn susceptible consumers to avoid a hazardous food.

> *The Committee recommends that the FDA establish an effective system of mandatory pre-market notification for genetically engineered foods.*

[37] 57 Fed Reg. 22987.

The chart below, which appeared in the July 1995 edition of the Gene Exchange, provides an overview of the status of development of genetically engineered organisms.

STATUS OF DEVELOPMENT OF GENETICALLY ENGINEERED ORGANISMS

Product	Research	In the Pipeline[38]	Ready for Market[39]
Major Crops:			
Corn	Yes	Yes	Yes
Wheat	Yes	Yes	---
Soybean	Yes	Yes	Yes
Cotton	Yes	Yes	Yes
Sorghum	Yes	---	---
Barley	Yes	Yes	---
Oats	Yes	---	---
Rice	Yes	Yes	---
Minor Crops[40]			
Tomato	Yes	Yes	Yes
Tobacco	Yes	Yes	---
Potato	Yes	Yes	Yes
Squash	Yes	Yes	Yes
Canola	Yes	Yes	Yes
Cranberry	Yes	Yes	---
Broccoli	Yes	Yes	---
Cucumber	Yes	Yes	---
Alfalfa	Yes	Yes	
Fish and livestock			
Fish	Yes	Yes	---
Cows	Yes	---	
Sheep	Yes	---	---
Goats	Yes	---	---
Pigs	Yes	---	---
Chickens	Yes	---	---
Inputs			
Microbial pesticide	Yes	Yes	Yes
Animal Vaccines	Yes	Yes	Yes
Growth promoters	Yes	Yes	Yes

Reproduced from "The Gene Exchange., July 1995

[38] "In the pipeline" means that the product is in field testing or clinical trials in the U.S..

[39] "ready for market" means that the product is on the market or awaiting final agency action on applications to commercialize in the U.S..

[40] The list of minor crops is only a sample of a much larger list of crops that have been genetically engineered.

3. Regulation of Genetically Engineered Marine Species

Regulation of the development and aquaculture of genetically engineered fish and shellfish is one of the areas that is still developing in the structure of the Coordinated Framework. While the FDA claims responsibility for the ultimate safety to human consumers of fish and shellfish products, their statutory mandate to do so may be in question, and no agency has clear statutory authority to regulate and protect against environmental and ecological risks in the development and aquaculture of such organisms. As Maine is a primary site for the development of aquaculture industries, the Commission is concerned that the absence of effective regulation in this area may create ecological risks.

FDA's James Maryanski has stated that the FDA is considering the position that the FDA could regulate those transgenic fish which have extra copies of a fish growth hormone gene as "new animal drugs", but concedes that if the FDA decides it does not have authority to regulate transgenic fish, no statute covers the environmental impacts of commercializing them. The USDA's Agricultural Biotechnology Research Advisory Committee has recently developed guidelines for safely conducting research with genetically modified fish and shellfish, but these are voluntary guidelines as the USDA's current authority to regulate in this area is questionable. The USDA would be the appropriate Federal agency as it is currently the lead agency for aquaculture and has extensive experience overseeing the introduction of new products.

Currently, about 40 or 50 labs around the world are working on transgenic fish, with about a dozen labs located in the United States. Most of the research has focused on transforming growth hormone genes from other species to create fish which grow more rapidly in aquaculture settings. Some experimentation has also involved using anti-freeze genes to enable warm water fish to survive in colder water. A researcher from the University of Connecticut has transferred into common carp the growth hormone DNA from rainbow trout. The offspring of the first generation of transgenic fish grew 20 to 40% faster than their unmodified siblings. The researcher is also developing transgenic catfish, tilapia, striped bass, trout, and flounder. A researcher from British Columbia has modified the growth hormone gene in coho salmon with genetic material from sockeye salmon, resulting in transgenic coho which grew faster than unmodified fish. The modified salmon are large enough to be marketed after one year, in contrast to standard farmed salmon that do not reach market size for at least three years.

The principal environmental risk associated with the development and aquaculture of transgenic fish is that they will escape and interbreed with wild species, thereby threatening the genetic integrity of wild stocks. No evidence exists that interbreeding between farm raised fish and wild salmon stocks has occurred in Maine rivers. However, escaped farmed Atlantic salmon successfully interbred with wild Atlantic salmon in a New Brunswick, Canada river. Escaped farmed salmon in other countries, notably Norway, have also been documented as interbreeding with wild stocks. This has raised concerns that such interbreeding between aquaculture and wild stocks might impair recovery efforts for wild Atlantic salmon in New England, which have been proposed for listing under the US Endangered Species Act. In these instances, however, the farmed fish had not been genetically engineered. The potential interbreeding of farmed fish, including transgenic fish, with wild fish remains a concern whether or not the wild population in question is rare or declining.

The State of Maine, with assistance from the US Fish and Wildlife Service and the US National Marine Fisheries Service, is developing an Atlantic Salmon Conservation Plan which focuses on the need to minimize the escape of farmed stocks and to actually prevent cultured fish from entering rivers where wild salmon runs exist. Implementation of this plan will likely begin before policy questions relating to the Federal regulation of transgenic products are resolved.

Escaped aquaculture fish potentially could physically displace wild species, whether or not they are able to interbreed. Exotic fish introductions are causative factors in 28 of 86 fish species and subspecies currently listed as endangered or threatened. It is important for this discussion to understand, however, that no evidence currently exists suggesting that aquaculture has played a part in these reported declines and subsequent listing of wild fish. It remains to be seen whether transgenic fish, because they are able to grow faster or larger, may thus become more fit, and hence displace wild fish.

The actual risks imposed upon wild fish specifically by transgenic fish remain undocumented. Current research efforts include developing methods to sterilize aquacultured fish to prevent interbreeding. Although methods exist for sterilization, they are currently uneconomical to implement. Guidelines and additional research are necessary to prevent unnecessary damage to wild finfish and shellfish populations, while still encouraging a healthy aquaculture

This Commission is unaware of research or development of genetically engineered fish being conducted in this state. An effective system of federal legislation needs to be established to assess the risks of environmental release and regulation to address those risks.

In summary, the Biotechnology Study Commission's Review of the Federal Regulations has turned up three areas of concern with regard to adequate Federal Regulation coverage:

- **Labeling of genetically engineered food.**
- **Pre-notification of genetically engineered food to the FDA.**
- **Regulation of genetically engineered fish and shell fish.**

The Coordinated Framework is not perfect, but taking on this activity at a state level would be a daunting task from both technical and the funding perspectives. The Commission suggests that the areas of concern that have been noted be addressed through consumer education and formal recommendations to the respective federal regulatory agencies.

STATE REGULATION

An overview

In general, state legislatures have the authority to determine what products can and cannot be sold in a state. Exercising this legislative authority, several states declared a temporary moratorium on the sale and use of bST in dairy cows. States also have the right to monitor the development of a genetically engineered product, the use of inspections and permits are two mechanisms states employ. State regulation of genetically engineered plants, including food crops, varies from state to state. (See chart below) Most state departments of agriculture become involved in the process when a genetically engineered plant is moved into or out of the state or when it is ready to be field tested in the state. APHIS is required to notify a state regulatory agency, usually agriculture, when a company, university, or private researcher has applied for a movement or environmental release permit. Applicants for an importation or movement permit can expect to have the receiving facilities for the plant inspected by either federal and/or state authorities before the plant arrives. Applicants for an environmental release permit are told that federal representatives will inspect the field test site near the beginning of the field test and shortly after harvest and possibly at some time during the field test, and state officials may also inspect the field test site.

A 50 State Overview of Regulatory Authority Regarding Biotechnology

STATE	REGULATION
Alabama	Local businesses are prohibited from passing ordinances regulating pesticides.
Alaska	Alaska has no state regulation concerning biotechnology.
Arizona	The state biotechnology regulations spell out the procedures taken after USDA sends the department the permit. Applicants will comply with Arizona's quarantine laws and rules and, in some cases, may place restrictions on the permit.
Arkansas	Arkansas has no state regulation concerning biotechnology.
California	DNA samples are required of convicted sex offenders. The State Department of Health Services must classify as non-hazardous waste ash or residues generated from a biomass combustion process.
Colorado	DNA testing is allowed in paternity lawsuits.
Connecticut	Connecticut has no state regulation concerning biotechnology.
Delaware	Delaware has no state regulation concerning biotechnology.
Florida	Genetically engineered plants and plant pest organisms are regulated through the Plant Industry Law.
Georgia	Georgia has no state regulation concerning biotechnology.
Hawaii	A statute requires applicants for federal permits or approvals of field testing of genetically modified organisms to submit copies of their applications to the Hawaii Department of Health at the same time they are initially submitted to a federal agency. Both Confidential Business Information -- and CBI -- deleted copies are required. The criminal justice system requires DNA testing of certain convicted offenders and, in some cases, to determine parentage.
Idaho	Idaho allows genetic testing in paternity lawsuits.

Illinois	Notification and review of the release of genetically engineered organisms into the environment is required. DNA testing is permitted to determine parentage.
Indiana	Indiana has no state regulation concerning biotechnology.
Iowa	Iowa has a State Biotechnology Advisory Committee, does not have regulatory authority, but provides comment to the Federal Government during the permit application process for field testing.
Kansas	The criminal justice system requires DNA testing of certain convicted felons.
Kentucky	DNA testing is required of certain convicted offenders, with the information maintained in a DNA databank. Political subdivisions are prohibited from regulating agricultural pesticides.
Louisiana	Louisiana created in 1987 the Dedicated Research Investment Fund to promote biotechnological and biomedical research. A person contributing to the fund receives an income tax credit of 35% of the cash donation if the initial donation is greater than $200,000.
Maine	Medical waste is regulated through the Department of Environmental Protection. There is a state commission on testing and release of transgenic and recombinant organisms, currently on hold. The State appointed a panel in 1994 to reevaluate the commission and make recommendations to the Legislature.
Maryland	A five-year legislative act died because of a sunset clause; no reauthorization.
Massachusetts	Massachusetts has no state regulation concerning biotechnology.
Michigan	A company or manufacturer of veterinary biological can not distribute or sell any biological product within the state unless notification prior to sale and distribution is given to the Department of Agriculture.
Minnesota	The State assigns responsibility for genetically engineered organisms to the Environmental Quality Board. A state permit, issued by either a state or federal agency, is required for the release of genetically engineered organisms into the environment. In April, 1990, the state legislature approved a one-year ban on bovine somatotropin. Registration is required of laboratories using genetic engineering.
Mississippi	Genetic testing is allowed in paternity lawsuits.
Missouri	Missouri has no state regulation concerning biotechnology.
Montana	Beginning July 1994, the State Bureau of Investigation will track DNA samples from certain offenders. The Department of Livestock has issued a statute requiring a permit for all biologics and animals imported into the state.
Nebraska	Nebraska has no state regulation concerning biotechnology.
Nevada	Nevada has no state regulation concerning biotechnology.
New Hampshire	New Hampshire has no state regulation concerning biotechnology.
New Jersey	Municipalities are prohibited from regulating the development and use of biotechnology material and organisms. A Biotechnology Financial Assistance Fund was created in 1995 to provide financial assistance to biotechnology research projects.
New Mexico	New Mexico has no state regulation concerning biotechnology.
New York	A New York Public Health law covering recombinant DNA experiments requires all persons engaged in recombinant DNA activity to obtain a certificate or be affiliated with and act under the direction of one who has been issued a certificate by the Commissioner of Health. A bill was introduced in 1989 to establish a Committee on the Release of Genetically Engineered Microorganisms within the Department of Health.
North Carolina	The Genetically Engineered Organisms Act of 1989 regulates the sale, use, and outdoor release of genetically engineered organisms. This Act expired on September 30, 1995
North Dakota	North Dakota has no state regulation concerning biotechnology.

Ohio	Genetic testing is allowed in paternity lawsuits.
Oklahoma	The state legislature enacted the Oklahoma Biotechnology Agriculture Act in 1990 which prohibits movement, maintenance, or release of any recombinant DNA-produced organisms, with exceptions.
Oregon	Effective October 3, 1989, legislation regulates alternative corporate income and excise tax credits based on biotechnology research expenditure, while limiting eligible expenses to those incurred for research in Oregon. Tax credit of $500,000 awarded for research.
Pennsylvania	Pennsylvania has no state regulation concerning biotechnology.
Rhode Island	No vaccines or other biological products prepared for immunizing animals can be used in Rhode Island unless the product has been labeled and approved for that use by the biological division of the U.S. Dept of Agriculture and may be only be administered by an approved veterinarian under the supervision of the director of environmental management. An order for any product containing living organisms must be accompanied by a statement from a veterinarian containing names and address of the owner of the animals being treated.
South Carolina	South Carolina has no state regulation concerning biotechnology.
South Dakota	South Dakota has no state regulation concerning biotechnology.
Tennessee	DNA testing is required of certain criminal offenders. Cities and counties are barred from adopting or enforcing any regulation of pesticides.
Texas	The use of DNA testing is allowed to assist law enforcement officials in the investigation or prosecution of sex-related offenses. A DNA database is maintained by the Department of Criminal Justice.
Utah	Municipalities are prohibited from passing ordinances regulating pesticides.
Vermont	Vermont has no state regulation concerning biotechnology.
Virginia	In 1991, the General Assembly passed revised conflict-of-interest legislation allowing greater possibility for university faculty to participate in start-up companies based upon their research. The Pesticide Control Board has authority to regulate pesticides. The State Veterinarian regulates the approval of animal vaccines/biologics.
Washington	A bill passed during the 1995 session requires anyone with a federal permit for biotechnological agent release to inform the Washington State Department of Agriculture. A Commission on Pesticide Registration was also created by the legislature in 1995.
West Virginia	A DNA database was established in 1995 to catalog blood samples of those individuals convicted of certain crimes as a tool to assist law enforcement officials in crime investigation and prosecution
Wisconsin	Wisconsin regulates biotechnology field tests through requiring, in 1988 legislation, that one of two state agencies be notified of federal applications. The state agencies are required to notify the local communities, but are not given specific new state regulatory power. The state is expected to protect its interests through participation in the federal framework. In 1989, the state enacted a ban on the use of bovine somatotropin (BST) through June 1991, but it did so after seeing predictions that federal approval of BST would not be granted before that date.
Wyoming	DNA testing is permitted to determine parentage in child custody cases.

RISK ASSESSMENT

The public continues to be strongly interested in the regulatory process, but has a very poor understanding of the concept of risk assessment. The assessment of a regulation regarding biotechnology requires a weighing of costs and benefits. The costs of such regulation include enforcement costs and economic losses. Benefits include the protection of those who might be harmed either physically, or economically. Economic harm might include both a direct loss of income, and/or a reduction of environmental amenities.

Assessment of the costs and benefits associated with biotechnology and genetic engineering must depend specifically on the particular nature of the biotechnical innovation, and at this time must be more speculative than for activities and technologies that have more history. Forecasts of the effects of biotechnical innovations are, at this time, not very precise because of the unfamiliar nature of the technology.

Sources of risks from Bio-technology

Risks associated with the development and use of bio-technological products can be thought of as falling into three categories, although there may be some slight overlap among the categories. The categories of risk include; **environmental risks, health risks, and socio-economic risks.**

- **Environmental risks** include the possibility of a bio-technological product escaping into the general environment. These escapes might then become destructive themselves, or inter-breed with other indigenous species, which then become destructive. There is a long history of biological escapes. Most of these have been quite harmless and self limited, for example, many garden flowers and the Maine Coon Cat. A few are well known and destructive, for example, Africanized bees or chestnut blight. The latter must be the primary concern of the Legislature. It is clear, however, that the concern is not so much the risk of escape, but the risk of damage caused by such an escape.

- **Health risks** are considered to be the probability of direct negative effects on human health from the use of the bio-technical products, or the use of products that use bio-technical products in their production. Health effects include the possibility of allergic reactions and toxicity. Further, there is the possibility of indirect effects through immunological or genetic causes. A case such as this took place when a soybean was produced using Brazil nut genes. Laboratory tests indicated that people who were subject to Brazil nut allergenicity would have reactions to products from these soybeans, so the product was not marketed.

- **Socio-economic risks** include the possibilities of losses of income or occupation and the resulting decline of communities or institutions. These are not the result of the characteristics of the bio-technical product, but as the result of a technical change which may significantly alter the structures of industries. These change takes place at a rapid rate from many sources, so it is unclear as to whether it is useful to consider only the effects resulting from bio-technical change. Further, banning or otherwise restricting the use of bio-technical

products on this basis in a small state like Maine are likely to have the perverse effects of putting our industries at a competitive disadvantage.

In summary, it is important that policymakers recognize the following:

- **Risks are hard to determine without careful scientific study.**
- **There may be the possibility of <u>either</u> negative or positive unexpected results.**
- **Some risks are acceptable if the expected benefits outweigh the expected risks.**
- **The costs of regulating may be higher than the expected costs from the risks.**

Biotechnology Education

As biotechnology-derived foods start entering the marketplace and real food products begin to appear on supermarket shelves, consumers will need objective information through a variety of educational opportunities to help them form educated individual opinions. Given the gap between public understanding and public perception of biotechnology, genetic engineering or gene mapping, it is unrealistic to expect the public to become engaged in a meaningful public policy debate regarding biotechnology and food. The task of providing such educational opportunities is a responsibility shared by all of those involved in biotechnology from educators, researchers and scientists to industry personnel w,hether or not they are associated with public or private institutions or companies.

In the report **BIO-MAINE '93**, the authors noted that the anticipated impact of biotechnology/life science innovations will affect Maine's citizens at four distinct levels:

- Those individuals directly employed in the industry;
- Those individuals employed in occupations which will be directly impacted by the use of such innovations;
- The consumers of the resulting products; and
- Government regulators who must make educated decisions regarding the safest and most effective means of delivering these new biotechnology/life science-derived products, processes, and services.

If Maine's biotechnology/life science industry is to develop, it will require a sustained education/training effort targeted at all four levels of impact. Maine's education/training institution programs are not currently set up to respond to this imminent need.

Such educational opportunities could take a variety of formats. Granted, not every scientist is a teacher by profession, but all scientists can teach by simply sharing their knowledge and expertise with others in variety of ways. These may include giving a presentation to students on Career Day at the local school, serving as a mentor for an aspiring student to become a biologist, or talking to a local civic organization. The important point is to be able to communicate effectively about their research and scientific discipline. Knowing where to find supporting education and communication materials on biotechnology can make the task that much easier.

Again, the **BIO-MAINE '93** report notes that "...if Maine's fledgling biotechnology/life science industry is to develop, a sustained, well coordinated, statewide "K-20+" science-education/training strategy must be established." In addition, the report recommends the establishment of a common core of practical biotechnology/life science experience via a statewide certification mechanism, and the establishment of an adult education biotechnology/life science retraining programs.

Models of how such educational process should be accomplished both in Maine and in other states are currently available. The University of Maine Cooperative Extension is in the process of developing information packets designed to educate the public and Maine's legislators on the different issues of biotechnology and food. Both the Jackson Laboratory, Bar Harbor, Maine and IDEXX, Westbrook, Maine provide speakers from their staff to schools and different public and civic groups. Resource guides are a quick way to track down supporting materials, people, and organizations that can provide assistance and know-how about biotechnology education and communication. The following are some examples.

- The Biotechnology Education Resource Guide from the University of Wisconsin is intended for teachers, 4-H leaders, extension agents, and anyone interested in obtaining materials or assistance in teaching biotechnology. It is updated regularly and is available from the University of Wisconsin Biotechnology Center, 1710 University Avenue, Madison, WI 53705. The guide is also available at the UWBC gopher site at calvin.wisc.edu.

- The Biotechnology Industry Organization (BIO) has produced a resource guide for educators entitled "Tools for Teaching Biotechnology: A Bibliography of Resources" in 1994. Prepared by the BIO Education Committee, the guide provides pointers on appropriate books, compilations of lab exercises, videos, and other educational materials. Single copies of the guide are available from BIO, 1625 K Street, NW, Suite 1100, Washington, DC 20006-1604, Tel. (202) 857-0244.

- "Science-by-Mail Program" Making a connection with kids, is designed to help students in the fourth through ninth grades understand more about a particular scientific niche, or help redefine the scientist stereotype. This national pen-pal program has been pairing scientists with kids around the country for the past 8 years. Science activity packets are provided to children twice a year and encourage them to solve the science challenge with the advice and encouragement of their scientist pen pals. Previous experience indicates the program benefits both student and scientist. Many of the local programs are run by non-profit Science-by-Mail chapters housed at 12 regional science museums. There is no cost to scientist to participate and only a minimal fee for classroom use. For more information about the scientist-by-mail program, contact the Science-by-Mail National Office, Museum of Science, Science Park, Boston, MA 02114-1099, or call (800) 729-3300 or (617) 589-0437.

The commission supports the recommendations in BIO-MAINE '93, which in its final report notes "...that if Maine's fledgling biotechnology/life science industry is to develop, a sustained, well coordinated, statewide "K-20+" science-education/training strategy must be established."

PUBLIC PERCEPTION ISSUES IN BIOTECHNOLOGY

An overview

The recent introduction and debate in Maine surrounding BST milk (bovine somatotropin injections to increase milk production in cattle) as well as the labeling of genetically engineered foods, has demonstrated the increasing interest of the public to biotechnology applications.

> *The Commission firmly believes that policy makers must accept and involve the public as a legitimate partner in the biotechnology debate.*

In this section of the report the commission identifies specific issues that concern the public by reviewing the numerous articles, focus groups and surveys that have been conducted in the past 10 years.

Biotechnology has already had a significant impact on food production and processing, with exponential growth expected. While many of the underlying issues have been discussed throughout the report, there remain many unanswered questions from the perspective of the public. The public remains concerned, in spite of the economic, social, and environmental benefits, about the safety and ethics of biotechnology, including concerns about whether government is able to adequately regulate biotechnology now or in the future. The commission recognizes that it is the consumers who will in the end make the final decisions about the acceptability of foods produced through biotechnology. Educational efforts are needed to facilitate public understanding of the variety of applications and issues associated with agricultural biotechnology so they can make informed decisions.

in the last 5 years, Several studies have been conducted attempting to quantify and articulate the public perceptions of biotechnology. One study conducted in conjunction with the Extension Service of the U.S. Department of Agriculture surveyed more than 1200 adults as to their awareness, interest and attitudes about the use of biotechnology in agriculture and food production. Their findings were consistent with similar studies conducted in New Jersey, the UK and Australia[41]

USDA Study

The USDA study first looked at the issue of science generally, questioning participants about their views on science and technology, concern for the environment, and the role of citizens in technology and the environment. The study found that participants had positive views about the effects of science and technology on their own lives and on society in general, although there were concerns about negative consequences. Most participants had strong feelings about

[41]Hubard, Thomas and Kendall, Patricia. "*Consumer Attitudes about the Use of Biotechnology Agriculture and Food Production*", Project Summary to the Extension Services - USDA, July 1993.

the importance of the natural environment and noted considerable concern for environmental pollution and were as a whole supportive of environmental protection efforts. Finally, most believed that citizens must play a greater role in decisions about science and technology, but many acknowledged such decisions are best left to the experts. Participants were divided in their confidence that government can protect them from environmental risks.

In addition, the USDA study further questioned participants attitudes about biotechnology, noting the following:

- There was a limited awareness of the use of biotechnology in agriculture and food production.
- Awareness of traditional agricultural practices to improve plants and animals (such as cross-breeding) was as low as awareness about biotechnology.
- About two-thirds expressed positive attitudes about the general use of biotechnology in agriculture and food production, including greater government support for research.
- Most felt biotechnology will have a positive effect on food quality, nutrition, the environment, and farmers' economic conditions. Most agreed that biotechnology will personally benefit them in the next five years.
- The use of biotechnology to change plants was considered much more acceptable than its use with animals.
- Uses of biotechnology considered unimportant, such as creation of larger sport fish, were less well received than uses perceived to have direct consumer benefit (for example, improved taste) or societal value (for example, insect resistant plants).
- Dramatic transgenic applications of biotechnology, such as the insertion of animal genes into plants, were acceptable to many consumers. They cited food safety, ethical, and emotional concerns. Moral and ethical concerns were particularly important for a number of people, especially as related to animal biotechnology.
- Many consumers expressed concern about the potential for long-term and unknown negative impacts of biotechnology. In particular, this resulted in strong feelings among participants that potential environmental and food safety risks must be adequately addressed through testing and regulation. [42]

A closer look at the labeling issue: the public perspective

While the Commission has recommended earlier in the report that **any action on mandatory labeling of genetically engineered products occur at the Federal level**, it is worth highlighting a few key points from the USDA study concerning public perceptions on the issue of labeling.

[42] Id. at 4-6.

- **Importance of Labels.** The majority of survey participants said they paid considerable attention to package labels that describe food ingredients. Participants said they would use the information to make informed purchasing decisions. Participants expressed the desire for information on food labels about a variety of factors, including whether biotechnology has been used.

- **Types of Labeling Information Desired.** Focus group participants suggested that labels use standardized wording to indicate the use of biotechnology in product development or processing. They also wanted the label to include an address or toll-free number for more information.

- **Level of Detail.** Most did not want details about the biotechnology processes used to develop the foods. When asked about the need to label cheese made with rennin that had been derived using biotechnology (instead of traditional means), most focus group participants indicated that labeling could be overdone.

- **Labeling Cost.** Some focus group participants indicated willingness to pay a little more for label information, but most perceived it as information that companies should already have and it therefore should not cost much to add the label. They were not aware of the added cost of labeling and inventory control. Most felt that whatever costs are involved should be borne by the company.[43]

Public wishes to be better informed

One common theme throughout the different studies, and consistent with testimony provided at Legislative public hearings in Maine on both rBST and the labeling issue is that consumers are interested in being better informed. However, simply providing the information may not be sufficient. As one study notes, there is a high level of skepticism among members of the public as to label information. Despite this concern, common themes are apparent in terms of the type of information consumers are interested in hearing.

A study on public perceptions conducted in conjunction with the National Biological Impact Assessment Program at Virginia Polytechnic Institute and the USDA reviewed more than 600 sources, consisting of surveys, newspapers and popular press magazines. These sources were examined to help ascertain common themes of public concern and perceptions about science, the environment and the potential impacts of biotechnology. The study noted that strong interest was expressed regarding public input into the decision-making process, although the mechanics of how participation should happen were not readily apparent. The authors noted that, "...the specific issue is best expressed as whether or not decisions about the use of genetically engineered products will be made with consideration for those people who will be most affected by outcomes, or will economics be the main criteria for decision-making." [44]

[43] Id. 6-7.

[44] King, Doug and Traynor, Patricia. "Public Perception Issues in Biotechnology", National Biological Impact Assessment Program at Virginia Polytechnic Institute

The Commission recommends that policymakers consider the following when deliberating on issues involving biotechnology and genetic engineering.

- *Public policy information, including who regulates and oversees the development and use of biotechnology, as well as how biotechnology is regulated.*
- *Information about the potential benefits and risks of using biotechnology, including effects on the environment and economy.*
- *Information on safety, including potential allergens, nutritional value, taste, cooking techniques, and storage properties.*
- *General information about the science behind the use of biotechnology.*[45]

[45] King and Traynor.

Appendix A

Resolve, Establishing the Commission to Study Biotechnology and Genetic Engineering

Emergency preamble. Whereas, Acts and resolves of the Legislature do not become effective until 90 days after adjournment unless enacted as emergencies; and

Whereas, this legislation establishes the Commission to Study Biotechnology and Genetic Engineering; and

Whereas, the commission is required to submit its report to the First Regular Session of the 117th Legislature by December 1, 1994; and

Whereas, in order for the appointments to be made, the commission to be convened and the report to be submitted in a timely fashion, this legislation must take effect immediately; and

Whereas, in the judgment of the Legislature, these facts create an emergency within the meaning of the Constitution of Maine and require the following legislation as immediately necessary for the preservation of the public peace, health and safety; now, therefore, be it

Sec. 1. Commission established. Resolved: That the Commission to Study Biotechnology and Genetic Engineering, referred to in this resolve as the "commission," is established; and be it further

Sec. 2. Membership. Resolved: That the commission consists of 15 members appointed as follows:

1. Two Legislators, appointed jointly by the President of the Senate and the Speaker of the House of Representatives;

2. Four representatives of industry, including one person who has practical experience in and knowledge of agricultural procedures, one person who represents the food processing industry, one person who represents the biotechnology industry and one person who represents the marine fisheries industry;

3. Four representatives from the academic community, including one economist who has practical experience and knowledge of natural resources, one ethicist, one environmental scientist with knowledge of biotechnology and genetic engineering issues and one public health professional;

4. Four representatives from the public, including one person who represents a nonprofit consumer advocacy organization, one person who represents a nonprofit public interest environmental organization, one person who represents the general public and one person who is an organic farmer; and

5. The President of the Maine Science and Technology Foundation, who is an ex officio member.

All members of the commission, with the exception of the President of the Maine Science and Technology Foundation and the Legislators, are appointed jointly by the Governor, the President of the Senate and the Speaker of the House of Representatives. The committee shall at its first meeting select 2 members to serve as cochairs; and be it further

Sec. 3. Appointments. Resolved: That all appointments must be made no later than 30 days following the effective date of this resolve. The appointment authorities shall notify the Executive Director of the Legislative Council upon making their appointments. When the appointment of all members is complete, the chair of the Legislative Council shall call and convene the first meeting of the commission no later than August 15, 1994; and be it further

Sec. 4. Duties. Resolved: That the commission shall study and make recommendations on the role of State Government in the oversight of biotechnology and genetic engineering. In examining these issues, the commission shall review the existing Commission on Biotechnology and Genetic Engineering established in the Maine Revised Statutes, Title 7, chapter 8-C and also do the following:

1. Identify and review existing state statutes that provide authority for regulating products and activities, including statutes governing food and agriculture, health and safety, confidential business information and the environment;

2. Advise the legislative and executive branches, including regulatory agencies, on the adequacy of existing state and federal oversight frameworks and recommend needed action at state and federal levels;

3. Assess the adequacy of communication pathways among responsible state agencies, federal agencies and local communities and recommend a strategy for informing local community policymakers of state and federal oversight frameworks and the roles of local government in making regulations concerning biotechnology and genetic engineering and in communicating with the public on these issues;

4. Consider mechanisms for effective public involvement in the oversight process;

5. Consider mechanisms by which risks and benefits, including social or economic consequences, to the public and the environment created by the use of biotechnology and genetic engineering products and waste products may be evaluated;

6. Consider the role of research in the public sector and the need for oversight of research involving state resources; and

7. Include the public, outside experts, state agencies and businesses in the State involved in biotechnology and genetic engineering in the commission's deliberations; and be it further

Sec. 5. Staff assistance. Resolved: That the commission shall request staffing and clerical assistance from the Legislative Council; and be it further

Sec. 6. Reimbursement. Resolved: That the commission members who are Legislators are entitled to receive the legislative per diem, as defined in the Maine Revised Statutes, Title 3, section 2, for each day's attendance at meeting of the commission. All members of the commission are entitled to reimbursement for travel and other necessary expenses upon application to the Legislative Council. The Executive Director of the Legislative Council shall administer the commission's budget; and be it further

Sec. 7. Report. Resolved: That the commission shall submit its report with any accompanying legislation to the First Regular Session of the 117th Legislature by December 1, 1994; and be it further

Sec. 8. Appropriation. Resolved: That the following funds are appropriated from the General Fund to carry out the purposes of this resolve.

	1993-94	1994-95
LEGISLATURE		
Commission to Study Biotechnology and Genetic Engineering		
Personal Services	$200	$660
All other	1,500	5,000
Provides funds to the Commission to Study Biotechnology and Genetic Engineering for the per diem of legislative members, expenses of all members and miscellaneous commission expenses.		
LEGISLATURE TOTAL	$1,720	$5,660

Emergency clause. In view of the emergency cited in the preamble, this resolve takes effect when approved.

Appendix B

MAINE ACADEMY OF SCIENCES AND ENGINEERING CONCEPT

Purpose: To provide, upon request, the Maine State Legislature, the Executive Branch, and private organizations guidance on technical and social matters of science, engineering, and human and environmental health; and to promote Maine's scientific communities.

Organization: State-chartered not-for-profit subsidiary of the Maine Science and Technology Foundation.

Membership: Members will be distinguished social and natural scientists, engineers, humanists working or living in Maine and who are dedicated to the furtherance of science, engineering, and health and their use for the general welfare. Members will be elected by peers from the academic, industrial, state government, and institutional communities in Maine. Membership may include out-of-state distinguished scholars where appropriate.

Governance: Council and Executive Committee of the Council elected from membership.

Standing Technical Committees: The committees will be organized to relate the expertise of members to the public policy needs of the people and to Maine State Government. (e.g., Transportation and Communications; Energy; Agriculture, Food and Nutrition; Land and Water; Economic Development; and Marine Environment).

Staff: Executive Director and secretary. Office to be co-located at the Maine Science and Technology Foundation in Augusta.

Funding: New state appropriations ($120K - $150K annually) via the Maine Science and Technology Foundation to cover administrative costs. Funding for studies will be provided by requester. Private contributions will also be accepted.

THE STUDY PROCESS

Examples of specific activities:

- undertake studies of scientific or technical problems and associated-social and ethical implications related to public policy issues
- evaluate the scientific and technical content of reports and studies by others
- answer technical questions
- provide or suggest resource persons in Maine or elsewhere
- evaluate or design research and associated social and ethical issues related to public policy issues
- brief state officials on the impact on public policy of new scientific or technological developments

Study Requests: Initiated by the Legislature, state agency, and private organizations. Requests are made directly to the Academy.

Approval of Requests: Academy's Council will discuss and approve or deny a request and provide justification to requester. This decision would conclude a negotiation phase between the Academy and the requester on the nature of the subject, the actual question(s) to be asked of the Academy, and whether the Academy has the resources and expertise to assist.

Committee Selection and Meetings: Once approved the study will be assigned to the appropriate standing committee which is well balanced, free from conflict of interest and can provide the range of expertise required.

Oversight and Report Review. The Academy's Council will oversee the study process to ensure its integrity. Reports are released to the requester and the public only after outside reviewers, anonymous to the committee that prepared the report, agree that the findings are fully supported by the evidence presented.

STEPS AND TIMELINE

(December 1995 - January 1998)

December 1995 - January 1996: Initial meetings with key members of Maine's scientific communities. Purpose is to ensure buy-in into concept before taking next steps with Maine's scientific communities. This group will flesh out the concept more and add organization and structure to the concept. Members of the group will also be key organizers and possibly facilitators of focus groups discussions.

February 1996 - June 1996: organize and conduct a series of focus group discussions with Maine's scientific communities academic, industrial and institutional organizations in different parts of Maine to generate interest and buy-in.

July 1996 - August 1996: Draft legislation to create the Academy. Legislation may include charter members.

September 1996: Submit appropriation as part of the Foundation's biennial budget request.

January 1997 - February 1997: Introduction of legislation

July 1, 1997: Effective date of legislation (earlier if emergency)

July 1997 - December 1997: Startup

January 1998: Operational

NOTE: The timeline could be shortened by 6-months if the legislation is introduced under emergency provisions and enacted by January or February 1997.

Appendix C
Glossary

Agrobacterium: A natural bacterium that can be used to transfer DNA genes into broadleaf plants, such as tobacco, tomato, or soybean.

Biotechnology: Development of products by a biological process. Production may be carried out by using intact organisms, such as yeasts and bacteria, or by using natural substances (e.g., enzymes) from organisms.

Bovine somatotropin: (also called bovine growth hormone) A hormone secreted by the bovine pituitary gland. It has been used to increase milk production by improving the feed efficiency in dairy cattle.

Chromosome: A cellular structure comprised of a long, folded DNA molecule and protein.

Deoxyribonucleic acid (DNA): The molecule that carries the genetic information for most living systems. The DNA molecule consists of four bases (adenine, cytosine, guanine, and thymine) and a sugar-phosphate backbone, arranged in two connected strands to form a double helix. See also Complementary DNA; Double helix; Recombinant DNA.

DNA: Deoxyribonucleic acid, the substance within cells that carries the "recipe" for the organism and is inherited by offspring from parents.

DNA fingerprinting: Cutting a DNA chromosome with restriction enzymes and separating the pieces by electrophoresis to generate a unique pattern, the "fingerprint" for each species, breed, hybrid, or individual, depending on which enzymes and probes are used.

Electrophoresis: A lab technique for determining DNA fragment sizes by separating them in a gel placed in an electric field.

Electroporation: Using an electric shock to transfer DNA into the cells of an organism; one of several procedures called transformation.

Enzyme: A protein catalyst that facilitates specific chemical or metabolic reactions necessary for cell growth and reproduction.

Expression: In genetics, manifestation of a characteristic that is specified by a gene. With hereditary diseases, for example, a person can carry the gene for the disease but not actually have the disease. In this case, the gene is present but not expressed. In industrial biotechnology, the term is often used to mean the production of a protein by a gene that has been inserted into a new host organism.

Gene: A functional unit of DNA, one "word" in the DNA recipe.

Gene: A segment of chromosome. Some genes direct the syntheses of proteins, while others have regulatory functions. See also Operator g.; Regulatory g.; Structural g.; Suppressor g.

Genetic code: The information contained in DNA molecules that scientists describe on the basis of a 4-letter alphabet (A, C, G, and T).

Genetic engineering: The process of transferring DNA from one organism into another that results in a genetic modification; the production of a transgenic organism.

Genetic engineering: A technology used to alter the genetic material of living cells in order to make them capable of producing new substances or performing new functions.

Genetic map: The locations of specific genes along a chromosome marked with probes.

Genome: The entire DNA "recipe" for an organism, found in every cell of that organism.

Mutation: A change of one of the "letters" in the DNA "recipe" caused by chemicals, ultraviolet light, X-rays, or natural processes.

Operator gene: A region of the chromosome, adjacent to the operon, where a repressor protein binds to prevent transcription of the operon.

Particle gun: A gun that shoots DNA into the cells of an organism; the most versatile of a series of procedures called transformation.

PCR: Polymerase chain reaction, which rapidly duplicates specific DNA molecules in response to temperature changes in a computer-controlled heater.

Plasmid: A small, circular DNA that is used to transfer genes from one organism into another.

Probe: A very short piece of DNA used to find a specific sequence of "letters" in a very long piece of DNA from a chromosome or genome.

Recombinant DNA: DNA formed by joining pieces of DNA from two or more organisms.

RFLP: Restriction fragment length polymorphism, which describes the patterns of different (polymorphism) sizes of DNA (fragment length) that result from cutting with restriction enzymes (restriction). See DNA fingerprinting above.

Regulatory gene: A gene that acts to control the protein-synthesizing activity of other genes.

Structural gene: A gene that codes for a protein, such as an enzyme.

Suppressor gene: A gene that can reverse the effect of a mutation in other genes.

Transgenic organism: An organism formed by the insertion of foreign genetic material into the germ lime cells of organisms. Recombinant DNA techniques are commonly used to produce transgenic organisms.