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## Scientific Criteria and Performance Standards to Control Hazards in Seafood

### BACKGROUND

The word seafood encompasses a vast array of animals that include not only various genera and species, but also various phyla such as mollusca (e.g., clams and oysters), arthropoda (e.g., crabs and crayfish), and chordata (e.g., finfish). This diversity manifests itself in life forms of different sizes, shapes, and functions, each adapted to their unique environments and roles within the ecosystem. More than 350 species of fish are commonly consumed (FAO, 2002a). In a culinary sense, this diversity is expressed as a broad spectrum of sensory attributes, product forms, and preparations that are particular to seafood. Whether from traditional harvest or aquaculture production, seafood presents some unique safety concerns that arise from both the intrinsic characteristics of the animals and the environmental conditions from which they are harvested. For example, for some species, food safety issues are dependent on the harvest location and season. In addition, as it is the case with meat and poultry products, conditions and handling at harvest and processing, as well as through distribution and final preparation, constitute significant factors that enhance or reduce the risk of seafood-borne disease.

Because of these unique features, certain seafood may present a hazard to public health. First, given the diversity of aquatic animals and environmental conditions within the aquatic environment—saltwater, freshwater, estuarine water, tropical, polar, in-shore, off-shore, pristine, polluted—it is not surprising that specific animals and environmental conditions may result in products unsafe for consumption. Interestingly, most seafood safety problems are present prior to harvesting and are a consequence of the accumulation of natural contaminants in the aquatic environment, such as the presence of *Vibrio vulnificus* in raw molluscan shellfish or methyl mercury in various fish from certain waters (IOM, 1991). Second, although the expansion of aquaculture production would seem to offer opportunities for greater environmental control, concerns similar to those of land-based muscle foods have emerged; such is the case with the presence of therapeutic agents and human pathogens in seafood as a consequence of the production environment and practices. Third, all these concerns are further complicated by an increasing dependence on seafood products from some international waters less subject to surveillance by domestic authorities.

Additional factors that increase the risk of seafood as foodborne disease vehicles relate to handling, distribution, and preparation. For example, unique and notable characteristics of seafood consumption are that a significant portion is consumed live (e.g., oysters, mussels and

clams), raw (e.g., sushi) or cooked to a rare state (e.g., cod and mahi-mahi). Also, many recipes include consumption of nonmuscle components such as eyes, eggs, and viscera (raw and cooked), some of which may pose unique risks. In addition, the fact that seafood is the largest commodity group with an extensive recreational element can have serious public health implications. For example, recreational fishermen can thermally abuse scombroid-susceptible species, leading to scombroid fish poisoning, an acute illness associated with the consumption of certain fish having elevated levels of biogenic amines. The elevated levels of biogenic amines are a result of growth of certain bacteria when temperature abuse of fish occurs during or after harvesting (FDA, 2001). Furthermore, vacationers have been known to ignore or misunderstand posted advisories prohibiting the harvest of molluscan shellfish from nonapproved waters, thus exposing themselves and their families to potentially contaminated toxic shellfish. It is believed that some recreationally harvested seafood enters commercial channels (e.g., when sold directly to restaurants), which could also contribute to outbreaks attributed to commercially produced seafood. The true extent to which this practice occurs is not known, but recent undercover investigations have revealed illegal fish sales from recreational harvest exceeding six figure incomes for the culprits (Sun Sentinel, 2002). Bootlegging, which is the sale of molluscan shellfish illegally harvested from closed areas, is another issue with significant food safety implications, but the true extent of the problem is not known.

*Listeria monocytogenes* and the debate over zero tolerance have not escaped the seafood industry. As with other muscle protein foods, the concern with seafoods is focused on ready-to-eat products. Especially problematic are products such as fresh crabmeat and cold-smoked fish. The processes involved are traditional for the respective products, but relatively uncommon for most meat-type products. Fresh crabmeat, for instance, does have a terminal heat step that destroys most foodborne pathogens, including *Listeria*, but it precedes the meat removal step, which is traditionally done by hand. With respect to cold-smoked fish, this product does not have a lethal heating step, therefore other parameters such salt concentration become important risk minimization steps.

## DESCRIPTION OF THE SEAFOOD INDUSTRY

Although the United States seafood-processing sector includes approximately 5,000 firms (NMFS, 2002), less than 20 percent of these firms produce over 80 percent of the products. When the Food and Drug Administration (FDA) issued the Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products; Final Rule (the Seafood HACCP rule) (FDA, 1995), a significant objective was to primarily apply it to the processing sector, even though many factors outside the processing plant contribute to risks from seafood consumption. The processing sector is more identifiable, accessible, and controllable than the harvesting, distribution, and transportation sectors; moreover, it is more concentrated than retail or food service operations. However, although the processing sector can be better monitored, the abundance of small processing operations has added complexity to the implementation of, and compliance with, the seafood HACCP rule. These smaller firms—which are a majority in the processing sector—often have limited financial resources and operations that are significantly influenced by seasonal fluctuations in supply and demand. This situation has discouraged long-term investments and has created a specialized industry that is dependent on imported products.

Current trends in international seafood commerce further add to the complexity of the food safety aspects derived from seafood diversity and the uniqueness of the industry. In 2000, the

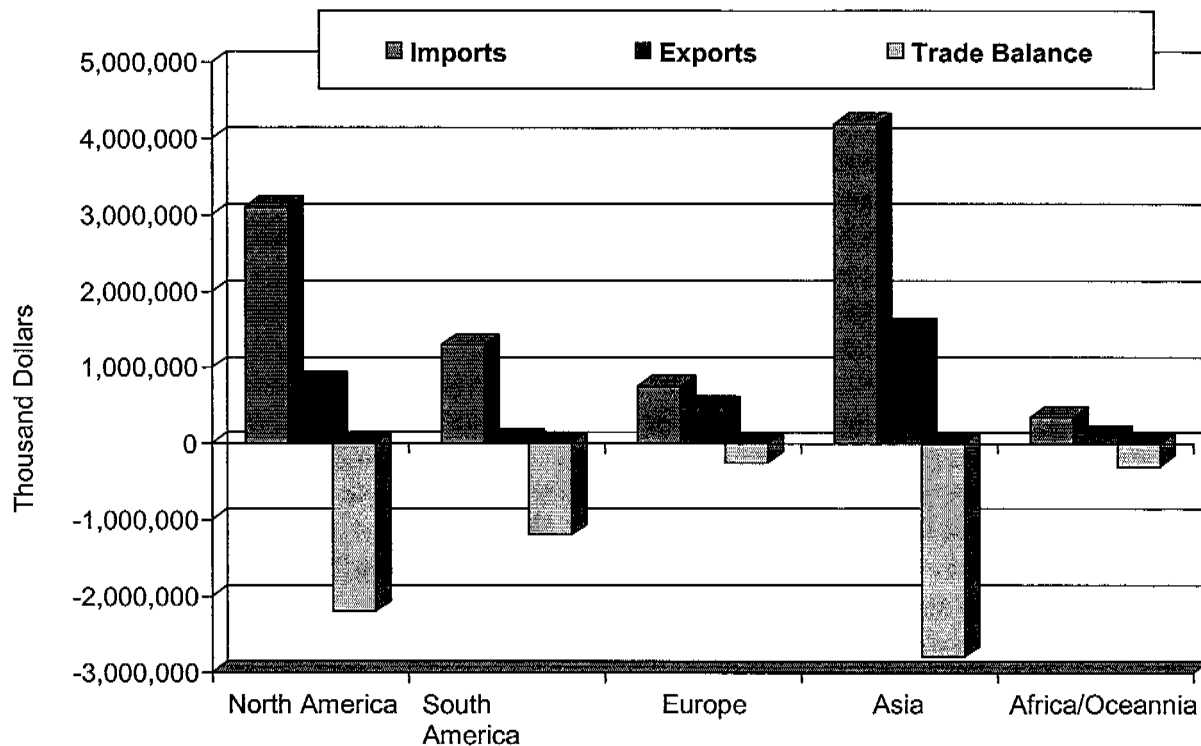


FIGURE 5.1 United States trade in edible fishery products during 2000. SOURCE: NMFS (2001).

estimated total international trade in fishery commodities, by volume (live weight equivalents) and including aquaculture, was approximately 37 percent of the total world production. In terms of value, exports from developing countries in 2000 represented over 50 percent of total exports of fishery products (FAO, 2000). International trade is expected to increase in response to efforts by various industrialized nations to supplement their dwindling domestic seafood resources. Supply is becoming the most significant issue in the world of seafood commerce. The anticipated significant shortfalls for the next decade may result in the reduced availability of seafood and elevated prices in industrialized countries, while serious shortages could occur in regions of the world that are dependent on subsistence fisheries.

This situation could influence international decisions relative to seafood safety, and because over 50 percent of domestic seafood consumption involves imported products (Figure 5.1), it should be thoroughly considered when developing food safety regulations in the United States. Imports to the United States exceed 80 percent for certain popular seafood products. FDA recently estimated that over 8,500 importing firms are subject to surveillance in accordance with the seafood HACCP rule.

A relatively recent additional development in world fisheries production is an increase in dependence on aquaculture products, illustrated by the growth in the volume of cultured shrimp, one of the most prominent aquaculture products in the world (Figures 5.2 and 5.3). As mentioned previously, there is a need to develop specific strategies to address the unique challenges presented by aquaculture production of seafood (e.g., indigenous levels of *Salmonella* and use of unapproved antibiotics). For example, recent evidence for residual chloramphenicol,

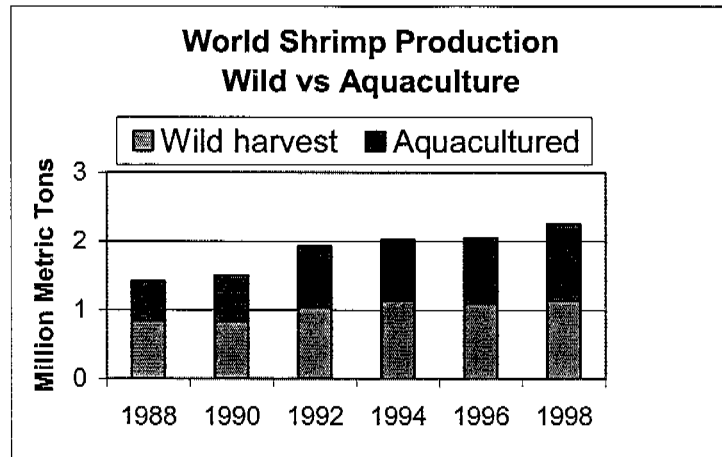


FIGURE 5.2 World shrimp production: wild vs. aquaculture. SOURCE: FAO (2000).

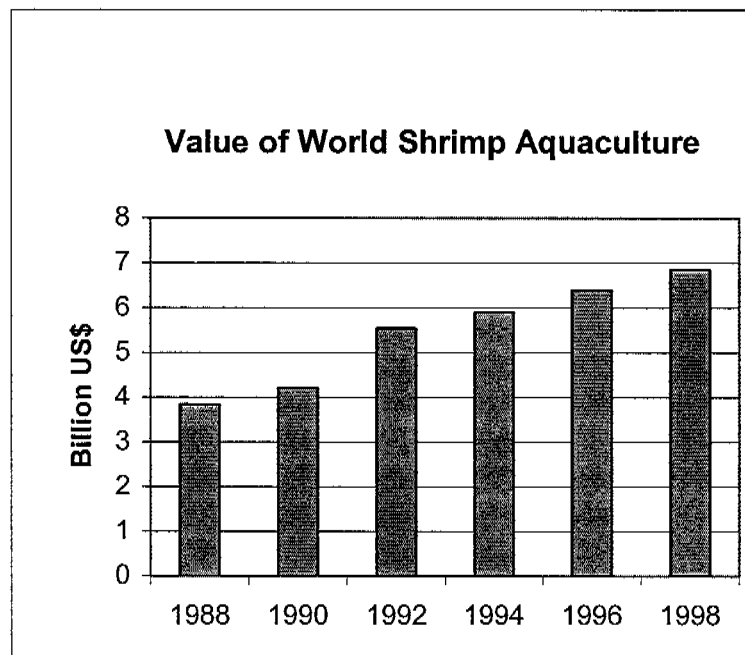


FIGURE 5.3 World volume and value of aquaculture production of shrimp. SOURCE: FAO (2000).

an illegal antibiotic, in aquaculture shrimp from various Asian farms and processing plants in China, Vietnam, and Thailand resulted in major product recalls involving numerous retail operations in the United States and Europe (Alabama Department of Agriculture and Forestry, 2003; NFI, 2002a, 2002b). At one point the European Union banned the import of cultured shrimp from China and neighboring countries with shrimp aquaculture. Regulatory response in the United States was initiated by state agencies and there was general confusion concerning the

proper sampling methods and analytical procedures for residual detection in the parts per billion range.

## **REVIEW OF CURRENT FOOD SAFETY CRITERIA FOR SEAFOOD**

### **Current Food Safety Criteria**

FDA and the Environmental Protection Agency (EPA) have established various food safety criteria that address the intrinsic nature of seafood (e.g., scombrotoxicity) or characteristics of the environment from which it was harvested (e.g., paralytic shellfish toxin, methyl mercury, fecal coliforms). The current list of regulations intended to ensure the safety of seafood that is harvested or cultured domestically or is imported reflects the extreme and unique diversity of this food group. Among these regulations there are microbiological criteria associated with specific microorganisms, such as *Salmonella* and *Clostridium botulinum*, and with product categories, such as ready-to-eat products and molluscan shellfish.

The traditional approach used by FDA to develop performance standards for food safety can be a somewhat slow and lengthy process or it can be a precipitous one resulting from the agency's need to react to a sudden crisis. Irrespective of how they are developed, once seafood safety criteria are in place, there is no mechanism for periodic review to modify or rescind them. This poses a challenge because the previously mentioned increasing dependence on international seafood sources and aquaculture products is introducing new regulatory challenges not fully anticipated in prior regulations.

As reliance on international supply and demand for seafood items continues to increase both in terms of product volume and diversity, food safety issues will become more challenging and varied. Therefore, the committee concludes that food safety regulations will need periodic review by the regulatory agencies to remain up-to-date (i.e., be aligned with current science, commercial practice, and public health objectives) in such an evolving situation. These reviews should be conducted by the regulatory agencies and include discussions that address not only the safety issues associated with the products and their sources, but also the capacity of regulators to communicate the food safety risks and to enforce compliance within the existing regulatory frameworks in both the domestic and international settings. The reviews must prioritize the issues in need of more immediate attention, based on the application of risk assessment.

### **The Hazard Analysis and Critical Control Point System for Seafood Safety Control**

Concerns within industry, government, and consumer groups about the need to improve seafood safety began in the 1980s and eventually culminated in the federally mandated seafood HACCP rule. This rule was initially proposed on January 28, 1994 (FDA, 1994) and published in final form on December 18, 1995, with an implementation date of December 18, 1997. As a regulation based on HACCP, the seafood HACCP rule was based on identification and implementation of preventive critical control points (CCPs), with processors responsible for development and maintenance of the program. (Processor is defined in the HACCP rule as "any person engaged in commercial, custom, or institutional processing of fish or fishery products, either in the United States or in a foreign country. Persons engaged in the production of foods that are to be used in market or consumer tests are also included. Persons who only harvest or

transport seafood, without otherwise engaging in processing, are not covered by these regulations” [FDA, 1994]). The system differs from that in the meat and poultry industry in that government inspections are not performed on a continuous, on-site basis. One reason for this is that such a program is difficult to justify due to the wide variety of species, variable sources, and diverse product forms characteristic of the seafood industry. Most importantly, however, organoleptic inspections of freshly harvested marine species would be of little significance in terms of product safety. Moreover, because such performance standards as specific pathogen reductions are not included in the seafood HACCP rule, verification testing is not part of the FDA inspection. Seafood safety concerns are not dominated by any single pathogen or contaminant. Data reported by the Centers for Disease Control and Prevention indicate that from 1993 through 1997, seafood was the vehicle of transmission in 6.8 percent of the total foodborne disease outbreaks during this period, but involved less than 2.3 percent of the total cases. The percentage of outbreaks associated with shellfish was 1.7 percent. Fish (species other than shellfish) were associated with 5.1 percent of the outbreaks. Most of the outbreaks associated with fish were the result of chemical hazards such as ciguatoxin and scombrototoxin (CDC, 2000). It is important to note the seafood HACCP rule did not replace existing regulations and that, therefore, it must be implemented along with Good Manufacturing Practices (21 CFR part 110) as foundational prerequisites. Required monitoring and recording of sanitation control procedures (21 CFR part 123) are also prerequisites for implementing a HACCP plan.

Although the National Marine Fisheries Service of the U.S. Department of Commerce conducts a fee-for-service National Seafood Inspection Program derived from the Agricultural Marketing Act of 1946, the inspection is voluntary. In addition, these inspections are designed to ensure compliance with minimum sanitation practices and product-grade standards, not with the HACCP rule. Inspections, whether of domestic or imported products, are carried out for quality purposes, not for safety.

### **Application of Food Safety Criteria in HACCP**

FDA has been responsible for developing an extensive list of seafood regulations (Appendix C). Many of these regulations consist of food safety criteria—categorized as tolerances, action levels, and guidelines—with the underlying purpose of protecting public health through adherence to Good Manufacturing Practices, and prevention of product adulteration and misbranding. While public health is a common goal for all criteria, the specific scientific basis for each of them differs, depending mainly on the availability of data about a hazard. As examples, the tolerance for methyl mercury content in fish (1.0 ppm) is based on the level necessary for consumer safety, the labeling requirement for sulfite residues (10 ppm) is based on the lower limit of analytical capability, and the fecal coliform standard for shellfish harvesting waters is based on the potential presence of microbial and viral pathogens. Apart from scientific data, there are other factors that have been considered when establishing seafood safety criteria, such as the perception of risk by the public or the availability of technologies that reduce the hazard to a level of public protection deemed appropriate by FDA. Although the final decision regarding development or modification of a food safety criterion resides with FDA, the rule-making process requires periods of review by and comment from the various stakeholders, which unavoidably make it a slow process.

As mentioned previously, all food safety criteria established prior to the seafood HACCP rule remain in place within the current regulatory system; thus, in addition to HACCP, processors are

obligated to produce seafood that comply with all relevant food safety criteria. In most cases these criteria are not useful for inclusion as critical limits for CCPs in HACCP plans; however, they can be used as verification criteria in situations where end product testing may be warranted. The National Advisory Committee on Microbiological Criteria for Foods (NACMCF), an advisory body to federal food safety agencies, specifically addressed the issue of microbial criteria with the following statement: “. . . the use of microbiological testing is seldom an effective means of monitoring CCPs because of the time required to obtain results. In most instances, monitoring of CCPs can best be accomplished through the use of physical and chemical tests and through visual observations. Microbiological criteria can, however, play a role in verifying that the overall HACCP system is working” (NACMCF, 1998).

Although the NACMCF statement is focused specifically on microbiological criteria, the same rationale could apply for many of the food safety criteria the regulatory agencies have developed for chemical hazards. Although EPA and FDA have established limits for some chemical contaminants, direct monitoring with analytical tests for chemical contaminants in seafood is often impractical as a CCP because the variability in concentration for some of these contaminants among geographic areas is significant and required sampling would be impractical. As an alternative, the geographical variability in contaminant concentration indicates that the potential exists for reducing exposure through restrictions of harvesting sites (IOM, 1991). As the FDA *Fish and Fisheries Products Hazards and Controls Guide* states, such a CCP could be described as follows: “No fish may be harvested from an area that is closed to commercial fishing by foreign, federal, state, or local authorities; and no fish may be harvested from an area that is under a consumption advisory by federal, state, or local regulatory authority based on a determination by the authority that fish harvested from the waters are reasonably likely to contain contaminants above the federal tolerances, action levels, or guidance levels” (FDA, 2001).

Chemical hazards that are not of environmental origin (i.e., biogenic amine, such as histamine) require a different control strategy. Elevated biogenic amine levels, a potential food safety hazard in some finfish such as tuna, mackerel, and mahi-mahi, are produced as a result of the growth in fish of certain indigenous bacteria during improper cooling or storage conditions. FDA has established an action level of 50 ppm histamine in any edible portion of the fish. Monitoring of histamine levels in each fish received at a processing plant is impractical, expensive, and not a viable method of control by seafood processors. In contrast, review of the harvest records—time and temperature—associated with each lot of fish is deemed an acceptable alternative. If this control alternative is used, harvest vessel records for each lot must include the following information: “1) Icing onboard the harvest vessel was performed in accordance with the vessel’s cooling rate study that validates cooling to 50°F (10°C) or below within 6 hrs of death regardless of maximum exposure temperature, or placement in ice within 12 hrs of death if the maximum exposure temperature does not exceed 83°F (28.3°C); 2) method of capture; 3) date and time of landing; 4) estimated time of death; 5) method of cooling; 6) date and time cooling began; 7) sea and air temperature if exposure temperatures exceeds 83°F (28.3°C); 8) adequacy of ice during onboard holding” (FDA, 2001).

As noted before, the option to apply the current standard on histamine (i.e., a histamine limit of 50 ppm) in the HACCP plan does exist; however, this is seldom practical. If a concentration of 50 ppm histamine were used as the critical limit in tuna processing operations, an argument could be made that all histamine-susceptible fish would have to be tested to ensure compliance with the HACCP plan. Given the current analytical methods for histamine determination, this

would require excessive time and additional product handling that could further jeopardize product quality and safety. Even if more rapid or less expensive histamine analytical methods for use in a commercial setting were forthcoming, the utility of such tests would be limited by the viability of the sampling plan parameters (number and size of samples) required to obtain statistically meaningful data. Consequently, in keeping with the preventive character of HACCP, the processor will customarily choose preventive options that are the least costly and disruptive to plant operations and will thus avoid after-the-fact analyses or end-product testing as verification tools for a particular hazard. In the case of histamine, therefore, processors will typically opt for preventing high histamine levels through the already described option: control of abusive handling conditions that lead to histamine formation in fish and recording of time and temperature parameters in the vessel and at the plant. These records can be further supplemented with sensory screening for early signs of temperature abuse and evidence of adequate refrigeration. When appropriate, specific analytical tests are performed as part of HACCP verification; in this case, verification may include periodic analysis of histamine concentration in fish showing signs of temperature abuse. If the process is under control, the expectation is that such histamine analyses would indicate levels of less than 50 ppm.

### **Scientific Basis, Public Health Impact, and Economic Feasibility of Safety Criteria**

HACCP has been acclaimed as an appropriate, science-based food safety assurance system by the food science community (IOM, 1991; NRC, 1985a, 1985b), although it has not yet been universally applied in the food industry. For some groups, implementation of HACCP raises concerns about reduced government oversight of food processing. For example, a report issued by the General Accounting Office (GAO, 2001) suggested that FDA's oversight of seafood firms did not sufficiently protect consumers against foodborne disease. Despite these controversies, recent reports suggest that HACCP has played a role in reducing some of the nation's notifiable foodborne illnesses (CDC, 2002). As described in Chapters 2 and 4, and because of the many confounding factors, a relationship between HACCP implementation and reduction of illness attributable to specific food groups cannot be fully established from the available data. However, HACCP has had a very distinct impact on the seafood industry, primarily through enhanced awareness and understanding of potential seafood safety hazards from production and processing through preparation and consumption. Since enactment of the seafood HACCP rule, extensive education and training programs for industry personnel have been made available through the Seafood HACCP Alliance (SHA, 2001) and other programs. This training has been among the most beneficial developments in assisting industry managers to recognize food safety as an integral aspect of their operations in promoting change (Gall, 1999). A recent FDA progress report for 2002 reveals that the continuing increase in compliance with seafood HACCP programs has increased the margins of safety for American consumers, and that areas of concern are better identified for further government oversight and for emphasis by education programs (FDA, 2002).

Further benefits from mandatory HACCP will depend not only on continuing education, but also on continuing technical innovations. An example that clearly illustrates this point is the

**TABLE 5.1** Abbreviated Table of Compliance for Source States as Specified in the Interstate Shellfish Sanitation Conference’s *Vibrio vulnificus* Management Plan

Deadline	Postharvest Treatment <sup>a</sup>	Illness Reductions <sup>b</sup>
December 2004 2005–2006	25% capacity	40% (average)
December 2006 2007–2008	50% capacity	60% (average)
> 2008	If the 60 % illness reduction rate is not collectively achieved by 2008, additional controls can be imposed including harvest restrictions or closures relative to water temperatures and special labels designating product to be shucked by a certified oyster dealer.	

<sup>a</sup> Post harvest treatment “capacity” will be based on all oysters intended for raw, half shelled market during the months of May through September harvested from sources states, to include the capacity of all operational plants and the capacity of plants under construction.

<sup>b</sup> Illness reductions will be based on the average illnesses rate for years 1995-1999 of 0.306/million persons, using data from California, Florida, Louisiana and Texas. Adjustments in methodology can be adopted based on further reviews.

attempt to reduce illness caused by consumption of raw oysters. Despite the impact of HACCP, foodborne illness from consumption of raw oysters remains a major and serious seafood safety concern. The principal culprit is the pathogenic bacterium *V. vulnificus*. Infections caused by this microorganism are relatively rare and usually involve consumers with preexisting liver diseases or immune deficient conditions (approximately 40 reported cases of primary septicemia per year), but the fatality rate is high—approximately 50 percent of total reported cases (Mead et al., 1999; Glatzer, 2001). The oyster industry and the respective regulatory authorities, working through the Interstate Shellfish Sanitation Conference (ISSC), have determined that in addition to consumer education programs, alternative processing technologies such as high hydrostatic pressure are needed to reduce the recurrent illnesses due to *V. vulnificus* and the related species *V. parahaemolyticus* (ISSC, 2001a).

The ISSC is modeled after the Interstate Milk Shippers Conference, which allows participation of state and federal regulatory authorities as well as consumer and industry representatives. The combined expertise and interests of the ISSC participants result in a unique approach, detailed in their Model Ordinance for oyster processing. Among other requirements, this Model Ordinance requires implementation of new postharvest treatments that hopefully will progressively reduce the average annual reported illnesses attributed to raw oysters (ISSC, 2001a). The reduction goals, 40 percent by 2005 and 60 percent by 2007, were considered reasonable based on the decisions of the ISSC committees and board, which involve industry, state agencies, and federal agencies meeting in Norfolk, VA July 21-27, 2001. Certain states that do not meet the required reductions in *V. vulnificus* illnesses stipulated in a mandated schedule of annual declines face regulatory consequences that include reduced production and seasonal closure of harvestable waters (Table 5.1). This unique approach requires adequate industry performance without mandating a specific process or performance standard, but by establishing a public health objective. The flexibility of this approach reflects a regulatory shift from establishing a specific standard to requiring that processors choose and validate technologies appropriate to their specific operations. In fact, their choice of strategy must result in a measurable and improved performance through an increase in the capacity to implement processing alternatives and through a reduction in illnesses. The capacity is defined as the actual

documented ability to perform in terms of having appropriate procedures and facilities for the implementation of a particular processing alternative to reduce *V. vulnificus* in raw oysters. The reduction in illnesses, in turn, is determined using an annual average based on reported illnesses. This is a unique and challenging approach that focuses on encouraging innovation within a mandated HACCP format.

In the absence of an initial risk assessment, FDA and state regulatory agencies have used a nondetectable level (i.e., essentially zero tolerance) as the benchmark for performance (performance standard) for *V. vulnificus* in oysters intended for raw consumption (ISSC, 2001b). This measure currently recognizes the fact that some postharvest treatments can be applied to raw oysters for food safety purposes. Oysters thus treated may not only be exempt from a public advisory or warning statement, but may also be accompanied with a product declaration such as “processed for added safety” (ISSC, 2001b). The decision to allow or mandate the use of specific product labels or statements rests with individual state authorities. In time, use of recent (FAO, 2001) and pending (FAO, 2002) *Vibrio* risk assessments might support the establishment of science-based microbiological performance standards for *V. vulnificus* that ensure a reasonable level of public health protection while allowing more flexibility and innovation in the application of postharvest treatments. For example, a risk assessment may conclude that the use of treatments resulting in levels and types of *V. vulnificus* equivalent to those found in oysters during the less problematic winter season reduces this hazard to a tolerable level of risk.

As another alternative to zero tolerance, FDA may consider use of risk assessments to establish food safety objectives that specify the level of this hazard at the point of consumption; however, as discussed extensively in Chapter 3, the use of food safety objectives is a new concept that has not been fully explored and, in some cases, may encounter opposition.

One of the attractive elements of the current HACCP-based system is the increased involvement from industry in determining appropriate food safety control strategies for hazards associated with specific commodities and processes. While there is opportunity for even a greater level of industry participation, most seafood processors still request advice to direct their decisions and practice.

Given the diversity within the seafood industry, FDA determined that specific guidance would be necessary to assist industry to productively focus its HACCP plan development and implementation efforts. Anticipating this need, FDA issued a special guide, the *Fish and Fisheries Products Hazards and Control Guide*, commonly referred to as “the Guide,” to help implement HACCP in the seafood industry (FDA, 2001). The Guide contains all FDA performance standards for food safety that are relevant to seafood, as well as guidance in process controls for seafood-borne safety hazards.

The Guide was complemented with a national education program, the Seafood HACCP Alliance, which involved academic and regulatory expertise in every state, plus numerous international training efforts based on a cadre of qualified trainers (SHA, 2001). This Alliance also developed a “Compendium of Fish and Fishery Processes, Hazards, and Controls” that can be accessed via the Internet for detailed information on HACCP programs for various seafood commodities, processes, and hazards (Price and Tom, 1997).

The Guide (FDA, 2001) provides recommendations for identifying CCPs, setting critical limits, monitoring CCPs, and setting corrective actions for various seafood species and processes. The Guide is a significant and innovative contribution that benefits field inspectors, the seafood industry, and consumers. However, in many cases, in the absence of other guidance, the recommendations made in the guide are interpreted by industry and field inspectors as legal

requirements, despite the fact that the introduction in the Guide specifically states that “The controls and practices provided in this guidance are recommendations and guidance to the fish and fishery products industry. This guidance provides information that would likely result in a HACCP plan that is acceptable to FDA. However, this is not a binding set of requirements” (FDA, 2001).

The recommendations and general guidance provided by the Guide (in addition to established and specified standards) do not limit its utility and impact, except in some instances when the scientific basis for the recommendations contained therein is not readily evident. For example, FDA recommendations to use packaging film with elevated oxygen transmission rates (i.e., breathable film) to avert potential germination and growth of *C. botulinum* in reduced-oxygen packaging of fresh, refrigerated fishery products may be based on the best currently available science (FDA, 2001); nonetheless, the description of and accessibility to such packaging materials is not readily evident or well communicated.

Likewise, the Guide does not consider the commercial and regulatory implications of some of the recommendations it contains. For example, in some cases, while the recommendations for recording the details on harvesting conditions such as time of fish death and duration of handling until iced storage is science-based (FDA, 2001), documenting these details can pose impractical situations for the fishermen. In another example, avoidance of potentially toxic fish is based on excluding designated ciguatoxic-prone waters. (Certain tropical reef waters support food chains that progressively accumulate toxins generated by plankton along the food chain; large predator fish at the top of the food chain, in turn, become toxic to humans.) While this approach appears reasonable and scientifically valid, designated waters are often not properly mapped, and many fish are highly mobile so that geographic limits may be meaningless. Such problems do not indicate a weakness in the regulatory approach, but rather a need for continuous attention to advance and improve the Guide for use by both the inspectors and the commercial sector.

The committee recognizes that the Guide is both an innovative and useful document that effectively assists seafood processors with the development of their HACCP plans. To improve its utility, the committee recommends that FDA consider introducing a more transparent and collaborative process (i.e., one that allows routine and structured involvement by the respective users and beneficiaries) in further developing the Guide. In keeping with its recommendations about flexibility of the regulatory process made in Chapter 3, the committee further recommends that the progress, utility, and impact of this Guide for seafood safety be enhanced through the addition of programs and actions to better communicate relevant changes in science, commerce, and public health objectives and to facilitate their incorporation into the Guide.

In addition, the committee recommends that general guidance for all products and processes in the Guide be complemented by FDA with more transparent and detailed scientific justification, citing reasons, sources, and limitations for the respective seafood safety criteria, in an accessible format. The intent should be to offer explanations that can support decisions in accordance with the best available science and to help focus appropriate responses to the needs for scientific research, technical innovations, and modifications of regulatory requirements.

To attain the above, and in accordance with the Federal Advisory Committee Act, the committee further recommends that FDA appoint a Hazards and Controls Guide Advisory Committee that has balanced and qualified representation from third-party expertise. This committee should routinely convene to critique the Guide and prepare submissions for changes and interpretations based on current science and commercial practices, and suggest priorities for scientific, commercial, and regulatory attention.

When situations involving questionable seafood safety issues have emerged, some processors have sought assistance from a third party or processing authority to help validate or verify specific seafood processing methods or variances from traditional methods. The term “processing authority” may refer to private consultants, academics, or other experts. However, there are no current FDA guidelines for establishing the credentials of processing authorities, or for conducting process validations or verifications required for a HACCP plan to be accepted by FDA. In particular, the validation of modern, rapid microbiological methods and the design of appropriate sampling plans need adequate FDA guidance.

The committee recognizes that the use of processing authorities is consistent with the seafood HACCP rule (FDA, 1995). However, the committee recommends that the issues of expert capability and process confidentiality be further addressed by FDA in the light of food safety considerations. A transparent and structured protocol must also be developed by FDA to guide process validations. This protocol must address criteria for distinguishing the creditability of processing authorities, sampling plans, experimental designs, and appropriate methodologies. Validation and verification guidelines, including recommendations for adequate analytical methods and sampling plans, should accompany the recommended controls in the Guide. Similarly, a regulatory protocol is necessary to recognize the application of analytical methodologies such as new rapid test procedures that can be utilized in process validation and in routine verification.

In addition, the committee recommends more timely and continuous communications to ensure awareness, understanding, and consistent application of the Guide. The intent of this recommendation is broad and includes FDA’s intraprogram activities, state and federal partnerships, individual firms, and the responsible authorities in countries exporting to the United States. Efforts to enhance communications should include any reports and recommendations from the recommended Hazards and Controls Guide Advisory Committee.

The magnitude of concerns about current HACCP governance for seafood safety is further compounded in international commerce. The regulatory response to the volume and diversity of seafood trade could set the tone for international commerce and regulation of other foods. FDA’s new approach regarding international commerce considers all seafood processors equal and challenges each nation to demonstrate the capability of its respective authority for seafood safety. A similar approach has been introduced by Canada (CFIA, 2002) and the European Union (EEC, 1991). Although these regulations require recognition of “competent authorities” and responsible criteria and standards, some nations’ efforts to scrutinize other nations’ competence and commercial performance appear to be defensive and have been perceived as trade barriers (CAC, 1999). The Codex Alimentarius offers some cooperation among national authorities, but its recommendations often lack the necessary details to address the issues raised by specific countries or products. As mentioned earlier, this situation must be addressed by FDA in anticipation of the increasing U.S. dependence on seafood imports.

The committee concludes that application of the Guide to ensure seafood safety in international commerce requires immediate FDA attention, and that the intent of the Guide and its contents need to be clarified to U.S. trading partners. In addition, the committee recognizes that screening limited quantities of seafood products at points of entry is not consistent with the preventive concept of HACCP; hence, prevention of seafood safety hazards in imported seafood must place greater emphasis on intervention prior to shipment.

Consequently, the committee recommends that FDA give immediate attention to the application of the Guide to ensure food safety equivalence in international seafood commerce.

Moreover, the committee recommends that FDA clarify the intent of the Guide and its content and establish more regulatory oversight prior to receiving foreign seafood products at points of entry into the United States.

Also, with a continuing reliance on a science-based approach, there is a need for more scientific collaboration among nations and for more extensive sharing of information on seafood safety issues applicable in the respective nations. The committee suggests that a scientific program with international participation and support could incorporate the concerns of the authorities regarding specific products, so that agreements regarding appropriate seafood safety standards are reached. This approach could be driven by collaborative research in support of the Codex Alimentarius. Similar efforts have already made in the area of joint United Nations Food and Agricultural Organization (FAO)/World Health Organization (WHO) microbiological risk assessments (FAO, 2002b). The United States, through EPA and FDA, and using the Guide as a model, could initiate an international seafood safety exchange program. This international program could include research and training to address common concerns about such hazards as *Salmonella* and *Listeria* in fresh seafood and methyl mercury tolerances, and develop recommendations for best practices such as Best Aquaculture Practices. The Best Aquaculture Practices could be similar to Good Agricultural Practices for produce and other land-based crops (FDA, 1998), and consistent with Good Manufacturing Practices. The Best Aquaculture Practices could be developed in collaboration and could be recognized as the international prerequisite for the expanding aquaculture production around the world.

In summary, the committee recognizes that limitations in supply are becoming one of the most significant issues in the world of seafood commerce, and that trends in the United States reflect a growing dependence on international sources, particularly with regard to aquaculture products. Regulatory decisions and priorities to address seafood safety must account for this situation.

Therefore, with an awareness of existing international seafood safety programs and efforts (e.g., within Codex Alimentarius, FAO/WHO, and others), the committee recommends that FDA initiate an International Seafood Safety Exchange Program to foster and generate support for international collaboration in seafood safety research and training. A common topic for initial consideration could be the development of Best Aquaculture Practices. The existing FDA *Fish and Fishery Products Hazards and Controls Guide* could be used as a proven format.

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