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MARINE BIOTECHNOLOGY:
A PROPOSAL FOR REGULATORY REFORM

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Abstract

Biotechnology companies are developing transgenic fish, shellfish, and microorganisms to supplement conventional marine aquaculture and aid in the bioremediation of polluted coastal waters. These products may be ready for open-environment field trials or commercial applications within two to four years. Regulatory authority in the field of marine biotechnology is poorly defined and ill prepared, however, and the science base presently available is not adequate to support credible ecological risk assessment of genetically engineered marine organisms.

In response, I offer two specific public policy recommendations: one, an accelerated program of basic and applied research in marine ecology underwritten by a combination of government and private funds; and, two, the creation of a dedicated unit within the National Marine Fisheries Service responsible for regulatory oversight of transgenic marine organisms. If implemented, these reforms will encourage development in the marine biotechnology industry while laying the groundwork for appropriate ecological risk assessment and management.

I. Introduction

Biotechnology companies are developing transgenic fish, shellfish, and microorganisms to supplement conventional marine aquaculture (mariculture) and aid in the bioremediation of polluted coastal waters. This poses a two-fold challenge for which government officials are unprepared. As presently configured, regulatory agencies are unable to (1) appropriately assess and manage the threat to natural marine ecosystems presented by genetically engineered organisms (GEOs) or (2) provide the consistent, standardized oversight of product development required to foster private sector economic advancement in marine biotechnology.

If policy changes are not implemented, society faces the dual risk of having ecologically dangerous products approved or having development of safe and beneficial products discouraged. In this paper, after examining both issues, I offer specific recommendations that would improve the knowledge base in marine ecology and lay the groundwork for effective regulatory oversight.

II. Marine Biotechnology and Ecological Risk

Populations of terrestrial organisms subject to modern genetic engineering, both plants and animals, are largely domesticated and therefore dependent upon human mediation for survival. As a result, the probability that viable, fugitive populations will become established in the wild and directly alter natural ecosystems is limited. In fact,

transgenic organisms have been used in agricultural and pharmaceutical applications over the course of the past decade without significant negative environmental impact being observed (Levin, 1998).

This does not mean, however, that open-environment applications of terrestrial GEOs are without risk; indirect ecological effects may be expected. For example, insects may evolve in response to induced pest resistance in agricultural crops, and native weeds may acquire herbicide resistance through hybridization with related crop plants modified to express this trait (Snow and Moran-Palma, 1997). Ecological and evolutionary responses may then lead to a series of changes in the population dynamics of predators, parasites, and competitors of affected organisms. Such secondary and tertiary effects may ultimately alter community structure by reducing or enhancing the fitness of a variety of species. The implications of these more subtle and indirect impacts are difficult to assess through experimental trials and may take years or even decades to manifest themselves.

Marine GEOs, through a combination of direct and indirect effects, have the potential to cause broader and more obvious ecological disturbance. Compared with species used in agriculture, marine GEOs will be more difficult to contain, and most will retain their natural survival skills (Gutrich and Whiteman, 1998). In particular, marine microorganisms likely to be modified to enhance bioremediation capabilities cannot be field tested without a high probability of escape. Genetically engineered fish will also be difficult to isolate from environmental interactions, as mariculture pens will be subject to damage resulting from violent ocean weather and attacks by powerful marine predators (Christensen, 1997). Since some accidental release is virtually certain, regulators in the United Kingdom have stated that applications to introduce genetically engineered fish

into mariculture facilities must be assessed as if the intent were actually to release organisms directly into the natural environment (MacKensie, 1996). Finally, the effects of escapes may not be localized; many marine organisms use long-distance dispersal mechanisms that allow them to establish populations in widely separated regions of the oceans they inhabit (Gutrich and Whiteman, 1998).

The likely effects of escapes are hard to predict (de la Fuente, 1998). No experimental evidence specifically relating to marine GEOs exists to provide direct support for any conclusions about the potential for ecological damage. At present, the only source of information is indirect: the historical record of the effects of exotic species introductions (Levin, 1998).

Generally, non-native species introduced into new environments, either intentionally or accidentally, do not survive (Holdgate, 1986). Those that do, however, can cause dramatic and widespread disturbance. Biological invasions threaten native species, disrupt ecosystem functioning, and generate substantial economic losses (Wilcove et al., 1998). The zebra mussel (introduced accidentally as transoceanic ships cleared ballast water) is outcompeting native shellfish and clogging up industrial inflow and outflow pipes throughout the Great Lakes basin; the brown tree snake (transported inadvertently in cargo containers from the Philippines) is decimating indigenous bird populations in Guam; and the melaleuca tree (brought from Australia and intentionally seeded in the Everglades in the 1930s) is overgrowing the “river of grass” at the rate of fifty acres per day (Begley, 1998). If safety features applied to the products of marine biotechnology fail, it is possible that escaped GEOs could cause similar unacceptable levels of ecological disturbance.

The principal risk management strategies designed to prevent disruption of natural ecosystems by marine GEOs depend on strict physical and biological containment. These efforts may reduce but will not eliminate the risk of ecological disturbance, however. As mentioned above, experience with physical containment in hatcheries and conventional mariculture pens demonstrates that occasional escapes are inevitable (Christensen, 1997). The effectiveness of biological containment methods also cannot be guaranteed; for example, laboratory studies have indicated failure rates of up to 3% for induced sterility (e.g., triploidy or tetraploidy) in transgenic fish and shellfish (USDA Agricultural Biotechnology Research Advisory Committee, 1995).

Therefore, some ecological disturbance is certain to result from commercial applications of marine biotechnology. More precise characterization of the nature and extent of the risk will have to wait until an application is made to introduce a specific organism into a particular environment. At that time, regulators will formally evaluate the likely impact of genetic manipulation on the life history, fecundity, and fitness of the test organism. Ultimately, however, since micro- and mesocosm studies can never fully replicate natural ecosystem dynamics, we may have to depend on ecological assessments conducted after the fact for a full accounting of the effects of an introduction.

III. Marine Biotechnology and Economic Development

The first agricultural biotechnology product was field tested in 1986 (Fowle, 1987). Since then over two thousand pharmaceutical and agricultural GEOs have been developed. While many of these products are still experimental, others are being applied on a commercial scale. To date, the economic results have been mixed. Some uses of

biotechnology are financially successful, insulin production by genetically modified *E. coli*, for example, while others have not yet realized expectations, such as tomatoes modified to have a longer shelf life. Nevertheless, there are promising indications of economic viability for many agricultural and pharmaceutical applications, and research and development are continuing at a rapid pace.

The first successful gene transfer in a marine organism also occurred in 1986 (Levin, 1998). Scientists isolated the segment of DNA that codes for expression of growth hormone production in rainbow trout and transferred it into the common carp. The result was a fish that grew faster and reached a larger size than its unaltered siblings. However, marine biotechnology has been much slower to develop marketable products. In the dozen years since the efficacy of the technology was first demonstrated, not one genetically engineered mariculture or bioremediation application has been approved for widespread use.

The reasons for this discrepancy are not hard to divine. First, agriculture and pharmaceuticals are multibillion-dollar segments of our national economy, so the level of investment available for research and development is greater by orders of magnitude. Second, for cultural reasons, consumer wariness relating to biotechnology may be less of a concern in the case of synthetic insulin or disease-resistant soybean plants, for example, than for giantism in genetically altered fish. Nevertheless, it is likely that within the next two to four years some marine biotechnology products will be ready for the marketplace—strains of genetically engineered salmon, in particular, show early promise (MacKensie, 1996; Hite and Gutrich, 1998).

During development, marine GEOs are subject to oversight by government agencies, and outlays associated with regulatory review may affect the economic viability of some companies. Costs to industry of regulatory compliance are difficult to predict. Protocols that will apply have not been established, nor is it clear which offices in which agencies will exercise federal, state, and local oversight authority. It is possible that a firm may have to comply separately with nonstandardized procedures administered by various agencies with differing agendas, levels of expertise, and institutional cultures.

Despite these uncertainties, some general observations can be presented. First, because the potential for direct impact on human health from biotechnology-based mariculture or bioremediation is likely to be relatively small (de la Fuente, 1998), firms developing such products will not have to meet costs borne by companies attempting to introduce new pesticides or food additives (Matheson, 1997). Satisfying regulatory requirements for such products can take several years and cost several million dollars (Shapiro, 1990). In contrast, ascertaining that transgenic fish and shellfish are safe for human consumption, and receiving agency approval for production and marketing based on this criterion, may have associated compliance costs that are modest by comparison, perhaps \$50,000 or less (Matheson, 1997). This is because characteristics induced by inserting foreign genes—more rapid growth or disease resistance, for example—are unlikely to affect food-safety qualities of products derived from modified fish or shellfish (de la Fuente, 1998; Matheson, 1997).

Companies may find that significantly larger expenditures are required to bolster the inadequate science base presently available to regulators attempting to estimate ecological risk. Private companies, particularly those first in line with products requiring

approval, may have to fund their own research in marine ecology and the effects of genetic manipulation on morphology, life history, and fitness to provide data to support their applications. This may pose a substantial burden to small businesses. When added to in-house research and development costs, and outlays for public relations and advertising that marketing such products to a wary public will demand, it is clear that private development of marine biotechnology products is a capital-intensive undertaking.

IV. Recommendations

A. Research

Basic research is necessary to serve as a foundation for credible ecological risk assessment (von Schomberg, 1996). Unfortunately, support for research related to transgenic organisms is being reduced, not expanded. The program for biotechnology risk assessment at the Environmental Protection Agency (EPA) has been terminated, and the equivalent program at the United States Department of Agriculture (USDA) has seen its funding decline. In addition, agencies involved in policy analysis associated with biotechnology have also suffered cutbacks. Both the Congressional Office of Technology Assessment and the USDA Agricultural Biotechnology Research Advisory Committee (ABRAC) have been defunded (Krimsky, 1996).

This trend should be reversed. Research and development efforts to create products for commercial exploitation need to be matched with concomitant studies to investigate marine ecology and the impact of GEOs on natural ecosystems. These studies would provide regulators with data they need to make informed decisions to protect the environment without unnecessarily curtailing economic development when products

come up for review. Such research would serve the interests of both the marine biotechnology industry and the nation as a whole.

Among general issues that need to be investigated are (1) the microbial ecology of aquaculture systems, (2) biotic and abiotic factors that affect fishery populations, and (3) the impact of non-native species on marine ecosystems (Balint et al., 1998). Studies of these issues, which have implications for risk assessment relating to marine GEOs but also have wider value, should be supported by public funding. Industry should pay for targeted research on such matters as (1) factors influencing the reversion to reproductive status from induced sterility in marine GEOs, (2) the potential for life history shifts due to transgenic manipulation, and (3) potential interactions between the specific organisms being developed and the environments into which they may be introduced. As results come in from these two lines of inquiry, new questions will be raised that will determine the direction for further research.

B. Regulatory Oversight

1. Background

The weakness of the present regulatory structure stems from three associated problems. First, oversight authority for genetically engineered marine organisms is not centralized in one agency. Second, no mandated, standardized protocols are in place to oversee these products as they are developed for commercial applications. Third, environmental concerns are only accorded secondary consideration—each agency gives primary consideration to its own area of statutory responsibility, e.g., human health or food safety (Miller and Matheson, 1996).

Genetically engineered microorganisms presently fall under the jurisdiction of the EPA by virtue of authority granted by the Toxic Substances Control Act. The Center for Veterinary Medicine (CVM) at the Food and Drug Administration (FDA) oversees the development of transgenic fish designed for mariculture under the aegis of the Federal Food, Drug and Cosmetic Act (Levin, 1998). This is an administrative anomaly; one would expect USDA, not FDA, to regulate biotechnology products created for marine aquaculture since USDA oversees conventional fish farming. The present situation arose because introduced transgenes that express growth hormone production are judged to be equivalent for regulatory purposes to growth hormones administered in a conventional fashion. In both cases, according to this approach, a hormone is being administered to an animal (Matheson, 1997). Delegating regulatory authority to CVM may be appropriate from the standpoint of ensuring the safety of an animal drug. For the purposes of assessing and managing ecological risk, however, this office does not have the necessary resources or expertise (Matheson, 1997).

Under the present system, ecological risk assessment is conducted by the agency with primary jurisdiction in each case. EPA evaluates ecological risk for transgenic marine microorganisms, and FDA assesses ecological risk for genetically engineered fish and shellfish. To further complicate matters, the procedures employed by the various agencies are not standardized. FDA follows guidelines promulgated by ABRAC to oversee development of transgenic fish. EPA uses its Points to Consider document to evaluate genetically engineered microorganisms.

These two risk assessment protocols are quite different. The ABRAC documents, published in 1995 just before the council was defunded, provide a pathway of over

twenty flowcharts and worksheets designed to be followed to ensure safety and security during research and development of genetically engineered aquaculture products (USDA Agricultural Biotechnology Research Advisory Committee, 1995). In contrast, EPA's Points to Consider document lays out a more general framework of basic questions that need to be asked to determine the level of scrutiny to be applied in each particular case (U.S. Environmental Protection Agency, 1997).

From an ecological standpoint, both of these risk assessment methodologies are handicapped by two fundamental weaknesses: basic scientific information is lacking, and the agencies in charge do not give ecological risk primary consideration. To correct the former, as indicated above, more basic research needs to be undertaken. To correct the latter, responsibility for ecological risk assessment should be separated from human health, food safety, or animal drug concerns.

2. Proposal for Reform

I recommend that a dedicated unit responsible for regulatory oversight of marine biotechnology be established at the National Marine Fisheries Service (NMFS), a branch of the National Oceanic and Atmospheric Administration in the Department of Commerce. NMFS is the appropriate agency for this task because it was created to "conserve and manage living marine resources" (U.S. National Marine Fisheries Service, 1997).

Statutory authority for this unit can be derived from the following legislation: (1) the National Invasive Species Act (NISA) of 1996 (the reauthorization and expansion of the Nonindigenous Aquatic Nuisance and Control Act of 1990); (2) the Lacey Act of

1900 and its subsequent amendments; (3) the Endangered Species Act (ESA) of 1973; and (4) the Magnuson-Stevens Fisheries Conservation and Management Act (enacted in its original version in 1976).

The precursor to NISA was originally promulgated as a response to the zebra mussel invasion of the Great Lakes region; the 1996 reauthorization extends coverage of the act to include all U.S. territorial waters. One component of the Lacey Act is to prevent the spread of animals that may harm any wildlife resources of the United States. ESA is designed to halt actions that imperil endangered species and their habitats. The Magnuson-Stevens Act is intended to manage marine fisheries. Even though none of these laws specifically mentions GEOs, the products of biotechnology can be regulated under authority granted by these statutes as potential nuisance species and as potential threats to natural fisheries and endangered marine organisms (Stenquist, 1998).

This proposed unit of NMFS will be staffed by personnel knowledgeable and experienced in marine ecology and marine biotechnology, with the authority to call upon outside experts as necessary. Close coordination with the Fish and Wildlife Service, a branch of the Department of the Interior, will be required. This new NMFS unit need not be large since to date only a few companies are developing marine biotechnology products. (A staff of two scientists at CVM is responsible for overseeing transgenic fish and shellfish under the current regulatory configuration.) As the marine biotechnology industry grows, the proposed NMFS unit can be expanded.

Up to this point I have focused on federal action. The national government, of course, has an interest in all territorial waters of the United States and has authority over activities conducted in the Exclusive Economic Zone beyond the twelve-mile limit.

Inside that demarcation, however, regional, state, and local agencies may also exercise oversight responsibility. The Magnuson-Stevens Act, for example, empowers eight Regional Fishery Councils to oversee the management and conservation of coastal fishing grounds.

Federal and state agencies often do not have standardized procedures and do not cooperate efficiently. In addition, many seaboard states that may have an interest in regulating commercial enterprises in their waters that are related to biotechnology are not prepared to undertake such supervision. They have not enacted the requisite statutes and do not have the appropriate expertise (Stenquist, 1998). Dialogue must begin now if various levels of government are to develop a coordinated statutory and regulatory response to issues raised by marine biotechnology.

Policymakers must not overlook international implications. For economic reasons pertaining to global competitive standing, and for ecological reasons relating to the dispersal characteristics and life history traits of marine organisms, the strengthening of multilateral agreements—such as the Convention on Biological Diversity negotiated in conjunction with the 1992 United Nations Conference on Environment and Development in Rio de Janeiro—will be an important component of any effort to manage risk in a comprehensive manner. Developed nations need to standardize their responses to the products of marine biotechnology, and developing nations need to be encouraged not to compromise environmental safety in their efforts to attract private investment.

The creation of a unit at NMFS dedicated to assessing and managing ecological risks associated with marine biotechnology will facilitate domestic and international

coordination. Other jurisdictions will have a model they can follow and a resource they can call upon to improve their levels of preparedness.

V. An Overview of Costs and Benefits Associated with the Recommendations

To maximize economic benefits and minimize ecological risks associated with marine biotechnology, I have outlined a proposal for regulatory reorganization and accelerated basic research. The former will require public funds; the latter, both public and private outlays.

A. Costs

Since no additional legislation will be required and no new executive branch agency will be created, expenses associated with the proposed regulatory realignment will be relatively minor. I estimate that the small staff initially required, perhaps three to four scientists along with necessary office space and administrative support, will cost perhaps \$500,000 a year. A percentage of this funding could be covered by reallocating resources from offices at EPA and FDA now responsible for overseeing marine biotechnology.

A program to fill in gaps in the science base will be more costly. If an average study has a yearly budget of approximately \$100,000, annual expenditures of \$2 million would support twenty such projects. As outlined above, I recommend that these costs be shared between the public and private sectors. In sum, I estimate that implementation of the two recommendations will have a total annual cost of approximately \$2.5 million.

B. Benefits

Benefits are harder to quantify, but are likely to outweigh costs both in direct positive results and in negative outcomes avoided.

First, the research will generate a substantial return on investment reaching beyond issues associated specifically with marine biotechnology. The knowledge acquired will have application to management of natural fisheries, protection of endangered marine species, abatement of coastal pollution, and productivity improvement in conventional mariculture.

Second, rationalized and streamlined regulatory oversight will facilitate development of the domestic marine biotechnology industry and potentially enhance U.S. competitiveness. The market for farm-raised salmon in the United States is approximately \$375 million a year—\$75 million produced domestically and the remainder imported (USDA Economic Research Service, 1997). If genetically engineered salmon significantly improve the productivity of domestic salmon farms, American firms will capture a larger portion of the market. Similar gains may be possible in other segments of the mariculture and seafood industries.

Third, in addition to economic benefits associated with industrial expansion, enhanced mariculture productivity may reduce pressure on natural fish populations. While the global harvest from natural fisheries has declined over the past several years, total fish production has continued to climb because of increasing maricultural output. Worldwide, the percentage of total seafood consumption provided by fish farming has risen from 8% to 20% in the past decade (Hite and Gutrich, 1998). As aquacultural

productivity increases, natural fish populations may have a chance to rebound from the precipitous declines of recent years.

Fourth, improved risk assessment and management will reduce the likelihood that inappropriate introductions of marine GEOs will produce ecological and economic losses similar to those caused by damaging exotic species introductions. The power industry in the Great Lakes region currently spends approximately \$300 million annually to control zebra mussel infestations in water intake systems (Great Lakes Commission, 1996), and the \$40 million annual shellfish harvest in Puget Sound may be threatened by the Atlantic green crab, a non-native predator of juvenile shellfish (Begley, 1998). If one such invasion is prevented by enactment of the proposals outlined above, the nation will more than recoup the costs of regulatory reconfiguration and increased research.

VI. Conclusion

Five points underlie the recommendations presented in this report. One, marine biotechnology has the potential to create applications that will provide significant social benefits. Two, if transgenic fish, shellfish, and microorganisms are employed on a commercial scale, some ecological disturbance is inevitable. Three, the nature and extent of both the potential ecological risks and the potential economic and social benefits defy accurate prediction. Four, the science base presently available is not adequate to serve as a foundation for credible ecological risk assessment. Five, regulatory authority in the field of marine biotechnology is poorly defined and ill prepared.

The first three points demarcate the public policy dilemma. If risks are minor and benefits substantial, development in the industry should be promoted; if the converse is

true, development should be discouraged. The fourth and fifth points direct us toward an appropriate response: creation of a dedicated unit responsible for oversight of marine biotechnology and expansion of basic and applied research in marine ecology and mariculture. If these recommendations are enacted, we will maximize the opportunity to realize potential benefits and minimize the possibility of ecosystem disturbance at a level of public expenditure commensurate with these goals.

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