Public Policies Regulating the Use of Genetically-Modified Aquatic Organisms: Current and Future Needs Internationally

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Abstract
The development and use of genetically-modified organisms (GMOs) pose both economic benefits and environmental risks. To optimize the mix of benefits and risks, a number of countries and international organizations have implemented policies regulating activities with GMOs. The applicability of these policies to activities with aquatic GMOs is, however, limited. The United States, the Organization for Economic Cooperation and Development, and the Food and Agriculture Organization of the United Nations have initiated efforts to develop regulatory instruments specifically addressing concerns posed by development and use of aquatic GMOs. Additional scientific information and well directed public policies will be needed before the commercialization of aquatic GMOs can go forward with minimal environmental risk.

Introduction
Genetic improvement of aquatic species has long encompassed classical breeding practices, such as domestication, selection, crossbreeding, and hybridization. In recent years, breeding experiments involving aquatic organisms have come to encompass biotechnology-based techniques, such as chromosome set manipulation and gene transfer. The development and evaluation of genetically-modified aquatic organisms (aquatic GMOs) is a highly active area of research (Hallerman et al. 1990; Ihssen et al. 1990).

Biotechnology-based methods of genetic improvement pose important implications for aquaculture, fisheries management and conservation. Against the background of the potential benefits posed by aquatic GMOs and the ecological concerns posed by utilization of GMOs in the aquatic environment, the objectives of this study are:

> to review existing public policies regulating the development and use of aquatic GMOs, and

> to identify areas of concern that should be addressed through development of appropriate public policies.

Technical Background

- Benefits Posed by Genetically-Modified Aquatic Organisms

  » Chromosome set manipulation

Chromosome set manipulation of animal genomes involves suppression of normal
meiosis or mitosis to retain additional haploid sets of chromosomes, prevention of the genetic contribution of sperm or egg nuclei, or both. A large number of experiments have evaluated chromosomally-manipulated aquatic species for aquaculture, sport fishery or aquatic weed control purposes. Interest in the various types of chromosomally-manipulated aquatic species stems from their reproductive sterility, the possibility of rapid growth, eased production of interspecific hybrids, rapid production of inbred lines, and possible production of trophy fish (Thorgaard and Allen 1987; Ihssen et al. 1990).

To date, technical factors have limited the use of chromosome set manipulation of many species for aquaculture and fisheries management purposes. Studies of chromosome set manipulation have just recently emerged from the technical demonstration stage for a wide variety of species and treated groups of eggs have often been too small to commence field trials of performance (Thorgaard and Allen 1987). For example, whether adult triploids can provide trophy fish or more economical aquaculture production is still unclear, because results to date are inconsistent, especially among species (Ihssen et al. 1990). Still, some chromosome set manipulated aquatic organisms, such as triploid grass carp (Ctenopharyngodon idella) and Pacific oyster (Crassostrea gigas), have proven utility and are available commercially.

Gene transfer

To effect transfer of a gene, a recombinant DNA construct is introduced into recently fertilized eggs, usually through microinjection. Of animals developing from eggs so treated, generally 20% will have incorporated the introduced gene construct into their own chromosomal DNA. A large research and development effort has been focused on transgenic fish, with 14 species subject to gene transfer experimentation in 13 countries (Hallerman et al. 1990). Most work aimed at practical applications has addressed transfer of growth hormone genes for purposes of growth enhancement or of antifreeze polypeptides for freeze resistance. Development of genetic lines of fish bearing introduced genes is at an early stage. The first field tests of transgenic fishes are now underway in the United States (NBIAP 1992a), China (Perry Hackett, University of Minnesota, personal communication), Israel (Boaz Moav, Tel Aviv University, personal communication) and other countries. The results of field performance tests have not yet been published. However, data on performance in laboratory systems have indicated significantly improved growth rates among fish expressing introduced growth hormone genes and a minor degree of freezing point depression among fish expressing an introduced antifreeze polypeptide gene. Reliable quantitative estimates of the degree of performance enhancement should become available within the next two years.

In general, the potential of biotechnological means of genetic improvement for the enhancement of aquacultural productivity and profitability will become clearer over the next decade.

Concerns posed by genetically-manipulated aquatic organisms

Although the potential economic benefits posed by use of aquatic GMOs are clear, there is also a considerable likelihood that such organisms pose significant ecological impacts (Kapuscinski and Hallerman 1990a, 1991, Hallerman and Kapuscinski 1992a, 1992b, 1993; Gregory 1992). Many geneti-
Genetically-modified organisms are not greatly altered from the wild type, suggesting that were they to escape from confinement, they would be likely to persist, reproduce, and disperse. Because they express novel phenotypes, the entry of aquatic GMOs into natural ecosystems poses environmental impacts of unknown type and magnitude.

As the basis for ecological impacts of a GMO, neither the source of the transferred gene nor the presence or absence of a homologous gene in the host genome will prove important, but rather the type and magnitude of phenotypic alteration of the modified organism (Tiedje et al. 1989; Kapuscinski and Hallerman 1990). Although we cannot predict the full range of phenotypic or performance changes that might be expressed among GMOs, broad classes of phenotypic alterations that could give rise to ecological impacts include: (a) metabolic rates, (b) tolerances to physical factors, (c) behavior, (d) resource use, or (e) resistance to predators, parasites and pathogens. Predicting the types and magnitudes of phenotypic alterations consequent to transfer of a given gene is complicated by the possibility of several types of unintended and uncontrollable genetic effects. These effects include expression of the transgene outside the control of normal homeostatic mechanisms, novel pleiotropy and insertional mutagenesis. These possibilities refute the assertions of some molecular biologists that the phenotypic effects of transfers of particular, well-characterized genes can be predicted with confidence.

Different phenotypic alterations would be expected to form the basis for different mechanisms giving rise to ecological impacts. It is possible that GMOs might prove able to adapt to new ecological niches or to a wider range of ecosystems. Given the complex and poorly understood inter-relationships of organisms within natural ecosystems, it is difficult to predict the range of mechanisms by which altered phenotype among GMOs might perturb biological communities. Further, it is impossible to predict the long-term responses of conspecific populations or of biological communities to a perturbation, and whether such responses would jeopardize the self-perpetuation of community structure or function. Thus, consideration of the implications of release of a given GMO involves not only the salient qualities of the GMO, but also of the receiving ecosystem.

Should aquatic GMOs reproduce within natural systems, any ecological or genetic impacts that they pose would be perpetuated. In determining the extent of such impacts, the key issue is the fitness of such fish in natural systems. Key unknowns affect the reproductive success and viability of aquatic GMOs. The impacts of reproduction of aquatic GMOs on the viability of conspecific natural populations cannot now be anticipated.

Public Policies Regarding Genetically-Modified Organisms and GMOs

Given that risks are posed by release of GMOs with altered phenotypes into the environment, there follows a need for policies that will lead to realization of economic benefits while minimizing environmental risks. The perception that development of GMOs might pose risks to human health or to the environment led a number of governments and international institutions to promulgate guidelines regulating research and development of GMOs as a broad class. Al-
though several regulatory schemes explicitly concede that GMOs are not intrinsically dangerous (e.g., Office of Science and Technology Policy 1992), the continuing focus on GMOs is due to the limited experience with their application and the potential for the novel roles that they might play in the environment. The design of safety procedures for GMOs might prove useful for other classes of organisms, such as non-modified pathogens or non-indigenous species (Working Group I 1991).

Reviews of existing safety procedures, regulations and guidelines from various countries and international organizations (Working Group I 1991; Hallerman and Kapuscinski 1992b; Custers and Sterrenberg 1992) indicate many common features. Contained laboratory use of GMOs is regulated on the basis of the classification of risk categories and safety procedures that have evolved after 20 years of laboratory experience (Working Group I 1991). Releases of GMOs into the environment are reviewed on a case-by-case basis and conducted in a step-by-step manner, because, in general, there are insufficient data to permit classification of risk.

Although aquatic organisms present a unique collection of potentials and concerns, no nation or international institution has yet implemented public policies regulating the development and use of aquatic GMOs. In this section, biotechnology policies of key countries and international organizations are reviewed with regard to their applicability to aquatic GMOs.

- United States

To some degree, biotechnology policies adopted by the United States affect the subsequent development of biotechnology policies in other countries. A detailed description of U.S. biotechnology policies is, therefore, useful for purpose of this review.

Federal biotechnology policies in the United States are based upon the Coordinated Framework for the Regulation of Biotechnology (Office of Science and Technology Policy 1985, 1986). The Coordinated Framework is based on the premise that no special legislation is needed to regulate biotechnology, i.e., that through promulgation of new regulations, the scope of existing statutes could be extended to effectively cover concerns raised by the development and commercialization of GMOs. Several agencies were directed to promulgate the relevant regulations, notably, the U.S. Department of Agriculture (USDA) to cover multicellular GMOs and the Environmental Protection Agency (EPA) to cover microbial GMOs.

Under the terms of the Coordinated Framework, regulatory authority over development and release of aquatic GMOs is incomplete (Hallerman and Kapuscinski 1990a):

> At institutions receiving federal funding, compliance with guidelines specified by the Coordinated Framework is required. Among institutions not receiving federal funding, voluntary compliance with appropriate guidelines is merely expected, leaving the private sector effectively unregulated. Although little work with aquatic GMOs currently occurs in the private sector, the proportion will grow larger with time.

> USDA regulates GMOs using regulations promulgated under the Plant Pest Act (USDA-APHIS 1987), even for organisms that could not
conceivably be considered plant pests. Because aquatic GMOs do not come under the legislative purview of the Plant Pest Act, they are not subject to direct legislative authority (NBIAP 1992a).

> Because the Constitution did not specifically reserve the power for the federal government, the states have the authority to regulate activities affecting fishery resources within their borders. The federal government has regulatory authority over fisheries only on federal lands or for migratory species. Although charged with oversight responsibilities for multi-cellular GMOs under the Coordinated Framework, the USDA has no statutory authority over aquatic organisms.

> Because the Coordinated Framework utilized authorities granted under statutes regulating interstate commerce, the regulatory authority of USDA or EPA over work with GMOs within particular states was limited (Stern 1986; Fanning 1988).

> The Coordinated Framework was at best sketchy on regulations for administering outdoor releases of GMOs and provided only minimal direction for regulating the commercialization of GMOs.

The Office of Science and Technology Policy (1990) subsequently modified the Coordinated Framework by adopting the draft "Scope" document. "Scope" modified U.S. regulatory policy in two key ways. First, it declared that regulatory purview was to be based, not on the process by which an organism was modified (e.g., through gene transfer), but on the characteristics of the organism itself. However, using the modified phenotype as the criterion for regulation complicates the issue of what is regulated by the body of evolving public policy. Second, the Scope Document declared that regulation of the products of biotechnology would be risk-based. The degree of regulatory oversight would be a direct function of the risks that the product poses to human health or to the environment. Yet, the risks posed by fish expressing an introduced growth hormone gene, for example, cannot be quantified on the basis of present knowledge. The Office of Science and Technology Policy (1992) subsequently announced a final "Scope" policy on exercise of federal oversight of introductions of biotechnology products into the environment.

As required under the Coordinated Framework and following the direction of the draft Scope Document, federal agencies promulgate draft biotechnology guidelines, USDA for multicellular organisms and EPA for microbes. The USDA guidelines (USDA-CSRS 1991) are designed to be used as research aids to assess the risk posed by a given proposed release of a GMO and to set appropriate confinement levels for designing a protocol to minimize the risk.

The development of policies on the environmental release of aquatic GMOs has been conducted on an ad hoc basis, to a large degree driven by requests for environmental release permits. The first was a request by Rex Dunham of Auburn University to release transgenic common carp (Cyprinus carpio) into a facility at the university's Agricultural Experiment Station. Controversies surrounding the permit request centered on
the degree of confinement offered by the pond complex and on the lack of an explicit policy on environmental releases of aquatic organisms. The permit request was granted, but a second, more secure facility was also built. A subsequent request to release transgenic channel catfish (*Ictalurus punctatus*) in the new, state-of-the-art facility was handled more smoothly (NBIAP 1992a), although again, on an *ad hoc* basis.

Anticipating further requests for release permits, the USDA Office of Agricultural Biotechnology, through a working group under its Agricultural Biotechnology Research Advisory Committee (ABRAC), is working to develop performance standards for safely conducting research with genetically-modified fishes, molluscs and crustaceans. Development of the performance standards is ongoing, and the draft document should be ready for publication by late 1993.

- State biotechnology regulations

Because federal regulatory authority over activities within particular states is limited and because of the limited scope and slow pace of development of biotechnology regulations at the federal level, nine states have enacted legislation regulating biotechnology (Committee on Biotechnology 1990, Biotechnology Working Group 1993). Most of these regulatory instruments go beyond the provisions of the Coordinated Framework and subsequent federal regulations to address key loopholes or procedural ambiguities. However, none of these effectively address concerns unique to genetically-engineered aquatic organisms. Regulatory authorities in one state, Minnesota, have actively solicited the advice of fisheries professionals in order to address this shortcoming. Additionally, the author is working with aquatic resources management agencies in Virginia to develop guidelines for safe development and use of aquatic GMOs.

- Organization for Economic Cooperation and Development

The Organization for Economic Cooperation and Development (OECD) is a group of 25 industrialized nations. An *ad hoc* group of technical experts was commissioned by the OECD to identify scientific criteria for the safe use of recombinant DNA-bearing organisms in industry, agriculture and the environment. Their report (OECD 1986) influenced development of biotechnology policies worldwide, and proved an important step toward international harmonization of biotechnology regulation. However, neither the 1986 OECD report, nor a subsequent one (OECD 1992) offered guidance on safe development or field testing of aquatic GMOs.

At an OECD-sponsored symposium on Aquatic Biotechnology and Food Safety in June 1992, the need was recognized for additional study of a set of related problems. Hence, an OECD workshop on Environmental Impacts of Aquaculture Using Aquatic Organisms Derived Through Modern Biotechnology was held in June 1993 in Trondheim, Norway. The output of the workshop will be a state-of-the-art report on aquaculture biotechnology, which will identify gaps in knowledge and further needs for priority attention. The report will help define the work needed to promote the sustainable development and use of aquatic organisms derived through modern biotechnology.

- European Community and its member nations

The European Community (EC) is an organization of 12 countries aimed at achieving high level economic and political coopera-
tion. With the drive for political integration came the need to coordinate biotechnology policy among all the EC countries. Against the background of diverse existing biotechnology regulations among member countries, directives on regulations for contained use (90/219) and for deliberate release (90/220) of GMOs were adopted by the European Commission. The directives set out general regulatory guidelines, and member countries have some degree of discretion regarding how to implement the directives in national regulations. The respective countries are at different points in the process of adopting legislation and developing administrative procedures for regulating research and field release activities with GMOs (Custers and Sierrenberg 1992). Policies addressing concerns particular to aquatic GMOs have not yet been addressed at the national level.

- **United Nations**

The program of the United Nations Conference on Environment and Development (UNCED), held in Rio de Janeiro in June 1992, included a component on environmentally sound management of biotechnology. The Preparatory Committee for UNCED (Working Group I 1991) requested that the Secretary General of UNCED follow the work of relevant international organizations on safety in biotechnology, with a view to expediting the elaboration of basic guidelines and facilitating the preparation of an international Code of Conduct. The Committee also asked the Secretary General to prepare a report on the methods that could be used internationally to assess biotechnology risks to human health and the environment and the impact of biotechnology on socioeconomic conditions. A conceptual plan for an integrated program on the environmentally sound management of biotechnology was described, which included a component for freshwater and marine aquaculture.

The biotechnology policy so commissioned was adopted as Chapter 16 of Agenda 21 (UNCED 1992), a document committing signatory nations to strive for environmentally sustainable development, which was adopted at the UNCED. The program areas set out in Chapter 16 seek to foster application of internationally agreed principles to ensure the environmentally sound management of biotechnology to engender public trust and confidence, to promote the sustainable applications of biotechnology, and to establish appropriate enabling mechanisms for these purposes. Chapter 16 specifically stated that government and non-government entities should evaluate the use of various biotechnology techniques to improve the yields of fish, algal and aquatic species.

As the U.N. body concerned with agriculture, forestry and fisheries, the Food and Agriculture Organization (FAO) is the lead agency for implementing the broad mandates of Agenda 21 into specific programs. FAO is planning to produce a publication stating its policy on biotechnology (H. De Haen, UN-FAO, personal communication). The purpose of the publication is to inform policy makers, research managers and technology managers at national and international levels of FAO's perception and approach toward increasing national capabilities, especially of developing countries, for rational and balanced exploitation of biotechnology.

To support its efforts in this area, the Fishery Resources and Aquaculture Service of FAO has asked the author to produce a technical review of aspects of biotechnology as they relate to aquaculture, fisheries management
and conservation. Now in preparation, the review addresses the potential benefits and risks associated with development and use of aquatic GMOs and the policy options available regulating activities with aquatic GMOs. The document is intended for distribution to fisheries departments, field projects, FAO professionals and local and regional governments, who will be faced with policy decisions regarding application of biotechnology in the aquatic sector.

- Norway

It is expected that a legislative proposal regulating the use of GMOs will be acted upon by the national assembly during the spring 1993 session (Jarle Mork, Trondheim Biological Station, personal communication). The purpose of the proposed Norwegian Law for Development and Use of Genetically-Modified Organisms is to ensure that production and use of genetically-modified organisms will be carried out in an ethically and socially proper manner in accordance with the principle of sustainable development and without health or environmental damage (Helge Klungland, Agricultural University of Norway, personal communication). The proposition is very similar to the EC and OECD directives, although it emphasizes ethical and social concerns to a greater degree.

Key definitions in the proposed Norwegian law imply that the scope of coverage will be limited to organisms derived from recombinant DNA or cell fusion techniques, i.e., that the law might not apply to ploidy manipulated organisms. The proposed law regulates commercialization of GMOs, addressing conditions of environmental release, product labeling, product liabilities and consequences for non-compliance.

Regarding aquatic GMOs, concerns about escape of fish from floating net-pens have led Norway to adopt a policy not to use organisms modified by genetic engineering as production animals in the aquaculture industry (Marylin Cordle, USDA, personal communication).

- Japan

Responsibility for regulating laboratory production of GMOs in Japan is divided among several public agencies, depending on where it is carried out (McCormick 1987). Research at universities is subject to guidelines promulgated by the Ministry of Education, at other agencies to guidelines of the Science and Technology Agency, and in industry, to guidelines of the Ministry of International Trade and Industry. Regulatory authority over agriculture-related environmental releases of GMOs lies with the Ministry of Agriculture, Forestry and Fisheries (McCormick 1987).

Only a single field trial of a recombinant DNA-bearing organism, a plant, has been carried out in Japan (Miller 1993). The biotechnology regulatory climate in Japan has been criticized (Miller 1993) for not providing clear, predictable, risk-based regulation to those contemplating field trials.

- Canada

The regulatory approach taken in Canada is to apply existing legislation to cover concerns posed by biotechnology. Laboratory production of GMOs is regulated under guidelines promulgated by the Medical Research Council (MRC). Weaknesses in existing regulatory authority (Kapuscinski and Hallerman 1990b) include the requirement to follow the guidelines only among projects funded by the MRC or by the Natural Sciences and Engineering Research Council.
leaving the private sector effectively unregulated.

Although the applicability of legislation such as the Canadian Food and Drug Act, the Quarantine Act, and the Animal Disease and Protection Act to the testing of veterinary biologics, food, or drugs produced through biotechnology seems straightforward, products such as genetically-modified animals, which are intended for use in the environment, are not well covered. The Canadian Environmental Protection Act may be applied in situations where regulatory coverage under existing legislation is absent or unclear (Government of Canada 1988). Draft regulations promulgated under the Act, including those for confinement of transgenic animals and for assessing permit applications for environmental releases, are in development.

Other countries

Research addressing the genetic modification of aquatic organisms is going forward in a number of countries where there are no public policies mandating safe laboratory practices or restricting environmental release of GMOs (Table 1). Outdoor releases of transgenic fishes have taken place in at least two of these countries (China and Israel).

A number of issues complicate development of public policies regulating development of GMOs in developing countries. Such countries often lack the relevant technical expertise and management experience (Working Group I, 1991). Further, public awareness or concern about activities regarding development of GMOs, may not be high enough to drive development of regulatory public policies.

In a pro-active approach to addressing the lack of relevant expertise in developing countries, the Stockholm Environmental Institute held a Biosafety Workshop in December 1990 to consider the organization of an independent international biosafety panel to provide advice on request with respect to the release of transgenic organisms into the environment (Working Group I 1991). Participants suggested that the concept be broadened to cover agricultural biotechnology, and made recommendations on panel structure, organization and implementation.

Future Policy Needs Regarding Aquatic GMOs

Despite the readiness of many lines of aquatic GMOs for field testing, there is a general lack of relevant and explicit guidelines for expeditious, but environmentally sensitive field testing. Some researchers have complained that the lack of explicit field testing guidelines has constrained the progress of their projects. The need for field testing guidelines is being addressed by certain countries and international groups (United States, Norway, Organization for Economic Cooperation and Development, UN-Food and Agriculture Organization). The development of detailed guidelines regulating the field testing of aquatic organisms remains a clear and present need. However, the lack of guidelines for field testing aquatic GMOs is but one issue that will need to be addressed in the foreseeable future. In this section, other policy issues are identified that will need to be resolved before aquatic GMOs can be utilized broadly for their intended applications.

Targeted research to support policy development

The justification for biotechnology regulatory policy is the maximization of benefits
Table 1. Examples of countries where research on genetic modification of aquatic organisms is conducted, and presence or absence of regulations over research with, or environmental release of, genetically-modified organisms (after Hallemann and Kapuscinski, 1992b).

<table>
<thead>
<tr>
<th>Country</th>
<th>Source of regulation</th>
<th>EC Member</th>
<th>OECD Member</th>
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<td>Canada</td>
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<td>France</td>
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<td>People's Rep. of China</td>
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<td>United States</td>
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1. In some cases, there may be regulation of research involving recombinant DNA at particular institutions.
2. Compliance with European Community (EC) directives implies prompt enactment of regulations.
4. Member of Inter-American Institute for Cooperation on Agriculture (IICA).

Accruing from use of GMOs and the minimization of associated ecological risk. Public policies must be science-based so that a demonstrably justifiable balance can be struck between commercial and environmental protection interests. In the aquatic sector, there is a lack of quantitative information upon which sound regulatory policies can be based.

Faced with a large number of unknowns, it is clear that only through field testing will quantitative data be assembled which (1) characterize phenotypic modification in manipulated lines, (2) quantify the fitness of genetically-modified lines under aquaculture and more natural conditions, and (3) identify and assess the likelihood of various ecological impact mechanisms. Experimental designs for quantifying phenotypic modification, in terms of both targeted performance traits and other traits, are relatively straightforward. However, practical experimental designs for quantifying fitness and likelihood of environmental impacts are not well established. Data from such experiments will provide the quantitative input for the process of
risk management, the process of using scientific data to reach decisions maximizing the benefits of using GMOs while minimizing risk (Gregory 1992).

- **Policies on commercialization of GMOs**

  The first commercialization of GMOs is underway. Rapid technical progress in the development of aquatic GMOs suggests that commercialization of many of them could be sought by the middle of the 1990s. Development of sound public policies on commercialization of biotechnology-derived products is supported by the industry because it is good business policy for the long term. By reducing the likelihood of undesired ecological impacts, it will engender greater investor and consumer confidence in the biotechnology industry. However, two issues relating to commercialization of the products of biotechnology are not yet fully addressed.

  The first issue is the determination of environmental safety for commercial-scale production of GMOs. The collection and interpretation of relevant field testing data, are necessary pre-conditions for the determination of environmental safety for commercialization of a particular GMO. Requests for permits to go forward with commercial production of GMOs have been handled on a case-by-case basis. The first wave of biotechnology products, mostly for medical applications, has been licensed. In the United States, for example, 45 biotechnology products, 39 for diagnosis of disease and six gene-deleted vaccines, have been licensed for commercial production (Senger 1993). In contrast, the first biotechnology-derived food products are only now reaching the commercialization stage. In October 1992, the USDA announced that CalGene’s Flavr Savr tomato was approved for commercial production, with the US Food and Drug Administration (FDA) expected to find the tomato marketable (NBIAP 1992c). In its proposed law, Norway asserts a high standard for environmental safety of GMOs. A product will not be approved for sales unless there is no possibility for adverse effects on human health or the environment. Assuming that many countries will require a finding of environmental safety, the commercialization of aquatic GMOs may be delayed because of difficulty in reaching such a finding.

  A second issue for public policy formulation concerns the food safety of products of biotechnology. Consumer groups, particularly in developed countries, have raised the issue of food safety to a high level. For example, in the United States, major controversies have addressed the safety of milk from cows injected with bovine somatotropin (growth hormone) and of the Flavr Savr tomato to be marketed by CalGene. The occurrence of these controversies implies that segments of the American public will not be satisfied with the FDA’s statement of policy that no special testing, labeling, or pre-market notification will be needed for foods derived from plant varieties developed through biotechnology (NBIAP 1992b). Taking the opposite approach, the proposed Norwegian law for development and use of GMOs provides for special labeling of products consisting of or containing GMOs. Of direct relevance to this workshop, a Symposium on Aquaculture Biotechnology and Food Safety was held by the OECD in June 1992 in Bergen, Norway.

- **International policy coordination**

  Because the environment of all countries is interconnected and because of the special needs of developing countries, a degree of
international policy coordination is needed for environmentally sound management of biotechnology. Chapter 16 of Agenda 21, adopted by almost all countries at UNCED in 1992, sets out a number of program areas to foster internationally agreed principles to promote development of sustainable applications of biotechnology and to establish appropriate enabling mechanisms. Activities called for include: evaluation of the use of biotechnology techniques to improve the yields of fish, algal and aquatic species; development of education programs for decision-makers and the general public regarding benefits and risks of biotechnology; enhancement of human resources in developing countries; and development of mechanisms for international cooperation for information exchange and for adoption of technical guidelines and safety procedures. Chapter 16, and indeed all of Agenda 21, is but a framework for action; much work must follow in order to achieve the adopted goals.

- International intellectual property protection

The development of GMOs requires a rather long-term investment of human and physical resources. The distribution of GMOs through channels in the private sector will depend on the ability of private producers to recover the value of their investment. The commercialization of aquatic GMOs will, thus, depend on the development and institutionalization of relevant intellectual property protection. The applicability of patenting and other forms of intellectual property protection has emerged as a contentious public policy issue, raising legal, economic, social and ethical questions (Hallerman and Kapuscinski 1990b). The political importance of intellectual property protection was underscored when the United States refused to sign the UNCED Biological Diversity Convention, specifically because insufficient intellectual property protection was offered to the products of biotechnology.

Differences exist among countries regarding what intellectual property protection is offered for biotechnological inventions (OTA 1991). The key legal precedents establishing the patentability of GMOs took place in the United States (OTA 1989), where four genetically-modified animals have been patented to date. Many countries grant patents for novel microorganisms, and a small proportion do so for plants. It seems likely that other nations will issue animal patents in the future (Raines 1988).

Several international agreements have been reached regarding protection of intellectual property rights for biological inventions (OTA 1989). While virtually all developed nations and many developing nations are signatories to key treaties, some countries are not. This is likely to give rise to resistance on the part of those who have developed aquatic or other GMOs to share biological materials or methodologies with prospective counterparts in non-signatory countries. For example, while Chile has a rather well-developed aquaculture industry, it is not a signatory of any patent-related treaty.

Perspective

Aquaculture, fishery management and conservation activities are practiced within the context of natural ecosystems. Results from laboratory and field tests suggest that use of aquatic GMOs poses considerable benefits. The goal of realizing the benefits posed by aquatic GMOs, while minimizing risk to natural ecosystems, will require concerted activity by a wide range of professionals.
> Production of aquatic GMOs will require the expertise of molecular geneticists and animal breeders,

> Development of risk assessment methods and data sets to support quantitative risk assessments will require interaction among ecologists, aquaculture scientists and risk assessment specialists,

> Other expertise will be needed for risk management, integrating benefit and risk information with input reflecting societal values to reach defensible policies for commercialization of aquatic GMOs,

> Environmentally responsible realization of the economic benefits posed by use of aquatic GMOs will require adoption of a long time horizon and sound judgement by public funding agencies and the private sector.

Taking these many functions into account, it is clear that realization of economic benefits with minimal environmental risk will depend upon the careful crafting of public policies to guide and expedite well safeguarded research and development activities with aquatic GMOs. The development of such policies is, therefore, timely and appropriate.

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