Microbiological Criteria for Raw Molluscan Shellfish

RECOMMENDATIONS BY THE NATIONAL ADVISORY COMMITTEE ON MICROBIOLOGICAL CRITERIA FOR FOODS

(Received for publication January 2, 1992)

ABSTRACT

The recommendations are designed to enhance the microbiological safety profile of raw molluscan shellfish which are likely to present inherent risks to consumers if adequate safeguards are not in place from harvest to consumption. Further, the document examines the “wholesale market standard” currently applied by the Interstate Shellfish Sanitation Conference (ISSC). Product testing alone is of limited value in assuring the safety of molluscan shellfish. For a market standard to be useful, it must be used as one of several control strategies. The recommendations are as follows:

* Proper growing water classification and restriction of harvesting to those water areas are two of the most essential points in controlling both enteric pathogens of human origin and indigenous vibrios in molluscan shellfish. Without proper water classification and harvesting, any market standard applied would have a minimal effect on consumer protection.

* Time/temperature control and monitoring during product distribution are essential to assure safety. Rapid cool down and continuous product chilling are also essential. When various combinations of warm harvest water and air temperatures exist, harvest requirements necessitating additional measures to assure rapid chilling should be implemented. In instances where this cannot be accomplished within a prescribed time, area closure may be necessary.

* Minimize the introduction and multiplication of bacteria in molluscan shellfish during distribution through adequate sanitation and refrigeration requirements.

* The Food and Drug Administration should develop a specific interpretation of the retail model code for HACCP-based control of raw molluscan shellfish to include purchase specification of properly tagged and refrigerated product.

* The ISSC should incorporate the recommendations contained in this report into a revised National Shellfish Sanitation Program (NSSP) Manual of Operations and reissue the document as the Shellfish Sanitation Model Ordinance for adoption into state law. Further, the current “wholesale market standard” should be changed to include a modified aerobic plate count procedure which encourages the growth of Vibrio spp.

* Fecal coliform/Escherichia coli should be retained as a guideline until state regulatory agencies are provided adequate assurance that all products have been harvested from properly classified growing waters. In the future, additional criteria may be appropriate if the National Indicator Study proposes changes in water classification standards.

* The NSSP Manual should be expanded to include strict control measures from harvest through retail distribution.

* Education programs can contribute to reducing risks associated with the consumption of raw molluscan shellfish. This is a shared responsibility of government and industry.

These recommendations were adopted by the National Advisory Committee on Microbiological Criteria for Foods on July 18, 1991.

MISSION STATEMENT

In order to protect the American consumer from microbial hazards, the National Advisory Committee on Microbiological Criteria for Foods (Committee) will provide impartial scientific advice to be used in the development of an integrated product safety systems approach from harvest to consumption through the establishment and application of uniform requirements to assure the safety of domestic and imported shellfish.

SELECTION OF COMMODITIES AND RATIONALE FOR CRITERIA

Background

The Committee determined that molluscan shellfish receive priority consideration for the development of microbiological criteria because: (a) biological hazards may be present in raw molluscan shellfish at the time of harvest; (b) no thermal process is applied prior to consumption to eliminate pathogens; (c) microbial multiplication is likely if time/temperature abuse occurs; (d) raw molluscan shellfish receive the second highest hazard rating, a category 5 (11); and (e) of the epidemiological data for molluscan shellfish-borne illness.

In August 1990, the Chairman of the Interstate Shellfish Sanitation Conference (ISSC) requested a review of the existing microbiological acceptability criteria for raw mol-
lusan shellfish at the wholesale level. The ISSC request included consideration of seasonal and species variations and geographic locations. During the Committee’s discussions with the ISSC, it was further determined that addressing the following questions would be beneficial: (a) What does the current “wholesale market standard” mean?; (b) Should there be different criteria for different species?; (c) What regulatory action level and response criteria should be established?; and (d) Should the same criteria apply to those raw products which are to be cooked prior to consumption?

**Epidemiological profile of raw molluscan shellfish-borne illness**

The Committee initiated consideration of this issue by assessing the known epidemiologic biological hazards associated with molluscan shellfish.

**Epidemiological data**

Epidemiological data show that consumption of raw molluscan shellfish is associated with foodborne illness (3,14). Shellfish are filter feeders and can filter pathogenic microorganisms, viruses, protozoa, helminths, or toxins from the aquatic environment (15). The major microbiological concern has been and remains waters contaminated with human sewage. However, shellfish can also become naturally contaminated with autochthonous *Clostridium botulinum* type E or *Vibrio* spp. from nonpolluted waters and mud. Cross-contamination from workers, shellfish processing equipment, or utensils can also result in the product being contaminated with low levels of bacteria.

Raw molluscan shellfish have been incriminated in the greatest number of seafood-associated illness. According to Centers for Disease Control (CDC) data, for the period 1978-1987, a total of 128 outbreaks and 3,747 cases of illness were reported as associated with molluscan shellfish (Tables 1 and 2). During the same period, 7,279 molluscan shellfish associated illnesses from all causes were recorded in the Food and Drug Administration (FDA) North East Technical Services Unit (NETSU) tracking system (Table 3) (3,13,14).

**Viral illness from raw molluscan shellfish**

The consumption of raw or undercooked shellfish taken from polluted estuaries has been linked with outbreaks of hepatitis type A, Norwalk-like agent, and ECHO virus. According to the National Academy of Sciences (NAS) Seafood Safety report (10), viruses are responsible for the vast majority of the raw molluscan seafood-borne illness in the United States. The vast majority of reported shellfish

<table>
<thead>
<tr>
<th>Etiology</th>
<th>No. cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unknown</td>
<td>3,271</td>
</tr>
<tr>
<td><em>V. parahaemolyticus</em></td>
<td>176</td>
</tr>
<tr>
<td><em>Salmonella</em> spp.</td>
<td>80</td>
</tr>
<tr>
<td><em>Shigella</em> spp.</td>
<td>77</td>
</tr>
<tr>
<td>Other viral</td>
<td>42</td>
</tr>
<tr>
<td>Hepatitis Type A</td>
<td>33</td>
</tr>
<tr>
<td><em>C. perfringens</em></td>
<td>28</td>
</tr>
<tr>
<td><em>V. cholerae</em> 01</td>
<td>14</td>
</tr>
<tr>
<td><em>V. cholerae</em> non-01</td>
<td>11</td>
</tr>
<tr>
<td><em>S. aureus</em></td>
<td>9</td>
</tr>
<tr>
<td><em>B. cereus</em></td>
<td>6</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>3,747</strong></td>
</tr>
</tbody>
</table>

As with most epidemiological data, the CDC data and the NETSU data probably reflect but a small proportion of the actual number of cases. Thus, the conclusions are often based on extrapolation of risk from rudimentary data. Furthermore, the question stands whether the implicated seafood was raw, cooked, improperly cooked, or recontaminated. This section will focus only on raw molluscan shellfish and viral- and bacterial-induced illness.

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<tr>
<th>Etiology</th>
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<tbody>
<tr>
<td>Unknown</td>
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<tr>
<td><em>V. parahaemolyticus</em></td>
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</tr>
<tr>
<td>Hepatitis Type A</td>
<td>7</td>
</tr>
<tr>
<td><em>Shigella</em> spp.</td>
<td>4</td>
</tr>
<tr>
<td><em>Salmonella</em> spp.</td>
<td>3</td>
</tr>
<tr>
<td><em>V. cholerae</em> 01</td>
<td>2</td>
</tr>
<tr>
<td>Other viral</td>
<td>2</td>
</tr>
<tr>
<td><em>V. cholerae</em> non-01</td>
<td>2</td>
</tr>
<tr>
<td><em>C. perfringens</em></td>
<td>2</td>
</tr>
<tr>
<td><em>B. cereus</em></td>
<td>2</td>
</tr>
<tr>
<td><em>S. aureus</em></td>
<td>1</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>128</strong></td>
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<table>
<thead>
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<tr>
<td>Unspecified hepatitis</td>
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<td><em>Shigella</em> spp.</td>
<td>84</td>
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<td>Norwalk and related viruses</td>
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<tr>
<td><em>V. parahaemolyticus</em></td>
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<tr>
<td>Hepatitis Type A</td>
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<td><em>Plesiomonas</em></td>
<td>18</td>
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<tr>
<td><em>Campylobacter</em></td>
<td>16</td>
</tr>
<tr>
<td><em>V. cholerae</em> 01</td>
<td>13</td>
</tr>
<tr>
<td><em>Aeromonas</em></td>
<td>7</td>
</tr>
<tr>
<td><em>Vibrio mimicus</em></td>
<td>5</td>
</tr>
<tr>
<td><em>Vibrio hollisae</em></td>
<td>5</td>
</tr>
<tr>
<td><em>Vibrio fluvialis</em></td>
<td>5</td>
</tr>
<tr>
<td>Hepatitis, non-A, non-B</td>
<td>1</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>7,279</strong></td>
</tr>
</tbody>
</table>

**TABLE 1. Molluscan shellfish-associated foodborne illness for 1978-1987 by case (3).**

**TABLE 2. Molluscan shellfish-associated foodborne outbreaks for 1978-1987 (3).**

<table>
<thead>
<tr>
<th>Etiology</th>
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</tr>
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<td>3</td>
</tr>
<tr>
<td><em>V. cholerae</em> 01</td>
<td>2</td>
</tr>
<tr>
<td>Other viral</td>
<td>2</td>
</tr>
<tr>
<td><em>V. cholerae</em> non-01</td>
<td>2</td>
</tr>
<tr>
<td><em>C. perfringens</em></td>
<td>2</td>
</tr>
<tr>
<td><em>B. cereus</em></td>
<td>2</td>
</tr>
<tr>
<td><em>S. aureus</em></td>
<td>1</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>128</strong></td>
</tr>
</tbody>
</table>

**TABLE 3. Shellfish-associated foodborne illness for 1978-1987 by case (14).**
related illnesses are listed as unknown. It is the considered opinion of many experts that the majority of cases with an unknown agent should be included in estimates of viral disease (Tables 1, 2, and 3).

As detection and isolation of viruses are difficult, attempts have been made to link levels of Escherichia coli, used as an indicator of fecal contamination in growing waters, to the presence of virus particles and/or enteric pathogens. However, the presence of E. coli, coliforms, or fecal coliforms does not correlate with the presence of pathogenic viruses (6) or other bacterial pathogens (10).

**Bacterial illness**

Compared to the number of illnesses thought to be caused by viruses transmitted through raw molluscan seafood, the number of cases associated with bacteria are considerably less (12). Molluscan seafood can become contaminated with a wide variety of bacterial pathogens. Outbreaks have been caused by *C. botulinum*, *Clostridium perfringens*, *Staphylococcus aureus*, *Salmonella*, *Shigella*, *E. coli*, and *Vibrio parahaemolyticus* among other vibrios.

*V. parahaemolyticus* is of greatest concern in the Orient where cultural dietary practices differ from the United States (15). A higher per capita consumption of raw seafood is the cause for a higher incidence of *V. parahaemolyticus* food poisoning in Asia. The illness appears to correlate with time/temperature abuse and/or undercooking of the shellfish during preparation. The current standards for shellfish appear to be inadequate because of poor correlation to indicator microbes. Additionally, it must be noted for this document that *Vibrios* are not associated with fecal contamination of growing waters (10).

*Vibrio cholerae*, of both the 01 and non-01 serogroups, has been detected and implicated at an increasing rate with foodborne illness in the United States. Although *V. cholerae* 01 has been considered linked to raw sewage and gross contamination of water, research indicated that *V. cholerae* non-01 is an autochthonous component of brackish waters (9), especially in the U.S. Gulf Coast environment. Because of the low isolation frequency and the inconclusive epidemiological data, testing seafood for *V. cholerae* has been considered to be of questionable utility (10).

In the past 5 years, *Vibrio vulnificus*, *Vibrio flavalis*, *Vibrio mimicus*, and *Vibrio hollisae* have been associated with shellfish food poisoning outbreaks. Of these, *V. vulnificus* is of greatest concern based on its high virulence factor especially for persons with underlying disease who subsequently suffer a high mortality rate from this disease (2,7,16). The risk is highest during warmer months when water temperatures can rise over 15-20°C (1).

*C. botulinum*, while one of the most serious foodborne illnesses, is not a major problem in raw shellfish. Vegetative cells or spores may be present, but the concern is with smoked or canned seafood. At present, there is debate about risk associated with raw, vacuum-packaged, or modified atmosphere packaged, refrigerated seafood.

Other pathogens such as *C. perfringens*, *S. aureus*, *Salmonella*, *Shigella*, *E. coli*, *Yersinia enterocolitica*, *Listeria monocytogenes*, and *Campylobacter jejuni* represent a risk, but proper postharvesting handling practices, processing, and preparation can reduce the frequency of outbreaks. The inherent risk of foodborne illness from these agents is low compared to viral and vibrio risks and in many cases the data are inadequate for risk characterization and exposure assessment (10).

**HISTORY OF GOVERNMENT ACTIVITIES**

The National Shellfish Sanitation Program (NSSP) was established as a result of a 1925 conference called by the Surgeon General. The conference was requested by state and local health officials and the shellfish industry following a typhoid outbreak that was traced to sewage-polluted oysters. The NSSP operates principally on the cooperative and voluntary efforts of state regulatory agencies, augmented by advice and assistance from the FDA and the shellfish industry. Although the basic public health principles of the NSSP have remained constant, the program has been updated and improved since its establishment. Those improvements have primarily included food safety control measures based on determinations of water quality rather than microbiological analysis of shellfish meats. Further efforts to strengthen shellfish safety resulted in the formation of the ISSC which is patterned after the successful National Conference of Interstate Milk Shippers. ISSC members include state shellfish regulators, industry, FDA, and other Federal agencies.

*History of the “wholesale market standard”*

The origin of the current “wholesale market standard” began with the NSSP when raw molluscan shellfish was first recognized as a major vehicle for the transmission of typhoid fever in the United States. (A summary of the developmental history of the standard is included as an addendum.)

At least three major shellfish-borne outbreaks were reported at the turn of the century. As a result of those illnesses, in 1911 the American Public Health Association (APHA) Committee on Standard Methods of Shellfish Examinations advocated bacteriological testing of raw oysters. The APHA report, in part, concluded: “The committee wishes to state emphatically that the results of bacteriological examinations should not be used as the sole basis for interpretation of sanitary quality of shellfish. The results of the sanitary survey in all cases should be considered of at least equal importance.” (18).

Part II of the 1990 NSSP Manual of Operations states:

"d. Shellfish shall be examined bacteriologically if: i. Shellstock*** shipping temperature exceeds 10°C (50°F), but is not higher than 15.6°C (60°F), and if shucked**** product shipping temperature exceeds 7.2°C (45°F), but is not higher than 10°C (50°F), even though there is proper product identification and compliance with other shipping conditions. ii. Deemed necessary by the State Shellfish Control Agency (SSCA) at any other time.

***Shellstock temperatures will reflect internal body temperature."
Temperature of shucked products will be determined as described in Section F, of this Manual."

The NSSP Manual's decision tree for using those guidelines is given in Fig. 1.

The Committee understands that under current NSSP guidelines, microbiological testing is required only upon receipt of an interstate product shipment where shellstock oysters have been held between 10 and 15.6°C and testing of shucked product is required when the oysters have been held between 7.2 and 10°C. The Manual states that samples must be tested by the receiving State agency within 24 h of receipt of the shipment. For those shipments found to be mildly temperature abused, fecal coliform (FC) and standard plate counts (SPC) are required to be performed on five randomly collected sample units (each sample unit contains approximately 12 shellfish).

Current criteria and definition of terms for 3-class plans

Expressed in terms of the International Commission for Microbiological Specifications for Foods (ICMSF) defi-

Current APHA Methodology Shall Be Used To Determine FC (fecal coliform), E. coli MPN (Most Probable Number per 100 g), and SPC (Standard Plate Count) levels.

Figure 1. NSSP Manual's decision tree for sampling and adjudicating shellfish shipments.
n = 5  m = 230  c = 2  M = 330

In a 3-class plan, a shipment is rejected if one sample unit exceeds the value of “M” or more than the designated number for “c” exceeds the value of “m.” Under the NSSP wholesale market standard, a shipment is “adjudicated” if any sample unit exceeds an SPC of 1,500,000/g (“M”) or 2 or more of the five sample units exceed an SPC of 500,000/g (“m”). A shipment may also be “adjudicated” if any sample unit exceeds a most probable number (MPN) of 330 for E. coli/100 g (“M”) or 2 or more of the five sample units exceed a MPN of 230 E. coli/100 g (“m”).

Assessment of current NSSP criteria

Although the NSSP Manual of Operations has helped to improve the handling and the safety of molluscan shellfish, several major concerns have not been addressed. (a) The Manual requires refrigeration temperature control only at certified dealers and during interstate shipment between certified dealers. (b) The criteria setting forth temperatures at which sampling is required do not consider the time out of refrigeration, i.e., the length of exposure to temperature abuse. (c) No public health rationale for selecting different temperature limits for shellstock and shucked product has been presented to the Committee. (d) In the opinion of the Committee, the 1990 NSSP Manual does not define a sufficient number of critical control points to adequately control time/temperature abuse.

The Committee believes that the current “wholesale market standard” was established using the following assumptions: (a) There is or there may be a quantitative correlation between the numbers of indicator bacteria in the growing waters and the presence of pathogens from human fecal pollution. (b) A quantitative correlation exists or may exist between the numbers of indicator microorganisms in growing waters and in the shellfish. (c) Postharvest multiplication of indicator organisms in shellfish that does not exceed the standard does not constitute an increased public health risk.

The Committee believes only the third assumption may be useful as a rationale for applying a market standard. Although the current NSSP “wholesale market standard” for shellfish may not be a valid measurement of the original microbiological condition of the harvested product and application may not contribute to public health protection, a revised market standard would accomplish this goal.

If an adequate microbial standard for shellstock and meats were combined with mandatory time/temperature requirements, the safety of raw molluscan shellfish would be improved. These factors include: monitoring the sanitary classification and temperatures of growing waters, improving hygiene and refrigeration for postharvest handling, and improving enforcement against “bootleg” shellfish harvested from prohibited areas.

With respect to postharvest handling practices, the Committee has determined that the establishment of time/temperature controls is one essential element in assuring a safe product from harvest to consumption. The Committee believes mandatory time/temperature and sanitary requirements are necessary to provide a documented product history and foster safe product handling practices. The NSSP Manual should be revised to incorporate these important time/temperature handling requirements.

MICROBIOLOGICAL SAFETY PROFILE
OF RAW MOLLUSCAN SHELLFISH

A review of epidemiological data shows documented associations between foodborne disease and the consumption of raw molluscan shellfish. Further, microbiological data indicate that significant opportunities for contamination exist. The extent of microbial contamination includes not only enterics and viruses of human origin but also the pathogenic vibrios. This problem is compounded by the lack of safeguards from temperature abuse that will allow multiplication of pathogens. According to the NAS report on seafood safety, “A means must be investigated and implemented to eliminate or at least reduce levels of pathogenic Vibrio spp. in raw shellfish.” The Committee offers one fundamental advisory to the ISSC on this point:

Minimize the introduction and multiplication of bacteria in these products during distribution through adequate sanitation and refrigeration requirements.

Increased risk of illness and death from consumption of pathogen-contaminated shellfish has been identified in consumer groups with greater susceptibility to foodborne illness. Principal among the pathogens in severity is V. vulnificus, a microbial pathogen of marine origin, which can cause septicemia and death in susceptible individuals. Persons at increased risk for life threatening illness from this pathogen include cirrhotics, diabetics, persons with hemochromatosis, and those who are immunosuppressed.

In the United States, vibrio-caused illnesses from shellfish are primarily associated with the consumption of raw oyster meats from shellstock harvested in the coastal waters of the Gulf of Mexico during the summer months. A recent study indicates a 10- to 100-fold increase of V. vulnificus between harvesting and processing. Greater increases in numbers of V. parahaemolyticus were also observed at the same abuse temperatures (4). Also noted was similar magnitudes of population increase above harvest levels following storage for 1 d at 22-30°C. In addition, it has been reported that during the depuration process V. vulnificus reproduces to noticeable levels unless temperatures are maintained near 4°C (40°F) (17).

The Committee concludes from this that avoidance of time/temperature abuse would limit multiplication of these organisms and therefore likely reduce the incidence of human disease or death from the consumption of raw oysters. Effective temperature controls, therefore, will require rapid cool down and continuous chilling of molluscan shellfish products. If product temperature control cannot be accomplished, harvesting should be prohibited.
CONCLUSIONS AND RECOMMENDATIONS

Food and Drug Administration

As the primary Federal agency having jurisdiction over seafood, the FDA should develop a model plan for control of microbial hazards in raw molluscan shellfish considering all points from harvest to retail sale and counsel the ISSC on its application. The FDA should also issue a model code interpretation for handling shellfish at retail.

Interstate Shellfish Sanitation Conference

The primary recommendation for the ISSC is to develop a molluscan shellfish model sanitation ordinance based upon the information in the NSSP Manual of Operations Part II (Sanitation of the Harvesting, Processing and Distribution of Shellfish). The ISSC should encourage states, counties, and municipalities to adopt the ordinance as a legal instrument for enforcement. This would provide a uniform policy and consistent application that would better improve public health protection. Further, a model ordinance would facilitate the shipment and acceptance of molluscan shellfish of high sanitary quality in both interstate and intrastate commerce. The ordinance must include time/temperature control provisions that are mandatory from harvest to retail sale.

With respect to the questions posed by the ISSC, the Committee provides the following recommendations:

(a) What does the current “wholesale market standard” mean?

The standard is based on the indicators E. coli and SPC. Each of these tests have specific historical intent. E. coli (Bacillus coli) was originally intended to indicate the possible presence of pathogens. Later this method was modified to use the FC indicator as an index of fecal pollution. No evident correlation has been demonstrated between these indicators and the presence of hazardous marine vibrios. Viruses, which have been reported to cause the greatest number of illnesses associated with the consumption of raw molluscan shellfish, show little or no correlation with indicators of human fecal pollution.

The current SPC procedure was added as a standard to assess the microbiological quality of molluscan shellfish and indirectly monitor time/temperature abuse during shipment between dealers. It was intended to be applied upon receipt within the state of destination. In recent years, the ISSC provided guidance, with the concurrence of FDA, that whenever product was selected for microbiological testing, it should be accomplished within 24 h. This prompt sampling requirement was mandated to ensure that product was not held for a long period before testing which would result in higher SPC.

The Committee agrees that any product “standard” should be applicable to product at any point in the food/distribution chain. However, greater assurance against the presence of pathogens in product is best provided by:

i. proper classification of growing areas through shoreline surveys and growing water analysis;
ii. aggressive enforcement and leveling of severe penalties to discourage “bootlegging” of shellstock from areas closed to shellfish harvesting; and
iii. time/temperature control (chilling or refrigeration) of products during all shipments of shellfish from harvest through retail sale.

Strict adherence to recommendations a, b, and c, as listed, coupled with a revised aerobic plate count (APC) criterion, offer a greater margin of public health protection. The NSSP is strongly encouraged to adopt these recommendations.

(b) Should there be different criteria for different species?

No need has been demonstrated for the establishment of specific microbial criteria for each species of shellfish. A single criterion should be applied to all species of raw molluscan shellfish.

(c) What regulatory action level and response criteria should be established?

The ISSC should adopt a market standard based on an APC criterion favorable to but not exclusive for the growth of halophilic bacteria. Since microbiological data are currently used to supplement temperature monitoring, microbiological counts should be used to indicate if postharvest temperature abuse and subsequent microbial multiplication have occurred. The literature indicates that vibrios and other gram-negative, nonfermentative bacteria such as Pseudomonas, Acinetobacter, Moraxella, and Flavobacterium predominate as natural flora in oysters and can be enumerated by APC (5). Also, microorganisms from seafood grow better at 25°C in media with added sodium chloride (NaCl) at a final concentration of 1.0% than at 35°C without NaCl (8).

The existing market standard and the proposed new standard are both 3-class plans. The Committee recommends that when “c” or more sample units exceed “m” or when any single sample unit exceeds “M,” then the lot should be rejected. Further, even when only one of the 58 sample units exceeds “m” but not “M,” the lot should be accepted, but investigations should be initiated to determine if product temperature abuse has occurred.

(d) Should the same criteria apply to those raw products which are to be cooked prior to consumption?

From a scientific standpoint, a wholesome product would not create a safety or public health concern when an adequate thermal process is applied. Therefore, scientifically—the answer is no. However, from a regulatory standpoint, molluscan shellfish harvested for commercial canning or other thermally lethal processes often cannot be effectively monitored by regulators from product which may be consumed raw or be inadequately cooked. Consequently, the answer is yes, the same criteria should be applied to all molluscan shellfish. This recommendation would include applying the standard to the fresh water clam Corbicula.

State regulatory agencies

The primary responsibility for monitoring the safety of shellfish, both domestic and imported, falls to state regula-
tory agencies. A modified APC criterion is recommended because it can be applied at multiple points from postharvest through retail distribution. The criterion assumes that the product has been harvested from approved growing waters and that time/temperature controls as well as proper product handling criteria have been met.

Since some states currently have regulations which include a market standard for FC/E. coli, it is recommended that this criterion be retained but only as a guideline and not a standard until the ISSC and the states adopt and adequately enforce the control procedures and criterion recommended in this document. Specifically, the Committee recommends that the FC/E. coli portion of the existing market standard be reformulated as a guideline and the "adjudication" now recommended in Part 2 of the NSSP Manual be defined. The basis of this recommendation is that the current NSSP philosophy on public health protection narrowly centers on the fact that, historically, molluscan shellfish associated epidemics and outbreaks were caused by Salmonella typhi and Hepatitis A. Further, the Committee strongly encourages states to support the rapid development of the National Indicator Study and increased efforts to upgrade classification practices.

If a receiving state determines that microbiological criteria other than the criterion recommended herein be applied to product entering the state, the Committee strongly recommends that the same criteria including testing frequency be applied to product harvested within its own state.

NSSP Manual

The Committee recommends that a generic matrix of air/water temperature guidelines be developed and included in the NSSP Manual to provide refrigeration requirements and temperature guidelines showing when harvesting should be prohibited. (An example is given as Fig. 2.) Specific matrices should be developed by each state after consideration of local harvest water and environmental conditions. Matrices should be incorporated into the recommended model ordinance. Additionally, the NSSP Manual should develop control procedures for all aspects of the product flow:

Harvest

* Require harvesters to deliver shellstock to the dock within the day harvested, i.e., a day is defined as midnight to midnight.
* Restrict harvest times to facilitate patrolling and monitoring by regulatory agencies.
* Establish time/temperature limits and control procedures from harvest through landing, taking into account seasonal variations in harvest water conditions.
* Establish the relationship of harvest water temperature on the indigenous bacterial load and the effect of on-board cool down on increases in numbers.
* Establish procedures to prevent temperature abuse, e.g., shade the harvest from direct sunlight.
* Require potable water or approved growing area water for washing and wet-chilling steps.
* Reduce contamination through improved on-board sanitization practices.

Dock

* Develop bag and lot tag controls to ensure that the product received at the certified dealer has met time/temperature requirements.
* Prohibit reuse of containers or, at a minimum, require that containers be sanitized to control the transfer of pathogens to shellstock and prevent contamination of dealer packing areas and foodservice establishments.
* Prohibit used meat and poultry boxes for packing of shellfish under any circumstances.
* Monitor and enforce the maintenance of established time/temperature controls.
* Place product in refrigerated storage within 2 h of receipt or at a time deemed reasonable by the state regulatory agency.
* Require refrigeration units be equipped with automatic temperature controls and capable of holding the shellstock between 7.2 and 1.7°C as measured in the warmest part of the unit.
* Palletize refrigerated shellstock providing adequate distance between pallets to allow proper air circulation and refrigeration.
* Hold shellstock between 7.2 and 1.7°C as measured by the internal temperature of the shellfish meats, except in cases where the product will be moved less that 50 miles or 1 h from the dock.

Transportation (dock-to-plant)
* Establish time/temperature control:
  * Prechill shellstock to 7.2°C prior to loading.
  * Prechill trucks to 7.2°C or below prior to loading, and
  * Maintain 7.2°C or below during transportation.
* Prepare decision matrix.
* Require tamper proof temperature measuring techniques and requirements to monitor shellstock temperature.

Plant
Follow the shellfish Hazard Analysis Critical Control Point (HACCP) flow charts as outlined in the National Marine Fisheries Service proposed HACCP regulatory model for molluscan shellfish plants. (Five flow charts are shown as Fig. 3, 4, 5, 6, and 7).

*Receiving
Storage (Dry)  *Storage (Wet)
Wash
Declump/Cull
Wet/Chill
*Packing
Refrigerated Storage
Freezing
*Repacking
Frozen Storage
*Shipping

*Critical Control Points
Figure 3. Shellstock flow diagram including optional steps in oyster, clam, and mussel processing.

Education and training
The Committee believes that effective education can contribute to the overall safety of shellfish. The educational programs currently conducted by industry and the ISSC, which are aimed at compromised consumers and health care providers, are very valuable. These efforts should be continued and expanded.

Microbiological criteria
Revising the NSSP Manual to include the Committee recommendations and incorporating it into a Shellfish Sanitation Model Ordinance will largely eliminate the need for lot-by-lot product testing unless temperature abuse has been demonstrated. However, if product lots have no documented transportation history, then testing should be set at the rate of 100%.

Figure 4. Shucked shellfish flow diagram including optional steps in oyster, clam, and mussel processing.

*Receiving
Storage (Dry)  *Storage (Wet)
Heat Shock (Steam)  Heat Shock (Hot Dip)
Hand Shuck
Inspection/Seperation of Foot
Evisceration
Washing
*Bubble/Soak
Grind/Chop
*Packing
Refrigerated Storage
Freezing
*Repacking
Frozen Storage
*Shipping

*Critical Control Points
1 Upgraded to "critical" by MSSP staff due to economic fraud possibility

Figure 5. Mechanized surf clams/ocean quahogs flow diagram.
Spread plating is recommended by the Committee over the conventional pour plate procedure. Spread plating does not subject microorganisms to the molten agar temperature of 44°C+, all microbial colonies are on the surface and pre-poured plates are easier to handle. Spread plating usually uses 0.1 ml inoculum versus 1.0 ml for the pour plate procedure.

Questions are often asked whether commercially available rapid methods may be substituted for the Standard Methods. This should be encouraged if the microbiological procedure is made simpler or easier. Such substitutes, however, have to be proven equal to the modified method recommended herein.

Properly documented time/temperature controls will help assure that any low number of potentially hazardous microorganisms possibly present in molluscan shellfish at harvest will not be able to multiply to levels which could cause illness. This criterion is recommended on the assumption that the history of the product is known to the appropriate shellfish regulatory control agencies. Further, the numerical values are provisional in nature and must be validated.

The recommended APC criterion is:

\[ n = 5 \]
\[ c = 2 \]
\[ m = 100,000 \text{ per g} \]
\[ M = 1,000,000 \text{ per g} \]

Rationale for recommending a change in the market standard

Historically, the presence of *E. coli* in shellfish was found at a level of frequency to allow its use as an indirect measure of the sanitary quality of the growing areas. However, the Committee does not believe that coliform, FC, or *E. coli* should be retained as a market standard because it does not serve as an adequate indicator in the product for various pathogenic microorganisms now being recognized in the changed environment for molluscan shellfish. Because the FC/*E. coli* criterion provides insufficient public health protection, its use should be discontinued. Until the ISSC and the states adopt and adequately enforce the control procedures and criteria recommended in this document, the states may wish to retain the FC/*E. coli* criterion as a guideline on an interim basis. The rationale for temporarily retaining FC/*E. coli* is that positive results from these tests are of value as an indirect measure of the safety of the product and proper classification of the growing waters. Fecal coliform bacteria and *E. coli* are indicators of both point sources, e.g., sewer outfalls and nonpoint source pollution--runoff from farms and wildlife areas. When test results are positive, further testing should be conducted to determine the presence of pathogens.

This criterion is limited by environmental conditions, e.g., human enteric viruses from point sources in winter months or marine vibrios in the summer which would likely remain undetected. When these pathogens are detected, classification criteria for growing waters should be reexamined. It is recognized that this issue may need to be further explored upon completion of the National Indicator Study.
Application of criteria

The criteria for APC (using 1.0% added NaCl) should be applied as the single market standard. This standard is applicable at any point from harvest to retail sale.

Application of 3-class attributes sampling plans

The Committee has followed the definitions contained in the 1986 edition of the ICMSF Microorganisms in Foods 2 Sampling for Microbiological Analysis: Principles and Specific Applications:

Lot. "In the commercial sense, a lot is a quantity of food supposedly produced under identical conditions, all packages of which would normally bear a lot number that identifies the production during a particular time interval." "Statistically, a lot is considered as a collection of units of a product from which a sample is to be drawn to determine acceptability of the lot."

Sample. "The total number (one or more) of individual sample units drawn from a lot (ideally at random) which will be tested in accordance with a specific sampling plan and method(s)." For shellfish, a lot should be one harvest area on a particular day and so identified. Repacking and commingling should be prohibited.

\( n = \) "The number of sample units which are examined from a lot to satisfy the requirements of a particular sampling plan."

\( m = \) "A microbiological limit which in a 2-class plan, separates good quality from defective quality or, in a 3-class plan, separates good quality from marginally acceptable quality. In general, values equal to "m," or below, represent an acceptable product and values above it are either marginally acceptable or unacceptable."

\( M = \) "A microbiological limit which, in a 3-class plan, separates marginally acceptable quality from defective quality. Values above "M" are unacceptable."

\( c = \) "The maximum allowable number of defective sample units (2-class plan) or marginally acceptable sample units (3-class plan). When more than this number are found in the sample, the lot is rejected."

Further, when "m" is exceeded but the number of sample units does not exceed "c" but is greater than 0, i.e., transitional concern, regulatory agencies should initiate some investigative action directed along the distribution chain. This action may range from simple notification of findings to increasing inspection frequency, resampling, or warning letter.

It is recognized that there will be variability between "m" and "M" for shellfish due, in part, to various conditions of harvest, i.e., water temperature and season. This fact and the historical public health records of these products have been taken under consideration in establishing this recommended microbiological criterion.

Statistical characteristics of the proposed sampling plan

For lot acceptance the sampling plan proposed for APC allows none of the 5 sample units to exceed \( M = 100,000 \, \text{g} \) but does permit up to 2 of the 5 sample units to exceed \( m = 100,000 \, \text{g} \). Lots with 3 or more sample units above \( m \) but less than or equal to \( M \) or with one or more sample units above \( M \) are declared unacceptable.

For this sampling plan, Table 4 presents the performance characteristics (i.e., probabilities of lot acceptance) for selected combinations of the percent of sample units in a lot above \( m \) but \( \leq M \) and the percent of sample units in the same lot above \( M \). For example, when a lot contains 20% of the sample units above \( m \) but \( \leq M \) and an additional 10% of the sample units above \( M \), the proposed sampling plan for APC will accept this lot 54% of the time.

**TABLE 4.** The performance characteristics (i.e., probabilities of lot acceptance) for selected combinations of the percent of sample units in a lot above \( m \) but \( \leq M \) and the percent of sample units in the same lot above \( M \) for the proposed APC sampling plan:

<table>
<thead>
<tr>
<th>% of sample units in the lot &gt; ( m ) but ( &lt; M )</th>
<th>Probability (%) of lot acceptance</th>
</tr>
</thead>
<tbody>
<tr>
<td>% of sample units in a lot &gt; ( M )</td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>100</td>
</tr>
<tr>
<td>10</td>
<td>99</td>
</tr>
<tr>
<td>20*</td>
<td>94</td>
</tr>
<tr>
<td>30</td>
<td>83</td>
</tr>
<tr>
<td>40</td>
<td>68</td>
</tr>
<tr>
<td>50</td>
<td>50</td>
</tr>
</tbody>
</table>

*Example interpretation: When a lot contains 20% of the sample units above \( m \) but \( \leq M \) and an additional 10% of the sample units above \( M \), the proposed sampling plan will accept this lot 54% of the time.

Actions based on analytical results

When the number of sample units is "c" or less but greater than 0 for "m," action should be taken to determine where the abusive conditions occurred. However, no action is required for the product.

When one or more sample units exceeds "M" or more than "c" sample units exceeds "m," regulatory action would be initiated to condemn the lot and to identify the cause which resulted in a loss of control.

**OTHER**

The stated mission of the Committee is to "protect the American consumer from microbial hazards." The proposed criteria, educational efforts and HACCP activities recommended in this report do not by themselves accomplish this mission. Additional measures must be taken to develop a biobarrier to human pathogens and thus better assure shellfish safety. Some of these recommended measures are as follows:

Depuration

Depuration is controlled purification designed to reduce the number of pathogenic organisms that may be
present in shellfish harvested from moderately contaminated (restricted) waters. Specific NSSP procedures are in effect to approve the design, operation, and monitoring of such systems. Some questions remain as to the effectiveness of depuration in reducing levels of viruses and vibrios. In the case of vibrios, water temperature and other conditions are of particular concern.

Irradiation

Irradiation to reduce the levels of microorganisms in seafood is not currently an approved process in the United States, although a petition is before the FDA. Experimental trials have shown irradiation can reduce microorganisms in shellstock without loss of the oysters viability. Further experimentation and review from a food safety perspective on practical food irradiation system processes and economic feasibility perspectives are indicated.

Heat treatments

With the exception of canning scheduled thermal process approvals, there is no standard pasteurization or subcommercially sterile process recognized throughout the industry. If such are developed, they should be done under an experimental design approved by the Federal Government. Labeling products as “pasteurized” when produced under an approved process would then ensure an adequate heat treatment for all pathogens of concern in shellfish.

Enforcement programs and growing water classification

The Committee encourages the ISSC to actively develop the National Indicator Study for development of more suitable criteria for growing water classifications. This effort should be coupled with increased efforts by the FDA in technical support of states in conducting sanitary surveys of harvesting areas. The states should also pursue increased resources for patrol activities against illegal harvest and for regulatory monitoring and oversight. The ISSC should take an active role in pursuing resources to strengthen the NSSP and to improve public health.

REFERENCES


ADDENNUM

Chronological History of National Shellfish Sanitation Program Shellfish Meat Guidelines and/or Standards - Including Background Notes

PRE-NSSP PERIOD

1815 - France - Typhoid outbreak
- Reported by Pasquier in his book, The Oyster From the Medical Point of View.
Source - Oysters from fattening grounds receiving sewage from a garrison.

1894 - Middletown, Connecticut - Typhoid outbreak
- Reported by T. F. Conn of Wesleyan University.
Source - Oysters from fattening beds in the mouth of the Quinnepic River, Long Island, NY, 300 feet from a sewer line on which were two (2) cases of typhoid.

1901 - Massachusetts State Board of Health
"The Massachusetts legislature passed acts to examine annually the conditions about the main sewer outlets of cities and towns and report thereon, and prohibiting the taking of oysters, clams, quahogs, and scallops from polluted sources." Analyses of water and shellfish were for the presence or absence of the colon bacillus.

1902 - Atlantic City, New Jersey - Typhoid outbreak
- Reported by the Atlantic City Academy of Medicine.
Source - Oysters and clams from a polluted beach.

1904 - Lawrence, Long Island, NY - Typhoid outbreak
- Reported by Soper.
Source - Shellfish from Jamaica Bay.
1910 - Bacteriological examination of oysters
- Reported in the Journal of the American Public Health Association (APHA), 1:578, 1911, by the Committee of Standard Methods of Shellfish Examination.

"The committee wishes to state emphatically that the results of bacteriological examinations should not be used as the sole basis for the interpretation of the sanitary quality of shellfish. The results of the sanitary survey in all cases should be considered of at least equal importance. We are not prepared to give expression of opinion at this time to any definite numerical relation between the various factors involved in the bacteriological results, nor in the sanitary survey, but expect that with the additional information to be available during the coming year, it will be possible to express these relations with some definiteness by means of the score card system. Looking forward to such a system, the committee suggests that in the case of shell stock the results of bacteriological examinations for B. coli be expressed by the following arbitrary numerical system, to be known as The American Public Health Association Method of Scoring Oysters for B. coli: . . ."

"The presence of B. coli in each oyster of the five examined is to be given the following values, which represent the reciprocals of the greatest dilutions in which the test for B. coli is positive:

If present in 1.0 cc. but not in 0.1 cc., the value of 1.
If present in 0.1 cc. but not in 0.01 cc., the value of 10.
If present in 0.01 cc. but not in 0.001 cc., the value of 100, etc.

The addition of these values for the five oysters would give the total numerical value for the sample and this figure should be the score for B. coli."

"The results should be expressed in the following tabular form:

RESULTS OF TESTS FOR B. COLI IN DILUTIONS INDICATED

<table>
<thead>
<tr>
<th>Oysters</th>
<th>1.0 cc.</th>
<th>0.1 cc.</th>
<th>0.01 cc.</th>
<th>Numerical value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>+</td>
<td>+</td>
<td>0</td>
<td>10</td>
</tr>
<tr>
<td>2</td>
<td>+</td>
<td>+</td>
<td>0</td>
<td>10</td>
</tr>
<tr>
<td>3</td>
<td>+</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>4</td>
<td>+</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>5</td>
<td>+</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
</tbody>
</table>

Total or score for B. coli 23

Presence of B. coli group in fermentation tube test with lactose bile where subsequent isolation tests have confirmed the results of the presumptive test or other satisfactory test.

Failure to demonstrate presence of B. coli group.

"It will be seen that if the B. coli score is divided by 5, the standard number of oysters tested, the results will approximate the number of B. coli per cubic centimeter of shell water. Partly because it does not do this exactly, but also for simplicity and the avoidance of fractions, the method of stating results as an arbitrary "score" is preferred by the committee. Practical experience with the method has also appeared to justify this conclusion. If some other number of oysters than 5 is tested, the results can be reduced to this score by following the same method and applying the rule of 3 to the total numerical value."

"Sometimes results similar to the following are obtained, that is, one or more oysters may show positive results in small quantities of shell water, while an equal number may show negative results in larger quantities. In this case the next lower numerical value should be given to the positive results in the high dilutions, and such positive results should be considered as being transferred to a lower dilution giving negative results in another oyster. This is done in order to avoid the unnatural result that could follow from what is probably an unequal distribution of the bacteria in the shell water. This recession of numerical values, however, should not be carried beyond the point where the number of such recessions is greater than the number of instances where other oysters in the series failed to give positive B. coli results."

"The committee is not as yet prepared to express an opinion as to the value of the results of bacterial counts in the sanitary shell-fish examination of shell stock, but suggests that reports upon such examinations would be of great value in arriving at a conclusion on this point."


1911 - Indicator - B. coli
Shellfish - Shell oysters
Standard/Discussion - "The score of the several lots of oysters is the numerical method of indicating the results of the colon test as adopted by the Committee on Standard Methods. A perfect score, that is no colon bacilli found, would be zero, while if every oyster of the five showed colon bacilli present in one one-hundredth of a cubic centimeter of the shell water the score would be 500. The standard adopted by the United States Pure Food Board is that all oysters showing a score of 32 or above be condemned."


1924 - 1926 - Indicator - B. coli
Shellfish - Shucked and shell oysters
Standard/Discussion - "The B. coli content of shellfish has been adopted by the American Public Health Association as an index of the sanitary quality of this seafood. The B. coli findings, according to the standard procedure, are expressed in the form of a score, which is an arbitrary summation of values based upon the presence or absence of the organism in multiple portions of the sample examined. The score generally adopted for control purposes by enforcing agencies in producing districts is not to exceed 50 for both shucked and shell oysters."

"Experience seems to indicate that the period of greatest danger from contaminated oysters is in the months of September and October and these are the months of highest B. coli scores in the Illinois market."

"The fact that B. coli multiply in shucked oysters in transit at proper low temperatures seems to justify, for this type of
product, a less rigorous \textit{B. coli} standard in consuming states far from the point of production and shucking than at or near the source.

“The findings in living shell oysters, however, do not justify a less rigorous \textit{B. coli} standard in markets at a distance from the source of supply.”

“In view of these facts and the experimental findings cited, it seemed not unreasonable to recommend as a tentative standard, a \textit{B. coli} score of not to exceed 140 for shucked oysters and a standard of not to exceed 50 for shell oysters and hard shell clams sold in the Illinois market, and accordingly this was done. It is recognized that these standards will be most difficult to meet in the months of September and October, but the September market for oysters in Illinois is small and therefore a bacterial standard which would exclude the high percentage of unsafe shipments in that would cause relatively little injury to the industry. It is believed that the majority of the October shipments can be made to comply with the proposed standards if necessary preparations for compliance are put into effect by the industry.”


\section*{NSSP Period}

1925 - Indicator - \textit{Bacillus coli} group

\textbf{Shellfish - Oysters}

\textbf{Standard/Discussion} - Relative to methods of examination and standards of bacterial content the committee recommends: (a) That the Standard Methods of the American Public Health Association be followed. (b) That pending the collection and analysis of further data now being collected, the generally current standard for shellfish-that is, a standard \textit{B. coli} score not exceeding 50 - be continued, with the understanding that if the facts collected warrant it, this recommendation will be altered.

“Shucked shellfish form a very favorable medium for the growth of \textit{B. coli} and other organisms, and during storage of the shucked stock the numbers of \textit{B. coli} originally present may be greatly increased by multiplication. This multiplication of \textit{B. coli} in shucked stock is favored by high temperatures (60° to 110°F), while it is retarded or checked by temperatures below 50°F. An increase in bacterial score due to such multiplication should not be interpreted as an index of increasing danger of infections, since it is highly improbable that shellfish taken from clean water sources would contain any typhoid bacilli, even though they did contain small numbers of \textit{B. coli}. Moreover, there is no direct evidence that typhoid bacilli, even if present, would multiply in shucked shellfish.”

“These facts as stated must be kept constantly in mind in the interpretation of the bacterial score of any sample of shucked shellfish taken from original sealed containers some days after the contents were packed. If the bacterial (\textit{B. coli}) score is low, this undoubtedly indicates that the shellfish have come from a clean source, have been handled in a cleanly manner, and that the shucked stock has been kept under conditions which have excluded further contamination and prevented multiplication of bacteria of the \textit{B. coli} type. On the other hand, if the bacterial (\textit{B. coli}) score be high, this may indicate either (1) that the shellfish were obtained from a polluted source, or (2) that they had been shucked and packed under uncleanly conditions, or (3) that the container had been opened and the contents contaminated after shipment, or (4) that temperature conditions after packing had been favorable for the multiplication of such \textit{B. coli} as might originally have been present. It is evident, therefore, that a high \textit{B. coli} score which, on freshly opened shellfish, would indicate gross sewage contamination, does not necessarily bear this interpretation in the case of shucked stock which has been subjected to storage.”

“With these considerations in mind, it is the opinion of the committee that, in judging the safety of shellfish, chief reliance should be placed (1) on the system of inspection and sanitary control of the beds from which such shellfish are taken and of the processes of shucking and packing, and (2) upon bacteriological examination of shell stock and of shucked stock as placed at the shucking plant. Bacterial examinations of shucked stock sampled in the market are subject to such a variety of interpretations that they are unreliable as a means of judging the presence or absence of dangerous contamination.”

“It seems to be a quite well established and general fact that oysters taken from their beds in winter, when the temperature of the water is lower than about 50°F, show much less contamination with \textit{B. coli} than do the oysters taken from the same beds in seasons when the temperature is higher. This fact, together with certain other observations upon the feeding habits of oysters under natural and experimental conditions, has led some of the foremost authorities on the subject to conclude that at low temperatures (probably below 50°F) oysters go into a state of hibernation. It is claimed that while they are in this state the oysters cease feeding and that, their shells being tightly closed, they are not exposed to contamination from the surrounding waters, but on the contrary undergo a process of natural purification, whereby the \textit{B. coli} originally present in the shell liquor and body cavity are destroyed. According to this view, shellfish taken from their beds during the season of hibernation are protected from dangerous contamination not only by the natural safeguards which protect the over­ lying waters but also by the additional safeguard of self purification during hibernation.”


1927 - Indicator - \textit{Coli-aerogenes} group

\textbf{Shellfish - Oysters}

\textbf{Standard/Discussion} - Bacteriological examination of shellfish: “The bacteriological examinations of shellfish should be made as defined in the Standard Methods of Bacteriological Examinations of Shellfish, American Public Health Association.”

“Samples should be taken from different points in the area and should be sufficiently numerous to give reliable data as to the conditions in the whole areas, and should be collected during the season (September-April) when shellfish are being taken for market.”
“The interpretation of the origin of the coli-aerogenes group found in oysters should be based on the same considerations as expressed above for those found in water. The numbers of the coli-aerogenes group in oysters, as shown by the quantitative findings on examination, are influenced by the varying biological activities of the shellfish which are, in a considerable degree, affected or controlled by meteorological and seasonal conditions.”

CONSIDERATIONS IN JUDGING THE SANITARY QUALITY OF OYSTERS AS OFFERED IN THE MARKET

“The problem which confronts state and local health authorities is that of deciding whether or not the oysters received in their local markets are of fit quality for sale to the public. As regards the state of preservation, this decision must be based upon processes similar to those applied to other perishable food products. As regards the danger of contamination with disease-producing microorganisms, the best evidence on which to base judgement is accurate and reliable information concerning the origin of the shellfish and the precautions which have been taken against contamination in all stages of production and transportation; and though bacteriological examinations of the shellfish as received from the producing area serve in some measure to check this information, they are not a substitute for it.”

“The dependence which may be placed upon bacteriological examination of market oysters is limited by the following considerations: (1) The ratio of the bacterial score of fresh shell oysters to that of the waters from which they have been taken shows a wide seasonal variation. When water temperatures are over 50°F, the oyster score is usually higher than that of the overlying water, so that in warm weather high scores may be expected in oysters taken from waters of good sanitary quality. At lower temperatures, especially under 40°F, the oyster score is usually less than that of the surrounding water, so that midwinter oysters from polluted sources may show low scores. (2) Independent of this characteristic seasonal variation, which is believed to be due to varying biological activity of the oyster, the bacterial score of oysters as received in the market is affected by a variety of circumstances which have very different sanitary significance. Thus, conditions which may give rise to high bacterial scores are: a. contamination from polluted water in beds or floats; b. contamination in shucking or other processes of handling within the producing area; c. multiplication, during handling or transportation, of organisms of the coli-aerogenes group which were originally present in much smaller numbers; d. contamination in handling subsequent to receipt in the local market.”

“In brief, a low bacterial score, though it may be confirmatory of other evidence indicating that the product is satisfactory with respect to origin and handling, is not, of itself, a guarantee of safety; and the significance of a high bacterial score depends largely upon what is known of the conditions which may have given rise to it. Therefore, the finding of a high bacterial score in market oysters should not be taken as a sufficient ground for condemnation of the product without further evidence of its unfitness, but should be considered as an indication for inquiry as to origin and history of the oysters.”

“The foregoing discussion refers to bacteriological examinations as made in the receiving market, more or less remote from the producing area. In producing areas, where full information is available concerning origin and handling of the shellfish, bacteriological examinations are of more definite significance, especially in relation to control of methods used in shucking plants, and as check upon the accuracy of information given as to the source of fresh stock.”


1928 - Indicator - Coli-aerogenes group
Shellfish - Oysters
Standard/Discussion - “B-hibernation: With reference to the recognition to be given to the hibernation of the oyster as a factor of safety, this subcommittee, after careful study of the subject, recognizes that the phenomenon of hibernation provides a factor of safety against dangerous contamination and recommends that the application of this factor in practice should be governed by the following limitations: 1. It should be limited to certain areas within Class 3, which are defined in the Supplementary Interim Report of the General Committee as usable under restrictions. 2. Areas should be certified only for the period during which the temperatures of the overlying waters continuously and consistently remain at or below 41°F. 3. No area should be certified in which, at any period, the water is of such shallow depth that material fluctuations in temperature are likely occur. 4. No area should be certified unless and until adequate bacteriological evidence indicates consistent low scores of the oysters taken therefrom. For administrative purposes consistent low scores may be defined as not over 5 as a general rule, and rarely over 50. Subject to the above limitations, the decision whether this factor of safety shall be applied in practice, and if so, to what extent, should be left to the discretion of the certifying official.”


1930 - Indicator - B. coli group
Shellfish - Oysters
Standard/Discussion - Oyster “... hibernation has become generally recognized as a factor of safety, subject to certain limitations. These limitations as to the protection afforded by hibernation have been described as follows in a subcommittee report prepared for the Surgeon General’s committee on sanitary control of the shellfish industry: 1. It should be limited to certain areas within class 3 which are defined in the supplementary interim report of the General Committee as usable under restrictions. 2. Areas should be certified only for the period during which the temperatures of the overlying waters con-
tinuously and consistently remain at or below 41°F.
3. No area should be certified in which at any period the
water is of such shallow depth that material fluctua-
tions in temperature are likely to occur.
4. No area should be certified unless and until adequate
bacteriological evidence indicates consistent low scores
of the oysters taken therefrom. For administrative pur-
poses consistent low scores may be defined as not over
5 as a general rule, and rarely over 50.
Subject to the above limitations, the decision as to whether
this factor of safety should be applied in practice; and if so,
to what extent, should be left to the discretion of the
certifying officials.”

Reference - Scott, W. J., (Chr.) 1930. Report of the
Committee on Shellfish Sanitation. In Transactions of the
Ninth Annual Conference of State Sanitary Engineers, Pub-
lic Health Bull, No. 196. 7 pp.

1937 - Indicator - B. coli group
Shellfish - Oysters
Standard/Discussion - Shipping:
(a) “Shucked stock shall be stored and shipped under such
temperature conditions as will prevent spoilage. Out-
side containers shall be provided for ice, and no ice or
other foreign substance shall be allowed to come in
contact with the shellfish during shipment storage. (It
is recommended that shucked stock be kept at a tem-
perature of 50°F. or below, from the time it leaves the
shipper until it reaches the consumer, but that it be not
allowed to freeze except where approved freezing pro-
cesses are employed.)”
(b) “Shucked oysters and clams shall be packed and shipped
in approved containers sealed in such manner that
tampering is easily discernible, and marked with
packer’s certificate number impressed or embossed on
the side of such container and preceded by the state
abbreviation. Shipments shall be so tagged or labeled
as to show the name and address of the consignee, the
name and address of the shipper, the name of the state
of origin, and the certificate number of the shipper.”
(c) “Use of containers bearing the certificate number of
another shipper shall not be permitted.”
Reference - U.S. Public Health Service Minimum Require-
ments for Endorsement of State Shellfish Control Measure
and Certifications for Shippers in Interstate Commerce.

1944 - Indicator - Coliform organisms
Shellfish - Oysters - Shellfish other than oysters
Standard/Discussion - “2.6 Hibernation (Oysters) - Under
written permission from and under strict control by the
state regulatory authority subject to the following restric-
tions oysters may be taken for market purposes from
moderately polluted areas during the period that the oyster
is in hibernation.”
“The taking of oysters will be permitted only during the
period when the temperature of the water remains consis-
tently at or below 41°F and permission will not be given by
the state regulatory authority until it has determined that the
coliform content of the oysters does not exceed 20 per 100
ml, expressed as MPN.”

“Public Health Reason: It is recognized that the oyster
enters a state of hibernation during periods when the tem-
perature of the water overlying the growing area is 41°F or
less and that while in that state is relatively free of bacterial
of the coliform group.”

“Satisfactory Compliance: This item shall be deemed to
have been satisfied if:
(1) Written permission to take oysters from a specified
area is issued by the state regulatory authority.
(2) The taking of oysters from the area be limited to the
period when the overlying water remains consistently
at or below 41°F.
(3) No oysters are taken for market purposes until bacte-
riological examination shows a coliform content of 20
or less per 100 ml, expressed as MPN.
(4) The state regulatory authority maintains a strict control
over the operations.”

“3.3 Procedure to be Employed in the Bacteriological
Examination of Shellfish and Shellfish Waters - The proce-
dures to be followed are those given in the Report of the
American Public Health Association Standard Methods
Committee to the Committee on Research and Standards,
33, No. 5, May 1943, pp. 582-91. The report is entitled:
Recommended Method of Procedure for Bacteriological
Examination of Shellfish and Shellfish Waters.”

“These procedures include those for bacteriological exami-
nation of shellfish growing waters and for bacteriological
examination of shellfish. The interpretation and applica-
tion of results of the bacteriological examination of shellfish
growing waters have been set forth in 2.3, 2.4, 2.5, pp. 9
and 10 of this manual.”

“Until more data are available, any attempt to interpret the
results of bacteriological examinations of shellfish other
than oysters as taken from growing areas or cleansing
processes in terms of their probable freedom from patho-
genic organisms is questionable. For the time being, the
chief reliance should be placed on the quality of the water
over the growing areas or that used in cleansing processes.
It seems reasonable to assume, however, that an MPN
value of 2,400 or more coliform organisms per 100 ml
occurring in successive samples of shellfish other than
oysters, as taken from the growing area, at point of shuck-
ing or after cleansing should be interpreted as an indica-
tion of unfavorable conditions or practices surrounding the
producing and handling of the product and should necessitate
investigation and further control activities on the part of the
regulatory agency.”

“The following applies to the interpretation and application
of results obtained from the bacteriological examination of
oysters only.”

“When an MPN value of 230 or more of coliform organ-
isms per 100 ml of sample persists in oyster shellstock
sampled at the growing areas or in shellstock or shucked
oysters at the point of shucking, it should be interpreted as
an indication of unfavorable conditions or practices sur-
rounding the production and handling of the product and
should necessitate investigation and improved control mea-
ures on the part of the supervisory agency, providing that
in occasional samples, an MPN value of 2,400 coliform

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organisms per 100 ml may be tolerated in some samples. If this occurs in more than two consecutive samples, corrective measures shall be enforced by the regulatory authority.”

"3.4 Comparison of Coliform Organism Scores with Most Probable Number of Coliform Organisms Per 100 Milliliter-

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* Copies are available from the American Public Health Association, 1790 Broadway, New York, NY, for 25 cents per copy. “


1946 - Indicator - Coliform organisms

Shellfish - Oysters - Shellfish other than oysters

Standard/Discussion - “2.6 Hibernation (Oysters) - Under written permission from and under strict control by the state regulatory authority subject to the following restrictions, oysters may be taken for market purposes from moderately polluted areas during the period that the oyster is in hibernation.”

“The taking of oysters will be permitted only during the period when the temperature of the water remains consistently at or below 41°F and permission will not be given by the state regulatory authority until it has determined that the coliform content of the oysters does not exceed 20 per 100 ml, expressed as MPN.”

“3.3 Procedure to be Employed in the Bacteriological Examination of Shellfish and Shellfish Waters. - The procedures to be followed are those given in the Report of the American Public Health Association Standard Methods Committee to the Committee on Research and Standards, Journal of the American Public Health Association, Vol. 33, No. 5, May 1943, pp. 582-91. The report is entitled “Recommended Method of Procedure for Bacteriological Examination of Shellfish and Shellfish Waters.” (Copies are available from the American Public Health Association, 1790 Broadway, New York, NY, for 25 cents per copy).”

“These procedures include those for bacteriological examination of shellfish growing waters and for bacteriological examination of shellfish. The interpretation and application of results of the bacteriological examination of shellfish growing waters have been set forth in 2.3, 2.4, 2.5 pp 5, 6, 7 of this manual.”

“Until more data are available, any attempt to interpret the results of bacteriological examination of shellfish other than oysters as taken from growing areas or cleansing processes in terms of their probable freedom from pathogenic organisms is questionable. For the time being, the chief reliance should be placed on the quality of the water over the growing areas or that used in cleansing processes. It seems reasonable to assume, however, that an MPN value of 2,400 or more coliform organisms per 100 ml occurring in successive samples of shellfish, other than oysters, as taken from the growing area, at point of shucking or after cleansing should be interpreted as an indication of unfavorable conditions or practices surrounding the production and handling of the product and should necessitate investigation and further control activities on the part of the regulatory agency.”

“The following applied to the interpretation and application of results obtained from the bacteriological examination of oysters only: When an MPN value of 230 or more of coliform organisms per 100 ml of sample persists in oyster shell stock sampled at the growing areas or in shell stock or shucked oysters at the point of shucking, it should be interpreted as an indication of unfavorable conditions or practices surrounding the production and handling of the product and should necessitate investigation and improved control measures on the part of the supervisory agency, providing that in occasional samples, an MPN value of 2,400 coliform organisms per 100 ml may be tolerated in some samples. If this occurs in more than 2 consecutive samples, corrective measures shall be enforced by the regulatory authority.”

“3.4 Comparison of Coliform Organism Scores with Most Probable Number of Coliform Organisms Per 100 Milliliter-

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1956 - Indicator - Coliform bacteria - Standard plate count

Shellfish - Shucked Eastern oysters at the wholesale market level.

Standard/Discussion - “...Canadian experience with market standards for oysters was discussed at the 1956 National Shellfish Sanitation Workshop (2) and the Workshop adopted on an interim basis the following bacteriological standard for shucked Eastern oysters at the wholesale market level:”

“Class 1, Acceptable: Shucked oysters with a Most Probable Number (MPN) of coliform bacteria of not more than 16,000 per 100 ml, and/or a Standard Plate Count of not more than 50,000 per ml.”

“Class 2, Acceptable on Condition: Shucked oysters with a coliform MPN greater than 16,000 per 100 ml, but less than 160,000 per 100 ml, and/or a Standard Plate Count greater than 50,000 per ml, but less than 1 million per ml. (The oysters will be accepted on the condition that the shellfish sanitation authority in the originating state will make
mediate investigation of the producer’s plant and operations and will submit a report of such investigations to the control agency in the market area. On the basis of this report the control agency in the market will reject or permit further shipments from the producer in question.

“Class 3, Rejectable: Shucked oysters with a coliform MPN of 160,000 or more per 100 ml, and/or a Standard Plate Count of 1 million or more per ml.”


1958 - **Indicator** - *E. coli* - Total bacteria count

**Shellfish** - Fresh and frozen shucked oysters at the wholesale market level.

**Standard/Discussion** - “The 1958 Workshop changed the 1956 interim bacteriological standard for fresh and frozen shucked oysters at the wholesale market level to the following:”

“Satisfactory. *E. coli* density of not more than 78 MPN per 100 ml of samples as indicated by production of gas in E. C. liquid broth media nor more than 100,000 total bacteria per ml on agar at 35°C will be acceptable without question. An *E. coli* content of 79 to 230 MPN per 100 ml of sample or a total bacteria count of 100, 000 to 500,000 per ml will be acceptable in occasional samples. If these concentrations are found in two successive samples from the same packer or repacker, the state regulatory authority at the source will be requested to supply information to the receiving state concerning the status of operation of this packer or repacker.”

“Unsatisfactory. *E. coli* content of more than 230 MPN per 100 ml of sample or a total bacteria count of more than 500,000 per ml will constitute an unsatisfactory sample and may be subject to rejection by the state shellfish regulatory authority. Future shipments to receiving markets by the shipper concerned will depend upon satisfactory operational reports by the shellfish regulatory authorities at the point of origin.”

“*E. coli* was defined as coliforms which will produce gas from E. C. medium within 48 h at 44.5°C in a water bath will be referred to as fecal coliforms.”


1961 - **Indicator** - *E. coli* - Total bacteria count

**Shellfish** - Fresh and frozen shucked oysters at the wholesale market level.

**Standard/Discussion** - “The 1961 Workshop reviewed still more data collected by the collaborating agencies during the 1958-61 period and after considerable deliberation agreed to continued use of the interim bacteriological standards arrived at by the 1958 Workshop.”


1964 - **Indicator** - Fecal coliform - 35°C plate count

**Shellfish** - “All species of fresh and frozen oysters at the wholesale market level, provided they can be identified as having been produced under the general sanitary controls of the National Shellfish Sanitation Program.”

**Standard/Discussion** - “The 1964 Workshop considered all bacteriological data available up to that time (Nov. 17-19), including data relative to *Crassostrea gigas*, and adopted the following standards on a permanent basis, versus the previous interim basis.”

“Satisfactory. Fecal coliform density of not more than 230 MPN per 100 grams and 35°C plate count of not more than 500,000 per g will be acceptable without question.”

“Conditional. Fecal coliform density of more than 230 MPN per 100 g and/or 35°C plate count of more than 500,000 per g will constitute an unsatisfactory sample and may be subject to rejection by the state shellfish regulatory authority. Future shipments to receiving markets by the shipper concerned will depend upon satisfactory operational reports by the shellfish regulatory authorities at the point of origin.”

“In establishing the above bacteriological standards the 1964 Workshop took cognizance of the fact that no known health hazard was involved in consuming oysters meeting the standard; that oysters produced in the Gulf Coast States with warmer growing waters, could meet the standard if harvested, processed, and distributed according to the National Shellfish Sanitation Program requirements, and that the oysters harvested were from ‘approved’ growing areas complying with the standards for growing areas established in Part I of the PHS Publication No. 33.”


1968 - **Indicator** - Fecal coliform - 35°C plate count

**Shellfish** - All species of shellfish in the NSSP.

**Standard/Discussion** - “The 1964 Workshop considered all bacteriological data available up to that time (Nov. 17-19), including data relative to *Crassostrea gigas*, and adopted the following standards on a permanent basis, versus the previous interim basis.”

“Satisfactory. Fecal coliform density of not more than 230 MPN per 100 g and 35°C plate count of not more than 500,000 per g will be acceptable without question.”

“Conditional. Fecal coliform density of more than 230 MPN per 100 g and/or 35°C plate count of more than 500,000 per g will constitute an unsatisfactory sample and may be subject to rejection by the state shellfish regulatory authority. Future shipments to receiving markets by the shipper concerned will depend upon satisfactory operational reports by the shellfish regulatory authorities at the point of origin.”

500,000 per g will constitute a conditional sample and may be subject to rejection by the state shellfish regulatory authority. If these concentrations are found in two successive samples from the same shipper, the state regulatory authority at the source will be requested to supply information to the receiving state concerning the status of operation of this shipper. Future shipments to receiving markets by the shipper concerned will depend upon satisfactory operational reports by the shellfish regulatory authorities at the point of origin.”

“In establishing the above bacteriological standards the 1964 Workshop took cognizance of the fact that no known health hazard was involved in consuming oysters meeting the standard; that oysters produced in the Gulf Coast States with warmer growing waters, could meet the standard if harvested, processed, and distributed according to the National Shellfish Sanitation-Program requirements, and that the oysters harvested were from ‘approved’ growing areas complying with the standards for growing areas established in Part I of the PHS Publication No. 33.”


**1971 - Indicator** - Fecal coliform - 35°C plate count

**Shellfish** - All species of shellfish in the NSSP.

**Standard/Discussion** - The Seventh National Shellfish Sanitation Workshop voted unanimously to adopt a Receiver Agency Program which included a “Guide to Interpretation of Wholesale Market Bacteriological Data” and a “Standard Interstate Shellfish Shipment Report Form.” The “Guide” and “Report Form” are attached.


**1983 - Indicator** - Fecal coliform - 35°C plate count - *E. coli* type I (interim indicator)

**Shellfish** - Oysters

**Standard/Discussion** - “The ISSC adopted an interim standard of 230 fecal coliforms per 100 g and/or 500,000 per g standard plate count to be applied only to oyster meat as a screening procedure. Any oyster meats exceeding 230 fecal coliform per 100 g will be tested for *E. coli* type I using both the methodology recommended by the ad hoc committee (Modified methodology attached) and the APHA recognized methodology.”

“Any oyster meats exceeding a level of 230 *E. coli* per 100 g and/or 500,000 per g standard plate count will be subjected to regulatory action. This procedure will be applied for one year only. The result of all testing will be forwarded to FDA who will be requested to correlate and analyze the results and report back to the 1984 Conference annual meeting.”

**Reference** - Summary of Actions Taken - 1983 Annual Meeting of the ISSC.

**1984 to 1988 - Indicator** - Fecal coliform - 35°C plate count

**Shellfish** - All species of shellfish in the NSSP.


**1989 - Indicator** - Fecal coliform - 35°C plate count

**Shellfish** - All species of shellfish in the NSSP.

**Standard/Discussion** - “The ISSC modified Appendices A and F which had been incorporated in Part II of the NSSP Manual during 1988. The modified Appendices (A and F) are attached.


**1990 - Indicator** - Fecal coliform - 35°C plate count - *E. coli*

**Shellfish** - All species of shellfish in the NSSP.

**Standard/Discussion** - See attachment.