

Microbiological Criteria for Cooked, Ready-to-Eat Shrimp and Crabmeat

Advisory committee recommends criteria to assess the presence of specific pathogens and maintenance of process integrity

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□ OVER A TWO-YEAR PERIOD, the Seafood Working Group of the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) discussed, debated, and deliberated on a range of topics pertaining to the development of a systems approach to enhancing the safety of cooked, ready-to-eat shrimp and cooked, ready-to-eat crabmeat (NACMCF, 1990).

Multiple reasons underlay the selection of these products. While they have had a generally good history of safety, an endemic level of disease outbreaks has been attributed to these highly perishable products when abused in the production-distribution-retail chain. Furthermore, since the industry is international, these products are produced under conditions that range technologically from relatively primitive to highly sophisticated. These and other reasons were among those cited by the Commissioner of Food and Drugs when giving the working group its initial charge, including a request that these products be among the first brought up for consideration.

The working group's recommendations, which were subsequently adopted by the entire advisory committee, cover a variety of areas, including establishment of a Hazard Analysis and Critical Control Point (HACCP) approach that emphasizes the maintenance of product safety from harvest to consumption, a distinct departure from the fragmented approach used traditionally. Included in the recommendations are four microbiological criteria for verification. This article will summarize the rationale underlying these criteria and describe some of their salient features.

Verification Criteria Concept

The concept of microbiological criteria for verification evolved during the deliberations of bodies such as NACMCF and the International Commission on Microbiological Specifications for Foods (ICMSF, 1988), when they considered means for assessing the effectiveness of HACCP programs. Traditional end-product microbiological testing is usually ineffective as a means of making real-time decisions regarding the microbiological safety of a product. Instead, HACCP systems typically concentrate on physical, chemical, or administrative means for assessing the degree of control of critical control points (CCPs). Likewise, the principal means of reviewing the effectiveness of an HACCP-based system is through an evaluation of CCP records. However, there is a need for an independent, microbiologically based approach that allows outside parties such as corporate auditors or regulatory agency personnel to verify that the total system is operating as intended and that no unanticipated sources of error have crept into the system over time. Implicit in the verification process is the ability to assess whether breakdowns in product safety have occurred due to loss of control associated with either known or as yet unidentified sources. Microbiological criteria for verification are a tool for achieving this goal.

It cannot be overemphasized that a verification criterion is not a standard against which the product is tested on a routine basis. Routine lot-based testing of product processed and

sold under the auspices of an established, well-planned and -administered HACCP program is typically unnecessary, a waste of time and resources. Instead, verification criteria can be viewed conceptually as the target level of microbiological safety that a system has been designed to ensure, and a means by which the integrated effectiveness of the system can be validated through periodic "snapshots" of the total operation. It is important to realize that no safety system can ensure absolute safety. Instead, there is a need for realistic criteria on which to base effective, defensible risk assessments that can be used to define the level of safety that can and should be achieved by systems initiated to assure microbiological safety.

In developing its recommendations, the working group employed a number of guidelines for the establishment of microbiological criteria based on (1) the earlier recommendations of the National Academy of Sciences/National Research Council (NAS/NRC, 1985) and ICMSF (1978, 1980, 1988); (2) deliberations by NACMCF; and (3) a detailed evaluation of the microbiological characteristics of the products. It is worth reviewing the assumptions made, since these provide the rationale underlying the recommended criteria.

- Recommendations pertaining to microbiological criteria should be limited to issues associated with the safety of the product. The working group felt that inclusion of criteria related to other issues such as product quality would dilute the attempt to emphasize safety-related concerns and is consistent with the committee's recommendations pertaining to the development of HACCP programs. A closely related guideline employed by the working group was that the criteria recommended should either be pathogens of concern with these specific products or microbiological attributes that are indicative of the level of control of the primary means whereby the safety of the products is ensured. In the case of cooked ready-to-eat shrimp and crabmeat, the primary areas of concern are control measures after thermal treatment, including maintenance of adequate refrigeration and preventing reintroduction of pathogens from food handlers, environmental sources, or cross contamination. This will be discussed more fully later. Implicit in this guideline is that effective microbiological criteria must be product specific.

- The microbiological criteria recommended for verification must have methods that are reasonable with regard to complexity, availability, ease of interpretation, time requirements, and costs. No matter how effective a criterion might be for verifying the level of control inherent in a safety system, it does no one any good if tests cost \$10,000 per sample or if only two or three people in the world are capable of performing the analysis. Whenever possible, criteria should not be established at the lower limits of detection of the methods being employed, a concept recommended in relation to any analytical procedure. Instead, the criteria should allow trends to be followed and corrective measures to be taken before "action levels" are reached. Furthermore, this allows the establishment of criteria that are designed around 3-class sampling plans. It should be recognized that this ideal is not always feasible, particularly when dealing with infectious agents (e.g., *Salmonella*) with low minimum infectious doses. In those instances, 2-class plans may be more appropriate.

- Microbiological criteria should be capable of being applied at any point in the product production-distribution-retail chain. It was emphasized to the working group that

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microbiological criteria recommended at the federal level should be applicable at both the state and local level. It can be realistically assumed that any criteria adopted at the federal level are likely to be adopted at the state and local levels with little or no change. Accordingly, any microbiological criterion that increases over time when the product is handled in a manner consistent with safety would be ineffective and lead to confusion. This will be discussed in more detail later.

- One of the important characteristics of both the shrimp and crabmeat is that, if processed properly, they receive a cook that is sufficient to inactivate vegetative cells of bacteria that are pathogenic to humans. Accordingly, the presence of pathogenic bacteria in the product after processing is due to either (1) insufficient thermal processing, (2) post-processing reintroduction of bacteria, or (3) survival and outgrowth of spore-forming pathogenic bacteria. Based on an evaluation of the epidemiological data on foodborne outbreaks associated with these products, the third possibility was assessed as being of minor concern. An immediate implication of the assumption pertaining to the lethality of the cook step is that any product that receives less than a "lethal cook" should not be classified as cooked, ready-to-eat shrimp or crabmeat and must be evaluated as a different product with separate criteria.

- The actual numerical values established in conjunction with the proposed criteria were developed with the assumption that the history of the product is unknown. This assumption takes into account the overall goal that the same level of safety must be required of manufacturers that are not operating under an approved HACCP plan and those that have initiated such a program. This is particularly important if there is a transition period in conjunction with the adoption of mandatory HACCP programs. The advisory committee recognized that the need for verification testing is greatly reduced when a well-planned HACCP system is operating and the frequency of sampling can be adjusted accordingly. Likewise, the maintenance of records on CCPs can help offset the significance of occasional marginal results from periodic verification testing and help find their cause.

- Whenever possible, the advisory committee attempted to use definitions for sampling plans, HACCP terms, etc., that were in accordance with those established previously by recognized scientific bodies such as the ICMSF. This is not to imply that the material and concepts were not critically evaluated in relation to the needs of the committee and modifications incorporated when deemed necessary. Rather, this represents an appreciation on the part of the committee that the food industry is international in scope and there is a need for harmonization of definitions in relation to establishment of microbiological criteria.

Recommended Criteria

Using the guidelines outlined above, the working group ultimately developed and recommended four microbiological criteria for verification for cooked, ready-to-eat shrimp and crabmeat (Table 1). These criteria include two for specific infectious agents, *Salmonella* and *Listeria monocytogenes*, and two microbiological indicators of process integrity. Before discussing each of the criteria individually, it is worth discussing the general concepts of process integrity.

Process integrity refers to the integrated system of controls that are responsible for maintenance of the microbiological safety of the product until and after it has reached the consumer. A process integrity indicator can be defined as a microorganism, group of microorganisms, or product of microorganisms whose presence can be correlated with the adequacy of process integrity controls.

As mentioned earlier, the primary process integrity concern with the shrimp and crabmeat is the handling of the product after the cooking step, particularly with regard to the reintroduction of pathogenic bacteria and the adequacy of refrigerated transport and storage. The sources associated with the reintroduction of bacteria include food handlers, raw product/seawater, and the production-distribution-retail environment. Ideally, a means for verifying control of each source would be available. However, after extensive consideration of various options, the working group concluded that there is no specific

Table 1—Microbiological Criteria for Verification recommended for cooked, ready-to-eat shrimp and cooked, ready-to-eat crabmeat^{a,b}

Micro-organism	Criteria		Explanation
	Shrimp	Crabmeat	
<i>Salmonella</i>	n = 30 c = 0 m = M = 0	n = 30 c = 0 m = M = 0	Analytical unit = 25 g
<i>Listeria monocytogenes</i>	n = 5 c = 0 m = M = 0	n = 5 c = 0 m = M = 0	Sample unit = 50 g; analytical unit = 25 g through compositing of 5-g portions from 5 sample units
<i>Staphylococcus aureus</i>	n = 5 c = 2 m = 50/g M = 500/g	n = 5 c = 2 m = 100/g M = 1,000/g	
Thermal Tolerant Coliforms	n = 5 c = 2 m = 100/g M = 1,000/g	n = 5 c = 2 m = 500/g M = 5,000/g	

^aThe methods recommended by NACMCF were those outlined in the AOAC *Bacteriological Analytical Manual* or other methods that can provide a similar degree of accuracy and precision

^bDefinitions (ICMSF, 1986): 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. 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. n = the number of sample units which are examined from a lot to satisfy the requirements of a particular sampling plan

pathogen or process integrity indicator currently available that would be suitable for measuring the degree of safety associated with cross contamination with raw product or seawater. Both specific pathogenic *Vibrio* species and the use of the genus *Vibrio* as a process integrity indicator were considered; however, methodological limitations relating to complexity, timeliness, and interpretation of results made adoption of such criteria impractical. One of the committee's recommendations for future research was the development of improved methods for the detection and differentiation of pathogenic *Vibrio* species, particularly *Vibrio cholerae*, *Vibrio parahaemolyticus*, and *Vibrio vulnificus*.

- ***Salmonella***. As an infectious agent capable of causing outbreaks in some instances at very low minimum infectious dose levels, the presence of this pathogen is deemed undesirable. Accordingly, a 2-class plan is appropriate, with the primary question being the level of sensitivity associated with the detection system. The current level already recommended by ICMSF and regulatory agencies for foods of this "hazard class" was supported by the advisory committee. Since the presence of salmonellae in the products at any point after the lethal step is inappropriate, the proposed criteria were consistent with the goal of providing a verification tool that could be used throughout the food production-distribution-retail chain.

- ***Listeria monocytogenes***. It has only recently been real-

ized that contaminated foods are a primary cause of both epidemic and endemic listeriosis outbreaks. The general lack of information pertaining to the minimum infectious dose, particularly in highly susceptible subpopulations (prenates and neonates, immunocompromised individuals, the elderly, etc.), has led to a general concern about the presence of this infectious, psychrotrophic pathogen in refrigerated ready-to-eat foods. Furthermore, recent studies have indicated that *L. monocytogenes* (1) can be isolated routinely from shrimp, crabmeat, and other estuarine crustaceans, (2) is not uncommon in the processing plant environment, and (3) is more resistant than most other vegetative foodborne pathogens. Accordingly, the committee deemed it prudent to recommend criteria for this bacterium that are consistent with the levels currently required for other ready-to-eat, refrigerated foods of animal origin (dairy products, ready-to-eat meats, etc.). Again, since its presence is undesirable at all times, these criteria can be used throughout the production-distribution-retail chain.

• ***Staphylococcus aureus***. At high levels ($\geq 10^6$ cfu/g), this organism is a well-known cause of food intoxications through its production of heat-stable enterotoxins. However, in the current instance, the microorganism is being used for another purpose, as a process integrity indicator of the adequacy of measures to control reintroduction of pathogens by food handlers.

The primary source of *S. aureus* in foods that have received a thermal treatment is human contact, with more than 50% of humans harboring the microorganism on their skin or in their upper respiratory tract. Its presence is considered an excellent indicator of post-thermal processing contamination by food handlers in a variety of products, including cooked, ready-to-eat shrimp and crabmeat (NAS/NRC, 1985; ICMF, 1978, 1980; Garrett, 1988). Furthermore, because the microorganism does not grow at refrigerated temperatures, if a product has been maintained under proper refrigeration there should be no increase in the number of *S. aureus* over the course of the food production-distribution-retail chain. Accordingly, levels of *S. aureus* $\geq M$ in the shrimp or crabmeat would be indicative of either gross contamination (as might be seen if the product were handled by a food handler with an infected lesion) or low-level contamination by food handlers followed by a period of significant temperature abuse.

The actual numerical values recommended with this criterion were derived from a review of pertinent literature (Foster et al., 1977; Godwin et al., 1977; ICMF, 1980; Swartzentruber et al., 1980; Phillips and Peeler, 1972; Abeyta, 1983; Duran et al., 1983; Matches and Abeyta, 1983; Wentz et al., 1983, 1985; Singh et al., 1987), along with an evaluation of microbiological data provided by the States of Oregon and Florida. Different numerical values for *m* and *M* were recommended for the shrimp and the crabmeat, reflecting differences in the extent of normal handling during their routine processing. In both cases, *m* \leq the indicated value is what can be expected with products that have been produced and maintained under good manufacturing conditions. Values $\geq M$ are indicative of loss of control of an important parameter associated with maintenance of safety.

• **Thermal Tolerant Coliforms**. This criterion generated the most discussion by both the working group and the full advisory committee. In part, this reflects past (often incorrect) use of coliforms as an indicator of fecal contamination. It cannot be overemphasized that the proposed criterion is not being used in this manner; instead, it is being used as an indicator of process integrity, particularly in regard to reintroduction of pathogens from environmental sources and maintenance of adequate refrigeration. The correlation between fecal contamination and "fecal" coliforms with both products is extremely poor. Instead, the source of coliforms after the thermal processing step for both products appears to be the processing environment, particularly in regard to the adequacy of both sanitation procedures and temperature control. The need to clearly eliminate any implication that the source of these organisms in both products is associated with fecal contamination was the rationale that prompted the working group to adopt the use of the term, "thermal tolerant coliforms," in lieu of the more traditional designation of fecal coliforms.

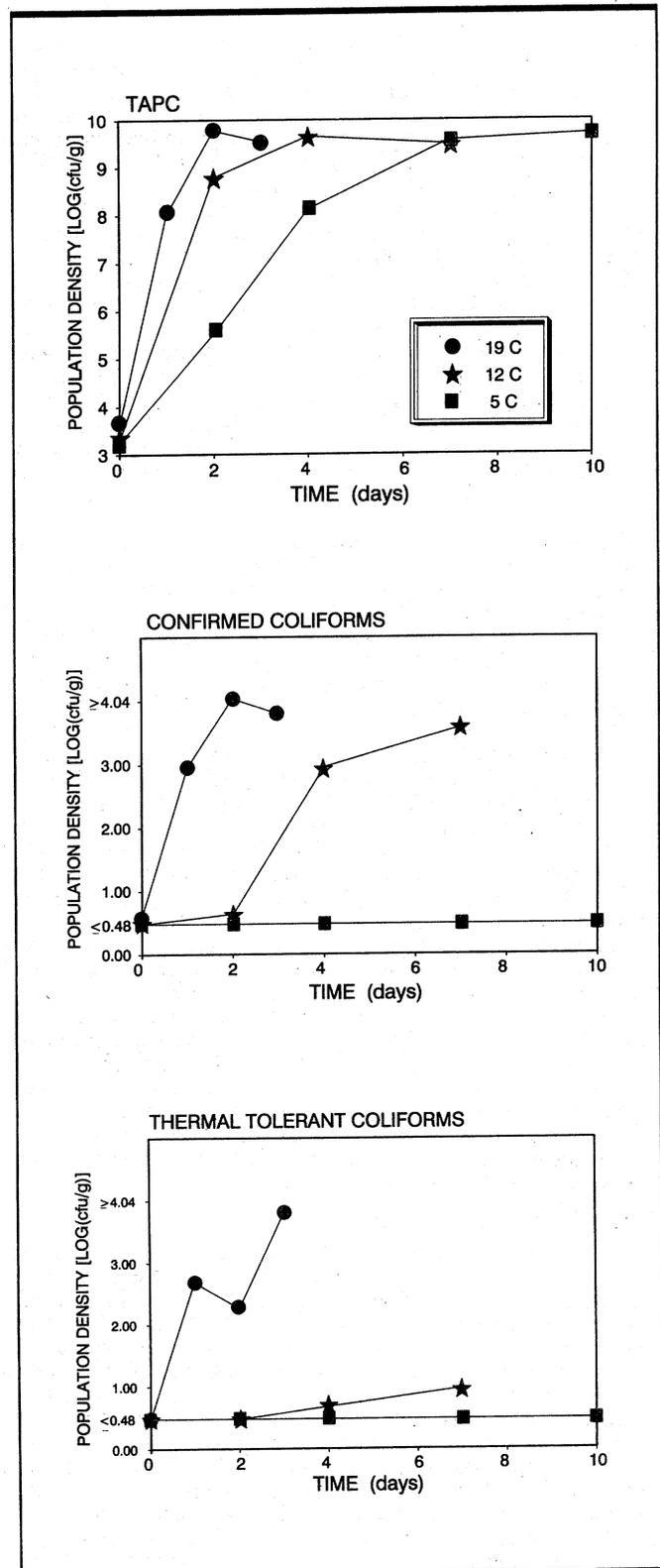


Fig. 1—Total Aerobic Plate Counts (TAPC), confirmed coliform counts, and thermal tolerant coliform counts for samples of retail cooked ready-to-eat shrimp stored under conditions of adequate refrigeration (5°C), mild temperature abuse (12°C), and gross temperature abuse (19°C); values represent the means of three replicates. (Unpublished data from the author's laboratory)

The general usefulness of coliforms and thermal tolerant coliforms as indicators of process integrity in refrigerated, ready-to-eat products, including shrimp and crabmeat, has

been well established (NAS/NRC, 1985). A number of other potential process integrity indicators were considered but were rejected for a variety of reasons. For example, the use of *Escherichia coli* as a process integrity indicator was considered ineffective because of its low incidence in both products. Alternatively, the use of Total Aerobic Plate Counts (TAPC) was rejected because the level of microorganisms increases over time even when the product is stored properly. This would have precluded its use over the entire product production-distribution-retail chain.

This concept is demonstrated in Fig. 1, which depicts an experiment conducted in our laboratory wherein the TAPC, coliform, and thermal tolerant coliform levels in cooked, ready-to-eat shrimp purchased at a local supermarket were monitored under storage conditions of (1) adequate refrigeration (5°C), (2) mild temperature abuse (12°C), and (3) gross temperature abuse (19°C). The results clearly demonstrate that the TAPC increased even in the adequately refrigerated shrimp, whereas the levels of coliforms and thermal tolerant coliforms increased only in the product that was temperature abused.

These data suggest that either coliforms or thermal tolerant coliforms would be suitable as indicators of the adequacy of refrigerated storage, with coliforms being a better indicator of mild abuse conditions. However, concern over the potential growth of psychrotrophic coliforms, as has been indicated with research in other commodities (Newton, 1979), prompted the working group to recommend a criterion based on thermal tolerant coliforms.

The specific numerical values recommended for the proposed thermal tolerant coliform criteria were again based on an evaluation of both available literature (Tobin and McCleskey, 1941; Lerke and Farber, 1971; Phillips and Peeler, 1972; Ray et al., 1976; Foster et al., 1977; Godwin et al., 1977; Ward et al., 1977; Richards, 1979; ICMSF, 1980; Cockey, 1980; Swartzentruber et al., 1980; Abeyta, 1983; Matches and Abeyta, 1983; Wentz et al., 1983, 1985; Singh et al., 1987) and submitted microbiological data. Again, a differential in the numerical values for the shrimp and the crabmeat was incorporated to account for the differences associated with normal processing under good manufacturing conditions.

As indicated earlier, the concept of thermal tolerant coliforms as an indicator of process integrity and its use as a safety criterion was relatively new and the most controversial of the criteria proposed by the committee. Accordingly, whereas the other three criteria were recommended for adoption as standards, thermal tolerant coliforms were recommended as a guideline with the recommendation that product recalls not be made on the basis of this criterion alone.

Fine-Tuning Expected

The advisory committee realized that it was covering a substantial amount of new ground and that its recommendations would likely require "fine-tuning" as the two industries and associated regulatory agencies gained additional information and experience. For example, the numerical values for thermal tolerant coliforms tended to be on the liberal side, whereas experience may prove the *L. monocytogenes* criterion too conservative. Likewise, there is a reasonable possibility that experience will indicate that the thermal tolerant criterion should be upgraded from a guideline to a standard. Similarly, methodological advances may justify reconsidering the desirability of a *Vibrio*-based standard. The committee felt strongly that its recommendations should not be static, but instead, "as technology and systems control improve, the microbiological criteria may need to be modified" (NACMCF, 1990). Hopefully, these microbiological criteria for verification, along with the committee's other recommendations for cooked, ready-to-eat shrimp and crabmeat, will prove to be good models for the development of integrated systems for improving and assuring the microbiological safety of foods.

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