

ACKNOWLEDGMENTS

This report was prepared under the direction of the Regulatory Panel of the Joint Subcommittee on Aquaculture and its able Chairman, Donald Hunt, U. S. Fish and Sea Administration. As the government Project Officer, Mr. Hunt provided thoughtful guidance throughout the duration of this effort.

The Project Director and principal author of the Final Report on regulatory constraints to aquaculture was Duane J. Wingerich, Esq., Director of the Aspen Research and Information Center. He was assisted by senior research associates, Payllis Zuckerman, with additional research assistance from Judith Kane, Anne Salton, Monrovia Desborough, Esq., Jeannie Katz, Esq., and Ann Tjoms.

AQUACULTURE IN THE UNITED STATES:

REGULATORY CONSTRAINTS

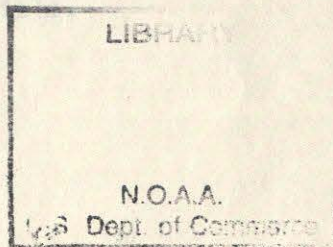
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- o A Literature Review of the Regulatory Constraints on Aquaculture Development with Accompanying Descriptor List and Index (150 pp.)
- o A Directory of Federal Regulations Affecting the Development and Operation of Commercial Aquaculture (150 pp.)
- o A Directory of State Regulations Affecting the Development and Operation of Commercial Aquaculture  
Volume 1: 8 Principal States (311 pp.)  
Volume 2: 24 Supporting States (457 pp.)
- o Case Studies of 12 Commercial Aquaculture Operations (125 pp.)
- o 8-State Permit/License Summary and Time Line Charts (81 pp.)

Taken in combination, these 6 volumes represent the first comprehensive survey yet undertaken of the vast body of state and federal statutes and regulations that both directly and indirectly impinge on how the aquaculture entrepreneur does business in this country.

For all of its broad scope, however, these are areas not covered by the total study, in particular, those local laws and regulations that specifically permit or prevent aquaculture operations. Nor for that matter are all of the states included. Of the 32 states surveyed, only 8 are analyzed in detail.

Nevertheless, for the first time, this series of reports specifically identifies the complex body of laws and regulations that impact, to a greater or lesser degree, on the development of commercial aquaculture operations in the United States. This information should help shape the foundation of a federal regulatory constraints action plan.

James J. Wingenrich, Esq.  
 Project Director



## PREFACE

This volume, entitled Aquaculture in the United States: Regulatory Constraints, represents the culmination of an 18 month research and writing effort. Five separately bound reports have preceded this final report. They are:

- o A Literature Review of the Regulatory Constraints on Aquaculture Development with Accompanying Descriptor List and Index (150 pp.)
- o A Directory of Federal Regulations Affecting the Development and Operation of Commercial Aquaculture (350 pp.)
- o A Directory of State Regulations Affecting the Development and Operation of Commercial Aquaculture  
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Duane J. Gingerich, Esq.  
Project Director

This volume consists of two interrelated parts:

- o Part 1: Regulatory Constraints Affecting the Development and Operation of Aquaculture in the United States

This part presents a synthesis of the information compiled and analyzed in previous reports including the literature review, the federal and state Directories of laws and regulations affecting aquaculture, the twelve case studies, and the time line charts. It is intended to be an "executive summary" of the research results achieved in identifying and analyzing the problem of regulatory constraints on aquaculture.

- o Part 2: Regulatory Constraints Action Plan

Part 2 takes the first step toward formulating a regulatory constraints action plan. Specifically, this section analyzes a limited number of federal regulatory constraints and outlines planning steps the Federal government might take to evaluate unnecessarily burdensome regulatory restrictions to aquaculture ventures. Because of budget constraints, only a small and selected group of federal regulations are treated.

As Congress itself recognized, however, the problems besetting the aquaculture industry are not uniform:

Despite its potential, the development of aquaculture in the United States has been inhibited by many economic, legal, and production factors, such as inadequate credit, diffused legal jurisdiction, the lack of management information, and the lack of reliable supplies of food stocks.

Furthermore, according to the same Congressional findings:

Many areas of the United States are suitable for aquaculture, but are subject to land-use or water-use management policies that do not adequately consider the potential for aquaculture and do not foster the development of aquaculture.

INTRODUCTION

Testifying at Honolulu field hearings on the 1979 version of the National Aquaculture Act, a pioneer in aquaculture development commented: "Sixteen years ago aquaculture was an idea that fell on stony ground. Now we find ourselves on the fertile ground of a willing and increasingly informed community."<sup>1</sup>

Just how fertile the "regulatory soil" is for aquaculture in the 80's is the subject of this report. To what extent current regulatory policy at all levels of government is designed or able to fulfill the promise of aquaculture as a commercial enterprise is one of the questions this research has sought to answer.

The cultivation of aquatic plants and animals certainly is hardly a recent phenomenon, governmental policy notwithstanding. Fish culturing has been carried on for centuries in Middle Eastern and Asian countries. Still a relative newcomer to the aquaculture field, the Federal Government has been supporting various types of aquaculture-related activity for more than 100 years through programs of the Departments of Interior, Commerce, and Agriculture. In fact, the position of U.S. Commissioner of Fish and Fisheries was created as long ago as 1871.

Nevertheless, even the recent passage of the National Aquaculture Act of 1980<sup>2</sup> cannot obscure the fact that aquaculture production in the U.S. continues to lag far behind nations such as China, Japan, and Russia. Current estimates are that the U.S. aquaculture industry produces only three percent of all fish and shellfish consumed domestically. China is said to produce 50 times as much; Japan approximately 12 times as much.<sup>3</sup> The fact that the U.S. imports over 50 percent of its fish products, and the adverse impact this has on the national balance of payments, has not been lost on Congress in its attempt to implement a national aquaculture policy.<sup>4</sup>

As Congress itself recognized, however, the problems besetting the aquaculture industry are many and varied:<sup>5</sup>

Despite its potential, the development of aquaculture in the United States has been inhibited by many economic, legal, and production factors, such as inadequate credit, diffused legal jurisdiction, the lack of management information, and the lack of reliable supplies of seed stock.

Furthermore, according to the same Congressional findings:<sup>6</sup>

Many areas of the United States are suitable for aquaculture, but are subject to land-use or water-use management policies that do not adequately consider the potential for aquaculture and may inhibit the development of aquaculture.

It was this perception of the "stony ground" of legal/institutional barriers to aquaculture development that generated interest in and momentum behind a study of regulatory constraints and an accompanying action plan.

## 1.1

### SCOPE OF THE REGULATORY CONSTRAINTS PROBLEM

Regulatory constraints, for whatever reasons, have developed a reputation as among the most constraining influences on aquaculture development. Whether that reputation is deserved is open to question, particularly in light of evidence from aquaculture entrepreneurs themselves about the overriding importance of financial and marketing constraints.

Nevertheless, the perception persists and it is due in no small measure to the multi-level complexity of the regulatory scheme affecting aquaculture. If the existing framework consisted entirely of federal laws and regulations, that might be headache enough. However, state and local laws and regulations in great profusion must also be added to the equation. These, in fact, represent perhaps the most significant regulatory constraints of any to be found. In short, the typical commercial aquaculture enterprise today must operate under an array of federal, state, and local legal requirements -- most of which spell time and money if they happen to be direct compliance requirements.

The broad scope of the regulatory constraints problem can be illustrated by grouping some of the major categories of regulation affecting aquaculture as follows:

- o Fish and fisheries management
- o Water use
- o Land use
- o Pollution management
- o Health and safety
- o Financial
- o Labor/transportation
- o Intergovernmental/International

There are few aspects of aquaculture uses of lands and waters, for example, that are not regulated to some degree or other at all three levels of government -- federal, state, and local. These regulations may range in scope from environmental impact statements to pond construction permits. Some regulations govern specific activities such as grading, construction, and effluent disposal regardless of location. Others regulate activities within specific geographic areas such as conservation districts and the coastal zone. In short, within each broad category of regulation, the aquaculture entrepreneur likely will be confronted by several levels of government.

A second level of complexity remains to be confronted, however. Within each level of government -- federal, state, and local -- are a variety of agencies with responsibilities touching on aquaculture. The propensity of many agencies within each level traditionally has been to stake out their piece

of the regulatory turf and to guard it against all comers. That scenario, however, is changing among federal agencies and in many state agencies involved with aquaculture.

The resulting regulatory maze, whether correctly or incorrectly, is perceived to be a barrier by the aquaculturist, from the perspective not only of getting into the business in the first instance, but also in staying in the business once in.

## 1.2

### REGULATORY CONSTRAINTS DEFINED

Just as beauty is in the eyes of the beholder so too is a regulatory "constraint" in the eyes of the regulated. One individual's constraint may, in fact, be another individual's opportunity. There may even be regulatory "constraints" that everyone subscribes to as desirable and necessary.

The original charter to undertake this research spoke of developing a data base of "legal restrictions impacting upon the development and operation of aquaculture in the U.S." The stated purpose was to "collect information on regulatory restrictions facing commercial aquaculture operations." A further element of the study was to examine the "practical effects of regulatory impacts." What this suggests is a broad-gauge approach to identifying regulatory constraints.

Accordingly, the approach taken in the research and in this synthesis was to identify the universe of laws and regulations that, broadly speaking, impacts the aquaculture entrepreneur and then make distinctions within that universe between those laws and regulations that are likely to have either a direct or indirect impact.

Regulatory gaps or inconsistencies, overlaps and duplication, and unnecessarily burdensome or intended applications all qualify as "constraints" to aquaculture to the extent that they create regulatory barriers to the initiation and operation of commercial aquaculture ventures. However, this report and the research upon which it rests carries no brief for a particular view of the broad societal purposes of regulation. As aquaculturists themselves were quick to point out, there are certain types of regulations, e.g., health and sanitation, which are essential to their livelihood and which they agree should be kept stringent.

At the same time, serious regulatory constraints can arise merely from the absence of proper coordination and direction of existing, even well-intended legislative programs for aquaculture. Here again, the nature of the "constraint" must be analyzed carefully to avoid responses whose net effect is yet another problem.

The approach taken throughout this research, therefore, was to define legal restrictions, not in terms of "good" or "bad", but rather in terms of whether and to what extent particular laws or regulations appear to significantly restrict the aquaculturist, either getting into the business or staying in business once it is established.

The first step taken in studying the regulatory constraints on aquaculture was a review of the relevant aquaculture literature. Reports and studies specifically and solely dedicated to that topic were found to be few and far between.

The research staff searched the Library of Congress, agency libraries at the Departments of Interior, Agriculture, and Commerce, the facilities of the National Bureau of Aquaculture Administration, and the Food and Drug Administration. Over one hundred public and private reference facilities across the United States were contacted for information relevant to aquaculture regulation. The extensive holdings of the National Aquaculture Information System also were available. Privately knowledgeable individuals in the field of aquaculture were contacted to identify additional sources of information on how aquaculturists are facing in the current regulatory environment.

Such a survey of information occurred, since the principal objective was to identify with some regulatory or legal nexus. For example, a study on genetic problems of mollusks might be included because of references to restrictions in government research which impede commercial development. Another article on mollusks might be excluded because it lacked such a stated or inferred connection to law or regulation.

The results of the literature survey appear in a volume entitled: A Literature Review of the Regulatory Constraints on Aquaculture Development with Accompanying Descriptive List and Index. It contains over 300 brief abstracts describing the scope and findings of each study selected. Highlights of this volume, organized by the broad categories of a taxonomy created for the regulatory constraints study, follow in subsequent pages.

#### REGULATORY ISSUES IDENTIFIED

The consensus of opinion among both private and public sector commentators was that legal constraints present a significant obstacle to the development and growth of aquaculture as an industry in the United States. Although the issues overlap to some extent, the current literature on regulatory problems affecting aquaculturists can be divided into the following categories of direct and indirect regulatory restrictions: aquatic species in general; water regulation; land regulation; aquaculture facility/wastewater management; processing operations; pollution; commercial/financial; and labor policy. Each category has its own problems and potential for regulatory improvements as summarized below.

## 2.0 REGULATORY CONSTRAINTS: LITERATURE REVIEW

### 2.1 INTRODUCTION

The first step taken in studying the regulatory constraints on aquaculture was a review of the relevant aquaculture literature. Reports and studies specifically and solely dedicated to that topic were found to be few and far between.

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Much screening of information occurred, since the principal objective was literature with some regulatory or legal nexus. For example, a study on genetic problems of mollusks might be included because of references to deficiencies in government research which impede commercial development. Another article on mollusks might be excluded because it lacked such a stated or inferred connection to law or regulation.

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### 2.2.1 Aquatic Species Regulation in General

A large body of literature treats the technical needs of species culturing, particularly with respect to salmon, oysters, catfish, and trout. Shrimp, tilapia, perch, lobster, crayfish, abalone and aquatic plants receive considerable coverage. What emerges in connection with aquaculture regulations is that the regulatory framework surrounding each species is widely divergent, with catfish culturing at the least restrictive end of a regulatory continuum and marine species at the opposite end. Trout farming lies somewhere between the two.

The logic behind this admittedly gross classification scheme is relatively simple. Relative to other aquaculture operations, catfish rearing is a non-obtrusive land and water use with a longer track record than many other species. Cultivation and harvesting generally occur on private lands in private waters, hence less involvement by governmental authorities. Another factor is the perception of catfish farming as an agricultural endeavor. Commentators single out catfish farmers as beneficiaries of the fact that agriculture is not as highly regulated in the U.S. as many other activities.

At the other end of the regulatory scale are anadromous and marine species. In spite of major differences in habitat requirements for oysters, salmon, and the like, a common thread linking their cultivation is that they are heavily dependent on public land and water resources. Predictably, the greater the use of public resources, the greater the level of scrutiny by regulatory officials.

### 2.2.2 Water Regulation

Water is the life blood of aquaculture. An aquaculturist initially must identify what water resources are needed and how to assure that supply. Ownership or control of water must be determined. Whether a particular body of water is subject to water management programs which could affect aquaculture operations must be established. Permitted and non-permitted uses must be clarified. Other water uses already sanctioned or protected which would be incompatible with aquaculture operations must be identified. The extremely complex and ambiguous nature of water regulation in the U.S. compounds the problems raised by these issues.

In that regard, the location and character of the water resource helps identify the regulator. For example, inland rivers and streams, lakes, and groundwater generally are regulated by the states where they are found, with reserved rights of navigation and water quality preservation vested with the U.S. government. Water courses on federal lands are under federal control to the extent that water rights are reserved. Bodies of water touching more than one jurisdiction are controlled by regional compacts and commissions.



Marine waters are another matter. Territorial waters within three miles of the coastal state are within its jurisdiction, while waters seaward of this for 197 miles are the exclusive economic zone of the U.S. and administered by the the Federal Government. International law controls the high seas.

Fortunately for mariculturists, much has been written to clarify these jurisdictional lines. Regulatory ambiguities exist primarily with respect to management programs affecting water use. Under the Coastal Zone Management Act, states are encouraged through federal grants to engage in planning for the use of these waters as well as shorelands. A more direct federal involvement in coastal waters is made possible by the Fishery Conservation and Management Act which undertakes to regulate all fishing in federal waters where necessary for sound fisheries management.

State water management directives affecting contiguous waters can directly affect the vitality of ocean fisheries since many species spawn in estuarine waters and then migrate to the open seas. State water leasing rights continue to dictate the ease of entry, the size of holdings, the amount of royalties, and approved harvesting practices for various aquaculture enterprises, with appreciable differences between states.

Statutory silence about a particular aquaculture water use has been identified as a problem by some. Aquisition of financing may be difficult if an entrepreneur is unable to establish property rights in an ocean plot and crop.

An extensive body of law has arisen around the issues of riparian and littoral water rights. An aquaculturist's most immediate concern for water rights may be at two levels. First, in siting a facility the aquaculturist must contend with complex and diverse state laws that determine the extent and legality of any acquisition of riparian rights. Second, the aquaculturist must ensure that the operation of a facility does not unduly infringe on the rights of other riparian owners.

Competition for the use of public waters leads to additional regulatory headaches for the fish farmer. Coastal water uses, for example, include shipping, recreation, commercial fishing, waste disposal, and mineral extraction. As several experts have pointed out, aquaculture will further test the ability of these diverse interests to co-exist.

In summary, water issues are among the most complex and diverse of any the fish farmer will face. They must contend with:

- o water rights and riparian ownership law
- o proscriptions on the use of public waters

- o competition from other water uses
- o federal, state, and local water management programs.

Several studies have looked at these issues, but usually from the perspective of what could happen rather than what did happen in a specific case. In other instances, extreme variations between the laws and regulations of various jurisdictions have frustrated efforts to comprehend the full scope of water use restrictions facing commercial aquaculture operations in the U.S. For example, no nationwide assessment has yet been made of the interaction of traditional fishery regulations with aquaculture.

### 2.2.3 Land Regulation

Land acquisition and use issues rank alongside water use issues as among the most regulated activities in aquaculture development. There are important differences, however. Land, unlike water, does not flow, so jurisdictional boundaries are more clear. Private ownership of land is less complicated than corresponding water rights. On the other hand, land is a finite item and has become more and more scarce in recent decades, a feature that has brought with it a host of regulatory controls.

Aquaculturists are subject to numerous site approval and permitting requirements at the city, county, regional, and state level before they can begin operations. Multiple use conflicts abound. The need for proximity to water places many aquaculture operations within the reach of coastal zone management areas. Yet there they must compete for costly land resources along shorelands where other uses such as commercial, recreational, residential, and industrial are entrenched. As a relatively unobtrusive resource exploiter with a natural dependency on water, the aquaculturist does have some bargaining tools in this competition. However, as some commentators point out, considerable opposition to the siting of aquaculture facilities on shorelands has surfaced in some states for environmental quality and for aesthetic reasons.

Federal land management programs to preserve wetlands, wildlife, and wilderness areas sometimes have the unintended effect of reducing the availability of prime aquaculture siting locations. Traditional land use planning and zoning restrictions, if not adjusted or reclassified for aquaculture uses may result in costly construction delays, for example. Related development constraints have been reported in jurisdictions where uncertainty persists about whether aquaculture is an agricultural or an industrial use.

In summary, the literature points to what some perceive as severe obstacles to the siting of aquacultural facilities resulting from land use policies governing coastal zone management, wetlands preservation, and flood control. Strict shorelands development control, a scarcity of prime coastal lands, and intense competition for waterfronting property combine to restrict prime sites

for aquaculture operations. Again, as with the water use literature, no comprehensive evaluation of the magnitude of these limitations on a national basis has yet been performed.

#### 2.2.4 Aquaculture Facility/Hatchery Mangement

As the new entrant to aquaculture soon learns, no sooner have land and water for a facility been secured than a new round of regulations surface. Most states require hatcheries to be licensed. A fish breeding license may be necessary as well as permits for acquiring wild stock for spawning purposes. Importation of eggs, larvae, or fish will require a certificate of freedom from disease. Commentators lament the scarcity of qualified diagnosticians and the burden this places on fish farmers.

Fish disease and disease control are major concerns of fish farmers, even apart from regulatory restrictions, since these issues affect the quantity and quality of their products. Disease control and inspection regulations exist in many states but fish farmers are often on their own in developing treatment methods for their species. Complicating matters is the fact that any drugs or chemicals to be used on food fish must be registered and cleared with the Food and Drug Administration, a time consuming and costly process that few drug manufacturers have braved because of the small size of the projective market.

In the absence of sufficient approved drugs and chemicals, there are reports that many aquaculture operators are left in the position of violating the law to protect their fish from disease. Fish vaccines are a similar problem. They are regulated by the Department of Agriculture, but few have been approved because manufacturers do not see an adequate market to justify the costs involved. Added to the aquaculturist's burden is the fact that drugs that are cleared for use are not approved for generic use, but rather must be separately certified for use with each species. Thus, drugs cleared for freshwater species are not available legally for use on saltwater fish.

A third agency, the Environmental Protection Agency, adds an additional layer of regulations through its control over pesticides, herbicides, and other chemicals used for predator control in aquaculture operations.

A number of other regulatory constraints affect aquaculture facility management decisions such as: equipment used; times of operation; size of catch; placement of structures; design of impoundments; use of feeds; and the use of well water/salt water. Commentators point out that while many of these regulations have legitimate purposes, they make entry into the aquaculture business a far more expensive proposition, and with the administrative uncertainties they create, may divert manpower and make it more difficult to obtain initial financing.

A final example of a potential legal obstruction to technological advance in the industry may develop as experiments continue with fish culture in power plant thermal effluent and other conventional waste discharges. While technical constraints focus on the presence of toxic metals and undesirable odors and tastes, legal constraints hinge on FDA food adulteration policies and food labelling requirements.

In summary, many federal and state statutory enactments have a bearing on the daily management of aquaculture facilities and hatcheries. A predominant concern in the literature on this point revolves around restrictions on the use of chemicals, drugs, and vaccines for fish disease and health control. Vastly oversimplified, the problem has a Catch-22 dimension:

- o fish farmers need drugs and chemicals to control disease;
- o they can legally use only cleared drugs and chemicals (FDA, EPA, USDA); but drug manufacturers see too small a market to justify the costs of production plus the considerable time and expense of getting clearances;
- o FDA and other agencies cannot act on drugs not submitted for clearance;
- o not enough approved disease control drugs and chemicals are on the market; so
- o faced with disease disaster, the fish farmer looks to an unapproved product.

#### 2.2.5 Processing Operations

Aquaculture operations are often integrated operations, with cultivators also acting as food processors and packagers. Aquaculturists must, therefore, confront licensing, operational, and labelling requirements imposed by the Food and Drug Administration and state health agencies. Sanitation regulation may begin as early as the site selection process for cultivation, and then move on to processing plant design.

The health of fish products is a strong regulatory concern of laws such as the Federal Food, Drug, and Cosmetic Act and parallel state enactments. Particularly scrutinized are additives used, toxic substance residues, and labelling and handling. Much more regulatory work should be done, according to some commentators, with respect to issuing formal tolerances for pesticides in fish so that operators have more certainty about the health and safety of their products.

#### 2.2.7 Some Regulatory/Financial Programs

Better enforcement of packaging and labelling requirements in food and drug laws is sought by some fish farmers who want better product differentiation between domestic and imported species. Others call for new legislative

initiatives to establish rational mandatory inspection and grading programs for fish products as already the case with meat products.

In summary, regulations affecting the processing side of aquaculture receive only minimal attention in the literature, perhaps because most of these regulations are not unique to aquaculture. On the other hand, problems of fish contamination and depuration of fish products are widely discussed. Fish health as a topic, if anything, appears to generate comments for continued strong regulation in order to ensure the public of the benefits of eating fish products.

#### 2.2.6 Pollution

Pollution affects aquaculturist in two distinct ways -- as a threat to crops, and as a by-product of culture operations. Uncontrolled environmental degradation can limit aquaculture development by destroying potential sites for operation. Water quality is the major concern. One report charges that illegal discharges and inadequate enforcement of the Clean Water Act are diminishing the availability of coastal locations and inland water resources. Fish kills from pesticide run off have been reported by catfish farmers in the Southeast. A New Jersey oyster cultivation project was severely damaged by wastewater from a municipal treatment plant. Pollution problems threaten not only the farmer's livelihood, but by introducing an additional business uncertainty they create difficulties for financing. A number of commentators, therefore, call for improved enforcement of the laws controlling water pollution, hazardous wastes, toxic substances, and air pollution already in place.

As a waste generator himself, the aquaculturist has a different set of regulatory issues to address. Organic wastes and chemicals used in operations are the two water pollutants involved. Both apparently have the potential to degrade water quality and disrupt animal and plant populations. There are mixed views expressed, however, with regard to the severity of the costs imposed by EPA effluent guidelines for aquaculture projects and about the stringency of such guidelines in the first instance.

In summary, with regard to the threat of pollution to crops, the literature contains only occasional criticism of the appropriateness of regulations applicable to fish farming. With regard to the position of the aquaculturist as a waste generator, EPA effluent guidelines come in for criticism as being insufficiently sensitive of unique developments in aquaculture technologies.

#### 2.2.7 Commercial/Financial Programs

A variety of commercial and financial regulatory issues play a role in the success of aquaculture ventures. For the most part, however, they receive

little attention in the regulatory literature. High on the list of perceived constraints in this category is the difficulty aquaculturists face in obtaining loans and financing. Commentators assert that conventional financing for aquaculture is so difficult to obtain that it precludes some small entrepreneurs from entering the business unless they can obtain major corporate backing. Major corporations can better withstand the long administrative delays that may result from regulations controlling loans and other financing vehicles. The IRS and SEC are singled out as having rules unfavorable to small business investment which may deflect capital away from aquaculture.

The consensus of most authors writing in this field is that there is ample room for government initiatives to enhance the commercial growth of aquaculture. The positive experience of the state of Hawaii is frequently cited as an example of the significant benefits possible from comprehensive aquaculture development planning.

Many aquaculturists perceive one of their major obstacles to success to be the uncertainties of product marketing. To illustrate how legal issues enter this discussion, it appears that while trout farmers have successfully engaged in nationwide advertising to expand their markets, some catfish farmers have complained that similar efforts on their own behalf have benefitted imported fish products to their detriment. They urge greater enforcement of labeling laws. Importers counter by saying that the entire aquaculture industry stands to benefit from enhanced consumer awareness of fish products. Federal Trade Commission and state regulations generally regulate advertising in this context, but the issue is less one of regulation than of marketing strategy.

In summary, numerous commercial and financial regulations bear on the initiation and operation of aquacultural enterprises. The available regulatory literature touches on topics ranging from investment, financing, and taxation to marketing and insurance issues. Commentators have stated that government involvement in these areas generally has been conducive to aquaculture development.

#### 2.2.8 Labor/Occupational Safety

Outside of a few articles, the literature scarcely touches on how labor law and occupational health and safety regulations impact aquaculture. Certain OSHA diving regulations are cited as being unduly restrictive because they allegedly fail to take into account differences between deep water diving and the kind of shallow water diving characteristic of certain aquaculture operations.

#### 2.3 SUMMARY COMMENTS

The literature on regulatory constraints generally suggests that the current regulatory framework is both extensive and extremely complex and that

its strong impact on aquaculture development is often unintended. The perceived or actual rigor of certain regulatory restrictions on aquaculture apparently has been a source of considerable discouragement to many who would enter the field. Regulatory costs stemming from such restrictions may be considerable, according to some commentators, although others believe that such costs are not prohibitive in monetary terms.

In the view of a significant number of commentators, business uncertainties created by regulatory constraints, their appearance and persistence in all areas of activity, and the time and attention they require, seriously detract from aquaculture development and discourage investment in the industry.

The Directory also indexes pending legislation and proposed regulations, to the extent available, to enable users to track possible changes which may affect the initiation or operation of aquaculture enterprises.

The organizing tool for this research was a taxonomy developed for the regulatory constraints study. The taxonomy classifies and organizes regulatory materials in terms of significance to fish farmers. The bulk of the regulatory materials selected for abstracting and indexing were drawn from the U.S. Code, the Code of Federal Regulations, the Federal Register, and miscellaneous Congressional and agency publications.

The Directory includes a wide range of federal laws and administrative regulations of both direct and indirect relevance to aquaculture as a business. Materials in the Directory are organized under the following broad categories:

- a. Direct compliance requirements
- b. Commercial, financial aid and assistance programs
- c. Scientific research and assistance programs
- d. Protective land and water programs
- e. Restrictive land and water programs

The materials compiled and indexed in the Directory of federal laws and regulations affecting the fish farmer are too voluminous to summarize in any detail below. The approach taken in subsequent pages, therefore, is one of touching only the highlights in highly summarized fashion. Reference should be made to the Directory itself for legal citations and more details.

### 3.0 FEDERAL REGULATORY CONSTRAINTS

#### 3.1 INTRODUCTION

The report upon which the following pages of section 3 are built is entitled: A Directory of Federal Regulations Affecting the Development and Operation of Commercial Aquaculture. The Directory is a compilation of statutes, implementing regulations, and permitting requirements which comprise the federal regulatory environment that directly or indirectly affects how aquaculturists do business in the United States.

The Directory also indexes pending legislation and proposed regulations, to the extent available, to enable users to track possible changes which may affect the initiation or operation of aquaculture enterprises.

The organizing tool for this research was a taxonomy developed for the regulatory constraints study. The taxonomy classifies and organizes key legal/institutional terms of significance to fish farmers. The bulk of the resulting regulatory materials selected for abstracting and indexing were drawn from the U.S. Code, the Code of Federal Regulations, the Federal Register, and miscellaneous Congressional and agency publications.

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SCOPE OF THE PROBLEM

The interests of the Federal Government in aquaculture are at the same time diffuse and specific. As many as eleven federal agencies are directly involved with aquaculture, and some ten other agencies have programs that are indirectly related. In contrast, agriculture is the primary responsibility of a major department, with substantial funds and a broad base of political support. Aquaculture, at this stage of its development, however, still does not fit neatly into any of the existing departments or agencies. Each of the three major federal departments concerned with aquaculture -- Agriculture, Interior, and Commerce -- historically have developed their own spheres of research and development activity in aquaculture. A number of other Federal agencies have important responsibilities and programs related to aquaculture as well.

Viewed as a whole, Federal agencies have responsibilities and programs that range from regulation of chemical agents and environmental protection to programs of research and development, financial assistance, technical assistance, advisory and information services, and education and training. The coordinating body established for all of these activities is the Joint Subcommittee on Aquaculture of the Federal Coordinating Council for Science, Engineering, and Technology. The position of Aquaculture Coordinator has been established within each of the Departments of Agriculture, Commerce, and Interior to maximize coordination of aquaculture activities both within and among the Departments.

For all of the inherent potential for duplication and perceived lack of coordination among federal agencies concerned with aquaculture, the regulatory constraints picture emerges in relatively sharp focus. In the first place, there are only a limited number of direct licensing requirements imposed by federal agencies on freshwater or marine aquaculture enterprises. Far more characteristic of the federal presence are its programs for indirect regulation of fish farmers. Federal drug clearance requirements exact no direct compliance burden on fish farmers, but they do restrict disease control options. Many federal environmental and food sanitation laws, for example, reach the aquaculturists only after being interpreted and administered through state agencies.

Another type of federal regulatory constraint occurs where laws and regulations, whether by intent or by inadvertence, exclude aquaculturists from beneficial marketing, financial assistance, and extension services provided by the Federal government to agriculture and the traditional fishing industry.

Important as these direct, indirect, and unintentional constraints may be, it is essential to recognize the positive aspect of nearly every "constraint" identifiable. For example, federal environmental regulations affecting the fish farmer are intended to protect waters from pollution and thereby ensure that this clear threat to the very existence of aquaculture is controlled. Health and sanitation laws protect not only the consumer of fish products but the producer as well to the extent that consumers presumably will not pay

for uncontaminated and healthful fish foods. Of course, by adding to entry and operations costs or by delaying operations, some of these laws may create disincentives to invest in aquaculture. Nevertheless, in order to be fair to the legislative purpose of a particular perceived constraint, objective benefits must be calculated along with compliance costs to arrive at a true picture of the regulatory burden.

### 3.3

#### FEDERAL REGULATORY PROGRAMS

Although a number of federal agencies have responsibilities and programs related to aquaculture, the primary programs and resources reside in three Departments: Agriculture, Commerce, and Interior.

According to a general division of responsibility outlined in an inter-agency agreement signed by these three Departments, the central focus of the aquaculture activities of each is as follows:

- o Department of Agriculture. Responsible for federal R&D activities in support of aquaculture for food, recreation, and other personal and agricultural purposes carried out by the private sector on privately owned or leased land and water. The Department's work is primarily geared toward fresh water aquaculture.
- o Department of Commerce. Responsible (through the National Marine Fisheries Service, and Office of Sea Grant) for R&D on marine, estuarine, and anadromous species. Work on anadromous species is coordinated with the Departments of Interior and Agriculture (Forest Service). The advisory services programs of the Office of Sea Grant are carried out in collaboration with the Extension Service of USDA.
- o Department of Interior. Responsible (through the Fish and Wildlife Service) for technical research and development of fresh water fin-fish for recreational and commercial purposes. Department activities are conducted in Fish and Wildlife Service laboratories engaged in research on nutrition, disease, genetics, drug restrictions, and environmental effects. Work on anadromous species is coordinated with Commerce and Agriculture (Forest Service).

Other federal agencies with significant responsibilities and programs in aquaculture include: Food and Drug Administration; Environmental Protection Agency; Small Business Administration.

### 3.3.1

#### Direct Compliance Requirements

Approximately 50 federal statutes (accompanied by implementing regulations) have a relatively direct impact on how, when, where, and with what the fish farmer does business. Not all affect every fish farmer, nor does each affect

everyone all of the time. Many affect aquaculture to no greater or lesser extent than other businesses. The highlights of this body of regulation follow.

- 3.3.1.1 Importation of Non-Indigenous Species -- Aquaculturists in some states, particularly Hawaii, claim that federal regulation of the so-called "exotic species" places unnecessary and burdensome limits on aquaculture. They see industry growth "taking off" via the introduction of new species. Other aquaculturists argue that controls on diseases and parasites are inadequate to prevent their introduction and that some exotic species themselves could prove to be undesirable.

The law restricting wildlife importation of most concern to aquaculturists is the Lacey Act (18 U.S.C. 42). It permits the Secretary of the Interior to prescribe by regulation any fish (including mollusks and crustacea), or their offspring or eggs found to be injurious to human beings or to "the interests of agriculture, horticulture, forestry, or to wildlife or the wildlife resources." The Secretary may prohibit importation as well as transshipment between the continental U.S. and Hawaii or Puerto Rico.

To date, fish or eggs of the family Clariidae (walking catfish) and the live or dead fish or eggs of salmonids of the fish family Salmonidae (salmon) have been proscribed by such regulation.

- 3.3.1.2 Water Construction Permits -- A number of laws require permits to erect structures in or discharge fill into navigable waters of the United States. The dredge and fill permit requirements of the Army Corps of Engineers are cited by some aquaculturists as unnecessarily time consuming and duplicative of state and local water construction permitting requirements.

A permit from the Corps of Engineers is required of all aquaculture entrepreneurs whose activities involve either: performing work in or affecting navigable waters of the United States; discharging dredged or fill material into U.S. waters; or transporting dredged material for the purpose of dumping it into ocean waters.

The permit form itself is relatively short; delays in obtaining necessary permits, however, reportedly have ranged from 2 months to 2 years depending on the nature of the construction.

- 3.3.1.3 Water Quality and Availability -- Aquaculturists agree that unpolluted water is essential to their business; many disagree, however, with EPA's regulatory scheme for controlling waste water effluents from aquaculture hatcheries and production facilities, criticizing the scheme for not distinguishing adequately between biodegradable wastes and chemical wastes. The aquaculture industry is concerned about what they believe to be prohibitive costs in treating large volumes of effluent from aquaculture operations.

The Clean Water Act (33 U.S.C. 1251) prohibits any person from discharging pollutants into a waterway from a point source unless authorized by EPA or an approved state agency. Section 1328 of CWA authorizes discharges of pollutants from aquaculture facilities under control conditions specified by a National Pollution Discharge Elimination System (NPDES) permit. Most sizable aquaculture operations will require an NPDES permit. However, effluent limitation standards and guidelines specific to concentrated aquatic animal production facilities have yet to be promulgated. On the other hand, such standards do cover effluents from fish processing plants. Finally, with regard to cost impacts, effluent limitation guidelines ultimately determine what kinds of pollution control equipment an affected aquaculture facility must use.

3.3.1.4 Health and Sanitation -- Federal laws regulate a variety of public health and sanitation issues that arise in the context of aquaculture operations:

- o Drug/chemical registration. The use of certain chemicals and pharmaceuticals is essential for the prevention and control of the common diseases and parasites of cultured fish. These chemical compounds must be registered with the Food and Drug Administration, a process which in some instances has been reported to take 6 years and \$4 million of preliminary research for initial approval and 3 to 4 years and \$1 million for compounds already registered for another use. Only a few drugs have been certified by FDA (in some cases EPA) for commercial aquaculture use. Many drugs not certified for aquaculture are used illegally because few individual producers can afford the certification process.
- o Fish product quality requirements. Aquaculturists are responsible under a wide variety of Food and Drug Administration laws and regulations (21 U.S.C. 342 et seq.) for producing wholesome products under sanitary conditions. The Delaney Amendment (21 U.S.C. 348) restricts utilization of waste heat from nuclear power plants for aquaculture aimed at human consumption. It provides that no substances can be added to food products that are carcinogenic to humans or test animals. Although radionuclides are known to be carcinogenic, some aquaculturists are not convinced of the hazard and claim they would use nuclear power plant cooling water if not prevented by the Delaney Amendment. See also, NPDES permits for "aquaculture projects" as defined. 40 C.F.R. 122.56
- o Vaccine approvals. How to control disease, given the fact that successful aquaculture requires the concentration of a much larger number of animals in a confined space than would be the case under natural conditions, is a serious and constant concern of fish farmers. Disease control viruses, serums, toxins, antitoxins, and analogous products are regulated by USDA's Animal and Plant Health Inspection Service, Veterinary Services (21 U.S.C. 151). The process of bringing more and better vaccines to bear on fish disease problems continues to be

a time consuming and costly one. Individual fish producers also complain of insufficient access to information in the areas of infections and toxicological conditions.

3.3.1.5 Financial -- A number of federal statutes bearing on tax and investment matters affecting business entities in general necessarily also impact on aquaculture ventures. They include, among others:

- o Exemption from tax on certain tax exempt organizations.
- o Exemptions for farmer's cooperatives.
- o FICA (Federal Insurance Contributions Act).
- o Federal Unemployment Tax Act. 26 U.S.C. 3301.
- o Income tax withholding.
- o IRS laws related to fishing profession.
- o Tax policies relating to agricultural land use.
- o Tax laws relating to estimated income tax calculations.

Important constraints to initiating a large aquaculture venture may be the SEC rules for encouraging or discouraging investment through public stock offerings.

Section 5 of the Securities Act of 1933 requires all companies to file a registration statement before offering securities to the public, and prohibits the sale of those securities to the public until this statement has been declared effective. The Act also gives the SEC authority to adopt rules and regulations which provide for an exemption from registration for relatively small offerings. These include Regulation A, Rule 240, Rule 242. A recent amendment enacted by Congress and signed into law in October, 1980, creates a limited offering exemption for sales of securities up to \$5 million.

The Office of Small Business Policy within the SEC was established to help small businesses such as aquaculture better understand the fundamental securities law requirements that must be addressed when seeking growth capital from external financial sources.

3.3.1.6 Workers' Compensation -- Aquaculture operators have cited the constraining, and, in their view, often unwarranted impact of the Longshoremen's and Harbor Workers' Compensation Act on their operations. One cost impact is, of course, insurance premiums.

The Act provides workers' compensation coverage to employees who suffer disability or death resulting from injuries occurring upon the navigable waters of the U.S., including any adjoining pier, wharf, dry dock, terminal building way, marine railway, or other adjoining area customarily used by an employee in loading, unloading, repairing, or building a vessel. Section 903 exempts crew members of, and persons loading, unloading or repairing vessels under 18 tons. The Act also authorizes the Labor Department to establish safety rules and regulations for places of employment.

The basic requirement of the Act is for the injured worker to receive 66 2/3 percent of his or her average weekly wage with the maximum compensation for disability not to exceed 200 percent of the national average weekly wage as determined by the Secretary of Labor.

3.3.1.7 Occupational Safety and Health -- The Occupational Safety and Health Administration regulates working conditions in all businesses affecting interstate commerce. Aquaculturists, in particular culture operations, view OSHA standards governing deep water diving as unnecessarily restrictive and costly and out of line with the more typical shallow water diving that they actually need to engage in. OSHA regulations (29 C.F.R. 1910.410 et seq.) govern, among other things:

- o Qualifications of dive team
- o Medical requirements
- o Safe practices
- o Pre-dive procedures
- o Procedures during dive
- o Post-dive procedures
- o Equipment
- o Recordkeeping requirements

3.3.2 Commercial/Financial Aid and Assistance Programs

The Federal Government is involved in more than a dozen major financial assistance programs of importance to aquaculture development. Most originally were slated for American agriculture and the traditional fishing industry. As a late-comer to the scene, the aquaculture industry has had to push hard to incorporate aquacultural enterprises into small business financial assistance and agricultural loan programs, and federal fish and wildlife research efforts. This effort has not always succeeded although progress has been made in recent years. The nature of the "constraint" as such in federal assistance

programs is that the aquaculturist may find it unnecessarily difficult to take advantage of various development assistance opportunities.

Among the financial assistance programs relevant to the aquaculture industry are the following:

- o Programs to develop processing, packaging, and marketing methods for agricultural products -- defined to include "fish and shellfish."
- o Farmer's Home Administration. FMHA administers nine loan programs that can provide credit to fish farmers including: 1) emergency loans; 2) economic Emergency Loan; 3) operating loans; 4) farm ownership loans; 5) soil and water loans; 6) recreation loans; 7) business and industrial loans; 8) resource conservation and development loans; 9) farm labor housing loans and grants.

The FMHA in 1979 processed approximately 363 loans for over \$15 million to aquaculture operators for development production and disaster-related purposes within farmer programs. Seventeen business and industry loans for aquaculture amounted to an additional \$23.1 million in outstanding loans for that year.

- o Farm Credit System. The Farm Credit Administration is an independent federal agency which regulates banks in the Farm Credit System. The Farm Credit System, comprised of cooperatively-owned lending institutions, provides credit to farmers, ranchers, producers and harvesters of aquatic products, and agricultural and aquatic cooperatives. Aquaculture is considered one of many forms of agriculture and normally is not segregated from other agricultural loans in financial reports. Nevertheless, the member banks estimate that approximately \$37 million was loaned in 1979 to aquaculturists by Farm Credit System institutions.
- o Small business loans. The Small Business Administration is vested with the responsibility of lending money to small capitalists. Reliable statistics on the total number of aquaculture loans to date are unavailable, but the amount in direct SBA dollars is known to be limited. However, the SBA has loan guaranty authority which amounted to over \$3 billion for fiscal year 1980 overall. The limit on SBA's guaranty program to aquaculturists is set at a guarantee of \$500,000 for as long as 10 to 20 years if that amount does not exceed 90 percent of the loan.

A number of additional federal financial assistance programs have potential relevance to aquaculture operators, including: flood insurance, vessel construction assistance, fish product price support, and fishing gear loss assistance.

### 3.3.3

#### Scientific Research and Assistance Programs

The three major Departments involved in aquaculture -- Agriculture, Commerce, and Interior -- each have longstanding scientific research and assistance programs in aquaculture. The concern of some aquaculturists with these programs has been less with the level of commitment of each Department to its own programs than with the perceived inability to maximize what is already being accomplished in a coordinated manner.

The Department of Agriculture provides a variety of aquaculture-related research and extension services. The Science and Education Administration (SEA) is the principal research and education agency of USDA. A SEA Aquaculture Program has been developed as part of the overall USDA Aquaculture Plan. The major SEA program components are in Extension (SEA-E), Cooperative Research (SEA-CR), and Agriculture Research (SEA-AR). The Soil Conservation Service (SCS) has programs to help individuals assess the potential of their resources for growing and marketing aquaculture products. Finally, the Animal and Plant Health Inspection Service (APHIS) through its Veterinary Services program licenses vaccines which are used for controlling aquacultural diseases.

The Department of Commerce, and its predecessors have been active for over a hundred years in research and development, training, information transmittal, and other phases of aquaculture. These activities have been primarily in the marine field. The National Oceanic and Atmospheric Administration (NOAA), through the National Marine Fisheries Service has long been active in developing hatchery systems for restocking depleted fish stocks. NOAA's Office of Sea Grant supports a \$4-\$5 million dollar program in aquaculture research and development, extending over about 30 universities and about 90 projects. NOAA also supports aquaculture research in the states through grants under the Commercial Fisheries Research and Development Act of 1966 and the Anadromous Fish Conservation Act of 1965. Another scientific research program in Commerce is an ocean pollution research and development program.

The Department of Interior has the largest freshwater and anadromous finfish aquaculture programs in the U.S. Its Fish and Wildlife Service operates nine laboratories engaged in specialized aquacultural research. Its Cortland, New York laboratory, for example, is the only one of its kind devoted exclusively to fish nutrition research. The Fish Farming Experimental Station at Stuttgart, Arkansas is a federally- authorized laboratory specifically set up to help the commercial freshwater aquaculturist, especially the catfish farmer.

In addition to two freshwater experimental stations, the Fish and Wildlife Service administers 88 fish hatcheries producing over 40 species of fish. At 10 locations across the U.S. the National Fish Hatchery System has a number of diagnostic specialists on staff to handle fish disease and fish husbandry problems. The National Fisheries Center at Leetown, West Virginia, administers and coordinates six geographically scattered fish husbandry labs. Its function



is to formulate and disseminate an up-to-date technological base for advancing fish culture practices. In fiscal year 1979, the Fish and Wildlife Service invested approximately \$6 million in technical research efforts.

Although each of the major Departments maintains its own scientific research niche, none possesses all of the expertise or all of the facilities necessary to cover the multifaceted problems of aquaculture R&D. As a result, cooperative research and extension programs have been established in several areas. For example, USDA's Science and Education Administration-Extension program has a cooperative understanding with NOAA's Sea Grant Program on marine activities. Several federal agencies (TUA, USDI, USDC, and USDA) jointly support a regional research project on freshwater food animals which aims to create a forum for the exchange of unpublished research information.

Finally, the Departments of Agriculture, Commerce, and Interior have developed a Memorandum of Understanding which outlines the general division of research responsibility each Department has undertaken as well as where these lines of responsibility cross.

#### 3.3.4 Protective Land and Water Programs

The Federal Government has legislated a variety of land and water programs whose rationale is protection or preservation of the environmental status quo. Although not specifically aimed at protecting land and water resources for the sole benefit of aquaculture, fish farmers are at least indirect beneficiaries of certain regulatory programs that have clean water and sound land use policies as their objectives. Whether they believe the price tag of these programs in terms of administrative costs and time delays to be worth the constraint imposed is less clear.

The following list is illustrative of the federal statutory programs of significant though perhaps indirect benefit to aquaculturists:

- o Water Conservation
- o Watershed Protection and Flood Prevention
- o Jellyfish, etc., Control
- o Reefs for Marine Life Conservation
- o Estuarine Areas
- o Marine Sanctuaries
- o River and Harbor Improvements

- Figure 3.3.5
- |   | Limitation of Siting Options | Nature of Effect Harvesting Restrictions | Land Use Restrictions |
|---|------------------------------|--|-----------------------|
| o Flood Control                               |                              |  |                       |
| o Oil Pollution of Sea                        |                              |  |                       |
| o Ports and Waterways Safety                  |                              |  |                       |
| o Ocean Dumping                               |                              |  |                       |
| o Oil Pollution Casualties on High Seas       |                              |  |                       |
| o Deepwater Port Act                          |                              |  |                       |
| o Safety of Public Water Systems              |                              |  |                       |
| o Water Resources Planning                    |                              |  |                       |
| o Reclamation and Irrigation of Lands         |                              |  |                       |
| o Appropriation of Waters                     |                              |  |                       |
| o Submerged Lands                             |                              |  |                       |
| o Outer Continental Shelf Lands               |                              |  |                       |
| o Outer Continental Shelf Resource Management |                              |  |                       |

### 3.3.5 Restrictive Land and Water Programs

For obvious reasons, the difference between "protective" and "restrictive" is seldom a bright line. Although such a grouping of federal programs has inherent limitations, it is nevertheless useful as a tool to gain an appreciation for the extent of the Federal Government's interest in issues affecting aquaculture. Three major categories of restrictions are:

- o limitations of siting options
- o harvesting restrictions
- o land use restrictions

Figure 3.3.5 depicts these statutory programs and the nature of their potentially restrictive effect.

### 3.4 SUMMARY

Over 120 statutory programs of the Federal Government have been identified a significantly related to aquaculture development. Some have a much greater

Figure 3.5.5

Title	Nature of Effect		
	Limitation of Siting Options	Harvesting Restrictions	Land Use Restrictions
National Conservation Recreation Areas	x		
National Parks	x		
Historic Sites	x		
Misc. Conservation Designations	x		
National Forests	x		x
Protection and Conservation of Wildlife	x		
Atlantic States Compact		x	
Wildlife Restoration	x		
Game and Bird Reserves	x		
Upper Mississippi Refuge	x		
Sockeye Salmon		x	
Federal Power Regulation	x		
North Pacific Fisheries		x	
National Wilderness Preservation	x		
National Trails System	x		
Wild and Scenic Rivers	x		
Water Bank Program for Wetlands Preservation			x
Coastal Zone Management			x (coastal)
Forest and Rangeland Renewable Resources			x
Federal Land Policy and Management			x

Figure 3.5.5

Title	Limitation of Siting Options	Nature of Effect Harvesting Restrictions	Land Use Restrictions
Protection of Wetlands	x		
Fishery Conservation and Management		x	
Outdoor Recreation	x		

4.0 and more direct impact than others. Slightly less than half require a direct compliance response by the affected fish farmer. The remainder are less likely to be perceived as regulatory constraints since their thrust is financial assistance, water resource protection, and the like. Nevertheless, even these "beneficial" programs can be viewed as constraining in circumstances where the activities of supposedly coordinating agencies are not mutually reinforcing.

The report upon which the following pages of section 3 are built consists of two volumes under the following title:

3. A Directory of State Regulations Affecting the Development and Operation of Commercial Aquaculture.

Volume 1: 5 Principal States

Volume 2: 24 Supporting States

The State Directory is a compilation of statutes, implementing regulations, and permitting requirements that constitute the state regulatory framework in which individual fish farmers operate. Only 32 of the 50 states are compiled in the Directory. The Regulatory Panel of the Joint Subcommittee on Aquaculture made the final selection of these 32 states.

The State Directory also indexes pending legislation and proposed regulations, where available at the time the research was conducted.

As with the companion Federal Directory, the taxonomy developed for the regulatory constraints study was used as the initial research tool. Researchers scanned the official codes of the 32 selected states, contacted many officials in state agencies, and canvassed industry association and state legislation reference specialists.

The State Directory includes a wide range of laws and regulations with varying degrees of impact on aquaculture development in each of the 32 selected states. The Directory contains summaries of or references to a body of over 1200 state laws. The complete regulatory universe is much larger, of course, counting the vast number of regulations promulgated to implement these statutes.

4.2 SCOPE OF THE PROBLEM

The majority of laws and regulations that specifically authorize, permit, or control aquaculture usually are found at the state level. The spectrum of state laws and regulations directly or indirectly affecting aquaculture development and operations is very broad indeed. Significant differences exist among the states regarding their approach to aquaculture development. Season-to-season ranching restrictions, for example, vary widely in particular states, ranging from virtual prohibition to sanction. Wide disparities also exist in the legal

## 4.0 STATE REGULATORY CONSTRAINTS

### 4.1 INTRODUCTION

The report upon which the following pages of section 3 are built consists of two volumes under the following title:

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Volume 2: 24 Supporting States

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political, economic climate for aquaculture among the 32 states studied. Accordingly, aquaculturists have had to develop unique approaches to reaching an accommodation with competing land and water uses in each state.

State health, environmental, fish and wildlife, and labor agencies, among others, exact a full measure of permits, licenses, and paperwork from the would-be aquaculturist. While steps are now being taken in a few states to streamline the entire permit maze that characterizes many state programs in aquaculture, much remains to be done to consolidate, and streamline, these regulations and more effectively promote aquacultural development in most states.

In a nutshell, the problem aquaculture entrepreneurs have in many states is not just the sheer volume of regulations to be complied with or the difficulty of obtaining the required permits. A more basic problem is that with only a handful of exceptions, few states themselves have developed the information management capability to present the applicant with a comprehensive list of all that will be required of that individual in starting up operations.

#### 4.2.1 State Regulatory Programs Affecting Aquaculture

The two-volume State Directory summarizes over 1200 laws and indexes a huge body of regulations that determine the state regulatory framework affecting aquaculturists in 32 states. Part 1 compiles the laws and regulations of the eight principal states originally selected by the Regulatory Panel, namely:

Florida	Hawaii
Idaho	Maine
Mississippi	Oregon
Virginia	Wisconsin

These states were selected on the basis of geography and species. The aim was to achieve a meaningful geographic mix of states as well as coverage of the legal framework surrounding diverse species culture including oysters, fresh water and marine shrimp, salmon, crayfish, trout, and catfish, among others.

Part 2 of the State Directory canvasses the regulatory scene in 24 additional states, again selected with species and geography in mind. They are:

Alabama  
Alaska  
Arkansas  
California  
Colorado  
Delaware  
Georgia  
Louisiana

Maryland  
Massachusetts  
Michigan  
Missouri  
New Jersey  
New Mexico  
New York  
North Carolina

Oklahoma  
Pennsylvania  
Rhode Island  
South Carolina  
Tennessee  
Texas  
Washington  
West Virginia

As a quick reference tool, preceding each state's laws affecting aquaculture as compiled in the Directory is a summary chart containing the title of the law, its legal citation, and a shorthand description of the nature of the law.

To avoid duplication of effort, and in view of the detail already provided in the State Directory, the following analysis offers only highlights of the regulatory framework generally applicable to all of the states surveyed. Reflecting the statement of work under which this study was performed, of the 32 states surveyed the original 8 remain the focus and are given the closest scrutiny.

In an effort to bring some conceptual order to the diverse body of laws and regulations that impact aquaculturists at the state level, certain descriptive categories of regulation were selected and superimposed on the research results. Each state's laws, therefore, were compiled under the following categories:

- o Species management
- o Water management
- o Land management
- o Health and Safety
- o Pollution control
- o Commerce and Labor

4.2.1.1 Species Management -- Heading up the list of statutes in this category are those authorizing fish and fisheries management agencies in the various states. The titles vary widely as do the responsible state agencies (e.g., California - Fish and Game Commission; Florida - Department of Natural Resources; Maine - Department of Marine Resources). Generally, from 3-6 major agencies, departments, or commissions play a key role in aquaculture in each state. In relatively few states are there adequate and effective aquaculture assistance programs that seek to coordinate all state agency functions and responsibilities as they relate to aquaculture.



A list of the types of activities and programs that typically come under scrutiny by the responsible fish and fisheries management agency would include:

- o Exotic species and egg importation
- o Aquaculture leases
- o Commercial fisheries research
- o Fishery harvesting
- o Species management
- o Endangered species
- o Aquatic plants
- o Licensing of hatcheries
- o Fishery conservation

4.2.1.2 Water Management -- State water management regulations facing fish farmers are extremely complex and diverse. Depending on the water resource tapped, aquaculturists confront a sizable body of law on water rights and riparian ownership. They must contend with proscriptions on the use of public waters, competition and protection from other water uses, and also may be subject to numerous federal and local water management programs. Again, the types of activities and programs that typically have restrictions placed around them by state law include:

- o Fishway construction
- o Dams and reservoirs
- o Navigational improvements
- o Dredging and filling - marine and inland waters
- o Harbor management
- o Wild and scenic rivers
- o Aquaculture facility construction
- o Boating management
- o Minerals mining
- o Estuaries management

- o Groundwater management
- o Watershed protection
- o Lake management
- o Brooks/Creek management
- o River authorities
- o Boundary waters

#### 4.2.1.3

Land Management -- Siting aquaculture facilities on suitable land is a significant problem in many states. Conflicting state as well as federal and local land use policies converge in programs such as coastal zone management and wetlands preservation and in the use of intertidal and submerged lands.

The aquaculture entrepreneur is sometimes faced with the reality that land use planning at the state level frequently favors established public uses or private uses that generate maximum tax revenues. Strong competition for coastal lands, for example, is likely to come from private housing and industrial developments, from public, or from recreation development interests.

The types of state statutes that impinge on aquaculture development in this area typically will include:

- o Coastal zone management
- o Submerged lands management
- o Wetlands management
- o Industrial/power plant siting
- o Floodplain management
- o Zoning
- o Regional planning schemes
- o Dredging and filling
- o Wilderness preservation
- o Forest management
- o Game preserves
- o Eminent domain

- o Agricultural land use
- o Recreation development/management
- o Soil conservation
- o Public lands
- o Mineral leases

4.2.1.4 Health and Safety -- Public health restrictions on the production and sale of fish and fish products exist in every state. These laws principally protect consumers against unsafe or unwholesome food products. They also directly impact on fish farmers in several ways including where and how they do business. For example, the Virginia State Health Commission is authorized to examine all fish and shellfish within the state, to inspect their natural environment as well as any facilities engaged in their handling, to condemn polluted areas, and to regulate imports of fish and shellfish into the state.

State authorities also heavily regulate fish processing plants, from approval of water supplies to plant design to plant operations. Typical of the health and safety concerns addressed by statute are:

- o Plant design and construction
- o Import restrictions
- o Quarantine
- o Commercial feeds
- o Disease control
- o Food and drug regulation
- o Sanitation
- o Processing restrictions
- o Inspection and grading
- o Occupational health and safety

4.2.1.5 Pollution Control -- Pollution affects the fish farmer as a threat to crops and as a by-product of aquaculture operations themselves. Among state statutes controlling water pollution is, for example, Idaho's Water Pollution Abatement law which establishes water quality standards to preserve the state's water for a variety of uses including fish culture.

Aquaculture operations themselves are sources of pollution. In addition to federal laws regulating wastewater effluent, many states have established pollution control standards to regulate waste products from pond or raceway cultures. Typical of these is a Maine statute entitled "Protection and Improvement of Waters - Water Improvement Commission - Tidal or Marine Waters" which sets standards for various water uses.

Other pollution control topics typically addressed by statute include:

- o Water pollution (classification of waters; bacteriological standards; chemical standards, industrial wastes, sewage disposal)
- o Liquid waste management
- o Solid waste management
- o Hazardous waste management
- o Toxic substances control
- o Air pollution control

4.2.1.6 Commerce and Labor -- Numerous commercial and financial regulations affect the formation and continued viability of aquacultural enterprises just as they would any other business. On the other hand, some state laws specifically address the needs of aquaculturists, for example, Mississippi's "Cooperative Aquatic Products Marketing Law." This act authorizes the formation of nonprofit co-ops for the purpose of growing, breeding, harvesting, handling, processing, shipping, marketing, or selling aquatic products.

Some state workers' compensation statutes such as those in Florida and Wisconsin expressly include fish farming in their exemption of agricultural labor.

Topics addressed by state statute under the commercial and labor umbrella include:

- o Aquaculture/agricultural assistance and loan programs
- o Crop insurance
- o Marketing associations
- o Fish product pricing
- o Wholesale and retail licenses

- o Board laws (to acquire hatcheries, fishways)
- o Taxation
- o Blue Sky investment protection
- o Economic development
- o Pollution control financing
- o Employment regulations

#### 4.3 SUMMARY OF EIGHT STATE PERMITTING PROCEDURES

##### 4.3.1 Introduction

A separately bound report entitled, "8-State Permit/License Summary and Time Line Charts," was designed as a companion volume to the State Directory. This report reviews state aquaculture permitting and licensing requirements in eight selected states -- Florida, Idaho, Hawaii, Maine, Mississippi, Oregon, Virginia, and Wisconsin. It analyzes the compliance burdens imposed on would-be fish farmers in these states and traces the wide variations that exist from state to state with regard to the nature and impact of such regulatory constraints. Accompanying charts graphically depict permitting obligations, the interaction of various state approval processes, and the minimum time required to process licenses and permits before start-up.

A summary of research findings follows:

##### 4.3.2 Florida

Florida's Mariculture Act, authorizing leasing of both submerged lands and the vertical water columns, represents a commitment to and interest in aquaculture. Despite this legislative encouragement, however, mariculturists have found the application procedure, hearing, and interagency review procedure costly and time-consuming. Applicants have been known to spend several years complying with requirements to apply for a proposed site in wetlands only to have the application rejected at both federal and state levels of review.

This delay and expense may be reduced in the future by more extensive communication between mariculturists and the Game and Fresh Water Fish Commission's Aquaculture Investigation Team. This Team has been charged with offering technical assistance on site choices, facility design, and restrictions on the importation of non-indigenous species, as well as on methods of preventing bird predation, preventing escape of non-native species, pond design, and disease prevention. Both the Division of Marine Resources and the Game and Fresh Water Fish Commission have declared their willingness to work with aquaculturists to

suggest ways a proposed activity could be made to conform to stringent state coastal zone management standards, or to prevent conflicts with other traditional uses of the shoreline, such as recreation, commercial fishing, and sport fishing. Nevertheless, the absence of a well-defined lead agency is currently an obstacle to aquaculture development in Florida.

While state officials show strong concern for preventing the release of non-indigenous species such as grass carp and walking catfish into state waters, the tropical fish industry -- producing some 80% of the nation's exotic fish -- has been relatively unregulated, because of the large number of producers and the small number of wildlife inspectors. However, the Aquaculture Investigation Team plans to develop greater contacts with tropical fish dealers, and to provide assistance where necessary rather than to increase the regulatory burden.

#### 4.3.3. Hawaii

Hawaii is a pioneering state in matters of streamlining the regulatory framework surrounding aquaculture development. As recently as three years ago, some aquaculture entrepreneurs spent as much as two years satisfying federal, state, and local permit requirements before launching their operations. A 1979 amendment to Hawaii's Coastal Zone Management Act exempting aquaculture and mariculture from the definition of development in coastal areas has had the effect of reducing permit approval time to as little as two months in some instances.

Standing in the forefront of the state-supported effort to reduce regulatory constraints to commercial aquaculture in Hawaii is the Aquaculture Planning Office in the Department of Planning and Economic Development. This office offers the aquaculture entrepreneur a range of consulting services to avoid costly, time-consuming delays. This is accomplished principally by paying special attention to siting issues before seeking the appropriate federal, state, and local permits. Rather than confront dredge and fill or shoreline setback requirements head-on, for example, the aquaculturist is advised to investigate alternative sites where such restrictions do not exist.

Although Hawaii by virtue of its location and climate is somewhat unique as an aquaculture state, it nevertheless represents an effective example of how legislative and administrative leadership can implement change in streamlining regulatory constraints to aquaculture development.

#### 4.3.4. Idaho

The existence of a large and vigorous trout industry in Idaho and the relatively small number of complaints by fish farmers suggests that the overall hindrance imposed by the Idaho licensing and operational regulations is minimal.

The single commercial fish rearing license required is relatively straightforward and less demanding than that of other states. There are no disease control importation restrictions. There also appears to be no overlap between commercial fishing regulations and those applied to the aquaculture industry. Trout farmers do not have to pay substantial license or poundage fees, and may harvest their fish at any time in any manner. Water appropriation and use regulations may hinder acquisition of water for aquaculture operations, but these regulations are a reflection of the state's concern for scarce water resource management.

Generally, Idaho trout farmers cite problems stemming from federal regulations as a greater burden to their operations than those posed by state requirements. In particular, they cite: 1) the lack of drugs to control trout diseases because of the FDA certification program; 2) the lack of a national program to certify fish/egg health; and 3) the lack of federal marketing assistance.

#### 4.3.5 Maine

Maine's regulatory system is generally perceived as protective of aquaculture interests rather than as an obstacle to development. Furthermore, under its aquaculture leasing program and recent Aquaculture Development Plan, Maine has begun to commit state resources to encouraging the industry's growth.

Nevertheless, because of resistance from traditional fishing interests, Maine's aquaculture law does not include the right to exclusive use of vertical water columns, a feature of similar laws enacted by Florida and, more recently, Rhode Island. Further, the marketability of aquaculture leases is reduced by the restriction on assignability of the leases. An amendment to be proposed in the 1981 legislative session would remove this limitation on assignments.

Two major needs cited by the industry are improved disease protection and parasite control. Increased accessibility of inspection facilities for seed oysters shipped from out-of-state would reduce delays and loss of business to oyster growers, according to some operators. Another major problem is the difficulty of obtaining therapeutics, due to the small market for vaccines against fish pathogens and the difficulty of obtaining FDA clearance for such drugs. There is currently no vaccine available, for example, for a bacterial kidney disease which is common in Maine waters. These and similar problems, such as the short supply of brook trout and landlocked salmon eggs could be alleviated, in the opinion of some respondents, by appointment of a lead agency to provide technical assistance to aquaculturists, as well as to coordinate state and federal regulatory procedures.

4.3.6

Mississippi

Generally, Mississippi regulation of aquaculture is far more permissive than most other states in the selected sample. This is particularly true of its regulatory posture toward catfish farming. The state explicitly categorizes these enterprises as agricultural and affords them the numerous exemptions from permitting requirements that more traditional forms of farming have enjoyed. There is no license required of a catfish farmer and far fewer restrictions in water and land uses exist than elsewhere in the eight state sample. This may perhaps be attributed to the fact that use of public resources is minimal in catfish culture, the disease problem is inconsequential, and operators have few unique requirements. On the other hand, regulations governing oyster farming in Mississippi are more rigorous because public waters and other resources are involved.

4.3.7

Oregon

Aquaculture regulation in Oregon is both permissive and rigorous. On the one hand, Oregon is the only Western state to allow for profit, commercial salmon ranching. (California, in special legislation, has authorized a single ocean ranching operation; Alaska permits only nonprofit salmon hatcheries; Washington prohibits the release of salmon but sanctions pen-rearing operations.) Thus, with regard to salmon, Oregon is legally more open to innovative culture techniques than other states. (It should be noted that there have been recent legislative efforts to rescind the salmon ranching authority.) But this initial permissiveness is balanced by a strong state policy that salmon ranches are not to detract from wild salmon populations or otherwise harm the environment. To ensure that this concern is respected, the administrative approval process for salmon hatchery permits is extremely arduous, time-consuming, and costly. Currently this process is suspended due to the lack of salmon eggs. Other aquaculture permitting requirements are not as restrictive but nonetheless allow the state to control the nature and impact of each phase of fish farming operations. Licenses are required to import fish, hatch eggs, propagate fish, and harvest them. Water and land use are regulated. Processing and food sanitation are controlled.

While the sum total of these licensing requirements and regulations is considerable, the State of Oregon has undertaken to simplify the procedures which new businesses must follow to obtain them. The State Permit Center in Salem and the entire State Regulatory Services Program are geared to add certainty and expeditiousness to the permit approval process. Oregon has published lists of every permit required by each state agency. Cost free services are provided to develop master applications, to arrange regulatory conferences between applicants and agencies, and when possible to consolidate any required public hearings.



#### 4.3.8 Virginia

Virginia's oyster industry is highly regulated by state and federal authorities, but these regulations generally are regarded as supportive to cultivators' interests, rather than as an obstacle to doing business.

The primary constraint on obtaining an oyster ground lease is the time it takes for the plat to be surveyed by the Marine Resources Commission. Because the department is some 700 applications and 5 - 6 years behind schedule, the time to obtain a lease may be as much as 7 - 8 years. While hydraulic dredges are not allowed in public areas, permits are occasionally issued to use hydraulic gear on private grounds.

Pollution problems have been a major concern of the oyster industry in Virginia and have led to the imposition of stringent inspection requirements on both seed and mature oysters transported out-of-state. In addition, the transplant of oysters from polluted to clean grounds is supervised by the Marine Resources Commission.

Virginia is somewhat unique in that permits, licenses, and leases necessary for shellfish cultivation and harvesting are available only to state residents. The state's rationale for discouraging investment in shellfish cultivation by non-resident firms is conservation of state resources for the benefit of state residents. Virginia's stand on this issue, however, is under court challenge.

The Marine Resources Commission has expedited its environmental permit review process by cooperation with the U.S. Army Corps of Engineers. The Commission acts as the lead agency in the application process, contacting the State Health Department for comments on the proposed activity. The responsibility for joint public notice in these two districts is assumed by the Corps.

#### 4.3.9 Wisconsin

Aquaculture in Wisconsin is officially promoted, and is guided by a comprehensive set of regulations. These regulations are particularly concerned with the impact of aquaculture on state navigable waters and raise a number of hurdles to the siting of and use of these natural resources. They are also concerned with the introduction and escape of diseased and non-indigenous species and implement a standard importation and release control program. The license fees and procedures are not perceived as unduly arduous. The estimated time required to obtain the necessary permits and approvals for a fish farm in Wisconsin is a little over a year at a minimal fee cost.

However, fish farmers in Wisconsin have to overcome a strong protective attitude toward natural streams and trout. Approval of proposed enterprises are enhanced by a willingness to proceed more slowly, with intensive consultation and cooperation with the Department of Natural Resources. Would-be fish farmers whose application is buttressed by professional support -- environmental consultant, an attorney, etc. -- combined with a flexible attitude toward modifying their proposed plans, probably stand a greater chance of overcoming regulatory burdens.

#### 4.4 SUMMARY OF STATE REGULATORY CONSTRAINTS

The spectrum of state laws and regulations directly or indirectly affecting aquaculture operations is very broad indeed. So great is this variety with respect to the states and species under study that all generalizations must be viewed with some scepticism. Nevertheless, there are some broad conclusions to be drawn from the accumulated data.

##### 4.4.1 Potential Regulatory Constraints

##### 4.4.1.1 Freshwater

- o Fish farming licenses and requirements for operation of hatcheries and cultivation facilities; these distinguish fish farmers from conventional fishermen;
- o Fish and fish egg importation permits and quarantine programs to control diseases; lack of standardized national program to ease compliance has direct impact on trout farmers;
- o Fish product transportation requirements, invoicing and labeling rules;
- o Exotic species regulations controlling species that may be imported;
- o Water laws governing use of surface and groundwaters; particularly critical in West where water is scarce and allocated pursuant to appropriative theory under which fish farmers must compete with traditional agricultural uses;
- o Laws regulating alterations to streams, etc. requiring permits for intakes, outlets, and diversion facilities for fish farms;
- o Local and state land management regimes preventing siting in flood plains and/or requiring permits to locate along streams;
- o State drug and vaccine control laws modeled after federal law;
- o State pesticide laws, again usually adopting federal requirements;

o State water pollution control requirements which parallel federal programs but are subject to local variation, more aggressive enforcement, and more stringent standards;

o State fishery laws such as wholesale fish dealer's licenses, baitfish dealer's license, fish canner's license, pondage fees, etc.

o Food processors' licenses.

#### 4.4.1.2 Marine Species

o Water bottom leases restricting number of acres cultivated, competing with traditional uses of intertidal areas;

o Vertical water column leases -- raft culture in Oregon, pen rearing of salmon in Washington -- are new and problematical to many agencies;

o Fish/oyster importation permits;

o Licenses to plant or transplant species;

o Culture licenses (see e.g., Oregon Wildlife Propagation license);

o Sanitation certificates to approve the sanitary conditions of growing areas;

o Restrictions on harvesting, transfer, etc., which mean greater potential for interface and confusion with commercial fishing regulations;

o Use taxes, rentals, workers' compensation programs;

o Land use restrictions, especially for land facilities in coastal areas and wetlands supporting marine operations;

o Dredging/filling regulations, which impose separate federal and state review procedures;

o Water pollution and effluent control restrictions;

o Food sanitation and processing licenses and certification requirements.

#### 4.4.2 Regulatory Constraints: Summary Overview

##### 4.4.2.1 In General

- o Generally, freshwater requirements tend to be less rigorous than marine, primarily because fewer public resources are involved.
- o Within the broad category of freshwater culture, warmwater aquaculture is less rigorously regulated (e.g., catfish) than cold-water fish farming (e.g., trout, salmon). Again, this is partially tied to the severity of the impact on public resources, i.e., proximity to pristine, fast-moving streams.
- o Innovative aquaculture techniques such as salmon ranching, rack culture, etc., are often monitored with unnecessary intensity by state agencies unfamiliar with the effects of such operations on native species and the environment.

##### 4.4.2.2 Regional Differences

- o There are no clear regional patterns explaining variations in the severity of compliance burdens. A rather high level of regulatory concern seems to be tied to how great the public interest is in the commercial use of natural resources. For example, Wisconsin recreational trout fishermen intervene on a regular basis to contest exploitation of streams for commercial enterprises. In Oregon, a strong concern for native salmon populations by commercial and sport fishermen hinders the licensing of private hatcheries which arguably could enhance conceivably the entire salmon industry in the long term.

##### 4.4.2.3 Licenses and permits

- o It is unusual for aquacultural facility licensing to be the principal constraint to setting up operations. Regulations and permits in this area generally are not as time consuming or exacting as environmental regulations.
- o The most difficult, time consuming, and costly hurdles are presented by land and water use regulations, e.g., water appropriation, stream alteration, coastal zone land use, wetlands permits, special management area permits, and the like.
- o Although the impact of local zoning ordinances and other land use controls was beyond the scope of the study, it is apparent that approvals at this level can sometimes be more difficult and more time consuming to obtain than state and federal permits.

Property rights in intertidal areas under state jurisdiction, including submerged land and vertical water column leases, need clarification, particularly where traditional fishing interests and aquaculturists are competing for use of the same resources.

- o The status of aquaculture as development under federal and state coastal wetlands laws is a major issue in natural resources planning.
- o Potential impacts of pollutants, including pesticides, radioactive wastes, toxic substances, and acid rain on environments suitable for aquaculture require further research.
- o Financial mechanisms now in place for agriculture are in many instances not readily available to aquaculturists, even though aquaculture is regarded as an agricultural enterprise in many state laws governing taxes, water use, and land use.

#### 4.4.2.4 State Regulatory Anomalies

- o Restrictions on salmon ranching vary widely from state to state (Alaska -- only non-profit; Washington -- not at all; Oregon -- yes, but under rigorous controls; California -- one operation).
- o Variations in disease control efforts and the absence of a consistent national program make it difficult to ship or import fish to or from some states, e.g., Wisconsin will not allow trout stock/eggs to come in from Idaho.

#### 4.4.2.5 State Promotion of Aquaculture

- o Hawaii is perhaps the most aggressive and successful state in its support of aquaculture. The key to its success is that state officials work with aquaculturists before the permit process begins, often eliminating unnecessary delays and denials.
- o In contrast to Hawaii's advocacy of aquaculture is Florida where a rigid regulatory stance sometimes has the effect of discouraging aquaculture.
- o Efforts to streamline the permit process and to create one-stop licensing of aquaculture operations have proven particularly effective in Hawaii, Oregon, and Maine. There is a clear trend toward increased state government support for such simplified procedures. The methods listed below give some indication of the variety of options available:
  - 1) joint applications for state and federal permits;
  - 2) one-stop permitting procedures;

5.0

CASE 3) identification of a lead agency to guide applications through interagency comment and review procedures;

6.1

INTR 4) preapplication consultations with applicants to weed out unacceptable proposals;

5) aquaculture planning office investigations to provide technical assistance on pond design, disease prevention, methods of preventing predation and escape of non-native species of fish into state waters.

The species and operations were selected by the Regulatory Panel of the Joint Subcommittee on Aquaculture. The sample cases were selected from among the top operators in each segment of the industry addressed, and represent operations scattered all across the United States from Maine to Hawaii and back to Florida. The twelve species selected correspond to the twelve species addressed in the draft of the national aquaculture plan prepared under the guidance of the Joint Subcommittee on Aquaculture. The twelve case studies are identified only by number, by species, and by state of operation as follows:

- a Case Study #1: Mussels (Maine)
- a Case Study #2: Oysters (New York and Connecticut)
- a Case Study #3: Trout (Idaho)
- a Case Study #4: Salmons (Oregon and Washington)
- a Case Study #5: Freshwater Prawns, etc. (Hawaii)
- a Case Study #6: Saltfish (Arkansas)
- a Case Study #7: Marine Shrimp (Florida)
- a Case Study #8: Crayfish (Louisiana)
- a Case Study #9: Catfish (Mississippi)
- a Case Study #10: Largemouth Bass (Kansas)
- a Case Study #11: Striped Bass (California)
- a Case Study #12: Hardshell Clams (Massachusetts)

Personal interviews were conducted, using a non-directive interview technique to allow the operator maximum opportunity to identify and discuss practical regulatory constraints as he himself saw them. Each interview report was then structured around five elements: 1) description of operations; 2) perceived regulatory restrictions; 3) apparent dollar impacts; 4) economic factors; and 5) other comments.

Conclusions from such a limited sampling of aquaculture operators must be viewed with caution. No claim is or could be made that these twelve cases are likely to yield statistically sound results. For one thing, the sample chosen was deliberately stratified to the top operators. These individuals themselves cautioned that new entrants and small or marginal operators would likely be even more seriously affected by certain regulatory constraints than they as generally successful and profitable operators. Furthermore, each case study

## 5.0 CASE STUDIES OF FEDERAL AND STATE REGULATORY CONSTRAINTS

### 5.1 INTRODUCTION

The regulatory constraints study called for case studies of twelve U.S. commercial aquaculture operations, representing a variety of marine and freshwater species, to determine the practical effects of aquaculture regulations. Aspen Systems Corporation sub-contracted this task to Pan-Technology Corporation.

The species and operations were selected by the Regulatory Panel of the Joint Subcommittee on Aquaculture. The sample cases were selected from among the top operators in each segment of the industry addressed, and represent operations scattered all across the United States from Maine to Hawaii and back to Florida. The twelve species selected correspond to the twelve species addressed in the draft of the national aquaculture plan prepared under the guidance of the Joint Subcommittee on Aquaculture. The twelve case studies are identified only by number, by species, and by state of operation as follows:

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tends to exaggerate individual aspects of the particular operation under scrutiny. Some small operations are not necessarily impacted by all of the same regulations as a large operation, e.g., NPDES permits.

Nevertheless, the data collected in the twelve case studies is a significant step forward in developing a sounder understanding of the entire industry, its component parts, its different stages of development, and how regulatory constraints are perceived by those who live with them.

The details of the twelve case studies appear in a separate volume entitled: Case Studies of Twelve U.S. Commercial Aquaculture Operations. The following pages capture the highlights of this report. The statements made approximate transcriptions of comments offered by individual operators.

## 5.2 PRINCIPAL REGULATORY IMPACTS CITED BY OPERATORS

### 5.2.1 Case #1: Mussels (Maine)

- o Reclassification as an industry with workers employed in and around docks and vessels increased workers' compensation costs about 10-fold, causing layoffs. [Longshoremen's Workers' Compensation Act]
- o Red Tide testing is slow and cumbersome and creates unnecessary financial burdens.
- o Review and approval process to build small additional dock took 7 months and required 86 peices of paper and threat to sue Corps. of Engineers before clearance. [Navigation and environmental laws].
- o Opening of Georges Bank to oil drilling creates risk of spills and damage to commercial shellfish and finfish operations.
- o Food poisoning liability suits are a constant threat. Better insurance coverage needed, with possibly some federal help needed.
- o Interstate transport of seed sets from southern state, such as Maryland, are not prohibited. Would permit early start in warmer waters and growth to maturity in cleaner, colder Maine waters.
- o Water rights are not a problem in Maine. EPA regualtions have not been a problem to shellfish activities.

### 5.2.2 Case #2: Oysters (Connecticut and New York)

- o Holding and expanding underwater land is the key regulatory constraint in Connecticut; less of a problem in New York. Operators in Connecti-



cut find it almost impossible to acquire new holdings from government leasing units.

- o EPA regulations have not been a problem to this operation, although this could change if agency decides to classify quick lime used to control star fish as a hazardous material.
- o IRS-imposed accounting practices caused large and uncertain inventories (40 feet below water) to be carried on less suitable accrual basis.
- o Four percent unemployment tax on payroll is a burden.
- o Sanitation regulators are doing their job with good will on all sides.
- o Controls on movement of oyster seed from one state to another benefits the industry.
- o OSHA is doing its job; strong in-house safety program in existence.

### 5.2.3 Case #3: Trout (Idaho)

- o The number one problem is obtaining FDA certification of an adequate inventory of drugs to treat trout diseases.
- o A uniform and approved method to certify eggs for both domestic and overseas shipments is lacking.
- o A lack of federal (State Department) help on overseas agreements is restricting alternative overseas markets.
- o Farm Credit Administration failure to clarify to Federal Land Banks that aquaculture is covered by definition of agriculture for loan purposes is constraining available funds.
- o Federal Aid program ship red meat overseas but not even more acceptable fish products.
- o Federal usurping of state water rights for federal energy projects will adversely impact Pacific Northwest aquaculture.
- o Local zoning application reviews have been erratic.
- o IRS shift from cash to accrual accounting has adversely affected trout operations.
- o OSHA regulations have presented no problems.

5.2.4 Case #4A: Salmon - Ocean Ranching (Oregon)

- o Commercial purchases of salmon eggs are at the bottom priority level in disposal (by gift or purchase) of excess eggs from state and federal hatcheries.
- o Industry is asked to shoulder both public and private benefit R&D on major ecological issues.
- o Absence of a national plan for aquaculture which identifies the roles and responsibilities of public agencies and private sector parties.
- o Regulations inhibit salmon culture expansion; no pen rearing in Oregon; no ocean ranching in Washington; almost total prohibition in California.
- o Miscellaneous: excessive paper work and reporting; insufficient number of drugs and medicines; inadequate salmon grading standards; inadequate marketing efforts here and abroad.

Case #4B: Salmon - Pen Rearing (Washington)

- o Failure to adopt a national development plan for aquaculture.
- o Competition of land and water uses.
- o Sea ranching is permitted in Oregon, but not in Washington; pen rearing vice versa.
- o Jurisdictional disputes among several dozen state and federal agencies involved in permitting process adds time delay and costs.
- o Corp of Engineer procedures in obtaining peripheral inputs caused delays and extra costs.
- o Inadequate inventory of certified drugs and medicines; FDA certification is expensive and slow.
- o OSHA regulations which are adopted from different industries.

5.2.5 Case #5: Fresh Water Prawns, etc. (Hawaii)

- o Burdensome permitting process in use of coastal zone sites.
- o EPA effluent control threshold for aquaculture operations is poorly thought out.

- o Most critical constraint in Hawaii is the restriction of exotic species importation. Although Clariidae family has been established in Hawaii for years, Lacey Act has stopped their transport.

5.2.5

Case #5: Tilapia (Hawaii)

- o Lack of national recognition of aquaculture as an important pillar in nation's economic future.

- o Lack of integrated R&D programs with private and public sector responsibilities clearly defined.

5.2.6

Case Study #6: Bait Fish (Arkansas)

- o Most important restriction is time and expense involved in clearance for chemicals used in bait operations.
- o Exclusion of bait fish from certain states.
- o Wetlands and navigable stream regulation are an impediment to availability of new land for expansion.
- o Favoritism of various state trucking laws constraints bait fish markets.
- o Miscellaneous: Wage and hour labor regulations; certain OSHA regulations on wet suits; certain EPA regulations -- if enforced.

5.2.7

Case #7: Marine Shrimp (Florida)

- o Restrictions on importation of superior shrimp species.
- o Absence of a centralized permitting facility; company must deal with 32 separate agencies located in different places.
- o Uneven level of support from state agencies; some are sympathetic and supportive, others appear indifferent to aquaculture needs and potential.

5.2.8

Case #8: Crayfish (Louisiana)

- o Crayfish farmers are unaware of restrictive regulations on their infant industry at this time.
- o Water quality regulations are only perceived as a potential threat in the future as pondage is expanded.
- o A basic R&D plan is needed for the industry.

- o On-going debate over value of more rigorous enforcement of food quality control standards continues.

#### 5.2.9 Case #9: Catfish (Mississippi)

- o Interstate shipment of catfish is sometimes prohibited.
- o Regulations on size, apparently adopted for wild fish, unnecessarily limit the fish-out business.
- o EPA effluent regulations have, so far, been only a threat.
- o Disease control drugs and chemicals are less of a problem for the catfish farmer than the trout farmer.
- o Practical regulation, not ban, on exotic species importation needed.
- o Positive regulatory action is needed in three areas: 1) clear labeling of catfish products to protect domestic farm industry from poorer quality wild varieties that are imported; 2) R&D in genetics and algae control; restrictions on indiscriminate application of aerial pesticides.

#### 5.2.10 Case #10: Largemouth Bass (Kansas) (Two Operations)

- o Most important constraint is the operation and competition of federal and state hatcheries to the private sector.
- o Availability of water is a constraint of future expansion. Currently, aquaculture is classified as industry and municipal and agricultural uses in Kansas have top priority.
- o Absence of a reasonable spectrum of FDA-approved medicines.
- o Concern that the Black Bass Act will be interpreted to inhibit commercial interstate shipments of bass in a manner adverse to aquaculturists.
- o Use of the Lacey Act to unreasonably restrict the commercial cultivation of non-indigenous species.
- o Various states charge producers a permit fee for transporting fish into or through their state, adding to industry cost.
- o Inadequate information on what the individual operator can or cannot do in various states.

5.2.11 Case #11: Striped Bass (California)

- o Access to brood stock or eggs is probably the biggest constraint on striped bass operations. Even with the necessary permits in hand, fishermen complaints of hatchery operations may force use of more costly East Coast sources.
- o The relevant land use legislation, passed in 1976, finally recognized aquaculture as a legitimate coastal land use activity, but there will be serious competition for these lands for recreation, wildlife, sanitation, flood control, and other purposes.
- o Rigorous state water quality laws appear to require that effluent waters must actually enhance bays or estuaries receiving such water; under current filtration technology this may be impractical.
- o Inland water quality regulations are only a little less restrictive for either surface or ground discharges.
- o Workers' compensation rates are not unreasonable if aquaculture is classified as agriculture; but if boats are used, however, much higher longshoreman rates apply -- unfairly, in the view of the company, since the risks are different.
- o Food product liability is a threat for which no insurance protection is carried at this time.
- o Fish and Game permits are required as a freshwater fish breeder, as well as approval for each shipment of out-of-state exotic species.

5.2.12 Case #12: Hardshell Clams (Massachusetts)

- o Already established ten years ago, it is estimated that if the present operation were started today, it would take a minimum of 5 to 6 years to obtain the necessary permits to duplicate the facilities now in place.
- o Access to suitable land and the necessary modifications to that land will become a critical constraint as the operation enters the grow out phase.
- o Bottom, surface or water column leases for clam operations are precarious since they run for only one year at a time.
- o New land leases for grow out purposes are difficult to obtain. Under local control, they are largely obstructed by an unsympathetic state attitude.
- o EPA requires effluent testing four times a year even though tests always show A-1 water.

- o EPA program for registration of hazardous or toxic materials may require filing on the storage of nutrients for algae growth.
- o Because of EPA restrictions on chemicals that might be used to stop predation in grow out areas, less efficient physical barriers must be used.
- o Absence of uniform minimum size limitation on clams shipped to or transported through some states poses a headache.
- o While strongly in favor of state and federal laws that protect reputation of industry as a whole, the National Shellfish Sanitation Program is sometimes overly restrictive. One example is the constraint placed on the use of frozen clams for chowder.
- o Labor costs will rise if clam operations are classified as longshore operations for workers' compensation purposes.
- o The many layers of government permitting (local, state, federal) is confusing and burdensome, particularly to the new entrant.

### 5.3

#### RANKING OF PERCEIVED REGULATORY CONSTRAINTS

The 12 case studies reflect wide differences in species, geography, technologies, and stage of development toward full commercialization. In view of the limited sample and its focus on top operators only, all conclusions drawn from the case studies must be viewed with healthy scepticism.

Nevertheless, the studies are valid for their bird's eye (fish eye?) view of the broad range of legal and regulatory constraints to aquaculture's growth as a viable industry. What they also reveal is that while the universe of regulation impacting on aquaculture is extremely diverse and numbers in the hundreds (see the Federal and State Directories), as a practical matter most of the regulatory headaches fish farmers complain about can be classified under much more finite and manageable categories. In fact, the case study sample of commercial aquaculturists divided their regulatory constraints into 21 problem areas. Based on response frequencies, these problem areas can be ranked to show what aquaculture operators in this diverse sample perceived to be their most pressing regulatory problems. Recognizing that the numbers have little statistical significance, the ordering of perceived regulatory constraints is interesting, nonetheless:

- o EPA effluent control and pressures to maintain the environmental status quo was noted in seven of the 13 cases, with four listing it as a primary constraint.
- o The FDA drug certification process was viewed as the next most important regulatory constraint. It was identified by six of the 13

commercial operations, and five indicated it was of primary importance to their activities.

- o Two constraints are ranked in third place. They are:
  - Constraints on the movement of endangered, deleterious and non-indigenous species across state or national boundaries; and
  - Insurance for workers' compensation.
- o The next important constraint affected five operators and was related to CZM and other land use restrictions.
- o Four of the 13 operators were impacted by problems related to:
  - Access to the certification of fish eggs; and
  - Wetlands and navigable water acts.
- o Three operators were concerned about each of the following:
  - Restrictive health regulations;
  - Tightening of the IRS accounting procedures;
  - Produce exclusions from certain states;
  - Misdirection of public R&D; and
  - Impractical OSHA regulations.
- o At least two operators felt that six additional categories of regulation significantly impacted their activities. They were:
  - Constraints in obtaining underwater lands;
  - Availability of water rights;
  - Favoritism toward instate truckers in certain states;
  - Size of fish limitations;
  - Farm Credit discrimination against aquaculture; and
  - Excessive paperwork and reporting.
- o A final group of two operators found that at least one regulation adversely affected their particular operations. They were:
  - Black Bass Act; and
  - Fuel allowance reductions. (1979).

## 5.4

PERCEIVED DOLLAR IMPACT

Although the operators interviewed were not asked for dollar or proprietary data, some volunteered information about the costs of obtaining permits and staying in compliance with various regulations:

- o The largest single expenditure reported which related to a regulatory requirement was \$200,000 to satisfy EPA effluent regulations.
- o Start-up permits, hearings, and related costs for the operations studied appeared to fall in the \$25,000 to \$50,000 range.
- o Start-up time delays were viewed as more critical, however. A year was not unusual; two not unlikely. Even higher figures were reported.
- o On-going regulatory costs represent only a few percentage points in the total costs picture, however.

These results, again, must be viewed in context. The sample was drawn from the top operators only; it is reasonable to expect that smaller or more marginal operators entering the business or expanding their operations might find the cost impact of some regulations more substantial.

## 5.5

GO/NO-GO IMPORTANCE

Some operators saw certain regulatory burdens as threats to their ability to get into the business or their ability to stay in business:

- o In three cases (mussels, crayfish, catfish) the market seemed sufficiently strong to give the operator confidence that he could cope with almost any regulatory situation.
- o In other cases, however, operators singled out one or more regulations or classes of regulation which they perceived as threats to their business:
  - Access to fish eggs and to non-indigenous species;
  - FDA drug certification/EPA environmental problems; and
  - Access to additional land.



SUMMARY

To illustrate why caution must be used with this particular ordering of perceived constraints, note that only one constraint was mentioned by more than fifty percent of the operators interviewed. Further, some perceived constraints appear to impact on only one or two operators. That is not surprising, however, given the species and geographical variables in the operations selected for study. In addition, certain environmental constraints such as NPDES permits for waste discharges are likely to impact only the larger sized operation.

At the same time, however the case studies revealed that not all regulatory constraints are viewed in negative terms. Indeed, over half of the operators interviewed volunteered that health and sanitation regulations (grading, labeling, etc.) generally work for the benefit of industry and should not be curtailed. Even some OSHA regulations received favorable comment.

Overall, there is some evidence that regulatory impacts tend to be most constraining at the margin, that is, on new entrants to the industry or on expansions by established firms.

Any effort to generalize about the costs of aquaculture regulation must take into account that the various sectors of the industry are presently at different stages of development, that they may have quite different economies of scale, and that they have varying histories of commercial success.

#### FOOTNOTES

1. Testimony of Taylor Pryor, Joint Hearings before the Comm. on Commerce, Science, and Trans. and the Subcomm. on Agr. Research And Gen. Legis. of the Comm. on Agr., Nutrition, and Forestry, 96th cong., 1st Session National Aquaculture Act of 1979, 28, Serial No. 96-57 (1980).
2. P.L. 96-362 (Sept. 26, 1980).
3. Report to Accompany H.R.20, National Aquaculture Act of 1979, 96th Long., 1st Sess., 7, Report 96-168 (May 15, 1979).
4. Report to Accompany S.1650, National Aquaculture Act of 1980, 96th Cong., 2d Sess., 4, Report No. 96-660 (April 23, 1980)
5. Id.
6. Id.

## INTRODUCTION

Part 2 of this report begins the process of identifying specific measures that the Federal Government might take to remove unnecessarily burdensome barriers to the initiation and operation of commercial aquaculture ventures. "Begins" is the operative term because as the voluminous research condensed in Part 1 illustrates, the scope of the regulatory constraints on aquaculture is simply too broad and complex to be amenable to quick or easy solutions.

Nevertheless, with a greater understanding of the regulatory problems involved in aquaculture operations comes a greater appreciation of steps that might be taken to minimize administrative burdens, regulatory barriers, and other related impediments to the growth of commercial aquaculture.

### AQUACULTURE IN THE UNITED STATES: REGULATORY CONSTRAINTS

Part 2, however, does not attempt to identify solutions by taking a closer look, not at the entire universe of regulatory constraints, but rather at a limited number of regulatory programs that the Federal Government authorizes and thus, presumably, can do something about.

#### THE NEED FOR AN ACTION PLAN

One initial conclusion of the aquaculture regulatory constraints study was that Federal, State, and local regulations act as a significant obstacle to the initiation and expansion of American aquaculture. The research generally bears this out but with some unexpected twists and turns. For example, the study found that Federal laws and countless regulations that in some ways seem to support aquaculture in fact create regulatory constraints.

#### Part 2: Regulatory Constraints Action Plan

The general types of constraints emerge -- permit and certification burdens, and exclusions from beneficial regulatory programs. While there is reason to support a less restrictive Federal role in some areas, there are other areas where aquaculturists conceivably could benefit by more active Federal support than currently is the case. No better example of that support, in the minds of many aquaculturists, is the initiative taken by Congress to pass the National Aquaculture Act of 1980.

Signed into law on September 28, 1980 by then-President Carter, the National Aquaculture Act culminated years of planning, research, and inter-agency cooperation. The bill articulates a strong national policy in support of aquaculture, creates a statutory mechanism for interagency coordination of aquaculture programs in the Federal Government, and authorizes funding to establish and implement the plan.

In hearings on the bill, a number of factors were identified as limiting the potential for growth of aquaculture, including: a) inadequate information

H.S. Rep. 95-600, 96th Cong., 2d Sess., 6-7 (1980).

## 1.0

### INTRODUCTION

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Nevertheless, with a greater understanding of the regulatory problems involved in aquaculture operations comes a greater appreciation of steps that might be taken to minimize administrative burdens, regulatory barriers, and other related impediments to the growth of commercial aquaculture.

Part 2, accordingly, begins the search for solutions by taking a closer look, not at the entire universe of regulatory constraints, but rather at a limited number of regulatory programs that the Federal Government authorizes and thus, presumably, can do something about.

## 1.1

### THE NEED FOR AN ACTION PLAN

One initial hypothesis of the aquaculture regulatory constraints study was that federal, state, and local regulations act as a significant obstacle to the initiation and expansion of American aquaculture. The research generally bears this out but not without some unexpected twists and turns. For example, the Federal Directory includes 122 laws and countless regulations that in some way or other involve the Federal Government in the way aquaculturists do business in America. Two general types of constraints emerge -- permit and certification compliance burdens, and exclusions from beneficial regulatory programs. While there is reason to support a less restrictive federal role in some areas, there are other areas where aquaculturists conceivably could benefit by more active federal support than currently is the case. No better example of that support, in the minds of many aquaculturists, is the initiative taken by Congress in passing the National Aquaculture Act of 1980.

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\* S. Rep. 96-660, 96th Cong., 2d Sess., 6-7 (1980).

tion; 2) inadequate funding; 3) marketing practices; 4) inadequate credit and financing; 5) existing laws and standards; 6) water resource development; and 7) duplication and lack of coordination among governmental agencies.

Thus, the National Aquaculture Act itself establishes the need for a regulatory constraints action plan. Both with respect to those parts of the federal regulatory web that may need untangling and those parts of the federal agency framework that may need better coordination -- there is ample opportunity for the federal government to take creative action in behalf of aquaculture.

## 1.2 SCOPE OF ACTION PLAN

The scope of the regulatory constraints action plan envisioned in the Statement of Work was limited and can best be described in terms of what it does not cover. The underlying research identified approximately 21 regulatory programs that could be addressed for further analysis and development of action strategies. This report investigates only five federal programs considered by aquaculturists to require attention. The underlying research also developed a data base of over 1200 statutes and related regulatory programs in 32 states that relate directly or indirectly to aquaculture, with varying degrees of impact on the start-up or continuation of aquaculture ventures. This report, however, deals primarily with the framework of selected federal laws and regulations. Its focus, therefore, is on programs emanating from the Federal Government and not from individual states.

## 1.3 SELECTION OF CANDIDATE PROGRAMS

A candidate list of five federal regulatory programs was approved by the Regulatory Panel of the Joint Subcommittee on Aquaculture for developing strategies for action. The programs were selected on the basis of the following criteria, among others: 1) degree of perceived restrictiveness; 2) degree of amenity to federal solution; and 3) potential for promotion of aquaculture. Not surprisingly, the list of programs selected has some degree of correlation to the ranking of perceived regulatory constraints reflected in the case studies of 12 commercial operations summarized in Part 1 of this report.

The five federal regulatory program areas addressed are:

- o Federal environmental regulations (water and use quality).
- o Drug and chemical registration and clearance procedures
- o Fish and shellfish health programs
- o Financial assistance programs.
- o Exotic species regulation

Although beyond the scope of this analysis, any effort to engage in regulatory reform whether it be permit simplification, better interagency coordination or the like must first come to grips with certain conceptual issues.\* There are, for instance, a number of constituencies that have strong interests, including: the development sector; the environmental interest sector; the governmental sector; and the general public. Each of these has its own view of regulatory processes; everything from the view that existing systems unnecessarily increase the cost of development, to the view that without them American society could not enjoy the health, safety, and environmental benefits it now does.

That on-going debate, while ultimately of utmost significance to the implementation of a regulatory constraints action plan for aquaculture, is here noted only in passing. On the other hand, an outline of action strategies conceivably available to address perceived regulatory constraints or inefficiencies as presented here, will facilitate an understanding of specific solutions in the context of aquaculture.

The problems caused by cumbersome, costly, and time consuming regulatory permit processes in general have been analyzed by environmental and planning departments of a number of states, including Hawaii, Maine, Oregon, and California. A recent study\*\* by the State of Hawaii Department of Planning and Economic Development, identified six causal factors that can lead to regulatory inefficiency and proposed a variety of techniques to counter their effect:

1. Poor Communication

- o Permit registers or checklists
- o Permit information centers
- o Pre-application conferences

2. Delay

- o Time limitations
- o Pre-application conferences
- o Joint hearings
- o Completeness requirements
- o Permit ombudsman
- o "Major" or "minor" permit distinctions

\*Drawn from the indepth analysis by Holmstrom, Problems of Regulatory Inefficiency and issues to be Considered in Reducing Them, Technical Supplement #15, Department of Planning and Economic Development, State of Hawaii (Jan. 1980).

\*\*Id.

### 3. Lack of Coordination

- o Master, or consolidated application
- o One-step permit procedures
- o Liaison staffing
- o Permit ombudsman
- o Inter-agency committees
- o Joint hearings
- o Coordinating agency
- o Lead agency
- o Consolidation of regulatory functions at one level of government
- o Area-specific super agencies
- o Use-specific super agencies

### 4. Redundancy of Procedures

- o Permit surrender
- o Impact assessment requirement revisions
- o Joint hearings
- o General permits

### 5. Lack of specific decision-making criteria in regulations

- o Standards determination

### 6. Non-conformance of regulatory procedures and their substantial objectives

- o Early clarification of objectives
- o Use of area exemptions

Many of the techniques proposed by the study have some relevance to the five programs selected here. Many of them start from the premise that better communication among the parties involved in the process is the first place to start toward reducing regulator inefficiencies. A problem for would-be aquaculturists is that frequently they are unaware of the steps they need to take to obtain a series of related permits and lack information about who to go to in government (federal or state) for ready answers.

It should be noted that not all of the regulatory programs selected for scrutiny involve matters of procedural efficiency. There are also substantive requirements of regulation (e.g., NPDES effluent guidelines applied to aquaculture) at issue in some instances, where the question is not whether the regulatory agency is doing or not doing its job well, but rather whether it should be doing a particular job at all, or at least to that degree of constraint. Questions of procedural and administrative efficiency therefore, must be distinguished from substantive issues.

## 2.0 ENVIRONMENTAL REGULATIONS: WATER USE AND QUALITY

### 2.1 INTRODUCTION

Unpolluted and productive bodies of water are essential to aquaculture. Granted, behind this truism lies some debate over just how pristine water bodies must be in order to fuel the aquatic ecosystem needed to support viable aquaculture enterprises. But this debate is not over the importance of water to aquaculture, rather one of degrees of water quality and how strictly that level of quality should be regulated.

Federal, state, and local authorities regulate the fish farmers' access to and use of water in many ways. Of principal concern here, however, is how the Federal Government, through two interrelated programs of the Environmental Protection Agency and the Army Corps of Engineers, regulates how the fish farmer either sets up for or continues in business. Specifically, these are the Corps of Engineers' dredge and fill permit program, and EPA's National Pollutant Discharge Elimination System (NPDES). These two programs are the principal vehicles mandated by Congress to achieve the goal of the Clean Water Act, which is the elimination of discharges of pollutants into navigable waters of the U.S. by 1985.

### 2.2 CORPS OF ENGINEERS DREDGE AND FILL PERMIT

#### 2.2.1 Statement of the Aquaculturist's Problem

That water quality is best left unregulated by federal or state and local authorities is not an argument thoughtful aquaculturists have raised. Rather, as expressed in numerous hearings conducted by Congressional committees on the National Aquaculture Act of 1980 and its predecessors, the sticking point is delay, lack of coordination among the governmental units assuming jurisdiction, and high opportunity and administrative costs in obtaining the necessary Corps permit for aquaculture activities in navigable waters. Regulatory agency review processes can be cumbersome, time-consuming, and costly, and are so viewed by a substantial number of fish farmers.

The potential for delay occurs at several points in the regulatory process: 1) notification that the application is incomplete and that additional information is required; 2) review of the application by a number of federal and state agencies; and 3) conflicting policy positions over aquaculture development among different branches of government, e.g., legislative encouragement of aquaculture conflicting with federal and state agency refusal to grant permits needed to develop an aquaculture facility.



On the other hand, the response of the Corps has been that many of the delays and attendant costs associated with its construction and fill regulations arise not from their inefficiency, but rather from the considerable time it actually takes for the applicant to perform surveys, prepare engineering plans, and conduct studies to complete a permit application.

The Corps contends that once the application has been completed to its satisfaction, normal review procedures generally are set in motion without undue delay. For example, the Corps is required by statute to notify applicants of the status of their application within 90 days. Nevertheless, particularly for controversial projects, public hearings and the need for environment impact statements have been known to prolong the actual review process for one or more years.

The cost and time constraint imposed by delay and related problems is compounded by the sheer number of agency reviews needed in some jurisdictions. In Florida, for example, a dredge and fill permit application could be reviewed by the Army Corps of Engineers, the Regional EPA office, the U.S. Fish and Wildlife Service, and the National Marine Fisheries Service -- at the federal level alone. Add to that state reviews by the Department of Environmental Regulation, the Department of Natural Resources, the Department of Marine Resources, and the Game and Fresh Water Commission. Finally, add additional reviews by county or municipal planning boards and by local residents at hearings and the potentially cumbersome nature of the review process becomes apparent.

### 2.2.2 Background

The U.S. Army Corps of Engineers was created in 1802 to build and maintain coastal defenses and fortifications authorized by Congress. With the passage of the Rivers and Harbors Act of 1899, the jurisdiction of the Corps expanded to include improvements in "navigable waters." More recently, flood control, shore protection, regulation of dredging and filling, and construction in rivers, harbors, and coastal zones have been added to the Corps' responsibilities.

Much controversy has arisen over the definition of "navigable waters" and the extent of the Corps' jurisdiction over such waters. Under English common law, waters were navigable if they were subject to tidal action. That definition however, was hardly satisfactory in the United States, with its network of inland waterways. The trend in U.S. Supreme Court decisions, as well as in federal regulations has been to expand the Corps' jurisdiction both inland along waters deemed "navigable-in-fact" and laterally to areas such as wetlands, where federal jurisdiction extends up to the mean high water mark.

The resolution of such jurisdictional questions is of considerable importance to aquaculturists both marine and freshwater. For example, fish farmers leasing portions of an ocean or estuarine bed for oyster farming or other fish culturing purposes are subject to Corps of Engineers authority over navigable

waters. In Lewis Blue Point Oyster Cultivation Co. v. Briggs, 229 U.S. 82 (1913), the court held that the rights of a private oyster bed lessee were subordinate to the Federal Government's power to regulate commerce, including dredging of a shipping channel in Long Island Sound.

In United States v. Kaiser Actna, 408 F. Supp. 42 (D.Hawaii 1976) the court held that under section 10 of the Rivers and Harbors Appropriation Act and section 403 of the Clean Water Act, a privately owned waterway might come within the definition of "navigable waters of the United States", and that where a waterway or marina was used in interstate commerce, it was subject to regulation by the Corps. As an expert cited by the court remarked: "[a] navigable river is any river with enough water to float a Supreme Court Opinion." Id. at 49.

### 2.2.3 Current Regulatory Scheme

The various types of activities that require Corps of Engineer permits include: 1) construction of dams or dikes in navigable waters; 2) other construction work in navigable waters including excavation, dredging, and/or disposal activities; 3) activities that alter the course, condition, location or capacity of navigable waters; 4) construction of fixed structures on the outer continental shelf; 5) all discharges of dredged or fill material into U.S. waters; and 6) all activities involving the transportation of dredged material for the purpose of dumping it into ocean waters.

The focus here, however, is on Clean Water Act § 404 permits for dredged or fill material, issued pursuant to EPA Guidelines by the Corps of Engineers in accordance with its own regulations appearing at 33 C.F.R. § 323.1 et seq.

#### 2.2.3.1 Dredge and Fill Material -- Section 404 of Clean Water Act authorizes the Army Corps of Engineers to regulate the discharge of dredged or fill materials into waters of the United States, including wetlands. 33 U.S.C. § 1344. Under Corps' regulations a "discharge of fill material" includes the following activities:

Placement of fill that is necessary to the construction of any structure in a water of the United States; the building of any structure or impoundment requiring rock, sand, dirt, or other material for its construction; site-development fills for recreational, industrial, commercial, residential, and other uses; causeways or road fills; dams and dikes; \* \* \*

#### 2.2.3.2 The Permit Process -- Would-be aquaculturists are likely to be confused, at least initially, about EPA's role in the permit process. And with good reason, since the responsibility for the § 404 dredge and fill program is split between the Corps and EPA. The Corps of Engineers (or an approved state program) is the

permitting authority. Section 404(b)(1) Guidelines issued by EPA, however, contain the substantive criteria for what discharges will or will not be permitted. Both are granted statutory veto power over particular applications, but neither has preemptive authority. The Corps may, for example, issue a permit even if EPA gives the application an adverse review. On the other hand, EPA may prohibit a particular discharge if the discharge would have an unacceptable adverse affect on fish and shellfish areas (including spawning or breeding areas), municipal water supplies, wildlife or recreation areas.

The Fish and Wildlife Service of the Department of Interior and the National Marine Fisheries Service of the Department of Commerce also may be given an opportunity to review and comment on dredge and fill applications, and to provide technical assistance for the purpose of protecting fish and wildlife resources and mitigating adverse project impacts.

The recently revised EPA Guidelines which apply to dredge and fill permits issued by the Corps, establish various criteria for issuing permits:

- o Discharges of dredged or fill materials are not permitted if there is a "practicable alternative" which would have less adverse impact on the aquatic ecosystem, as long as the alternative does not have other significant adverse environmental consequences.
- o Alternatives are "practicable" if it is available and capable of being done, cost, existing technology, etc. considered.
- o Where the activity involves a special aquatic site and is not "water dependent," practicable alternatives are presumed to be available unless clearly demonstrated otherwise.

The Corps has standard procedures (33 C.F.R. § 325.2(a)) and procedures for particular types of permit situations (33 C.F.R. 325.2(b)). Among the latter is a procedure applicable where water quality certification is necessary under the Clean Water Act, one for activities undertaken in a state operating under an approved coastal zone management program, one for activities involving property listed in the National Register of Historic Places, and still another for federal navigation projects.

Regarding the timing of processing these applications, Corps regulations (22 C.F.R. 325.2(d)) state:

In view of the extensive coordination with other agencies and the public and the study of all aspects of proposed activities required by the above procedures, applicants must allow adequate time for the processing of their applications.

For many aquaculturists, "adequate" has meant "too long."

#### 2.2.4 Outline of Action Strategies

The basis of the constraint that aquaculturists perceive in the Corps' permitting process appears to be administrative delay, time consuming multi-layered review processes, and related regulatory inefficiencies. The Corps already has embarked on joint ventures with a number of states to establish joint permit and hearing procedures, however. Guides for applicants to the Corps' permit program have long been available as well.

The types of activities and strategies outlined below are not simply aimed at reducing the time required for processing dredge and fill permits, although that should not be overlooked. Rather, the thrust of this action strategy is to improve efficiency, planning, and communication so that the process works for everyone concerned -- fish farmer and administrative agency alike. Ideas to improve the regulatory process might include:

- o Publication and dissemination of permit compliance guides specifically tailored to the needs of aquaculturists;
- o Expansion of existing program to encourage more states to establish joint permit and hearing procedures with the Corps;
- o Creation of an aquaculture permit ombudsman in conjunction with an aquaculture compliance information office for would-be aquaculturists (regional and/or state basis).
- o Legislative feasibility study of changing or eliminating regulations providing for pendency of Corps' permit application during state approval process. 33 C.F.R. 325.2.
- o Promotion of pre-application planning and consultation procedures (joint Corps/EPA/other federal agency/state agency).

#### 2.3 NPDES PERMIT PROGRAM

##### 2.3.1 Introduction

The National Pollutant Discharge Elimination System (NPDES) gives the Environmental Protection Agency authority to issue permits for any discharge of pollutants from "point sources" into the waters of the United States. Such discharges are illegal in the absence of an NPDES permit, unless an exemption applies. NPDES permits are issued by the state official responsible for water pollution control, or by the EPA Regional Administrator where there is no approved state program.

Specific NPDES procedures for "aquaculture projects" appear at 40 C.F.R. 122.56, and for "concentrated aquatic animal production facilities" at 40 C.F.R. 122.55 and Appendix C ("NPDES Criteria for Determining a Concentrated Aquatic Animal Production Facility").

### 2.3.2 Statement of the Aquaculturist's Problem

Fish and shellfish production creates wastes. The issue for many large aquaculture operators is whether these are the types of waste that should be regulated as discharges of pollutants and, if they are, whether they should be regulated to the degree they are. Some fish farmers have argued that EPA regulations are unnecessarily restrictive in that they fail to distinguish between biodegradable wastes produced by fish hatcheries and chemical wastes produced by industry, even though fish wastes are known to contain nutrients beneficial to receiving waters. Some fish farmers, in fact, use wastewater effluent for the cultivation of by-products such as seaweed. Furthermore, some aquaculturists argue that the regulations fail to recognize that in certain locations the flushing action of tidal waters may take adequate care of the wastes. The net result of NPDES permits, for some aquaculturists is additional costs for new treatment technologies.

On the other hand, fish farmers also are among the first to agree that water quality is of utmost importance to the success of their operation. Some point out that flexible interpretations of effluent regulations may improve management practices for bacteria control.

### 2.3.3 Current Regulatory Scheme

Two types of aquaculture operations are subject to the requirements of the NPDES program: "aquaculture projects" defined as those which use discharges of pollutants for the maintenance or production of aquatic species; and "concentrated aquatic animal production facilities", defined to include fish farms and hatcheries. The latter are considered point sources. For cold water fish species (e.g., trout, salmon) a permit is required if the facility discharges at least 30 days per year and produces more than 9,090 harvest weight kilograms (approximately 20,000 pounds) of aquatic animals per year, or feeds more than 2,272 kilograms (approximately 5,000 pounds) of food during the calendar month of maximum feeding. Facilities producing warm-water (e.g., catfish, minnows) species are regulated if they discharge at least 30 days per year, unless they are closed ponds which discharge only during periods of excess runoff, and if they produce more than 45,454 harvest weight kilograms (approximately 100,000 pounds) of aquatic animals per year. 40 C.F.R. 122 (Appendix C).

In addition, EPA may designate any aquatic animal feeding facility as a "concentrated aquatic animal production facility" if it decides the facility is "a significant contributor of pollution to waters of the United

States." 40 C.F.R. 122.55(c). Factors to be considered in making this determination include: 1) location and quality of the receiving waters; 2) holding, feeding, and production capacities of the facility; and 3) the quantity and nature of the pollutants reaching waters of the United States. Such a designation cannot be made without an on-site inspection of the site to determine whether it should and could be regulated under the NPDES program.

Under the current regulatory scheme, therefore, aquaculture production facilities which discharge wastes less than 30 days per year and which produce less than 20,000 pounds of harvest weight products per year for cold-water species or less than 100,000 pounds per year for warm water species, are exempted as regulated point sources. Special criteria exist for issuance of permits to "aquaculture projects" which receive controlled discharges to determine the feasibility of using pollutants to grow aquatic organisms which can be harvested and used beneficially. 40 C.F.R. 125.10.

To fill out an NPDES application, the applicant is to provide EPA with the following information: 1) the maximum daily and average monthly flow from each outfall; 2) the number of ponds, raceways, and similar structures; the name of the receiving water and the source of intake water; the total yearly and maximum harvestable weight for each aquatic species; and the calendar month of maximum feeding and the total mass of food fed during that month. Aquaculture applicants must report quantitative data on effluent characteristics of the same kind as manufacturing, commercial, mining, and silvicultural discharges.

#### 2.3.4 Outline of Action Strategies

- o Promote further research on biodegradability characteristics of effluent discharges from various species operations.
- o Through public hearing process, establish criteria and standards specific to discharges of wastes by concentrated aquatic animal production facilities.
- o Conduct legislative review of the rationale for and validity of the particular criteria selected for designating a "concentrated aquatic animal production facility". (Appendix C to Part 122).
- o Study the water quality and economic impact of regulating discharges from licensed aquaculture operations, including finfish and shellfish, if aquaculture were regulated the same as agriculture.
- o Promote research on productive uses of fish farm effluent.

## 3.0 DRUG AND CHEMICAL REGISTRATION PROCEDURES (FDA)

### 3.1 INTRODUCTION

Aquaculturists administer drugs to fish both directly, to cure disease, and indirectly, in fish feed, to prevent disease. Chemicals routinely are used in water where fish are raised in order to prevent growth of fungi and bacteria. Under the Food, Drug, and Cosmetic Act, every chemical used in treatment of food for human consumption must be approved by the Food and Drug Administration of the Department of Health and Human Services, and the drug must be re-registered for each additional use on any additional species. 21 U.S.C. §360b(i). The use of drugs and chemicals to prevent and control the common diseases and parasites of cultured fish is essential to the aquaculture industry. Therapeutants, anesthetics, herbicides, and piscicides play important roles in hatchery production, fish health and quality, and post-stocking survival rates.

### 3.2 STATEMENT OF THE AQUACULTURIST'S PROBLEM

Chemicals and pharmaceuticals must pass rigid and highly specific FDA certification requirements, an expensive and time consuming process. The process reportedly can cost millions of dollars and years of research for initial approval of a drug.

At the present time, only a small number of drugs have been certified by the FDA for use by fish farmers. Certain drugs and chemicals currently in use by aquaculturists, in fact, are used illegally. Because of the high cost and time needed to perform the tests required for FDA approval, and the relatively small market for chemicals for use on fish, private industry is reluctant to undertake the research and development needed to place more approved fish drugs on the market. While FDA's enforcement of this aspect of the Food, Drug, and Cosmetic Act has been minimal, and the agency does not conduct regular inspections to determine whether unregistered chemicals are being used in commercial hatcheries and farm ponds, fish farmers are nonetheless faced with the dilemma of having to choose between not using unregistered chemicals and losing valuable fish stock to disease, or using chemicals known to have therapeutic value, but at the risk of being in violation of federal regulations.

A second aspect of the problem relates to the fact that the registration process applies to the use of the drug, not the drug itself. Thus, a drug must be re-registered for each new use as well as for any additional species. Aquaculturists have proposed that drugs be given "blanket approval" for a variety of species and uses. Under the current system, separate studies, must be conducted for the same drug on brook trout and brown trout, or on Coho and Chinook salmon. However, FDA has consistently rejected the "blanket

approval" approach, arguing that the need to prevent unsafe drugs from entering the market outweighs the additional cost imposed on the industry.

In any event, few aquaculturists argue that the drug certification system should be by-passed; rather, that it take less time and expense.

### 3.3 FDA'S REGULATORY SCHEME

#### 3.3.1 The Drug Approval Process

The Food, Drug, and Cosmetic Act prohibits the adulteration or misbranding of any food or drug in interstate commerce. 21 U.S.C. §331b. Food is deemed adulterated for purposes of the Act if it contains "any poisonous or deleterious substance which may render it injurious to health." 21 U.S.C. §342a. The Act authorizes the FDA to create exemptions for substances which cannot be avoided by good manufacturing practice (§346), to establish tolerances for pesticides in or on raw agricultural commodities (§346a), and to require registration of new animal drugs (§360b).

Because there are no specific provisions for fish drugs, companies entering the fish health field are subject to regulations governing new animal drug registration. A new animal drug is deemed unsafe unless the drug has been approved for use in a particular animal feed, and the animal feed is labeled according to FDA regulations.

The application for registration of a new animal drug must include:

- 1) reports of tests to show the drug is safe and effective for the intended use;
- 2) a full list of articles used as components of the drug;
- 3) a statement of the composition of the drug;
- 4) a description of methods used in manufacturing, processing, and packaging the drug;
- 5) samples of the drug, its components, animal feed in which the drug is intended to be used, and edible portions of animals in which the drug is to be used;
- 6) specimens of the labels to be used;
- 7) a description of practicable methods for determining the quantity, if any, of such drug in or on food, and any substance formed in or on food, because of its use;



- 8) the proposed tolerance or withdrawal period or other use restrictions required for safety.  
21 U.S.C. §360.

Procedures for completing a New Animal Drug Application (NADA) are set out that 21 C.F.R. 514 et seq.

Drugs to be used solely for investigational purposes may be given limited clearance with the Investigational New Animal Drug application (INAD), under registration procedures set forth at 21 C.F.R. 511.1 et seq. The INAD approval allows an investigator to use a drug for scientific purposes in order to test its safety and effectiveness. The investigator may not use the drug in any other way than described in the investigational application. The investigator must keep complete records of the investigation for two years after it has been terminated or the new animal drug application has been approved.

### 3.3.2 Efficacy and Safety Testing

In order for approval to be granted, the applicant must submit data from efficacy and safety tests, proving that the drug presents no danger to human or animal health and that the drug is effective in controlling the disease for which clearance is sought. The applicant must submit information on the components of the drug; the methods, facilities, and controls used in manufacturing, processing, or packaging the drug; proposed labels; an environmental impact analysis report; and a Freedom of Information summary of safety and efficacy data. There is no difference in registration procedures for drugs added to fish feed and drugs added to water in fish ponds.

Efficacy studies must include data from tests on at least three groups of animals:

- 1) non-infected, non-medicated control group,
- 2) infected, non-medicated control group,
- 3) infected, medicated control group.

Safety studies must include data on subacute oral toxicity for rats and dogs, the time necessary for the drug to clear the fish's system, and a showing that there are no harmful residues remaining in the fish tissue after a specified withdrawal period, usually 21 days. The applicant must also provide an acceptable method for detecting residues in fish tissue, water, and soil, as well as an alternative method for confirming the preferred method.

Labeling requirements include information on kind of species, dosage level, applications, directions for use, warnings, and restrictions.

Before an applicant begins these studies, the FDA recommends a literature review of the disease or syndrome for which the drug is to be used, including literature on the disease organism, the species of fish affected, incidence and impact of the disease, environmental and other factors causing the disease, and known techniques for controlling the disease in fish or other animals.

Within 180 days of receipt of the application, the agency must notify the applicant whether further information is needed in order for the approval process to begin. However, this time constraint is often not met, because at least three bureaus within the FDA must review the application -- the Bureau of Veterinary Medicine, the Bureau of Foods, and the Bureau of Toxicology. The U.S. Fish and Wildlife Service of the Department of the Interior is also involved in the review process. Thus, the applicant might not be notified that further information is necessary for 15 to 18 months. Providing the requested additional information might take another year. Even then, the applicant has no assurance that the information needed for review is complete.

If the FDA decides not to approve the drug, it must notify the applicant within 180 days. The application will not be approved if

- 1) tests of drug safety are inadequate;
- 2) tests show that the drug is unsafe for use under the proposed conditions;
- 3) methods used in manufacture, processing, and packaging are inadequate to preserve its identity, strength, quality and purity;
- 4) there is insufficient information for determining whether the drug is safe for use under the proposed conditions;
- 5) there is insufficient evidence on which to evaluate the effectiveness of the drug for the proposed use.

#### 3.4 OUTLINE OF ACTION STRATEGIES

- o Conduct a comprehensive audit of staff and laboratory resources in appropriate federal agencies for the purpose of assessing the potential for reallocating resources, funds, etc. to support drug registration efforts as part of on-going programs.
- o Conduct first year evaluation of new FWS policy for cooperative agreements with other federal agencies, states, universities, the chemical

4.0

and drug industry, and other interested groups for the purpose of additional support or refinements.

4.1

- o Conduct Congressional hearings on the potential of tax and related financial incentives for increased private sector involvement in testing chemicals and drugs for aquaculture uses for FDA clearance.
- o Conduct an investigation of the problems and prospects of "blanket approvals" in certifications for aquaculture drugs and chemicals.
- o Promote multi-agency workshops and discussions to devise new strategies for more efficient drug registration efforts.
- o Investigate mechanisms (excise tax, royalties) for funding future research today.

4.2

STATUS

Under circumstances where the existing inventory of registered drugs and chemicals for disease treatment is small, and new ones slow in coming, fish and shellfish health concerns take on special urgency for many aquaculturists. Immunization, research, development of fish vaccines, and related programs offer long-term alternatives to the Catch-22 disease treatment situation some aquaculturists find themselves in today, but such more needs to be done if the aquaculture industry is to reach its commercial potential. The industry perceives a need for increased government support for developing a comprehensive fish and shellfish health research program encompassing both disease treatment and disease prevention.

Aquaculturists cite the absence of a readily accessible national program to certify fish and egg health where that is required prior to shipments across restrictive state lines. Federal programs to certify disease-free seed and stock exist, but are not routinely available to the individual entrepreneur except in special circumstances.

4.3

DISEASE TREATMENT DRUGS

The time and expense required for registration of drugs for use in disease treatment has tended to discourage private drug companies from investing in fishery compounds. Consequently, many of the drugs relied upon by fish farmers to prevent or control disease are unregistered, and substitutes are not readily available. Methylene blue, used until recently in public and private fish hatcheries as a fungicide, was undergoing testing by the U.S. Fish and Wildlife Service for registration, when studies showing evidence of teratology (birth defects) in rabbits led the FDA to recommend that the testing program be discontinued. However, even though the chemical has been officially withdrawn from the list of approved compounds, it is still available to private hatchery operators, and will probably continue to be used until alternatives are found.

## 4.0 FISH AND SHELLFISH HEALTH PROGRAMS

### 4.1 INTRODUCTION

Disease control and disease prevention are seldom far from the aquaculturist's mind. Where the economies of aquaculture dictate high culture densities, the problems of disease transmission tend to be compounded. Disease can be dealt with in several ways: prevention through, for example, selection of genetically superior organisms resistant to disease; immunization agents; and/or treatment of diseased fish and shell fish. Government supported research in each of these areas is conducted in federal and state laboratories and institutions around the country.

### 4.2 STATEMENT OF THE AQUACULTURIST'S PROBLEM

Under circumstances where the existing inventory of registered drugs and chemicals for disease treatment is small, and new ones slow in coming, fish and shellfish health concerns take on special urgency for many aquaculturists. Immunization research, development of fish vaccines, and related programs offer long-term alternatives to the Catch-22 disease treatment situation some aquaculturists find themselves in today, but much more needs to be done if the aquaculture industry is to reach its commercial potential. The industry perceives a need for increased government support for developing a comprehensive fish and shellfish health research programs encompassing both disease treatment and disease prevention.

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While numerous compounds have been registered for use on fish, only three have been approved for use on food fish, and one for use on aquarium fish:

- 1) sulfamerazine, added to fish feed to control furunculosis;
- 2) terramycin or oxytetracycline, approved for use on salmonids and catfish, administered orally in fish food, and used to control diseases in fish hatcheries;
- 3) tricainmethane sulfate or finquel, added to water to tranquilize fish when they are being transported or when their eggs are being removed; and
- 4) nifurpyranol, for use on aquarium fish only, for control of bacteria.

#### 4.4 DEPARTMENT OF INTERIOR (FWS) INITIATIVES

##### 4.4.1 Drug Registration

In response to the need for more efficient registration procedures, the Department of Interior's Fish and Wildlife Service has initiated a program of cooperative agreements with industry, universities, and other federal agencies to promote the timely development and registration of drugs and chemicals for fish disease treatment. The agency assesses the priority needs of its national hatcheries and identifies specific compounds to test in order to meet each of those needs. It then enters into cooperative agreements with industry, university research programs, or other agencies to share the cost of conducting the necessary tests. The Service spends approximately \$1 million/year on this program, which includes a major testing effort to re-register an important fish toxicant, rotenone, with EPA, after the chemical was withdrawn from the approved list in response to a study suggesting that the chemical was a possible carcinogen.

The Service has included a "Disclosure of Data" clause in its cooperative agreement in order to protect proprietary information. The Service reserves the right to release details and findings of any study funded by federal monies, but assures the cooperator that it will make a good faith effort to contact it for comment prior to a decision to release the information.

Arrangements with the Washington Department of Fisheries, Washington Department of Game, and the University of Idaho were completed in August, 1980, to begin new studies to generate additional efficacy data required by FDA for clearance of erythromycin phosphate to prevent vertical transmission of Bacterial Kidney Disease (BKD) in salmonids.

The majority of the FWS's work on drug clearance is performed or coordinated at the National Fishery Research Laboratory in LaCrosse, Wisconsin.

#### 4.4.2 Disease Research and Technical Assistance

Apart from its activities in developing cooperative agreements for registering priority compounds for fish disease purposes, the Fish and Wildlife Service has sponsored disease prevention research for many years in a number of laboratories around the country. The Service operates two disease laboratories at the National Fishery Research Center in the State of Washington and the National Fish Health Research Laboratory at Leetown, West Virginia. Research identifying the sources of fish viruses such as infectious pancreatic necrosis and other common fish diseases is emphasized.

The world-renowned Fish Farming Experimental station at Stuttgart, Arkansas, does extensive work in disease diagnostics. Another important health research program at the Service is the Hatchery Biologist Program, which employs 22 trained fisheries biologists at 17 laboratories in 6 geographic regions to: 1) provide diagnostic services; 2) disease inspections; and certification inspections.

The certification inspection program, however, is not available to the ordinary aquaculturist, except in special circumstances. Although no regulations exist, (there is no national fish disease law), FWS policy is to first serve the needs of the National Fish Hatchery System and only then provide certification services to the private sector in cases where an operator has nowhere else to turn or, in special cases where a foreign government, e.g., the U.K., will accept certification only by federally-employed (not just certified) biologists.

FWS disease-free certification services sometimes are also made available to the private sector in circumstances where an association of producers bands together and signs a cooperative agreement with the Service. The guiding principle in all of this is that the Service does not wish to compete with private diagnostic services. Limited budgets also preclude offering certification services more widely.

#### 4.5 DEPARTMENT OF AGRICULTURE DISEASE PROGRAMS

The Animal and Plant Health Inspection Service of the USDA consists of two units -- the Plant Protection and Quarantine Programs and Veterinary Services. The latter's services in aquaculture consist of: 1) providing differential diagnoses of infections and toxicological conditions of fish through the National Veterinary Services Laboratory in Ames, Iowa; providing field veterinary epidemiologists on a request basis, to local officials and individual fish

producers in the area of infections and toxicological conditions; 3) administration of the Virus-Serum-Toxin Act of 1913 under which Enteric Redmouth Bacteria and *Vibrio Anguillarum* Bacteria is licensed.

#### 4.6 DEPARTMENT OF COMMERCE DISEASE RESEARCH

The National Oceanographic and Atmosphere Administration, through the National Marine Fisheries Service and the Office of Sea Grant have supported fish health research programs related primarily to marine species for many years. NOAA's efforts have been most active in salmon, trout, oysters, clams, and shrimp -- both freshwater and marine -- aquaculture. For example, projects which have developed concepts for vaccination of salmonids against *Vibriosis angularum*, have been sponsored by NMFS in conjunction with Pacific Northwest universities. Sea Grant colleges in Texas, Rhode Island, and Oregon sponsor research on diseases that attack marine fish and shellfish and provide a variety of disease control services for fish farmers.

#### 4.7 OUTLINE OF ACTION STRATEGIES

- o Conduct, through Congressional hearings and other means, a study of the need and support for a federal disease clearance certification program.
- o Conduct a thorough evaluation of existing fish health programs in the Federal Government.
- o Revisit the premises of and current Congressional support for National Fish Disease legislation.
- o Promote professional certification and training programs in conjunction with state fish health programs to increase the availability of diagnostic services in areas of need.
- o Develop model regulations for interstate aquatic species disease certification.

## 5.0 FEDERAL FINANCIAL ASSISTANCE PROGRAMS

### 5.1 INTRODUCTION

The Federal Government is involved in more than a dozen major financial assistance programs of importance to aquaculture development. Most of these programs were originated to assist agriculture, however, and only more recently has aquaculture been included within the scope of their eligibility definitions.

### 5.2 STATEMENT OF THE AQUACULTURIST'S PROBLEM

A major research effort sponsored by the Joint Subcommittee on Aquaculture has been completed and when released will, hopefully, provide more definitive answers than now exist on what the financial needs of the aquaculture industry truly are. Many individual aquaculturists have expressed a need for various forms of aquaculture assistance in recent years, but were turned down by President Carter's veto of a 1978 bill to establish new federal assistance programs for the development of aquaculture.

Reserving the question of whether financial assistance is required, it is, nevertheless, possible to identify an "information constraint" in the area of federal financial assistance programs. That is to say, lack of knowledge on the part of potential users about existing federal financing programs reportedly has operated as a constraint to growth in the past.

### 5.3 DIRECTORY OF FEDERAL FINANCIAL ASSISTANCE PROGRAMS

A separate volume, submitted with this report, contains a more detailed description of various financial assistance relevant to aquaculture that supports programs the Federal Government supports or operates. Among those with the most direct financial impact are the following:

- o Farm Credit Act Amendment of 1980 (P.L. 96-365). Authorizes federal land banks to participate in long-term real estate mortgage loans to producers or harvesters of aquatic products for five to forty year terms.
- o Agricultural Credit (7 U.S.C. §§ 1921-1955). The Farmer's Home Administration administers nine loan programs that potentially are available to fish farmers including: 1) emergency loans; 2) economic emergency loans; 3) operating loans; 4) farm ownership loans; 5) soil and water loans; 6) recreation loans; 7) business and industrial loans; 8) resource conservation and development loans; 9) farm labor housing loans and grants.



- o Distribution and Marketing of Agricultural Products: Agricultural Marketing Act (7 U.S.C. § 1621). "Aquacultural products" is defined to include "fish and shellfish, and any products thereof...."
- o Small Business Development Act of 1980 (P.L. 96-302). Establishes a Small Business Economic Policy whose purpose is to create an economic environment favorable to the development of small businesses.
- o Aid to Small Business (15 U.S.C. § 631 et seq.). This Act which created the Small Business Administration in 1958 defines a small business concern as an enterprise which is independently owned and operated and which is not dominant in its field of operation. Aquaculture is included as an eligible industry for loans up to \$500,000 or 90% of the amount commercial banks would be willing to make.
- o Federal Crop Insurance Act of 1980 (P.O. 96-365). Aquacultural crops are eligible for insurance against loss due to unavoidable causes. However, no programs for aquaculture have been funded for FY 1981.

5.4

#### OUTLINE OF ACTION STRATEGIES

- o Through the JSA, publish a Directory of financial assistance programs available to fish farmers and disseminate through extensive services of the principal agencies.
- o Enter into cooperative arrangements with state governmental agencies involved with aquaculture promotion to share information for financial assistance programs.
- o Establish an "aquatic lending" data base of information on industry credit worthiness and lending experience as a tool to encourage easier access to money markets.

## 6.0 IMPORTATION OF NON-INDIGENOUS SPECIES

### 6.1 INTRODUCTION

Aquaculturists are subject to laws restricting the importation, exportation, and transportation of wildlife, including the Lacey Act, 18 U.S.C. §42, the Endangered Species Act of 1973, 16 U.S.C. §1531 et seq., the Marine Mammal Protection Act of 1972, 16 U.S.C. 1382, the Convention on International Trade in Endangered Species of Wild Fauna and Flora, and the Black Bass Act, 16 U.S.C. 852c. These laws are administered by the Fish and Wildlife Service of the U.S. Department of the Interior, in cooperation with the Department of Agriculture, the U.S. Customs Service of the Department of Treasury, and other federal and state agencies.

Successful recent efforts to cultivate non-indigenous species in freshwater and marine aquaculture include the freshwater prawn (*Macrobrachium*), the Pacific Oyster (*Crossostrea gigas*).

The law restricting wildlife importation that most directly affects aquaculture is the Lacey Act.

### 6.2 STATEMENT OF THE AQUACULTURIST'S PROBLEM

Particularly in Hawaii, aquaculturists have asserted that provisions of the Lacey Act prohibiting the importation of non-indigenous species places unnecessary burdens on culturing some of these species. For example, the Lacey Act prohibits the importation of the family *Clariidae* (Chinese Catfish) into Hawaii, a species long present there. Other restrictions relating to prawns and tilapia have been cited as hindering innovation in the industry.

Among arguments for importation of non-indigenous species: 1) species and culture techniques developed abroad and found to be successful ought to be given the opportunity to develop similar potential in the U.S.; 2) places such as Hawaii are, in fact, already providing a habitat for certain "exotic" species; and 3) certain non-indigenous species may have the disease resistant characteristics needed by U.S. aquaculturists as part of an overall disease prevention program.

At the same time, however, other aquaculturists caution against undue relaxation of the Lacey Act restrictions, on the basis that current controls on diseases and parasites are inadequate to prevent their introduction and that some exotic species themselves could prove to be undesirable. They argue that

1969 amendments prohibit the sale of any products manufactured from any wildlife "taken, transported, or sold in any manner in violation of any federal, state, or foreign law or regulation". 18 U.S.C. 43(d), as amended. The amended version extends the definition of "wildlife" to include "any . . . reptile, mollusk, or crustacean, or any part, egg or offspring thereof, or the dead body or parts thereof. . ." 18 U.S.C. 43(f) (3), as amended. "Taken" is defined in the amended version to mean "captured, killed, collected, or otherwise possessed."

#### 6.3.4 Labeling

Section 44 prohibits the transport in interstate or foreign commerce of wild animals or birds without plainly marking the package, as well as the transport of furs, hides, or skins of wild animals not plainly marked.

The 1969 amendment includes "reptiles, mollusks, crustaceans, their dead bodies, or parts or eggs thereof" in the list of species covered by the section.

#### 6.3.5 Penalties

Anyone who "knowingly violates, or who, in the exercise of due care, should know that he is violating" any provision of sub-sections (a) or (b) of section 43 is subject to a civil fine up to \$5,000. 18 U.S.C. 43(c), as amended, 1969.

Anyone who "knowingly and willfully" violates any provisions of subsections (a) or (b) is subject to a fine up to \$10,000 or up to one year in prison, or both. 18 U.S.C. 43(d), as amended, 1969.

### 6.4 IMPLEMENTING REGULATIONS

#### 6.4.1 Injurious Wildlife

50 C.F.R. 16.13 regulates the importation of live or dead fish, mollusks, and crustaceans, or their eggs. This subsection prohibits the importation, transportation, or acquisition of any live fish or viable eggs of the Clariidae family, without a permit from the Director of the Fish and Wildlife Service. All other fish, mollusks, and crustaceans, and their eggs, except members of the Salmonidae family, may be imported, transported, and possessed in captivity without a permit, provided a written declaration is filed with the District Director of Customs at the port of entry, as required under 50 C.F.R. §14.61. However, permission from the State Wildlife conservation agency is required before any live fish, mollusk, or crustacean, or their progeny or eggs, can be released into the wild.

#### 6.4.2 Disease-Free Certification

No live or dead fish or eggs of the Salmonidae family may be imported into the United States except by direct shipment, accompanied by a certification that the shipment is free of the protozoan that causes "whirling disease" and the virus that causes "Egtved disease." The certification must be signed by a qualified fish pathologist. Processed, canned, pickled, or smoked members of the Salmonidae family may be imported if all spores of the above-mentioned disease-producing agents have been killed. 50 C.F.R. 16.13(b)(1).

#### 6.4.3 Importation, Exportation and Transportation of Wildlife Regulations

On August 25, 1980, the Fish and Wildlife Service of the Department of the Interior issued final rules for Parts 10, 13, and 14 of 50 C.F.R. (45 Federal Register 56668 (August 25, 1980)). These rules replace the former permit system with a licensing system to regulate all persons who import or export wildlife for a profit.

The definition of "wild" in 50 C.F.R. 10.12 was broadened to include species covered by the Endangered Species Act, while domestic animals were excluded from coverage. Section 10.12, as amended, states:

"The term 'fish or wildlife' means any wild animal, whether alive or dead, including without limitation any wild mammal, bird, reptile, amphibian, fish, mollusk, crustacean, arthropod, coelenterate, or other invertebrate, whether or not bred, hatched, or born in captivity, and including any part, product, egg, or offspring thereof." 45 Federal Register 56673 (August 25, 1980).

The import or export of fish or shellfish products at any Customs port of entry is regulated under 50 C.F.R. 14.21.

In December 1980, the Fish and Wildlife Service further amended 50 C.F.R. Part 14 to exempt from the import/export license requirement anyone who imports or exports wildlife valued at less than \$25,000 per year. The purpose of this exemption was to relieve the burden of the license requirement on small businesses and individuals who export or import wildlife only occasionally. 45 Federal Register 86496 (December 31, 1980).

#### 6.5 OUTLINE OF ACTION STRATEGIES

- o Support research efforts, (e.g., like National Fishery Research Laboratory, Gainesville, Florida study on exotic fishes), to identify promising non-native aquaculture species

- o Establish a joint state/federal mechanism for developing scientific evidence of adverse effects on the local environment and native populations of non-native species whose entry would serve the public interest.

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