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Supplement

Response to the Questions Posed by the Food and Drug Administration and the National Marine Fisheries Service Regarding Determination of Cooking Parameters for Safe Seafood for Consumers†

ADOPTED 8 JUNE 2007, WASHINGTON, D.C.
NATIONAL ADVISORY COMMITTEE ON MICROBIOLOGICAL CRITERIA FOR FOODS

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EXECUTIVE SUMMARY

The National Advisory Committee on Microbiological Criteria for Foods (NACMCF) was asked to provide advice on cooking protocols for seafood so that the U.S. Food and Drug Administration (FDA) and the National Marine Fisheries Service (NMFS) could develop consumer messages on the cooking parameters necessary to ensure the safety of seafood. In the background statement relative to the charge, it was noted that seafood can be contaminated in the environment as well as postharvest. It was further noted that seafood products are consumed in a variety of forms (e.g., raw, lightly cooked, marinated, partially cooked or seared on the outside and rare on the inside, or thoroughly cooked). Additionally, it was also stated in the background statement that consumers need guidance relative to the temperature and/or time or other indications of ''doneness'' that must be attained during cooking to ensure safe seafood.

The general charge to the subcommittee was to determine the minimal requirements for achieving microbiologically safe cooked seafood and the associated methods for objective measurement. The subcommittee was to assess all pathogens of concern (bacteria, viruses, and parasites) associated heat-labile toxins, if applicable, and seafood cooking methods that may be used by consumers.

The specific charge to the Committee was to answer the following seven questions:

1. Do the cooking requirements differ by type of seafood, e.g., finfish, molluscan shellfish, or crustacean?
2. What pathogens and parasites are of concern in seafood purchased by consumers?
3. Do cooking methods differ in their ability to eliminate the identified organisms?
4. What effect, if any, does the condition of the seafood when purchased—raw, cooked, frozen—have on the cooking treatment required?
5. Is there a single temperature that will ensure safe seafood?
6. Are there other consumer methods of preparing seafood that need to be addressed? For example, some consumers believe that the lime juice used in ceviche will ''cook'' the product.
7. Should consumer advice vary based on any susceptible at-risk populations?

After examining the relative scientific, technical, and popular recipes with respect to the charge, the Committee made the following conclusions and recommendations.

Conclusions. The following conclusions were reached.

- The microbiological safety of seafood is enhanced greatly when it is properly handled, cooked, served, and stored as leftovers.
- Consumers sometimes choose to eat certain seafood products raw or undercooked.
- Available epidemiological data are inadequate to determine the relative contributions of raw, undercooked, or properly cooked and then recontaminated seafood to the burden of foodborne disease.
- The fragile nature of fish tissue results in a delicate balance between proper cooking (to inactivate the pathogen of concern) and overcooking for optimal eating quality of fishery products. However, food safety should take precedence over eating quality whenever possible.
- Cooking methods for seafood products differ and often are not necessarily based on scientific data.
- Although seafood cooking recommendations are widely available, there is no easy, practical measurement or indicator for the consumer to objectively determine sufficient cooking in order to ensure the safety of fishery products.
- Cookbook recommendations of bringing product to room temperature before cooking, then cooking for 1 to 2 min per side, do not necessarily take into account species or size of the fillet and may also deviate from recognized safe food handling practices or recommendations.
- Microwave heating is frequently found to be less effective than conventional heating due to nonuniform distribution of heat, resulting in the occurrence of cold spots. Furthermore, microwave cooking instructions frequently are based on time but not necessarily on cooking temperature.
- Nontraditional novel preparation procedures cannot be relied upon to assure the microbiological safety of seafood products.
- There is a lack of thermal inactivation data for relevant pathogens in appropriate seafood due, at least in part, to the wide variety of products available and the many methods of cooking that are commonly applied to these products.
- The *Listeria monocytogenes* 6-log reduction recommendation in the U.S. FDA *Fish and Fisheries Products Hazards and Controls Guidance,* 3rd edition *(89),* represents an FDA regulatory ''safe harbor'' for commercially prepared ready-to-eat (RTE) products; but this may lead to overcooking of certain products and may not be necessary for routine consumer cooking of fresh or frozen seafood. This FDA recommendation was designed to deal with a ''worst case scenario'' of potential contamination that needs to be inactivated in commercially processed and distributed seafood that may have a long shelf life. Commercially prepared and marketed RTE seafood products may be stored for long periods of time, but consumers generally cook seafood for immediate consumption, and any properly handled and stored leftovers are likely to be consumed within a short period of time, thereby reducing the risk from *L. monocytogenes.*
- Although a seafood cooking process may reduce the microbiological public health risk associated with the product, the extent of risk reduction differs by type of seafood, the cooking method applied, and the level of microbial pathogens.
- Some of the currently used cooking processes may not provide adequate public health protection (e.g., failure to destroy human enteric viruses in lightly cooked, steamed, or sautéed molluscan shellfish or helminths in seared finfish).
- Without additional barriers, such as reduced water activ-

ity, cooked seafood products require refrigeration to maintain safety.

- Refrigerator temperatures are reported to be variable and sometimes abusive, which may result in high initial levels of bacteria prior to cooking or allow for bacterial growth in stored leftovers.
- There is no single temperature, with or without a specified cooking time, that will ensure the safety of all cooked fishery products and result in a palatable product.

Recommendations. The following recommendations were proposed.

- Collection and review of epidemiological data should be more complete in order to specifically delineate the role of raw, undercooked, and properly cooked and then recontaminated seafood to the overall burden of foodborne disease.
- Inactivation of pathogens in seafood varies with type of seafood, cooking method, and type of pathogen (bacteria, viruses, parasitic protozoa, and/or other parasites). Therefore, the Committee recommends that thermal inactivation kinetics (e.g., *D*-values) be determined for the most appropriate and most heat-resistant vegetative bacterial, viral, or parasitic pathogen of concern in specific seafood types and that heat penetration studies be conducted for each seafood cooking method applied to each product type. This approach will allow a science-based selection of seafood cooking methods and parameters.
- In the absence of adequate pathogen inactivation data for various seafood products, the cooking guidance provided in the 2005 FDA Food Code *(91),* with *Salmonella* the target organism for inactivation during cooking, should continue to be followed by consumers even though the recommended cooking times and temperatures are not based on the inactivation of *Salmonella* (or other appropriate pathogens) in seafood. It should be noted, however, that this recommendation is predicated upon expectations that there is a low level of contamination, that the seafood is properly handled prior to cooking, that the cooked seafood will be consumed shortly after preparation, and that any leftovers will be handled properly and consumed within a short period of time.
- Cooking, as defined in this document, refers to only the application of heat. Consumers should be instructed not to rely on the use of exotic preparation procedures or use of uncontrolled heating sources, which cannot be relied upon to assure the microbiological safety of seafood products.
- At-risk populations should be instructed to avoid consumption of seafood that is uncooked, undercooked, improperly handled or stored, or prepared with methods other than heating or with the use of uncontrollable heating sources.
- Consumers should be made aware that heating to an internal temperature of 194°F (90°C) for 1.5 min is required for inactivation (4-log reduction) of hepatitis A virus (HAV) in molluscan shellfish, even though this heat treatment may result in a less palatable product.
- Consumers should be instructed that in order to enhance the microbiological safety of seafood they also need to follow sanitary and hygienic practices, avoiding temperature abuse and contamination of products before cooking and during storage of leftovers. This is particularly true for some seafoods prepared with certain cooking methods, e.g., steamed molluscan shellfish.
- Educational programs should continue to emphasize the importance of sanitation, temperature control, proper handling, and prevention of cross-contamination at the consumer and retail levels. These programs should be updated with appropriate cooking times and temperatures as additional information becomes available.

I. INTRODUCTION

It has been well documented that seafood consumption is an important source of foodborne illness in the United States *(75).* The causative agents associated with seafood-related illnesses are diverse and include viruses, bacteria, parasitic protozoa, other parasites, and various microbial and chemical toxins. A NACMCF staff analysis of the most recent data (1998 through 2004) available from the U.S. Centers for Disease Control and Prevention (CDC) *(19)* indicated that 11.2 and 5.2% of foodborne outbreaks and cases, respectively, were due to seafood consumption. If outbreaks due to toxins (e.g., scombrotoxin or ciguatoxin) and chemicals are excluded (because cooking would not substantially reduce the risk from these toxins), 7.1% of outbreaks and 4.3% of cases were due to seafood. The seafood safety issues are well defined, highly focused, and limited to a few species. For example, a review of the CDC data from 1998 to 2004 (where the food vehicles and etiological agents are known) revealed that 72% of the seafood associated outbreaks and 38% of the cases from these outbreaks were associated with only three different categories of illness: ciguatoxin (from isolated tropical reef fish), scombrotoxin (histamine toxicity resulting from mishandling and temperature abuse of a few species), and pathogens in molluscan shellfish.

According to the CDC *(18),* a foodborne disease outbreak is defined as an incident in which two or more persons (cases) experience a similar illness resulting from the ingestion of a common food. In addition to data originating from the CDC *(75),* others have also reported the involvement of seafood in foodborne illness in the United States *(84, 95).*

For the purposes of this document, NACMCF (the Committee) agreed that the concept of public health risk is intended to address whether the product bears or contains numbers of organisms of concern or levels of their heat-labile toxins that may be injurious to human health and that these risks can be mitigated by proper cooking. The level of public health risk is a function of (i) the specific type of pathogen(s), (ii) the initial number of pathogen(s), (iii) the ability of the food to support pathogen survival/growth, (iv) host susceptibility, and (v) processing, handling, cooking, or preparation of the seafood and storage and handling of leftovers, all of which affect the number of pathogens at consumption. The presence of some pathogens in seafood products does not necessarily indicate that a public health risk exists (e.g., the presence of pathogenic spore-forming bacteria such as *Bacillus cereus* in products that do not

support their growth). When a product supports growth of a pathogen, the length of its shelf life can influence the potential public health risk. For example, spores of certain bacterial pathogens (e.g., *Clostridium botulinum*) may not be inactivated by the cooking process, but their germination and outgrowth may be prevented through time and temperature control or other means. Furthermore, cooking does not protect public health when heat-stable toxins such as ciguatoxin, scombrotoxin, and staphylococcal enterotoxin(s) are present or when the product is subsequently recontaminated during manufacture, food service, or retail sale or in the home. Therefore, the above situations are not addressed in this document.

Chapter 16 of the U.S. FDA *Fish and Fisheries Products Hazards and Controls Guidance,* 3rd edition *(89),* indicates that cooking processes are generally designed to eliminate vegetative cells, not spores of bacterial pathogens. In addition, the FDA recommends that *Listeria monocytogenes* be the target pathogen for inactivation for commercial seafood processing because of its heat-resistance characteristics relative to other non-spore-forming bacterial pathogens and that a 6-log reduction process (a 1-log reduction is defined as a 10-fold decrease in the bacterial count) is adequate for assuring seafood safety. According to Chapter 5 of the FDA hazards guide *(89),* heating raw fish sufficiently to kill bacterial pathogens is also adequate for inactivation of helminths. It should be noted that in certain products (e.g., molluscan shellfish) parasitic protozoa and human enteric viruses may be more heat resistant than some vegetative bacterial cells *(30).* These agents are also able to cause disease at relatively low doses *(30).* Public health risks due to parasites are usually the result of consuming raw or undercooked seafood. A more complete description of concerns about parasites associated with seafood is contained in Appendix I.

II. WORK CHARGE AND BACKGROUND

Raw seafood may contain pathogens from the natural environment (including contaminated waters) and from poor postharvest sanitation practices aboard vessels, in food distribution, processing, and merchandising facilities, and in individual consumer homes. Seafood products are consumed in a variety of forms, e.g., raw, lightly cooked, partially cooked or seared on the outside and rare on the inside, or thoroughly cooked. Consumers need guidance relative to temperatures and/or times or other indicators of ''doneness'' that must be attained during cooking to ensure microbiologically safe seafood.

Microbial pathogens of concern may include *Vibrio* spp., *Salmonella, L. monocytogenes,* and *Staphylococcus aureus.* Viruses may also be present in seafood harvested from polluted waters or as a result of improper employee food handling practices. In addition, some species of seafood may harbor parasites.

Charge to the Committee. The charge to the Committee was to determine the minimal requirements for achieving microbiologically safe cooked seafood and the associated methods for objective measurement. The Committee was to assess all pathogens of concern (bacteria, viruses, and parasites) and their associated heat-labile toxins, if applicable, and seafood cooking methods that may be used by consumers. The information developed by the Committee will be used by the FDA and the NMFS to develop consumer messages on the cooking parameters necessary to ensure the safety of seafood.

The following questions were addressed.

1. What pathogens and parasites are of concern in seafood purchased by consumers?
2. Do cooking methods differ in their ability to eliminate the identified organisms?
3. Do the cooking requirements differ by type of seafood, e.g., finfish, molluscan shellfish, or crustacean?
4. What effect, if any, does the condition of the seafood when purchased—raw, cooked, frozen—have on the cooking treatment required?
5. Is there a single temperature that will ensure safe seafood?
6. Are there other consumer methods of preparing seafood that need to be addressed? For example, some consumers believe that the lime juice used in ceviche will ''cook'' the product.
7. Should consumer advice vary based on any susceptible at-risk populations?

The agency representatives and the Committee agreed to change the order of the questions submitted by the FDA and the NMFS to allow for a more logical progression for discussion and resolution. The questions have been addressed in the following order:

1. Do the cooking requirements differ by type of seafood, e.g., finfish, molluscan shellfish, or crustacean?
2. What pathogens and parasites are of concern in seafood purchased by consumers?
3. Do cooking methods differ in their ability to eliminate the identified organisms?
4. What effect, if any, does the condition of the seafood when purchased—raw, cooked, frozen—have on the cooking treatment required?
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7. Should consumer advice vary based on any susceptible at-risk populations?

III. SCOPE

Cooking does not eliminate certain hazards, such as heat-stable natural or microbial toxins and biogenic amines (e.g., histamine), if they are already present *(60).* Such hazards are generally controlled through effective use of industry good manufacturing practices (GMPs) and hazard analysis and critical control point plans. This document addresses control of microbial pathogens (e.g., viruses, bacteria, and parasites) that may be present in specific raw

TABLE 1. *U.S. per capita consumption of the most popular seafood products for 2005 (71)*

Seafood product	Per capita consumption	
	Pounds	Kilograms
Shrimp	4.10	1.86
Canned tuna	3.10	1.41
Salmon	2.43	1.10
Pollock	1.47	0.67
Catfish	1.03	0.47
Tilapia	0.85	0.39
Crab	0.64	0.29
Cod	0.57	0.26
Clams	0.44	0.20
Flatfish	0.37	0.17

seafood commodities. It excludes environmental chemical pollutants (e.g., polychlorinated biphenyls, dioxins, and pesticides), naturally occurring toxins (saxitoxin, domoic acid, ciguatera, and others), and microbial toxins (e.g., *C. botulinum* neurotoxins, *S. aureus* enterotoxins, and scombrotoxins). Commercially cooked products such as surimi-based products and crab meat, which may be subject to recontamination, are also excluded from consideration in this document.

Any temperature to be recommended to consumers for cooking seafood to achieve a safe product should be predicated on the following: (i) no preformed toxins are present, (ii) appropriate time, temperature, and hygienic conditions have been met at all points postharvest, and (iii) the consumer has taken responsibility to ensure proper transport, storage, and handling of seafood prior to cooking and storage of leftovers. Temperature abuse of the product prior to cooking may influence the efficacy of the cooking process. Temperature abuse considerations are adequately addressed in Chapters 12 and 13 of the FDA hazards guide *(89).* This document focuses on the cooking process itself, with the assumption that little or no temperature abuse of the product has occurred either prior to or after purchase by the consumer.

IV. RESPONSE TO QUESTIONS IN THE CHARGE

1. Do the cooking requirements differ by type of seafood, e.g., finfish, molluscan shellfish, or crustacean?

Federal regulations *(88)* define fish (seafoods) as fresh or saltwater finfish, crustaceans, all molluscs, and other forms of aquatic animal life (including but not limited to alligator, frog, aquatic turtle, jellyfish, sea cucumber, sea urchin, and the roe of such animals) other than birds or mammals, where such animal life is intended for human consumption. The term molluscan shellfish refers to any edible species of fresh or frozen oysters, clams, mussels, cockles, or scallops or edible portions of such species. Crustaceans include shrimp, lobsters, crabs, crayfish, etc.

The major fishery products, including their relative levels of per capita consumption in the United States in 2005, are presented in Table 1 *(71).*

Consumers and retail establishments cook or prepare seafood products for consumption using various methods, depending upon the type of seafood, convenience, and consumer preference. For purposes of this document, the Committee identified five major categories of seafood products: (i) finfish, (ii) crustaceans, (iii) molluscan shellfish eaten whole, (iv) molluscan shellfish eaten muscle only (i.e., scallops), and (v) other products. These categories are considered relevant because microbial contamination patterns differ by seafood product category, as do the cooking methods commonly employed.

As a general rule, the interior muscle tissue of a healthy live animal harvested from unpolluted waters is sterile *(13).* Limited studies have shown that the flesh of finfish harvested from polluted waters may be contaminated with bacteria *(12, 13).* Microbial contamination may be introduced during harvest (through physical damage of the external protective tissues), during processing (such as evisceration and filleting), and during handling at retail and by the consumer. In the case of finfish, bacteria present on the fish surface or in the animal's gastrointestinal tract can be introduced onto the cut surface of the muscle tissue. Viruses may contaminate the external surfaces of finfish as a consequence of human handling, and parasites may be present in the interior of muscle tissue and viscera. Likewise, for invertebrate specialty products such as squid, snail, and octopus, parasites may invade the muscle tissue directly. Both molluscan shellfish and crustaceans for which only the muscle is eaten are generally subjected to more human handling than are finfish. In addition, molluscan shellfish are filter feeders, using siphons and mucous membranes to sieve suspended food particles from the aquatic environment. If their surrounding water is contaminated by pathogenic bacteria, viruses, or parasitic protozoa, these mucous membranes may entrap the pathogens and transfer them to the digestive tract, where they are frequently concentrated. Thus, molluscan shellfish may act as passive carriers of microbial pathogens, especially because they are usually consumed whole and raw or only lightly cooked.

For the purpose of this document, the Committee defined cooking as the application of heat to a food to modify raw product properties in order to meet sensory expectations of consumers and to reduce its microbial load, which improves its safety and may extend its shelf life.

The Committee recognized that although a seafood cooking process may reduce the microbiological public health risk associated with the product, the extent of risk reduction differs by type of seafood, which often determines the cooking method applied; also, different types of seafood may differ in levels of microbial contamination. Some of the currently used cooking processes may not provide adequate public health protection (e.g., failure to destroy human enteric viruses in lightly cooked, steamed, or sautéed molluscan shellfish or helminths in seared finfish). Microbial inactivation addressed by cooking should not be equated with that achieved by commercial sterilization. Thus, without additional barriers such as high salt or acidification, cooked seafood products require refrigeration to maintain safety, whereas commercially sterile products are shelf stable.

Seafood cooking is achieved through exposure of the product to moist heat, dry heat, microwave energy, radiant heat, or their combinations. Popular seafood cooking methods used by consumers include boiling, steaming, and poaching (Table 2). Dry cooking methods include grilling, baking, and broiling. Multiple methods of frying also exist (e.g., deep frying and pan frying, including blackening, bronzing, and searing). Finfish are commonly prepared by grilling, frying, broiling, baking, steaming, poaching, sautéing, or smoking. The same applies to molluscs consumed as muscle only (i.e., scallops). In the United States, most finfish is consumed as fillets and steaks, although various other preparation procedures are also used for whole fish, particularly in certain ethnic communities. Availability of value-added finfish products, such as rolled and stuffed fillets, is increasing in the marketplace. Molluscan shellfish, although frequently consumed raw, are also prepared by steaming, boiling, frying, and sautéing. Whole crab is prepared by steaming, boiling, or grilling. Shrimp, the leading U.S. seafood product in terms of per annum consumption (Table 1), is usually boiled, grilled, fried, steamed, blackened, or sautéed.

The Committee noted that many printed cookbooks and electronic resources of cooking advice provide only subjective measures for determining whether a fishery product is adequately cooked (as defined in this document) while emphasizing the avoidance of overcooking seafood to prevent quality loss. For example, cookbooks generally recommend that finfish products are considered adequately cooked when the meat is opaque, flaky at the center, and separates easily from the bones, and adequate cooking for crustaceans is indicated by flesh opaqueness and color changes in the flesh and shell (Table 3). For the purpose of this document, ''doneness'' specifically refers to visual cues that lead consumers to perceive that a seafood product is cooked. Although these subjective criteria are present in the popular literature for food preparation, they are not necessarily science based and may not produce safe products. The Committee recognizes that the most objective method for a consumer to determine when a fishery product is properly cooked would be by measuring product temperature. However, using a thermometer may be impractical or inconvenient with certain types of cooking methods (e.g., frying) and products (e.g., thin fillets and molluscan shellfish). Consumers in an Audits International survey *(6)* cooked fish to a mean temperature of 151°F (66°C) with a range of 104°F (40°C) to 196°F (91°C) (201 samples); 38% of the products did not achieve the 145°F (62.7°C) temperature recommended in the 2005 FDA Food Code *(91).* Overall, there is a lack of easily determined objective measurements or indicators for the consumer to determine whether the product has been adequately cooked to ensure safety.

2. What pathogens and parasites are of concern in seafood purchased by consumers?

Two general classes of microbiological pathogens may be transmitted through consumption of seafood. The first group includes indigenous pathogens that are native to the marine environment such as members of the family *Vibrionaceae* and *L. monocytogenes,* which can also colonize food plant environments and home refrigerators *(70, 85).* The presence of these organisms is usually not associated with fecal pollution and therefore cannot necessarily be monitored using fecal coliform indices or other measures of water quality. The second group, referred to as nonindigenous pathogens, is composed of microbes that are not natural marine inhabitants, and their presence in seafood arises from either direct fecal contamination by human or animal reservoirs or is due to poor general sanitation and hygiene during harvesting, processing, merchandising, or preparation for consumption. Biological agents in this category include those of human origin only, such as the noroviruses, HAV, and *Shigella sonnei,* and those of human or animal origin, including *Salmonella, Campylobacter,* and pathogenic *Escherichia coli* serotypes *(58).*

Food-specific (e.g., seafood) data on U.S. foodborne illness are available through epidemiological investigations of outbreaks. However, it must be recognized that (i) not all foodborne illness outbreaks are investigated, (ii) a definitively implicated food is not always identified, (iii) the causative agent is not always identified, (iv) most of the foodborne illness in the United States occurs as sporadic cases rather than as part of outbreaks, and (v) no consumer outbreaks have been reported in recent years *(66).* For example, molluscan shellfish–associated *Vibrio vulnificus* illnesses tend to occur as single cases, and no outbreaks have been reported in recent years. In their deliberations, the Committee obtained the most recent data (1998 through 2004) from the CDC *(19)* regarding foodborne illness outbreaks associated with consumption of seafood products. These data were sorted by product classification and etiological agent (excluding toxins and chemicals), and summaries are presented in Table 4. For some pathogens, no outbreaks have been reported. This database contains reports of only U.S. outbreaks; outbreaks of foodborne illnesses occurring on cruise ships are not included because they are not considered U.S. outbreaks by the CDC.

As indicated in Table 4, most of the seafood-associated outbreaks (79.2%) and almost half of the cases (43.6%) were of unknown etiology. Molluscan shellfish is an important product category associated with foodborne illnesses, being responsible for 29.1% of seafood-associated outbreaks and 22.3% of cases of known etiology in the period 1998 through 2004 (Table 4). Unfortunately, the CDC data do not provide evidence as to whether the items implicated in these outbreaks were consumed raw or cooked, but because of consumer preference for raw or lightly cooked oysters and clams, the Committee assumed that most of these products were consumed with minimal or no cooking. The microbial agents most often associated with illness from consumption of contaminated molluscan shellfish were *Vibrio* spp. and noroviruses *(49).* Interestingly, the 2006 FoodNet data *(20)* (CDC's active surveillance network for foodborne illness at selected sites in the United States) indicated a 78% increase of *Vibrio*-associated illness over the 1996 through 1998 baseline estimates *(19).* For the period of 2000 through 2005, there were 385 cases of *Vibrio*-associated disease linked to molluscan shellfish: 357

cases from oysters, 26 from clams, and 2 from mussels *(98).* Similar data do not exist for viruses.

Finfish may also be a significant source of seafood-borne illness. Analysis of the CDC outbreak data (Table 4) revealed that 30.6% of seafood-associated outbreaks of known etiology and 42.5% of seafood-related cases of known etiology were associated with this product category. As with molluscan shellfish, insufficient information precludes ascertaining which outbreaks were associated with improperly cooked finfish (as opposed to raw products) or to cross-contamination. However, raw finfish consumption, although increasing in the United States, is still relatively infrequent compared with consumption of cooked products. The most commonly implicated groups of agents for finfish-associated illnesses were *Salmonella, Campylobacter,* and noroviruses (Table 4).

Review of the CDC data revealed occasional outbreaks associated with consumption of finfish, crustaceans, and other seafood items caused by *B. cereus, S. aureus, Clostridium perfringens,* and *C. botulinum* (Table 4). Although many of the products implicated in these outbreaks were cooked, historically these pathogens cause disease only after improper storage of the product that usually involves temperature abuse.

Crustaceans such as shrimp, lobster, and predominantly crab were also associated with outbreaks of foodborne illness reported to the CDC for the period 1998 through 2004, at a frequency for outbreaks of known etiology (26.9% of outbreaks) about the same as that for molluscan shellfish (29.1%) and lower than that for finfish (30.6%) (Table 4). Crustaceans are usually consumed cooked, and the most common etiological agents associated with them were *Salmonella, Vibrio parahaemolyticus,* and noroviruses due to undercooking or contamination after cooking. Other seafood products that have been implicated in human infections include ceviche (fish marinated in lime juice and spices), lomi lomi (salmon marinated in lemon juice, onion, and tomato), poisson cru (fish marinated in citrus juice, onion, tomato, and coconut milk), herring roe, sashimi (slices of raw fish), sushi (pieces of raw fish with rice and other ingredients), green herring (lightly brined herring), drunken crabs (crabs marinated in wine and pepper), cold-smoked fish, and undercooked grilled fish *(19).*

In summary, the microbial hazards associated with seafood safety are varied, as are the seafood products associated with outbreaks. In addition to *Vibrio* spp., other bacterial agents of concern are *Salmonella* and other enteric pathogens. Viral agents of major concern are HAV and the noroviruses. One of the primary parasitic agents involved in human illness from seafood is *Anisakis simplex.* Brief descriptions of pathogenic agents implicated in seafood-associated illness are provided in Appendix I.

3. Do cooking methods differ in their ability to eliminate the identified organisms?

Time and temperature parameters determine the effectiveness of a cooking process for destroying microbial contaminants. The cooking process should be designed to deliver the required heat energy to the area of the contaminated product that is the slowest to heat. In general, the time and temperature parameters needed for destruction of microbes in a given food product are dependent on (i) the thermal inactivation kinetics of the most heat-resistant pathogen of concern in a specific food product, (ii) the heat transfer properties of the specific food system, and (iii) the degree to which the contaminant must be inactivated. The pathogen of concern and the cooking requirements are usually product specific. Bacterial and viral contamination in finfish is generally assumed to be present on the external surface, whereas in molluscan shellfish and crustaceans contamination may be internalized in the intestinal tract and/or hemolymph. Parasitic agents in various fishery products are of special concern because they are located within the muscle tissue. Heat transfer is influenced by many factors, including the type of seafood and its physical characteristics (e.g., shape, size, and composition such as moisture and salt), whether the product contains multiple components (e.g., stew or gumbo), the physical state of the product (fresh or frozen), the consistency, the viscosity, and other factors.

As indicated above, cooking methods for seafood products are varied and often not necessarily based on scientific data. The fragile nature of fish proteins means that there is a delicate balance between proper cooking for optimal eating quality and overcooking of seafood products. Cookbook recommendations for bringing product to room temperature before cooking and then cooking for 1 to 2 min per side (e.g., blackening or bronzing) do not necessarily take into account species or size of the fillet and may also deviate from recognized safe food handling practices or recommendations *(87).* In particular, microwave heating is frequently found to be less effective than conventional heating because of nonuniform distribution of heat, resulting in the occurrence of cold spots. Properties associated with the process (e.g., power levels) and the equipment (e.g., physical dimensions, frequency, wattage, and age of the magnetron) are important. Furthermore, microwave cooking instructions frequently are based on time but not necessarily temperature.

4. What effect, if any, does the condition of the seafood when purchased—raw, cooked, frozen—have on the cooking treatment required?

The condition or physical state of a product, as well as the thawing conditions of frozen seafood before cooking, may have a major influence on the degree of microbial inactivation that can be achieved by heat due to differences in heat transfer characteristics, microbial thermal resistance, as well as other factors. Frozen versus fresh, different styles of shrimp (head on versus head off, stuffed versus unstuffed, and with sauce versus no sauce), season of harvest, and microbial load may affect efficacy of the cooking method.

Audits International *(6)* conducted a survey of retail and home refrigerator temperatures (Table 5). Depending on refrigeration, holding time, and temperature, the levels of pathogens present in seafood may increase, especially at abuse temperatures, resulting in the need for additional heating to achieve a safe product.

Partial thawing may affect the rate of heat transfer, and improper thawing conditions may allow microbial growth

TABLE 2. *Popular consumer cooking methods for seafood products*

Method	Description[a]	Applicable commodity examples[a]	Advantages	Limitations	Comments
Baking, en papillotte	Apply the ''10-min rule''[b]: bake for 10 min/in. (2.5 cm) of thickness. En papillotte involves using a sheet of parchment or butcher's paper to envelop the fish, seasonings, and other ingredients and baking using the 10-min rule but allowing a few extra minutes for heat to penetrate the pouch. Baking temperatures are typically 400–450°F (204–232°C).	Acceptable for nearly every form of seafood.	Relatively long heat exposure.	Crust formation during baking slows heat penetration. Product shape may lead to uneven cooking.	Baking and roasting are often used synonymously. Nonseafood components (stuffing, breading, batter, casserole) can influence temperature profile.
Barbequing	Baste seafood with a sauce containing oil. Seafood may be placed directly on the grating (ideal for whole, fillet, or fish steak or for most shellfish).	Thicker cuts and oily species are preferable, but nearly any form of seafood can be grilled. Frozen seafood should be thawed.	Good surface lethality.	Crust formation limits heat transfer, produces nonuniform heat. Weather conditions may affect cooking time.	Greater chance of cross-contamination by utensils.
Deep fat frying (complete immersion in oil)	Oil temperature is 375°F (191°C), cooking time is 3–5 min, except for squid (30–45 s).	This method is most appropriate for firm, lean fish (Table 3). Whole fish and thick fillets or steaks (>1 in. thick) may scorch before they are completely cooked.	High temperature at the heating surface, and complete product surface contact with the heating medium and heat carryover (temperature of product continues to rise).	Come-up temperature may be slow when cooking frozen product. Difficulty of taking internal product temperature while cooking. Interior may be undercooked because the exterior looks cooked.	Having the lid on or off can influence cooking time and uniformity. Undercooking is a bigger issue with larger products. Frozen breaded portions should not be thawed prior to cooking.
Grilling, broiling	Seafood should be placed in a single layer in a broiling pan placed 4 in. (10 cm) from heat source. Fish >0.5 in. (1.27 cm) must be turned when cooked halfway through.	Oily, whole fish (Table 3) with head and tail intact are most appropriate for broiling because they require little basting. Covering lean fish with strips of bacon or basting them frequently is acceptable.	Good surface lethality.	Crust formation on product limits heat transfer, producing uneven heating. For seared products (e.g., seared tuna), the inside of the product may still be raw.	Product placed below an intense heat source, i.e., broiler.
Microwaving	Seafood should be thawed prior to cooking and then cooked at a medium-high to high setting, depending on the oven's wattage. Consumers must refer to specific instructions for oven use and cooking times and temperatures included on product label. The 10-min rule does not apply.	Any seafood can be cooked or thawed in the microwave.	May be able to cook in the original packaging, thereby reducing the potential for cross-contamination.	Uneven heating. Cooking is affected by the volume of product in the oven, product characteristics (shape and composition), cooking container characteristics (material, shape, and whether covered), uneven heating, and product placement in the oven.	Differences in equipment make standardized cooking instructions difficult; inexperienced cooks (particularly children) may prepare foods improperly.

TABLE 2. *Continued*

Method	Description[a]	Applicable commodity examples[a]	Advantages	Limitations	Comments
Microwaving (cont'd)				Cooking continues in the food for several minutes after the oven has been turned off, which may result in overcooking.	
Oven frying	Fish is placed in a single layer in a greased baking pan and baked in a preheated oven at 500–550°F (260–288°C) until done. The 10-min rule does not apply because of the higher temperature.	Shrimp, scallops, and any finfish can be oven fried. Recommended thickness of filet should not exceed 1.5 in. (3.81 cm).	High temperature at the heating surface.	Can be difficult to assess doneness because of short cooking time and high temperature.	Breaded fish is cooked at a very high temperature to produce a low-fat alternative to other frying strategies while providing a similar taste.
Pan frying, sautéing	Requires adequate oil to cover the bottom of the pan. Oil should be heated to 375°F (191°C). Fish is typically cooked until one side is golden brown; the piece is turned once and cooked until the second side is browned. Shrimp are generally fried or sautéed until pink or opaque (if shelled).	Most appropriate for firm, lean fish (Table 3). Steaks and fillets should be no more than 0.5 in. (1.27 cm) thick, and frozen fish should be at least partially thawed.	High temperature at the heating surface.	Difficult to take internal product temperature while cooking. Uneven cooking; undercooking of interior because the exterior of product looks cooked.	Overfilling of the pan may prevent the preparer from observing whether the fish pieces are thoroughly cooked.
Planking	Fish is baked on a nonresinous, grooved wooden plank. The plank is oiled and warmed. Seasoned and oiled fish is placed on the plank, and baked in a 400°F (204°C) oven following the 10-min rule.	Finfish fillets and steaks.	Good surface lethality.		Difficulty cleaning and sterilizing the plank between uses.
Poaching	Seafood is cooked in liquid (water, wine, or stock) that is brought to a simmer (180°F [82°C]).	Firm finfish, usually whole or steak. Lobster, shrimp, and crab are poached in their shells; clams, oysters, and other shellfish are typically shucked before poaching.	Longer heat exposure; if crust formation occurs it happens after moist heat delivers adequate surface lethality.	Product shape may lead to uneven cooking. Temperature achieved may be insufficient to inactivate viruses in molluscan shellfish.	Includes cook-in-bag and foil wrap; nonseafood components (stuffing, breading, batter, casserole) may influence temperature profile.
Smoking	Hot smoking is addition of smoke and heat to 145°F (63°C) internal temperature in fish for 30 min in conjunction with the addition of salt at 2.5–3.5% water phase salt.[c]	Salmon, trout, mussels, and oysters.	The appropriate application of heat can inactivate vegetative pathogens in hot-smoked items.	Cold smoking (90°F [32°C]) does not include a thermal treatment capable of eliminating vegetative or other microbial contaminants.	Vacuum packaging of these products without proper water phase salt and temperature controls (40°F [4.4°C], or less) can create additional biological hazards such as outgrowth of *C. botulinum* and production of botulinum toxin.

TABLE 2. *Continued*

Method	Description[a]	Applicable commodity examples[a]	Advantages	Limitations	Comments
Steaming	Fish are suspended 1–2 in. (2.5–5 cm) over boiling liquid. Do not let the boiling liquid touch the fish. Any pot that can be closed tightly can be used, if there is some means to hold the fish above the liquid. Steam fish according to the 10-min rule. Steam live clams, mussels, and oysters until their shells open, using only 0.5 in. (1.27 cm) of boiling liquid. Shrimp are generally steamed until pink or opaque (if shelled).	Molluscan shellfish (live clams, mussels, and oysters), firm finfish, and crustaceans.	Good heat penetration.	Difficulty of taking internal product temperature while cooking. Overcrowding of product may reduce heat transfer. Ensure adequate liquid. Temperature may be inadequate to ensure destruction of viruses.	
Stir frying	Oil is heated to 375°F (191°C) in a wok or skillet; ingredients are added in the order of required cooking time. Food is stirred continuously until the fish is deemed cooked and the vegetables are crisp-tender.	Most appropriate for small pieces of firm textured seafoods.	High temperature at the heating surface.	Uneven cooking. Undercooking of the interior because the exterior looks cooked.	The combination of foods and overfilling of wok may prevent preparer from observing whether the fish pieces are thoroughly cooked.

[a] Information summarized from Wild Edibles *(97)*.
[b] The ''10-min rule'' (also called the Canadian cooking method) refers to heating a product for 10 min/in. (2.5 cm) of product thickness by a given method *(86)*.
[c] Information summarized from Jahncke and Herman *(48)*.

TABLE 3. *Consumer criteria for determining ''doneness'' of seafood products*

Seafood products	Subjective criteria for ''doneness''	Reference
Crustaceans		
Crab	Shell of live crab will turn from green or blue to scarlet or red; flesh will become opaque; apron will loosen.	*96*
Lobster	Shell will turn from green or blue to scarlet; flesh will become opaque. However, these changes may occur before the product is thoroughly cooked (an internal temperature of 165°F [74°C]). Check whether a small leg pulls off easily.	*96*
Shrimp	Cooked shrimp has a uniform shell color (pink, red, or deep red-orange); flesh should become opaque and springy. If boiled, shrimp will float when done. To check doneness, hold cooked shrimp between fingers and squeeze. If soft, with no resistance, it is undercooked.	*96*
Finfish		
Lean (e.g., cod, haddock, pollock, tilapia)	Muscle should turn from translucent to milky white or opaque throughout; ''fork tender'' flakes at the center and separates easily from the bones.	*72*
Oily (e.g., herring, mackerel, bluefish)	Muscle should become opaque throughout, flake at the center, and separate easily from the bones.	*72*
Oily: salmon	Muscle should become opaque, glossy, and orange; flake at the center; and separate easily from the bones.	*96*
Molluscan shellfish		
Eaten muscle only: scallops	Flesh becomes opaque and firm, not soft. Physical changes can occur before an appropriate temperature is reached, so scallops should be cooked to an internal temperature of 145°F (63°C).	*96*
Eaten whole (e.g., clams, oysters)	Clams and oysters in shells are considered ''done'' when the shells open during the cooking process. Cull any clams or oysters that are open before cooking (gaping shells) and any that do not open during cooking.	*96*

before cooking. The result may be inadequate pathogen inactivation during normal cooking, leading to an unsafe product. The 2005 FDA Food Code (chapter 3) indicates that frozen food should be thawed at 41°F (5°C) or less or completely submerged under running water at 70°F (21°C) or below before cooking. In either case, according to the 2005 FDA Food Code (chapter 3) the product should not be above 41°F (5°C) for more than 4 h, including the time needed for preparation prior to cooking *(91).*

5. Is there a single temperature that will ensure safe seafood?

There is no single temperature, with or without a specified cooking time, that will ensure the safety of all cooked fishery products and result in a palatable product. Although a single time and temperature combination could theoretically be selected to cover all contingencies, such a recommendation would not be practical for every type of fishery product available to consumers. In addition, there are no nonthermal methods applicable at the consumer level that can inactivate microbiological pathogens in fishery products. However, the commercial use of ''nonthermal'' methods is currently being explored (e.g., high hydrostatic pressure, irradiation, and freezing) *(21, 42, 52, 53).* Details are beyond the scope of this document because they do not relate to a consumer application. A discussion of recommended temperatures required to ensure safe seafood based upon the control of bacterial pathogens, viruses, and parasites follows.

Bacterial pathogens. In Question 2 of this document, the bacterial pathogens of concern were identified as *Vibrio* spp., *S. sonnei, Salmonella, Campylobacter jejuni,* and pathogenic *E. coli.* Limited thermal inactivation data currently exist for these seafood-associated pathogens across the range of relevant fishery product matrices (Table 6). In part, this lack of data may be due to the wide variety of seafood products available and the diverse cooking methods that are commonly applied to these products.

The FDA hazards guidance *(89)* indicates that cooking processes are generally designed to eliminate vegetative cells but not spores of bacterial pathogens. The FDA currently recommends using commercial processes that yield a 6-log reduction in *L. monocytogenes* numbers to provide a ''safe harbor'' for reduction of microbial contaminants that may be present in commercial RTE fishery products. *L. monocytogenes* was selected by the FDA as the target organism for inactivation in commercial RTE seafoods because it is regarded as the most heat-resistant non-spore-forming foodborne pathogen that may be present, thus providing a ''worst case scenario'' in terms of the heat treatment needed for inactivation of the types and numbers of bacterial pathogens that might be present in commercially processed and distributed seafood.

The limited data currently available for *L. monocytogenes* thermal inactivation in various seafood products are summarized in Table 7. Information on times and temperatures that provide a ''safe harbor'' for the inactivation of *L. monocytogenes* in foods is provided in Appendix II.

TABLE 4. *Outbreaks of foodborne illness associated with seafoods reported to the CDC (1998 to 2004) (19)*

Etiological agent	No. of outbreaks (total no. of cases)						
	Crustacean	Finfish	Molluscan shellfish	Multiple seafood items	Other seafood	Unspecified seafood	Total
Known agents							
Anisakis simplex		1 (14)					1 (14)
Giardia lambia						1 (3)	1 (3)
Bacillus cereus	1 (118)	1 (3)					2 (121)
Campylobacter jejuni		2 (140)	1 (2)		2 (10)		5 (152)
Clostridium botulinum		3 (8)					3 (8)
C. perfringens	1 (204)					1 (50)	2 (254)
Cyclospora cayetanensis		1 (56)					1 (56)
Escherichia coli	1 (12)	1 (41)				1 (14)	3 (67)
Plesiomonas shigelloides		1 (5)					1 (5)
Salmonella	10 (214)	14 (852)	2 (13)			3 (40)	29 (1,119)
Shigella sonneli	1 (2)	1 (47)	2 (6)				4 (55)
Staphylococcus aureus		1 (3)				1 (68)	2 (71)
Vibrio cholerae	1 (6)		3 (8)				4 (14)
V. fluvialis			1 (2)				1 (2)
V. parahaemolyticus	9 (142)		13 (507)	2 (16)		1 (23)	25 (688)
Multiple bacteria	3 (38)	1 (2)				1 (115)	5 (155)
Noroviruses	7 (294)	13 (668)	17 (429)			5 (142)	42 (1,533)
Hepatitis A virus	2 (14)	1 (4)					31 (18)
Total	36 (1,044)	41 (1,843)	39 (967)	2 (16)	2 (10)	14 (455)	134 (4,335)
Unknown agents	119 (921)[a]	207 (1,287)[b]	108 (661)[c]	24 (123)[d]	15 (73)[e]	37 (285)[f]	510 (3,350)
Total	155 (1,965)	248 (3,130)	147 (1,628)	26 (139)	17 (83)	51 (740)	644 (7,685)

[a] Of the 119 crustacean-associated outbreaks of unknown etiology, 7 were suspected noroviruses, 1 was suspected other viral, 5 were suspected *S. aureus*, 2 were suspected *B. cereus*, 10 were suspected *V. parahaemolyticus*, 3 were suspected *Salmonella*, and 1 was suspected *Shigella*.

[b] Of the 207 finfish-associated outbreaks of unknown etiology, 3 were suspected *B. cereus*, 1 was suspected *Campylobacter*, 2 were suspected *C. perfringens*, 5 were suspected *S. aureus*, 5 were suspected noroviruses, 1 was suspected rotavirus, 1 was suspected other viral, and 3 were suspected *Vibrio*.

[c] Of the 108 molluscan shellfish–associated outbreaks of unknown etiology, 27 were suspected noroviruses, 14 were suspected *Vibrio*, 6 were suspected *S. aureus*, 3 were suspected other viral, 1 was suspected *B. cereus*, 1 was suspected *C. perfringens*, and 1 was suspected other bacterial.

[d] Of the 24 multiple seafood items–associated outbreaks of unknown etiology, 3 were suspected *Vibrio*, 2 were suspected noroviruses, 1 was suspected *Salmonella*, 1 was suspected *S. aureus*, and 1 was suspected *C. perfringens*.

[e] Of the 15 other seafood items–associated outbreaks of unknown etiology, 1 was suspected norovirus, 1 was suspected rotavirus, 1 was suspected *C. botulinum*, 1 was suspected *S. aureus*, and 1 was suspected *V. parahaemolyticus*.

[f] Of the 37 unspecified seafood–associated outbreaks of unknown etiology, 3 were suspected noroviruses, 2 were suspected *V. parahaemolyticus*, 2 were suspected *C. perfringens*, 1 was suspected *B. cereus*, and 1 was suspected other bacterial.

These heating times and temperatures reflect conservative values for extended-shelf-life refrigerated products and were designed to address variations in heat resistance due to different strains of *L. monocytogenes,* different product types, and other factors. The highest risk for listeriosis cases in the United States is attributed to consumption of certain dairy food products and RTE meats that are not thoroughly reheated immediately prior to consumption *(90).* To establish effective preparation processes that will yield safe food products, it is also helpful to understand the relative likelihood of the presence of specific microbiological pathogens in the targeted foods. Seafood products are perishable, and storage times are typically short, which helps to limit growth of *L. monocytogenes* in the products. Therefore, the number of *L. monocytogenes* cells likely to be consumed is low, although this number is dependent on following GMPs and on proper handling at retail and by the consumer. The FDA and the Food Safety and Inspection Service (FSIS) *L. monocytogenes* risk assessment *(90)* predicted a low relative risk of listeriosis from consuming a serving of raw seafood. The levels of *L. monocytogenes* in raw seafood products at the time of consumption (which would reflect the numerical levels at the time of cooking) were calculated for the risk assessment. Specifically, the *L. monocytogenes* distribution shows that 91.3% of raw seafood is contaminated at less than 1 CFU per serving, and 7.2% contains 1 to 10^3 CFU per serving. Approximately 1.2% of raw seafood is contaminated at 10^3 to 10^6 CFU per serving, and $<0.3\%$ of the time the contamination level is greater than 10^6 CFU per serving. Any cooking would further reduce the numbers. In general, listeriosis attributed to seafood products is infrequent, despite the fact that *L. monocytogenes* has been isolated from raw seafood and cooked RTE crustaceans at retail *(90)* and from commercially pro-

TABLE 5. *Temperatures of retail and home refrigerators (6)*

Location	Avg refrigerator temp	% of refrigerators: 42°F (5.2°C) to <45°F (7.2°C)	45°F (7.2°C) to <51°F (10.6°C)	51°F (10.6°C) and higher
Retail fish counters[a]	40.0°F (4.4°C)	16	15	4
Backroom commercial refrigerators[b]	37.9°F (3.3°C)	11	5	1.4
Consumer home refrigerators[b]	39.2°F (4.0°C)	18	8	1.5

[a] Fish.
[b] Nonseafood product.

cessed smoked fish products *(40, 50, 73, 74).* To illustrate, *L. monocytogenes* was not identified as the cause of any U.S. seafood-associated illness outbreaks in the 1998 through 2004 CDC data set shown in Table 4, although most listeriosis cases are sporadic. Although *L. monocytogenes* is the pathogen of concern in commercially processed RTE foods, which may be stored refrigerated for a number of days, it may not be the most appropriate target pathogen in raw fishery products that will be cooked by the consumer prior to consumption.

It is evident that the biological agent of greatest public health significance is food category specific and that heat penetration may differ based on product type and location of the contaminant(s). Therefore, different cooking times and temperatures are required for different seafood products to make them safe for consumption. However, the time and temperature combinations needed to render some seafood products safe may reduce their palatability. In order to enhance the safety of some seafoods prepared with certain cooking methods, consumers should be instructed that in addition to cooking to a palatable state they need to follow sanitary and hygienic practices, avoiding temperature abuse and contamination of product before cooking and during storage of leftovers.

Salmonella is the bacterial pathogen that was the most frequent cause of outbreaks of seafood illness in the United States for the period 1998 through 2004 (Table 4). When *Salmonella* is present in seafood, its presence usually is due to fecal contamination of harvesting sites but occasionally is due to cross-contamination by human carriers, particularly food handlers. Outbreaks of human disease associated with the presence of *Salmonella* in seafood are well documented *(7).* The epidemiological evidence from the CDC (1998 through 2004) indicates that *Salmonella* infections associated with seafood are more commonly caused by finfish and crustaceans than other types of products (Table 4). This observation is in agreement with the FDA seafood *Salmonella* surveillance data for the period 1990 through 1998 *(45),* which indicated a prevalence of 11.8% (2,114 samples tested) in finfish/skinfish, 8.3% (4,440 samples tested) in raw crustaceans other than crab, and 3.7% (298 samples tested) in crabs and crab products. It should be noted that the same study demonstrated a *Salmonella* prevalence of 11.0% (803 samples tested) in various other aquatic food animals (i.e., raw frog and frog legs, squid, alligator, octopus, jellyfish, sea squirt, cuttlefish, sea cucumber, seahorse, and sea urchin).

More recently, U.S. investigators reported isolation of *Salmonella* from oysters harvested from all three U.S. coastlines (east, west, and Gulf) at a prevalence of 7.4% *(9).* Of the isolates collected, >75% were characterized as *Salmonella enterica* serovar Newport, a major human pathogen. Similar environmental prevalence studies have been done on European shellfish *(63),* although the prevalence was lower (1.8% overall). The prevalence of *Salmonella* in oysters was 2.2%. However, the public health significance of these findings has yet to be determined.

Using *Salmonella* as the target pathogen, the 2005 FDA Food Code (chapter 3) *(91)* recommends specific cooking times and temperatures for food products, including seafood, as follows:

- Comminuted fish, 155°F (68°C) for 15 s
- Stuffed fish or stuffing containing fish, 165°F (74°C) for 15 s
- Other raw fish, 145°F (63°C) for 15 s

The cooking guidance in the 2005 FDA Food Code is premised upon an expectation of a low level of initial contamination, and common cooking parameters are expected to destroy surface contamination on these foods. However, as noted, these cooking times and temperatures were not based on specific data for inactivation of pathogens in seafood. There are limited thermal inactivation data for *Salmonella* in seafoods; a single study provided *D*-values for *Salmonella* Senftenberg in oyster homogenate *(39).* Given the number of outbreaks and cases caused by *Salmonella* (Table 4), there is a need to determine the thermal inactivation kinetics of this organism in seafood in order to determine whether the 2005 FDA Food Code times and temperatures are adequate.

Viruses. Certain human enteric viruses may be more heat resistant than vegetative bacterial cells and can cause disease at relatively low doses *(30, 79).* Usually, viral contamination of fishery products is best controlled through proper sanitation and hygienic practices by food handlers and proper classification of shellfish growing waters, although the latter is not always effective *(30, 79).* Specific time and temperature cooking combinations for inactivation of enteric viruses in molluscan shellfish are provided in Table 8.

Outbreaks of HAV and norovirus infections have been associated with grilled, stewed, steamed, and fried oysters *(59, 65).* Koff and Sear *(54)* demonstrated that steaming clams until their shells opened, often used as an indication of doneness, is unlikely to achieve temperatures adequate for HAV inactivation. In the United Kingdom, standards set for commercial shellfish temperatures are based on research demonstrating a 4-log reduction of HAV in molluscan shellfish after holding at an internal temperature of 194°F (90°C) for 1.5 min *(59).* It is likely that this time and temperature combination will achieve a similar level of reduction for

TABLE 6. *Representative thermal inactivation data for bacterial pathogens in seafood matrices*

Microbial pathogen	Temp	*D*-value[a]	Product	Reference
Listeria monocytogenes	(see Table 7)			
Salmonella Senftenberg 775W	133°F (56°C)	3.5 min	Oyster homogenate	*39*
	158°F (70°C)	0.3 min		
Vibrio cholerae	120°F (49°C)	8.15 min	Crab meat homogenate	*81*
	129°F (54°C)	5.02 min		
	140°F (60°C)	2.65 min		
	151°F (66°C)	1.60 min		
	159.8°F (71°C)	0.3 min		
V. parahaemolyticus	122°F (50°C)	1.3–1.6 min	Oysters	*4*
	122°F (50°C) for 5 min	4.5- to 6-log reduction	Shucked oysters	*92*
V. vulnificus	122°F (50°C)	39.9 ± 1.2 s	Shucked oyster meats	*23*

[a] Time needed to inactivate 1 log unit of a given pathogen at a specified temperature for a given product.

noroviruses, although this assumption has not been confirmed *(30).* However, consumers may find that these time and temperature combinations are difficult to achieve without overcooking the product *(65).*

Parasites. Although parasitic agents such as nematodes, cestodes, and trematodes should be controlled by most popular cooking methods *(2),* a number of products likely to contain these parasites may be consumed when they are only partially cooked. This is significant because these organisms may be distributed within the flesh (rather than localized on the surface), and partial cooking may not result in sufficient inactivation. As a result, freezing prior to heating is frequently used for their inactivation. Thorough freezing kills parasitic agents if the fish is subjected to a low enough temperature for the required period of time *(3).* Candling or other visual inspection techniques cannot be relied upon to identify parasites in fish that have not been adequately frozen.

The effectiveness of freezing for inactivating parasites depends on several factors, including (i) the temperature of the freezing process, (ii) the length of time needed to freeze the fish tissue, (iii) the type of parasite present, (iv) the length of time the fish is held frozen, and (v) the fat content of the fish. The temperature of the freezing process, the length of time the fish is held frozen, and the type of parasite appear to be the most critical factors. For example, tapeworms are more susceptible to freezing than are roundworms, and flukes appear to be more resistant to the freezing process than are roundworms *(89).* The FDA hazards guidance *(89)* and the 2005 FDA Food Code (chapter 3) *(91)* describe three distinct combinations of freezing temperatures and times to destroy parasites in finfish:

- Frozen and stored at −4°F (−20°C) or below for a minimum of 168 h (7 days)
- Frozen and stored at −31°F (−35°C) or below for a minimum of 15 h
- Frozen at −31°F (−35°C) or below until solid and stored at −4°F (−20°C) or below for a minimum of 24 h

It should be noted that these freezing conditions may not be adequate for the control of parasites in large fish, e.g., thicker than 6 in. (15 cm).

The 2005 FDA Food Code *(91)* and the FDA hazards guidance *(89)* also state that the following tuna species do not require freezing because they are unlikely to contain parasites: *Thunnus alalunga* (Albacore), *T. albacares* (Yellowfin tuna), *T. atlanticus* (Blackfin tuna), *T. maccoyii* (Southern bluefin tuna), *T. obesus* (Bigeye tuna), and *T. thynnus* (Northern bluefin tuna). Aquacultured marine fish, such as salmon, raised in open-water net pens or raised in land-based operations (such as ponds or tanks) and fed a commercial diet without supplementation with raw fish do not require freezing because they are unlikely to be exposed to marine parasites *(89).*

There is little information to suggest that parasitic protozoa are involved in seafood illnesses (Table 4 and Appendix I); however, their presence in water raises potential concerns. Some data on the resistance of *Cryptosporidium* to heat and freezing are available *(31, 33).* Additional information on inactivation of parasitic protozoa in seafood may be needed if the epidemiological data suggest that these organisms are responsible for human illness from this source.

6. Are there other consumer methods of preparing seafood that need to be addressed? For example, some consumers believe that the lime juice used in ceviche will "cook" the product.

In general, other than heating, there are no other reliable methods that will ensure safe seafood. Traditional noncooking methods of preparing seafood include acidification (e.g., ceviche), cold smoking, brining, pickling, and fermentation. Nontraditional novel methods of preparing seafood include the use of alcohol (e.g., "drunken crabs") and uncontrolled heat sources for cooking (e.g., dishwasher or car engine blocks). There is a paucity of data regarding the efficacy of novel methods with respect to pathogen inactivation in seafood products. Although the use of acids (e.g., lemon or lime juice at pH ≤2.5) for the production of ceviche may reduce microbial numbers *(62),* it cannot be relied upon to result in a safe product. Consumers should be advised to use only reliable, effective methods of seafood preparation and to avoid product contamination postcooking.

TABLE 7. *Thermal resistance of* Listeria monocytogenes *in seafood products (revised from Doyle et al. (29), with permission)*

Seafood product	Temp °C	Temp °F	*D*-value (min)	*z*-value[a]	Source, comments
Crab meat	50	122	40.43	15.1°F (8.4°C)	Canned pasteurized blue crab meat was blended, inoculated (10^7 CFU/g) with strain Scott A, packaged in sausage casings, and heated in a preheated waterbath. Survivors were counted on tryptic soy agar (TSA) after 48 h at 98.6°F (37°C) *(44)*.
	55	131	12.0		
	60	140	2.61		
Lobster	51.6	125	97.0	9°F (5.0°C)	Cooked lobster meat was mixed with a 3.3% sodium chloride solution; blended, inoculated (10^7 CFU/g) with a five-strain mixture, and heated in a circulating waterbath in pouches (25-g samples). Survivors were counted on TSA after 96 h at 86°F (30°C) *(11)*.
	54.4	130	55.0		
	57.2	135	8.3		
	60.0	140	2.39		
	62.7	145	1.06		
Salmon	58	136	8.48	12.1°F (6.7°C)	Fresh raw fish fillets were inoculated by needle injection of 0.1 ml of cell suspension of strain O57 in the geometric center of each fillet at 10^5 cells/g, vacuum packaged, heated, and stored at 36°F (2°C) for 3 wk to simulate storage of sous vide cooked food and to allow anaerobic resuscitation of injured cells. Survivors were enumerated after enrichment in UVMII (Oxoid) broth and plating on Oxford agar, according to a U.S. Department of Agriculture (USDA) procedure *(8)*.
	60	140	4.23		
	62	144	3.02		
	65	149	1.18		
	68	154	0.22		
	70	158	0.17		
Salmon	58	136	10.73	10.1°F (5.6°C)	Fresh raw fish fillets were inoculated by needle injection of 0.1 ml of cell suspension of strain O62 in the geometric center of each fillet at 10^5 cells/g, vacuum packaged, heated, and stored at 36°F (2°C) for 3 wk to simulate storage of sous vide cooked food and to allow anaerobic resuscitation of injured cells. Survivors were enumerated after enrichment in UVMII (Oxoid) broth and plating on Oxford agar, according to a USDA procedure *(8)*.
	60	140	4.48		
	62	144	2.07		
	65	149	0.87		
	68	154	0.2		
	70	158	0.07		
Cod	58	136	6.18	10.3°F (6.1°C)	Fresh raw fish fillets were inoculated by needle injection of 0.1 ml of cell suspension of strain O57 in the geometric center of each fillet at 10^5 cells/g, vacuum packaged, heated, and stored at 36°F (2°C) for 3 wk to simulate storage of sous vide cooked food and to allow anaerobic resuscitation of injured cells. Survivors were enumerated after enrichment in UVMII (Oxoid) broth and plating on Oxford agar, according to a USDA procedure *(8)*.
	60	140	1.95		
	65	149	0.27		
	68	154	0.13		
	70	158	0.05		
Cod	58	136	7.28	10.3°F (5.7°C)	Fresh raw fish fillets were inoculated by needle injection of 0.1 ml of cell suspension of strain O62 in the geometric center of each fillet at 10^5 cells/g, vacuum packaged, heated, and stored at 36°F (2°C) for 3 wk to simulate storage of sous vide cooked food and to allow anaerobic resuscitation of injured cells. Survivors were enumerated after enrichment in UVMII (Oxoid) broth and plating on Oxford agar, according to a USDA procedure *(8)*.
	60	140	1.98		
	62	144	0.87		
	65	149	0.28		
	68	154	0.15		
	70	158	0.03		
Crawfish	55	131	10.23	9.9°F (5.5°C)	Frozen crawfish tail meat was bagged and heated by immersion in boiling water for 10 min at 185°F (85°C) to reduce background microflora; 100-g samples were inoculated with a three-strain mixture and blended; and 25-g samples were heated. Survivors were enumerated on TSA with yeast extract (TSAYE) and pyruvate at 81°F (27°C) for 48 h *(28)*.
	60	140	1.98		
	65	149	0.19		
Mussels	54	129	142.26	7.7°F (4.25°C)	Mussels were heated, shucked, brined, drained, and blended, and 25-g samples were placed in plastic bags and inoculated with a seven-strain mixture, blended, and heated for 16–24 h at 39°F (4°C). Survivors were enumerated on TSAYE at 95°F (35°C) after 4 days *(10)*.
	56	133	48.09		
	58	136	16.25		
	59	138	9.45		
	60	140	5.49		
	62	144	1.85		
Imitation crab meat	58	136	9.7	10.4°F (5.8°C)	After heating and cooling, *Listeria* enrichment broth (stationary phase) was added to pouches containing 5 g of homogenized imitation crab meat that had been inoculated with a four-strain mixture; five replicates per time and temperature combination were used to determine the most probable number of survivors as an average of triplicate experiments *(64)*.
	62	144	2.1		
	66	150	0.4		

[a] Temperature change necessary to change the *D*-value by 1 log unit.

TABLE 8. *Thermal inactivation of viruses in shellfish*

Agent	Temp and time	Complete inactivation	Product	Reference
Feline calicivirus (a norovirus surrogate)	Immersion in boiling water for 1–2 min; mean internal temp 78°C	~4 log	Cockles	*83*
Hepatitis A virus	Internal temp 185–194°F (85–90°C) for 1 min	>4 log	Oysters	*68*
	Temp 212°F (100°C) for 2 min; internal temp 85°C after 30 s, 90°C after 1 min	5.5 log $TCID_{50}$[a]	Mussels	*24*
	Immersion in boiling water for 3 min; mean internal temp 197.6°F (92°C)	~3.5 log	Mussels	*46*

[a] TCID, tissue culture infectious dose.

7. Should consumer advice vary based on any susceptible at-risk populations?

Food consumption advisories currently exist for informing consumers, especially at-risk human populations such as the elderly, immunocompromised (including those with liver disease), young children, or pregnant women, regarding the consumption of foods of animal origin that are raw, undercooked, or not otherwise processed to eliminate pathogens. These advisories include fish products such as sushi, sashimi, and raw molluscan shellfish *(91).* At-risk populations should be advised to consume only properly cooked and appropriately handled seafood products and to avoid products prepared by alternative methods.

V. CONCLUSIONS

- The microbiological safety of seafood is enhanced greatly when it is properly handled, cooked, served, and stored as leftovers.
- Consumers sometimes choose to eat certain seafood products raw or undercooked.
- Available epidemiological data are inadequate to determine the relative contributions of raw, undercooked, or properly cooked and then recontaminated seafood to the burden of foodborne disease.
- The fragile nature of fish tissue results in a delicate balance between proper cooking (to inactivate the pathogen of concern) and overcooking for optimal eating quality of fishery products. However, food safety should take the precedence over eating quality whenever possible.
- Cooking methods for seafood products differ and often are not necessarily based on scientific data.
- Although seafood cooking recommendations are widely available, there is no easy, practical measurement or indicator for the consumer to objectively determine sufficient cooking in order to ensure the safety of fishery products.
- Cookbook recommendations of bringing product to room temperature before cooking and then cooking for 1 to 2 min per side do not necessarily take into account species or size of the fillet and may also deviate from recognized safe food handling practices or recommendations.
- Microwave heating is frequently found to be less effective than conventional heating because of nonuniform distribution of heat, resulting in the occurrence of cold spots. Furthermore, microwave cooking instructions frequently are based on time but not necessarily on cooking temperature.
- Nontraditional novel preparation procedures cannot be relied upon to assure the microbiological safety of seafood products.
- There is a lack of thermal inactivation data for relevant pathogens in appropriate seafood due, at least in part, to the wide variety of products available and the many methods of cooking that are commonly applied to these products.
- The *L. monocytogenes* 6-log reduction recommendation in the FDA hazards guidance, 3rd edition *(89),* represents an FDA regulatory ''safe harbor'' for commercially prepared RTE products but may lead to overcooking of certain products and may not be necessary for routine cooking of fresh or frozen seafood by consumers. This FDA recommendation was designed to deal with a ''worst case scenario'' of potential contamination that needs to be inactivated in commercially processed and distributed seafood that may have a long shelf life. Unlike commercially prepared and marketed RTE seafood products that may be stored for longer periods of time, seafood purchased by consumers is generally cooked for immediate consumption, and any properly handled and stored leftovers are likely to be consumed within a short period of time, thereby reducing the risk from *L. monocytogenes.*
- Although a seafood cooking process may reduce the microbiological public health risk associated with the product, the extent of risk reduction differs by type of seafood, the cooking method applied, and the level of microbial pathogens.
- Some of the currently used cooking processes may not provide adequate public health protection (e.g., failure to destroy human enteric viruses in lightly cooked, steamed, or sautéed molluscan shellfish or helminths in seared finfish).
- Without additional barriers, such as reduced water activity, cooked seafood products require refrigeration to maintain safety.
- Refrigerator temperatures are reported to be variable and sometimes abusive, which may result in high initial levels of bacteria prior to cooking or allow for bacterial growth in stored leftovers.
- There is no single temperature, with or without a specified cooking time, that will ensure the safety of all cooked fishery products and result in a palatable product.

VI. RECOMMENDATIONS

- Collection and review of epidemiological data should be more complete in order to specifically delineate the role of raw, undercooked, and properly cooked and then recontaminated seafood to the overall burden of foodborne disease.
- Inactivation of pathogens in seafood varies with type of seafood, cooking method, and type of pathogen (bacteria, viruses, parasitic protozoa, and/or other parasites). Therefore, the Committee recommends that thermal inactivation kinetics (e.g., *D*-values) be determined for the most appropriate and most heat-resistant vegetative bacterial, viral, or parasitic pathogen of concern in specific seafood types and that heat penetration studies be conducted for each seafood cooking method applied to each product type. This approach will allow a science-based selection of seafood cooking methods and parameters.
- In the absence of adequate pathogen inactivation data for various seafood products, the cooking guidance provided in the 2005 FDA Food Code, with *Salmonella* as the target organism for inactivation during cooking, should continue to be followed by consumers even though the recommended cooking times and temperatures are not based on the inactivation of *Salmonella* (or other appropriate pathogens) in seafood. It should be noted, however, that this recommendation is predicated upon expectations that there is a low level of surface or internal contamination, that the seafood is properly handled prior to cooking, that the cooked seafood will be consumed shortly after preparation, and that any leftovers will be handled properly and consumed within a short period of time.
- Cooking, as defined in this document, refers only to the application of heat. Consumers should be instructed not to rely on the use of nontraditional novel preparation procedures or use of uncontrolled heating sources, which cannot be relied upon to assure the microbiological safety of seafood products.
- At-risk populations should be instructed to avoid consumption of seafood that is uncooked, undercooked, improperly handled or stored, or prepared with methods other than heating or with the use of uncontrollable heating sources.
- Consumers should be made aware that heating to an internal temperature of 194°F (90°C) for 1.5 min is required for inactivation (4-log reduction) of HAV in molluscan shellfish, even though this heat treatment may result in a less palatable product.
- Consumers should be instructed that in order to enhance the microbiological safety of seafood they also need to follow sanitary and hygienic practices, avoiding temperature abuse and contamination of products before cooking and during storage of leftovers. This is particularly true for some seafoods prepared with certain cooking methods, e.g., steamed molluscan shellfish.
- Educational and outreach programs should continue to emphasize the foodborne illness risks and importance of sanitation, temperature control, proper handling, and prevention of cross-contamination at the consumer and retail levels. These programs should be updated with appropriate cooking times and temperatures as additional information becomes available.

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APPENDIX I. VARIOUS FOODBORNE PATHOGENS ASSOCIATED WITH ILLNESS ATTRIBUTED TO THE CONSUMPTION OF SEAFOOD

Microorganisms

Aeromonas hydrophila. *A. hydrophila* was isolated *(1)* from raw oysters associated with a large outbreak of foodborne illnesses. This bacterium was also isolated from a shrimp salad associated with human illnesses *(57),* presumably as a result of recontamination after cooking of the shrimp. *Aeromonas* gastroenteritis has a sharp summer peak *(36).*

Bacillus cereus. *B. cereus* has been implicated in illness from a wide range of foods, including fish *(38, 56).* There are two documented outbreaks of illness linked to *B. cereus*–contaminated seafood between 1998 and 2004 (Table 4). Cooking of seafood does not inactivate the spores of *B. cereus* and would not be the

recommended means to control this pathogen. Proper hygiene and appropriate temperature control are needed to prevent *B. cereus* illness.

Campylobacter jejuni* and *Campylobacter coli. Friedman et al. *(35)* identified eating raw seafood as a risk factor for sporadic *Campylobacter* infection. Arumugaswamy and Proudford *(5)* isolated *C. jejuni* and *C. coli* from Sydney rock oysters. Although the heat resistance of *C. jejuni* in seafood has not been determined, the reported heat resistance of this organism in other products is low *(69).* Preventing campylobacteriosis from consumption of raw shellfish depends on protecting shellfish growing waters from fecal contamination.

Clostridium botulinum. Examples of illnesses due to *C. botulinum* neurotoxins present in seafood include commercially produced, uneviscerated, salted, air-dried fish (''ribbetz'' or ''Kapchunka'') *(82)*; commercially produced ''moloha,'' an ethnic, uneviscerated, salt-cured fish product *(15)*; commercially smoked vacuum-packed salmon (''Raucherfisch'') imported into Germany; and home-smoked vacuum-packed fish (''Lachsforellen'') *(61).* These illnesses were not due to undercooking of seafood but were related to temperature and/or the preservation process not providing adequate inhibition of outgrowth of *C. botulinum* spores, followed by reproduction of vegetative cells and subsequent neurotoxin formation.

An unusual outbreak of botulism (type B) from finfish occurred in Hawaii in 1990. Three adults became ill after consuming grilled fresh palani, a reef scavenger fish, that contained remnants of its intestines and that had been exposed to elevated temperatures; the retail display case cooling equipment was nonfunctioning and the internal temperature of the fish on top of the ice in the case was 52°F (11°C). Clinical manifestations were most severe in the two persons who ate the intestines *(14).*

Spores of *C. botulinum* can readily be isolated from soil and the marine environment and may contaminate fish and fishery products. Common public health controls to prevent outgrowth of all types of *C. botulinum* include retorting to inactivate spores or proper heating to inactivate vegetative cells combined with pH adjustment to a level at or below 4.6 with appropriate acidulants, limitation of available water to prevent outgrowth of spores (water activity below 0.93), or refrigeration below 38°F (3.3°C) *(61).*

Human enteric viruses. Viruses are probably the most significant microbiological agents causing seafood-associated disease *(55).* As with the enteric bacteria, viruses are not indigenous to the water but are transmitted by the fecal-oral route through contact with human fecal matter from infected persons. Viruses are of particular concern in raw molluscan shellfish, because the shellfish can obtain and even concentrate the viruses in the gastrointestinal tract if harvesting waters are impacted by human fecal pollution. An extensive review of shellfish-borne viral disease epidemiology has been provided by Potasman et al. *(76).* In finfish and crustaceans, as with prepared fish products, these viruses are more likely to be present because of poor hygienic practices of infected food handlers. There are many different enteric viruses, and they cause a wide variety of illnesses, including hepatitis, fever, diarrhea, gastroenteritis, meningitis, and myocarditis. Regardless of the large number of enteric viruses, the epidemiologically important ones are HAV and the noroviruses. Infectious hepatitis caused by HAV is perhaps the most serious viral illness transmitted through ingestion of contaminated seafood. Fulminant HAV, although rare, can be fatal *(25).* Recent epidemiological estimates suggest that the human gastrointestinal viruses, predominantly the noroviruses, are a significant cause of foodborne disease. These viruses cause a mild, short-lived gastrointestinal syndrome from which recovery is usually complete. Although it is difficult to detect viruses in foods, and diagnosis of norovirus infection in humans is not done routinely, it is estimated that noroviruses account for over 67% of all cases of foodborne illness *(66).* Thermal inactivation data are available for HAV and feline calicivirus (a norovirus surrogate) in several seafood matrices (Table 8).

Listeria monocytogenes. The FDA and the FSIS *L. monocytogenes* risk assessment *(90)* predicted that raw seafood will be contaminated at predominantly low levels (see ''Bacterial Pathogens'' section above). The risk assessment also predicted that at the time of consumption 96% of cooked RTE crustaceans are contaminated with <1 CFU per serving, approximately 3.2% are contaminated with 1 to 10^3 CFU per serving, and 0.7% are contaminated at levels of 10^3 to 10^6 CFU per serving. Only 0.1% of cooked RTE crustaceans are predicted to be contaminated at levels $>10^6$ CFU per serving. Thermal inactivation data for *L. monocytogenes* in various seafood matrices are listed in Appendix II. These guidelines indicate times and temperatures that provide safe harbor processes for inactivation of 10^6 CFU in foods and were developed based on the heat resistance of this organism in homogenates of chicken, beef, and carrot *(37).* These heating times and temperatures reflect conservative values for extended-shelf-life refrigerated products and were designed to address variations in heat resistance due to different strains of *L. monocytogenes,* different product types, and other factors *(22).* In the United States, there was an outbreak in 1989 of mild disease due to *Listeria* infection in which eating shrimp was a significant risk factor after controlling for consumption for other foods, but other foods may also have been involved *(78).* There have been several outbreaks in other countries associated with smoked seafood. In a case-control study of sporadic *Listeria* infections, Varma et al. *(94)* identified eating mussels and smoked salmon as potential sources of infection with *L. monocytogenes* serotype 4b. The association with mussels remained significant in the final multivariate analysis. In general, listeriosis is considered to be a problem associated primarily with recontamination of RTE foods, in particular those that support growth during refrigerated storage before consumption.

Plesiomonas. Although *Plesiomonas shigelloides* has been implicated in at least one finfish outbreak involving five cases in the period 1998 through 2004 (Table 4), its overall significance as a foodborne pathogen in general remains to be determined. It is a gram-negative organism and, similar to *Aeromonas,* is mostly associated with aquatic environments, which would make it of interest in seafood and fishery products *(36).* As is the case for *Aeromonas, Plesiomonas* gastroenteritis is more of a summer concern *(36).* Cooking processes to inactivate other enteric pathogens should also kill *Plesiomonas.*

Salmonella. Serotypes of *Salmonella enterica* are estimated to be involved in more than 1.4 million cases of nontyphoidal illnesses, 95% of which are foodborne. Although its case fatality rate is 0.0078, it is estimated to cause approximately 30% of all foodborne deaths annually *(66).* Based on FoodNet data, the overall incidence of *Salmonella* infection in 2006 was 14.81 cases per 100,000 population; this incidence rate did not change significantly from the 1996 through 1998 baseline *(20).* The most common *Salmonella* serotypes involved, in decreasing order, were Typhimurium, Enteritidis, Newport, Javiana, Montevideo, and Heidelberg *(20).* Based on data provided by the CDC for the period 1998 through 2004, *Salmonella* was the most frequent cause of

seafood-borne illness in the United States, being implicated in 10, 14, 2, and 3 outbreaks due to consumption of contaminated crustaceans, finfish, molluscan shellfish, and unspecified seafood, respectively; corresponding numbers of cases are 214, 852, 13, and 40 (Table 4). Additional information on this pathogen is presented in the main body of this report. Because the presence of *Salmonella* in seafood is due to fecal contamination at harvesting sites and cross-contamination during handling, proper sanitation procedures should limit the extent and frequency of contamination. Low levels of contamination should be inactivated when cooking according to recommendations by the Food Code *(91)* or procedures designed to inactivate other enteric pathogens of similar heat resistance and especially by cooking designed to inactivate *L. monocytogenes.*

Shigella. The significance of this pathogen is associated with its low infectious dose (<10 CFU) and the severity of the infection *(93).* These factors makes it a pathogen of concern in products exposed to human handling and potential cross-contamination. Thermal inactivation data are not available for this organism in relevant seafood matrices. However, as with most other non-spore-forming enteric pathogens, its heat resistance is lower than that of *Salmonella.*

Staphylococcus aureus. *S. aureus* is not considered to be a problem with respect to raw seafood; the organism does not compete well with other microbial flora that may be present, and thus it should be unable to reach the high cell numbers ($>10^5$ CFU/g) needed to produce sufficient enterotoxin to cause human illness *(93).* Potential problems could arise from contamination of cooked seafood through handling, followed by temperature abuse, or from growth of *S. aureus* in batter or breading used on seafood if it is contaminated and held at ambient temperature, allowing *S. aureus* to grow and produce heat-stable enterotoxins. Once formed in a food product, staphylococcal enterotoxins are extremely heat resistant, requiring 12.1 min at a temperature of 260°F (126.6°C) for inactivation in milk *(77).* The potential hazards associated with staphylococcal enterotoxin formation should be addressed during production of cooked seafoods and in the manufacturing of battered and breaded products utilizing appropriate time and temperature controls to prevent growth and enterotoxin production by this organism.

Vibrio cholerae. Serogroup O1 of this organism is generally associated with endemic cholera. Although no major outbreaks have been attributed to *V. cholerae* O1 in the United States since 1911, sporadic cases have been associated with consumption of raw shellfish or consumption of shellfish either improperly cooked or recontaminated after proper cooking. Although the South American endemic strain of *V. cholerae* O1 has been isolated from Gulf Coast waters, presumably transmitted by ships off-loading contaminated ballast water, no cases of cholera have been attributed to fish or shellfish harvested from U.S. waters. *V. cholerae* non-O1 is related to serogroup O1 but is generally associated with diseases that are less severe than endemic cholera. Shellfish harvested from U.S. coastal waters frequently contain *V. cholerae* non-Ol. Therefore, consumption of raw, improperly cooked, or cooked and recontaminated shellfish may lead to infection. Sporadic cases occur frequently along the coasts of the United States and are usually associated with consumption of raw oysters. However, no major outbreaks have been attributed to this organism in the United States *(93).* Shultz et al. *(81)* reported that when crabs were injected with 10^6 CFU of *V. cholerae* and cooked in boiling water (212°F [100°C]) for 15 min or in steam (212°F [100°C], 240°F [115.6°C], or 250°F [121°C]) for 10 min, no *V. cholerae* survived. Additional thermal inactivation data for this organism in a crab meat homogenate are shown in Table 6.

Vibrio parahaemolyticus. Based on the Committee's review of the recent CDC data, the most commonly implicated vehicle of *V. parahaemolyticus* infection is raw molluscan shellfish, followed by crustaceans. Historically, *V. parahaemolyticus* infection has occurred sporadically in the United States, and outbreaks are rare. There were, however, several highly publicized outbreaks in the late 1990s. In the summer of 1997, the largest outbreak of *V. parahaemolyticus* infection reported in North America occurred in the U.S. Pacific Northwest. Illness in 209 persons was epidemiologically associated with the consumption of raw oysters harvested from northern Pacific waters *(16).* The next summer another multistate outbreak associated with the consumption of raw oysters harvested from Galveston Bay, Tex., affected as many as 416 persons in 13 states. This outbreak was caused by the newly emerged *V. parahaemolyticus* serotype O3:K6 *(26).* Also in 1998, an outbreak associated with the consumption of bivalve molluscs harvested from Long Island Sound was attributed to the O3:K6 serotype *(17).* In a few of these cases, mean surface water temperatures were significantly higher (1.8 to 9°F [1 to 5°C]) than those reported in previous years. Prior to these outbreaks, which seem to have represented endogenous contaminants, *V. parahaemolyticus* infections in the United States were generally presumed to be due to gross mishandling of contaminated seafood, particularly improper refrigeration, insufficient cooking, or cross-contamination. Thermal inactivation data for this organism are shown in Table 6.

Vibrio vulnificus. This organism causes an infection that is characterized by gastrointestinal disease followed by primary septicemia, with mortality rates approaching 50% in individuals with underlying illnesses or those who are immunocompromised *(47). V. vulnificus* is a leading cause of seafood illness–related deaths, particularly in the southern states *(66).* Between 1998 and 2005, of the 173 cases of illness due to *V. vulnificus* where a single seafood item was involved, 85% were attributed to consumption of oysters *(98).* Cases of *V. vulnificus* infection usually occur sporadically rather than as outbreaks. Although *V. vulnificus* is most often responsible for *Vibrio*-related septic infections, other *Vibrio* species such as *V. parahaemolyticus, V. cholerae* non-O1, *V. fluvialis,* and *V. hollisae* are capable of producing morbidity *(47)* (Table 4). It is crucial to note that the majority of U.S. cases of *V. vulnificus* septicemic disease have occurred either in the Gulf States or as a result of the consumption of uncooked or lightly cooked oysters harvested from those states during the warm summer months *(80).* Thermal inactivation data for this organism are shown in Table 6.

Parasites

Helminths. Parasites (in the larval stage) consumed in unfrozen seafood that is uncooked or undercooked present a human health hazard, although one that is much less significant than the risk of illness from bacteria and viruses (Table 4). The process of heating raw fish sufficiently to kill bacterial pathogens is also sufficient to kill parasites *(3).* Among parasites, nematodes or roundworms (*Anisakis simplex, Pseudoterranova* spp., *Eustrongylides* spp., and *Gnathostoma* spp.), cestodes or tapeworms (*Diphyllobothrium* spp.), and trematodes or flukes (*Chlonorchis sinensis, Opisthorchis* spp., *Heterophyes* spp., *Metagonimus* spp., *Nanophyetes salminicola,* and *Paragonimus* spp.) are of most concern in seafood *(89).* Parasites in finfish are an emerging issue in industrialized countries and must be considered because of the increase in popularity of fish products that are typically eaten raw.

For example, sushi (pieces of raw or cooked fish with rice and other ingredients) or sashimi (slices of raw fish) fall into this category. Parasitic worms can be deeply imbedded in the fish muscle and, while normally not fatal, they can cause intestinal discomfort and other more severe symptoms *(86).* Although trematode diseases are endemic to countries other than the United States, interest in their control is increasing, given the number of diseases caused by these parasites *(51)* and the importation from these countries of seafoods that may be eaten raw. Wild-caught Pacific salmon (*Oncorhynchus* spp.) should be considered to have *A. simplex* larvae present *(67),* and prevalence may exceed 75% in various types of fresh U.S. commercial wild salmon *(27).*

Parasitic protozoa (*Cryptosporidium* and *Giardia*). Protozoan parasites such as *Giardia* and *Cryptosporidium* species may be present in water as a result of contamination with animal farm runoff or treated and untreated sewage waste. The ability of bivalve molluscs to concentrate parasitic protozoa has been demonstrated, and some researchers have postulated a potential role for oysters in the epidemiology of *Cryptosporidium* infection *(32),* although this link has yet to be confirmed epidemiologically. *Cryptosporidium* oocysts have been detected in eastern oysters harvested from commercial sites in the Chesapeake Bay *(32)* and along the U.S. Atlantic coast from Maine to Florida and New Brunswick, Canada *(34).* Effects of both high and low temperatures on the infectivity of *Cryptosporidium* have been studied *(31, 33).* Those studies indicated that when water containing *Cryptosporidium parvum* oocysts reached temperatures of 162°F (72.4°C) or higher within 1 min or when the temperature was held at 147°F (64.2°C) or higher for 2 min in a 5-min heating cycle, infectivity was lost. Additionally, when *Cryptosporidium* was frozen for up to 8 h, viability and infectivity were not lost but were lost when oocysts were frozen at −4°F (−20°C) for 24 and 168 h. High-temperature short-time pasteurization is sufficient to destroy the infectivity of *C. parvum* oocysts in water and milk *(43).* However, steaming mussels only until they open does not destroy the infectivity of *C. parvum* oocysts *(41).*

APPENDIX II. *Thermal inactivation of* Listeria monocytogenes[a]

Internal product temp:		Time for 6-log reduction (min)
°F	°C	
145	63	17.0
147	64	12.7
149	65	9.3
151	66	6.8
153	67	5.0
154	68	3.7
156	69	2.7
158	70	2.0
160	71	1.5
162	72	1.0
163	73	0.8
165	74	0.6
167	75	0.4
169	76	0.3
171	77	0.2
172	78	0.2
174	79	0.1
176	80	0.09
178	81	0.07
180	82	0.05
182	83	0.03
183	84	0.03
185	85	0.02

[a] Based on tables in the FDA *Fish and Fisheries Products Hazards and Controls Guidance (89)* and the Chilled Food Association *Best Practice Guidelines for the Production of Chilled Food*, 4th edition *(22)*, established for commercial refrigerated foods. The data are based on laboratory studies with *L. monocytogenes* because it is the most heat-resistant vegetative pathogen. The assumption is made that other vegetative pathogens such as *Salmonella, S. aureus, Campylobacter*, and *E. coli* O157:H7 also will have at least a 6-log reduction.