National Research Council (U.S.) Food Protection Committee, Subcommittee on Microbiological Criteria

An Evaluation of the Role of Microbiological Criteria for Foods and Food Ingredients

Subcommittee on Microbiological Criteria
Committee on Food Protection
Food and Nutrition Board
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Appendix A

Summary Responses to Specific Contract Items

The following comprises summary responses to the explicit requests included in the Scope of Work as defined by the Contracting Agencies. The responses are addressed more comprehensively in Chapters 1-11 of this book.

1. The contractor will initiate a reevaluation of sampling plans employed for various classes of foods and food ingredients that are determining *Salmonella* presence in raw and finished food and food ingredients that are subject to *Salmonella* contamination.[1]

The Committee on *Salmonella* of the National Research Council (NRC, 1969) emphasized that the sale of foods containing salmonellae cannot be condoned but at the same time recognized that salmonellae can be found in many products if a sufficient number of tests are made. The report called attention to confusion and uncertainty that existed then in the food-processing industry due to lack of a definitive sampling and testing plan. The following question was posed: When should we stop testing and conclude that a product is *Salmonella*-free (which may simply mean that the contamination level is below the sensitivity of the sampling plan and the analytical procedure)?

In recognition of the fact that there is no way to be absolutely certain that a particular lot of nonsterile food is free of salmonellae, the Committee on *Salmonella* recommended two specific actions: (1) evolve a realistic

[1]Excluded from these considerations were raw meats and poultry from which, given existing technology, salmonellae cannot be eliminated.

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assessment of the degree of hazard imposed by various foods, feeds, and drugs, and (2) develop sampling plans that will provide adequate assurance that the number of salmonellae present, if any, is below a statistically defined limit that offers minimal hazard to the consumer. The committee suggested a system by which the degree of hazard presented by any food could be assessed and it recommended a sampling and testing plan that could lead to a decision whether to accept or reject a particular lot of food.

Assessment of the degree of hazard presented by various foods was based upon three questions: (1) does the food contain a sensitive ingredient, (2) does the processing of the food include a controlled procedure that will destroy salmonellae, and (3) will salmonellae grow in the product if it is abused during distribution or after preparation for consumption? Based upon answers to the foregoing questions, eight different configurations of hazard characteristics are possible. These are delineated in Table A-1.

Five risk categories were recognized by the Committee on *Salmonella*:

Category I—foods that are intended for infants, aged, and the infirm, and that contain a sensitive ingredient.

Category II—foods with all three hazard characteristics.

Category III—foods with two hazard characteristics.

Category IV—foods with one hazard characteristic

Category V—foods with none of the three hazard characteristics.

TABLE A-1 Categories of Food Products Based on Product Hazard Characteristics

	Hazard characteristic[a]			
Type of Food	A	B	C	Category
Intended for infants, aged, and infirm	+	+ or 0	+ or 0	I
Intended for general use	+	+	+	II
	+	+	0	III
	+	0	+	III
	0	+	+	III
	+	0	0	IV
	0	+	0	IV
	0	0	+	IV
	0	0	0	V

[a]A = Product contains sensitive ingredient.
B = No destructive step during manufacture.
C = Likelihood for growth if abused.
+ = Hazard present; 0 = Hazard not present.

SOURCE: Olson, 1975.

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The Committee on *Salmonella* recommended testing and acceptance criteria for "questioned" lots of food. These are summarized in Table A-2. Application of these criteria contemplates the collection of random sample units from the lot in question. Multiple 25-g analytical units, the number based upon the risk category of the product, are then analyzed for *Salmonella*. The intensity of sampling and analysis is related to the degree of risk (hazard category) presented by the product. The objective was to have a sampling and testing plan that would provide adequate assurance that the number of salmonellae, if present, would be below a statistically defined limit offering minimal hazard to the consumer. The limit for each category is given in the last column of Table A-2, i.e., 95% confidence that the *Salmonella* contamination level is no more than 1 in 500 g for Category I; no more than 1 in 250 g for Category II; and no more than 1 in 125 g for Categories III, IV, and V. It will be noted that within each category, two sampling plans are provided, one permitting acceptance only if all analytical units tested are found negative for *Salmonella*, the other permitting a single positive result. For example, for products in Category I, one sampling plan permits acceptance if each of 60 25-g analytical units is analyzed and found negative. The other sampling plan permits acceptance if one of 92 25-g units is positive. Justification for the two different sampling plans was based upon the fact that one positive result from 92 analytical units or zero positive results from 60 analytical units provides the same probability (95%) that the level of salmonellae as shown in the last column of Table A-2 is not exceeded.

It should be emphasized that the sampling and testing plan recommended by the Committee on *Salmonella* was intended for application to (1) processed foods or ingredients as contrasted to, e.g., raw meats and poultry; (2) lots that conform to specific criteria that establish their integrity; and (3) lots

TABLE A-2 Acceptance Criteria

Product Category	Number of Units Tested with No Positives	Number of Units Tested with No More than One Positive	Significance[a] 95% Probability of One Organism or Less in
I	60 (1,500 g)	92 (2,300 g)	500 g
II	29 (725 g)	48 (1,200 g)	250 g
III	13 (325 g)	22 (550 g)	125 g
IV	13 (325 g)	22 (550 g)	125 g
V[b]	13 (325 g)	22 (550 g)	125 g

[a]Accuracy of Attribute Sampling, USDA Consumer and Marketing Service, March 1966.
[b]Not normally applicable.

SOURCE: NRC, 1969.

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that have been questioned because of the possible presence of salmonellae. The sampling plan was not designed or intended to replace routine surveillance operations, including testing, that a food manufacturer or a regulatory agency might employ. The plans were intended to be used in arriving at a final decision in order to accept or reject a particular lot in question.

After reviewing the report of the Committee on *Salmonella*, the FDA began to consider ways of responding to the various committee recommendations (Olson, 1975). It invited Dr. E. M. Foster, Director of the Food Research Institute, University of Wisconsin, to assemble a group of knowledgeable people representing both government and industry to develop a classification system and a sampling plan along the lines envisioned by the Committee on *Salmonella*. The Interagency-Industry Committee on *Salmonella* Control in Foods submitted its report to the FDA in October 1970, and the report was published in March 1971 (Foster, 1971). This report embraced the recommendations of the Committee on *Salmonella* both with respect to the establishment of categories of food products based upon product hazard characteristics and the sampling and analytical plans for determination of the acceptability of questioned lots. Further, it provided guidance on the assessment of hazard characteristics.

Subsequently FDA announced its position on *Salmonella* sampling and testing plans (Olson, 1975). Basically, FDA accepted the recommendations of the Committee on *Salmonella* (NRC, 1969) and the Interagency-Industry Committee (Foster, 1971) with the following exceptions. First, a sample lot would be accepted only if analyses of all analytical units were negative for salmonellae. The FDA position was that acceptance of any lot of food in which salmonellae were shown to be present would not be administratively feasible. Thus, the sampling plan shown in the second column of Table A-2 would be employed and the sampling plan shown in the third column (permitting a single positive among the analytical units tested) would not be utilized. Second, FDA provided for the compositing of multiple analytical units, the maximum size of a composite unit being 375 g. The composite unit was to consist of a series of 25-g analytical units. Finally, the FDA indicated that the acceptance criteria would be applied to any lot of product tested in connection with any of its surveillance or compliance programs. As previously noted, the two committees (NRC, 1969; Foster, 1971) had indicated that the sampling plan was not designed to replace routine surveillance operations, but was intended to be used in arriving at a final decision whether to accept or reject a particular lot in question. FDA's position on this point was made clear: "If we sample a lot we question it; otherwise why sample it?"

The fourth edition of the *Bacteriological Analytical Manual for Foods*

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(BAM) (FDA, 1976) reflected Olson's position paper (Olson, 1975). The classification of products by hazard categories and the attendant sampling plans were consistent with the report of the Committee on *Salmonella* and the recommendations of the Interagency-Industry Committee on *Salmonella* Control in Foods. Indeed, a vast number of industry quality control programs utilized the sampling plans routinely in their *Salmonella* control programs, not just for determining the status of suspect lots.

The fifth edition of the BAM (FDA, 1978), set forth a revised *Salmonella* sampling plan, one that departed radically from the recommendations of the Committee on *Salmonella*. Three categories of food were identified as follows:

Food Category I—foods that would normally be in Category II except they are intended for consumption by the aged, the infirm, and infants.

Food Category II—foods that would not normally be subjected to a process lethal to *Salmonella* between the time of sampling and consumption.

Food Category III—foods that would normally be subjected to a process lethal to *Salmonella* between the time of sampling and consumption. The following tabulation shows the number of sample units to be collected in each food category:

Food Category	Number of Sample Units
I	60
II	30
III	15

The categorization of foods and the sampling plans prescribed in the 1978 edition of the *Bacteriological Analytical Manual* depart both in philosophy and substance from those contained in the 1976 edition of the BAM. Likewise, of course, they depart from the recommendations of the NAS Committee on *Salmonella* and those of the Interagency-Industry Committee on *Salmonella* Control in Foods. The present system employed by the FDA for categorizing foods, as well as the sampling plans tied to such categorization, are unrelated to risk. The key issue, rather, is whether the food would normally be subjected to a process lethal to *Salmonella* between the time of sampling and consumption. This parameter played no role in the designation of food categories by the Committee on *Salmonella*, the recommendations of which were embraced by the Interagency-Industry Committee on *Salmonella* Control in Foods and the FDA. Ignored in the present classification system are: risk A: the product or an ingredient of the product has been identified as a significant potential source of salmonellae (i.e., it is "sensitive"); risk B: the *manufacturing* process does

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not include a controlled step that will destroy salmonellae; and risk C: there is a substantial likelihood of microbial growth if the product is mishandled or "abused" in distribution or consumer usage. The present system utilized by the FDA recognizes, only, that if a product were to be classified in "new" Category II, it would be classified in Category I if the product were to be consumed by high-risk groups. It is of interest to note that the Committee on *Salmonella* of the NAS classified any food consumed by high-risk groups in Category I if it contained a sensitive ingredient (risk factor A). Under the present system, such a product would be assigned to Category III if the food would normally be subjected to a process lethal to *Salmonella* between the time of sampling and consumption. Table A-3 lists examples of foods in Categories II and III as presented in the 1978 edition of the BAM. Table A-4 shows examples of "interesting shifts in classification" that have occurred as a result of the revised *Salmonella* sampling plan introduced in that edition.

It is difficult for this subcommittee to understand the rationale for the changes in food category classification and sampling plans between the 1976 and the 1978 editions of the BAM and thus, in effect, the rationale for the FDA rejection of the recommendations of the NRC Committee on *Salmonella*. In section A, Sampling Plans for *Salmonella* of Chapter 1 of the 1978 BAM the following statements are made: "Generally, the assignment of food categories has depended on the sensitivity of a consumer group (e.g., the aged, the infirm and infants), the history of the food, and whether there was a step lethal to *Salmonella* during the manufacturing process or in the home. Of these criteria the sensitivity of the consumer group and whether the food normally underwent a process lethal to *Salmonella* either at the manufacturing or consumer level appeared to be the most important considerations in the selection of a sampling plan. The history of the food would be more important in a decision on whether to sample rather than how many sample units to take." This subcommittee offers the following comments on these statements:

1. As stated, the sensitivity of the consumer group influences the assignment of food categories. But, as indicated above, the present FDA system would classify foods containing sensitive ingredients in Category III if such foods were normally subjected to a process lethal to *Salmonella* between the time of sampling and consumption. The NRC Committee on *Salmonella* would classify the same foods in Category I if they contained a sensitive ingredient regardless of their "normal" subsequent handling. The present FDA system simply assigns products in Category II to Category I if high-risk groups are involved. But if the same foods were "normally" subjected to a process lethal to *Salmonella* between the time of sampling

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TABLE A-3 Food Categories II and III

Food Category II—Foods that would normally be subjected to a process lethal to *Salmonella* between the time of sampling and consumption.

Product Code	Food
03	Bread, rolls, buns, sugared breads, crackers, custard and cream-filled sweet goods
05	Breakfast cereals, ready-to-eat
07	Pretzels, chips, and specialty items
09	Butter and butter products; pasteurized milk and raw fluid milk and fluid milk products for consumption; pasteurized and unpasteurized concentrated liquid milk products for consumption; dried milk and dried milk products for consumption
12	Cheese and cheese products
13	Ice cream from pasteurized milk and related products that have been pasteurized; raw ice cream mix and related unpasteurized products for consumption
14	Pasteurized and unpasteurized imitation dairy products for consumption.
15	Pasteurized eggs, egg products from pasteurized eggs; unpasteurized eggs and egg products from unpasteurized eggs for consumption without further cooking
16	Canned and cured fish, vertebrates; other fish products; fresh and frozen raw oysters and raw clams, shellfish and crustacean products; smoked fish, shellfish, and crustaceans for consumption
17	Unflavored gelatin
20–22	Fresh, frozen, and canned fruits and juices, concentrates, and nectars; dried fruits for consumption; jams, jellies, preserves, and butters
23	Nuts and nut products for consumption
26	Oils consumed directly without further processing; oleomargarine
27	Dressings and condiments (including mayonnaise), salad dressing, vinegar
28	Spices, including salt; flavors and extracts
29	Soft drinks and water
30	Beverage bases
31	Coffee and tea
33	Candy, chewing gum
34	Chocolate and cocoa products
35	Pudding mixes not cooked prior to consumption, gelatin products
36	Syrups, sugars, and honey
38	Soups
39	Prepared salads

Food Category III—Foods that would normally be subjected to a process lethal to *Salmonella* between the time of sampling and consumption.

Product Code	Food
02	Whole grain, processed grain, and starch products for human use
04	Macaroni and noodle products
16	Fresh and frozen fish; vertebrates (except that eaten raw); fresh and frozen shellfish and crustaceans (except raw oysters and raw clams for consumption); other aquatic animals (including frog legs)
24	Fresh vegetables, frozen vegetables, dried vegetables, cured and processed vegetable products normally cooked before consumption
26	Vegetable oils, oil stock, and vegetable shortening
35	Dry dessert and pudding mixes that are cooked prior to consumption
37	Frozen dinners, multiple food dinners
45–46	Food chemicals (direct additives)

SOURCE: FDA, 1978.

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TABLE A-4 Selected Examples of Categories—BAM 1976 vs. BAM 1978

Foods	BAM Classification 1976	1978
Salt, flavors and extracts, mayonnaise, fresh fruits and juices, jams, soft drinks, water, beverage bases, coffee, tea, snack items (dry), syrups.	CAT. III[b]	CAT. II[a]
Frozen dinners.	II	III
Fresh and frozen shellfish and crustaceans (ex. raw oysters and clams), other aquatic animals, fresh vegetables.	III	III

Sampling:
[a]Category II: Thirty 25-g samples.
[b]Category III: Fifteen 25-g samples.

SOURCE: Silliker, 1980.

and consumption, these foods would be assigned to Category III *regardless of the group at risk*.

2. The term "history of the food" is difficult for the subcommittee to interpret. One might equate this to a food with a history indicating it to be a *Salmonella* problem, i.e., a sensitive product. It is stated that the history of the food would be more important in a decision on *whether to sample* rather than on how many sample units to take. Thus, it would appear, and logic would dictate this, that one might be more concerned with a product in Category III (one containing a sensitive ingredient) than one in Category II. For example, one would certainly be more concerned with dry dessert and pudding mixes that are cooked prior to consumption or frozen dinners than with salad dressing or vinegar. Yet the former are classified in Category III and the latter in II. It seems, however, that to classify salad dressing and vinegar in Category II is ill-advised. These products are classified in Category II solely on the basis that they "would not normally be subjected to a process lethal to *Salmonella* between the time of sampling and consumption." Vinegar, for example, clearly belongs in Category V (according to the report of the Committee on *Salmonella*), because (1) it contains no sensitive ingredient, (2) its acidity would destroy *Salmonella*, and (3) salmonellae are incapable of growth in the product. Yet the 1978 edition of the BAM would clearly place this product in Category II with a sampling plan "twice as stringent" as would be applied to dry dessert and pudding mixes or frozen dinners.

3. It is stated: "Of these criteria, the sensitivity of the consumer group and whether the food normally underwent a process lethal to *Salmonella*

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either at the manufacturing or consumer level appeared to be the most important considerations in selection of a sampling plan.'' The report of the Committee on *Salmonella* with reference to classification of food products according to risk is concerned with whether the manufacturing process does not include a controlled step that would destroy salmonellae. In this regard, the hazard relates to the manufacturing process, not to what occurs in the hands of the consumer. The report did recognize: ''Obviously, the food or ingredient that will ultimately be used under conditions resulting in *Salmonella* destruction is far less hazardous than one that will be consumed without decontamination and quantitative guidelines take this into account. This does not ignore the danger of bringing the contaminated food into the kitchen or processing area but does recognize that the level of risk entailed is influenced by the ultimate usage.'' These considerations result, for example, in placing sensitive products, such as frozen dinners in Category III, even though such products contain (1) sensitive ingredients, (2) no final kill step at the manufacturing level, and (3) the potential of *Salmonella* growth if mishandled.

4. If ''the history of food'' is to be equated to whether it contains a ''sensitive ingredient,'' then this characteristic of the product is not ''more important in a decision on whether to sample rather than how many sample units to take,'' according to the recommendations of the Committee on *Salmonella*. It is, indeed, one of four factors that are considered in classification of a food into one of the five hazard categories. The others are the population at risk, whether the food is subject to a ''pasteurizing'' step at the manufacturing level, and whether *Salmonella* growth may occur in the product if it is mishandled. The present FDA scheme eliminates the ''history of the food'' as a determinant of the sampling plan when, indeed, the Committee on *Salmonella* gave equal weight to this and two other factors (kill step and potential of growth) in establishing its classification scheme.

This subcommittee supports the recommendations of the NRC Committee on *Salmonella* with respect to the classification of foods into five categories and the establishment of sampling plans, the stringency of which is related to the degree of hazard. It feels that the present FDA categorization of foods, and the sampling plans tied to these, ignore the recommendations of the NRC Committee on *Salmonella* and substitute these with a less effective system.

The recommendations of the NRC Committee on *Salmonella* not only were endorsed by the Interagency-Industry Committee on *Salmonella* Control in Foods and by the 1976 edition of the BAM but in addition by the International Commission on Microbiological Specifications for Foods (ICMSF, 1974).

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II. The contractor will evaluate whether or not suitable microbiological testing procedures and data bases have been developed and validated sufficiently to be useful for: regulatory purposes, for purchasing specifications, and/or for quality control purposes. If further work is indicated, the contractor will list priorities for the tasks that must be completed so that suitable microbiological tests and data bases will be available for the various purposes listed above.

Test procedures for pathogenic and indicator organisms are discussed and evaluated in Chapters 4 and 5 of this report. Adequate procedures are available for the aerobic plate count and the quantitation of coliform, fecal coliform, *Escherichia coli, Staphylococcus aureus, Clostridium perfringens*, enterococci, and yeasts and molds. Reliable procedures exist for the detection of *Salmonella*, staphylococcal enterotoxins, *C. perfringens* alpha toxin, and *Clostridium botulinum* toxins.

Additional satisfactory procedures are available (*Compendium of Methods for the Microbiological Examination of Foods*, APHA, 1984) for the direct microscopic count, and to detect and/or enumerate psychrotrophic, thermoduric, lipolytic, proteolytic, halophilic, osmophilic, pectinolytic, and acid-producing microorganisms, as well as for mesophilic aerobic sporeformers, mesophilic anaerobic sporeformers, aciduric flat-sour sporeformers, thermophilic flat-sour sporeformers, thermophilic anaerobic sporeformers, and sulfide spoilage sporeformers.

At present, *E. coli* is the most reliable bacterial indicator of fecal contamination. The standard enrichment-plating procedures routinely applied to detect and enumerate this organism in foods are time-consuming, laborious, and expensive, and there is some question about their accuracy. There are more rapid and accurate procedures for *E. coli* such as the Anderson-Baird-Parker direct plating method and recent modifications of this procedure.

Although existing procedures for *Bacillus cereus* and *Vibrio parahaemolyticus* seem to perform well in some laboratories, certain problems are encountered with these procedures. In the detection and enumeration of *B. cereus*, existing procedures do not always clearly separate this organism from other contaminants. In the case of *V. parahaemolyticus*, a recent study (ICMSF, in preparation) has revealed some inconsistencies regarding the MPN procedure.

Although rapid progress is being made, procedures for the detection of *Yersinia enterocolitica, Yersinia pseudotuberculosis*, and *Campylobacter fetus* subsp. *jejuni* (*Campylobacter jejuni/coli*) from foods require additional studies.

Continued studies are recommended for the detection and quantification of mycotoxins, particularly to develop more practical and precise methods. Similar recommendations are proposed for toxins important in certain fish

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and shellfish such as ciguatoxin, saxitoxins, and closely related toxins.

One of the most severe problems related to microbiological criteria is the time necessary to obtain the results of microbiological test procedures. For this reason, additional studies are needed to develop microbiological techniques that require a minimum of time, are simple, sensitive, cost-effective, and usable on-site, in-process as part of microbiological control programs.

Microbiological criteria for viruses in foods are not feasible at the present time primarily because of lack of practical methods. Development of methods for the detection of viruses in foods that can cause human illness is highly recommended.

An evaluation of available data bases for microbiological criteria of various foods has been made in Chapter 9. Additional information related to this contract item can be found in Chapters 4, 5, and 9.

III. The contractor will determine the relative merits of: aerobic plate count, fecal coliform, coliform, *E. coli*, and coagulase-positive *Staphylococcus* procedures currently used to identify contamination of foods during and after processing.

In perishable foods, the aerobic plate count (APC) can reflect the microbial condition of the raw materials and ingredients used, the effectiveness of processing methods (for example heat treatment), the efficacy of cleaning and sanitation procedures employed, the microbiological condition of the processing equipment, and the conditions of storage (time-temperature abuse). One or more of these conditions, if not adequately controlled, can be responsible for higher than expected APC during and after processing. Thus, to identify a specific cause of contamination by the APC, it would be necessary to eliminate the other potential causes. Results of testing final products only do not tell which event(s) may have caused a high APC, but if used in conjunction with observations made during plant inspection they may provide information to make some inferences. To identify where contamination occurred, APCs of line samples before and after critical control points have merit. In shelf-stable foods that do not support microbial growth, results on finished products also will not give information about specific causes of high APC. Contamination, however, can be identified by APC as described for perishable foods. In fermented food, the APC offers no information about contamination.

From their original fecal, water, soil, or plant environment, coliform bacteria can reach the food processing and preparation environments and become established there. The principal value of determining coliform bacteria is as an index of postprocessing contamination of foods that are heat processed for safety. Coliform bacteria are used for this purpose,

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primarily because they are heat-sensitive organisms and a relatively simple test is available for their detection. *E. coli*, the most sensitive bacterial indicator of fecal contamination, is a member of the coliform group. Unfortunately, the fecal connotation of *E. coli* is often linked to any food in which coliform bacteria are found, most of the time inappropriately. Thus, the presence of coliform bacteria in food does not mean that there was necessarily fecal contamination or that pathogens are present. Small numbers of coliform bacteria are normally present in raw milk and on vegetables, meats, poultry, fish, and many other raw foods. These organisms are readily destroyed during heat processing of foods. The presence of coliforms in foods thus indicates either (1) presence of these organisms in a raw product that was not heat processed, (2) ineffective heat processing, and/or (3) contamination after heat processing by contact with contaminated equipment, utensils, or employees. Excessively high coliform counts may result from massive contamination, process failure, or from growth resulting from extended processing delays and/or from improper storage practices (time-temperature abuse). The use of the coliform count as an index of contamination requires a thorough knowledge of the significance of coliform bacteria in various foods and even in a single food at different stages of processing. In some cases, it may also require examination of line samples. For example, some coliform bacteria can be expected in raw milk. After proper pasteurization, the presence of coliform bacteria indicates postpasteurization contamination. Although this seldom poses a health hazard, the presence of coliforms may be indicative of contamination of the product with spoilage bacteria that could materially reduce shelf-life. Results of line samples are needed to identify the source of contamination.

The merit of the fecal coliform or *E. coli* count to identify contamination is subject to the same limitations as described above for the coliform count, although the possibility of direct or indirect involvement of fecal contamination becomes greater with a positive fecal coliform test and even greater when *E. coli* is detected. Without doubt, *E. coli* is presently the most reliable bacterial indicator of fecal contamination. If fecal coliforms in a food are used as an index of *E. coli* and thus as an index of fecal contamination, this relationship must be established for the product where fecal coliforms are used for this purpose. In summary, fecal coliform and *E. coli* counts are made for the purpose of determining fecal contamination; for post-heat treatment contamination, coliform determinations are more appropriate. The presence of coagulase-positive staphylococci in foods indicates that direct or indirect contamination resulted from either human or animal sources. Although some may survive mild heat processing, their presence in these foods usually represents postprocessing

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contamination. Small numbers, therefore, do indicate contamination, whereas large numbers usually result from time-temperature abuse and represent a more serious condition that eventually may pose a health hazard. If large numbers of staphylococci occur in a food as a result of growth, it usually occurs in a food that has been heat processed to eliminate competing organisms, thus with temperature abuse setting the stage for unrestricted growth of staphylococci. It is necessary, however, to point out that the absence or low numbers of coagulase-positive staphylococci in heated or fermented foods does not imply safety—they may have been destroyed during processing but their enterotoxins still may be active.

Additional information related to this contract item can be found in Chapters 4 and 5.

IV. The contractor will evaluate the optimal number of samples that should be taken from a lot of food to establish the number of indicator organisms present when the result is to be used for: (1) quality control purposes, (2) purchase specifications, and (3) regulatory purposes. The contractor shall include consideration of cost vs. benefit in determining the optimal number.

This contract item raises a number of interesting aspects to sampling. To evaluate the optimal number of samples for indicator organisms is not a simple process. The task is made more difficult if one has or uses three different sampling procedures, i.e., for quality control, purchase specifications, and regulatory purposes. From a philosophical point of view, it would be undesirable to suggest that such a procedure be adopted if one wishes to have the same level of confidence in each result. As a manufacturer, one would expect the same sensitivity in the microbiological testing program as that of the federal government, especially if court procedures were to be involved. Likewise, if one purchases raw material from a supplier at an agreed specification, one would like to know the risks involved in processing that material using the same sampling procedure as the supplier. Thus, the same method and sampling plan should be used for all three purposes.

The development of optimal number of samples has been dealt with in part in Chapter 6 and relates to the stringency of the sampling plan. The significance of indicator organisms varies with the food. The presence of these in a pasteurized food or shellfish means something different from their presence in raw foods like meat (see Chapter 5). The ICMSF concept of relating the stringency of the sampling plan to the degree of hazard is generally accepted as a useful and meaningful way of making such a selection. The number of analytical units examined (n) and the number of analytical units permitted to exceed the established limit (c) vary with the degree of hazard.

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In summary, to determine optimal numbers of samples for indicator organisms, one needs to know:

1. degree of risk involved to the consumer
2. hazards involved
3. processing steps before eating
4. final use of food, i.e., cooking, storage, etc.

The cost-benefit consideration for indicator organisms follows the same concern as listed in item VIII of this Appendix. Current information is that 3-class plans can be used for indicator organisms.

Additional information also can be found in Chapter 6 of this report and in Chapter 1 of ICMSF (1974).

V. The contractor will determine the usefulness of a zero tolerance for such indicator organisms as *E. coli* and *S. aureus*; e.g., no *E. coli* in one gram.

For foods, *E. coli* is the best bacterial indicator of fecal contamination of relatively recent origin. Thus, the presence of *E. coli* in a food indicates the possibility that fecal contamination may have taken place and that other microorganisms of fecal origin, including pathogens, may be present. However, it does not imply that pathogens are present or, if present, the level of contamination. On the other hand, the absence of *E. coli* does not imply the absence of enteric pathogens. In many raw foods such as milk, fresh meats, and poultry small numbers of *E. coli* can be expected because of the close association of animals with fecally contaminated environments during production and the likelihood of spread to carcasses during slaughter-dressing operations. Because *E. coli* is relatively heat-sensitive, the presence of *E. coli* in a heat-processed food, such as cooked crabmeat, for example, indicates underprocessing and/or postprocessing contamination through equipment, utensils, by persons handling the cooked food, or from cross-contamination with raw foods. Occasionally a few of these organisms will reach the product even under reasonably good manufacturing practices. However, the criteria for heat-processed products should be strict. This can be achieved by proper selection of n, c, m, and M (see Chapter 6).

An evaluation of the usefulness of a zero tolerance for the indicator organism *E. coli*, i.e., less than one *E. coli* in one gram of food, requires an examination of the purpose of the microbiological limit and, most important, a recognition of the limitations of the analytical procedure. A microbiological limit of less than one *E. coli* per gram implies the use of a MPN procedure. The current AOAC MPN procedure for *E. coli* (AOAC, 1980) is laborious and requires several days to complete. More important, however, the limits in precision of the MPN procedure are often ignored

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when MPN values are interpreted. Even under the best of experimental conditions, there are distinct limitations to the precision of the MPN estimate. The MPN estimate is not one value but represents a range, the extent of which depends upon many factors, one of which is the number of tubes in a set. Woodward (1957) reported that for a 3-tube test the 95% confidence limits cover a 33-fold range from approximately 14% to 458% of the actual tabular MPN estimate. For a 5-tube multiple detection test, the 95% confidence limits cover a 13-fold range from approximately 24% to 324% of the MPN. In practice these intervals may be considerably larger than those calculated from standard MPN tables. For example, results on coliform determinations in peanut butter, dried buttermilk, and dried egg albumen (Silliker et al., 1979) indicated 95% confidence intervals for a single log value of ± 0.88, ± 1.03, and ± 0.87 log units respectively, indicating ranges of 1.76, 2.06, and 1.74. The average range for the three products was 1.85 and the average 95% confidence interval for a single log value, ± 0.925. Thus, in the application of a microbiological criterion involving a MPN procedure (including one of <1 *E. coli* per g) it is important to know the precision of the analytical method so that the criteria can be properly administered and interpreted.

A direct plating method (Anderson-Baird-Parker Method and modifications) is available that not only detects typical *E. coli* but also lactose-negative and anaerogenic indole-positive variants (Anderson and Baird-Parker, 1975; Holbrook et al., 1980; Mehlman, 1984; Rayman et al., 1979; Yoovidhya and Fleet, 1981). Modifications of this procedure include a resuscitation step to recover injured cells. Additional advantages of the direct plating method include availability of results in 24 hours compared to 4 days or longer using conventional MPN procedures, better recovery from frozen samples, decreased requirement for laboratory media, and decreased cost for technical personnel. In enumerating *E. coli* from raw meats (Rayman et al., 1979), the direct plating method yielded higher counts than the MPN method for frozen samples. For oysters (Yoovidhya and Fleet, 1981), the direct plating method was sensitive and accurate in the range of two to five *E. coli* cells per gram of oyster homogenate. By placing 1 ml of a 1:5 dilution of meat on duplicate filters a lower limit of detection of 2.5 cells per gram of meat could be reached (Rayman et al., 1979). With 1 ml of a 1:10 dilution, the lower limit of detection would be <10 per gram of food.

Small numbers of *S. aureus* are to be expected in foods that have been exposed to or handled by people. Large numbers (1,000 or more per gram of food) result either from extensive contamination or more likely from growth. The latter situation most often occurs in a food in which competing microorganisms have been destroyed by processing, with subsequent time-

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temperature abuse creating conditions for extensive growth of staphylococci. Although very high numbers (10^6 or higher per gram of food) indicate the possibility of presence of toxin, lower numbers do not imply absence of toxin because the number of viable cells may have decreased by some food-processing procedure such as heating. A few staphylococci are likely to reach foods even though good manufacturing practices were applied.

An evaluation of the usefulness of a zero tolerance for *S. aureus* in foods also requires a recognition of the purpose of the criterion and the precision of the analytical method. The purposes for examining foods or food ingredients for low levels (<100/g) of *S. aureus* include: to determine whether the food or ingredient is a potential source of enterotoxigenic *S. aureus* and/or to demonstrate postprocessing contamination, which usually is due to human contact with processed food or exposure of the food to inadequately sanitized food equipment surfaces. Detection and enumeration of relatively low numbers of *S. aureus* in foods is sometimes complicated by the presence of large numbers of other microorganisms and/or by the presence, particularly in processed foods, of injured (sublethally stressed) cells of *S. aureus*. Injured cells may not be recovered on media that are satisfactory for noninjured cells.

For a limit of <1 *S. aureus* per gram of food a MPN procedure is commonly used. The present AOAC MPN procedure (AOAC, 1980), which uses a 3-tube dilution procedure with trypticase soy broth containing 10% NaCl, has been shown to be inhibitory to injured cells of *S. aureus* (Brewer et al., 1977; Flowers et al., 1982; Flowers et al., 1977; Gray et al., 1974). Some work (Flowers et al., 1982; Giolitti and Cantoni, 1966) has shown that other enrichment broths such as that of Giolitti and Cantoni (1966) may be more productive. The basic limitations in the precision of the MPN procedures as described for *E. coli* also apply to MPN procedures for *S. aureus*. The direct plating method is another approach for the detection and enumeration of *S. aureus* in foods. Baird-Parker agar and some of the more recent modifications of this medium have proven to be superior to other selective media particularly by being less inhibitory to injured cells (Baird-Parker and Davenport, 1965; Devriese, 1981; Flowers et al., 1977; Gray et al., 1974; Idziak and Mossel, 1980; Rayman et al., 1978; Stiles and Clark, 1974; Tatini et al., 1984). Direct plating of a 0.1-ml portion of a 1:10 dilution of the sample on a single plate or a 1-ml portion divided equally over triplicate plates of Baird-Parker agar would allow estimates of <100 or <10/g, respectively. In view of the limitations associated with current MPN procedures for *S. aureus*, it is questionable whether the public health relevance of a processed food with levels of <100 or <10 *S. aureus* per gram as determined by a direct plating method (Baird-Parker agar) is significantly different from that of the same food

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in which the level was <1/g using a MPN technique. Taking into account the precision and accuracy of current MPN procedures, a microbiological limit of <1 *S. aureus* per gram of food does not appear meaningful. In conclusion, zero tolerances (<1/g of food) for either *E. coli* or *S. aureus* are meaningless unless they take into account the variability of the MPN procedures.

Additional information related to this contract item can be found in Chapters 4 and 5.

VI. The contractor will determine whether aerobic plate count together with coliform or *E. coli* counts are complimentary or redundant for processed foods.

The same basic conditions may be responsible for higher than normal APC, coliform, or *E. coli* counts in processed foods, namely: inferior quality raw materials and ingredients, inadequate heat processing, post-heat processing contamination, and time-temperature abuse. However, this does not mean that these counts are affected to the same degree by these conditions. In a heat-processed food there may be some postprocessing contamination that does not result in significant changes in APC. However, the presence of a few coliforms may indicate that some lack of good manufacturing practices existed. For example, the presence of 1-10 coliform bacteria per ml of pasteurized milk still constitutes a legal product but this count should alert the processor that postpasteurization contamination has taken place.

As pointed out earlier (no. III in this appendix), a distinction should be made in the merits of the *E. coli* and coliform counts. *E. coli*, a member of the coliform group, is presently the most reliable bacterial indicator of fecal contamination. However, the presence of coliform bacteria in a processed food does not necessarily mean the presence of either *E. coli* or fecal contamination. For example, in Grade A pasteurized milk, the presence of a few coliform bacteria is unrelated to fecal contamination but results in most cases from contamination of improperly cleaned and sanitized equipment used to store, transport, or package the pasteurized product.

In northern Europe, the coliform test has been supplanted by the *Enterobacteriaceae* test, simply because this encompasses a larger group of organisms that share properties with the more restricted group of the coliforms. In summary, the three determinations clearly are not redundant.

Additional information related to this contract item can be found in Chapter 5.

VII. The contractor will evaluate the public health relevance of *Salmonella* and other foodborne pathogens of similar resistance to heat in raw seafoods, in food-processing plants, in restaurants and in family kitchens.

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Small numbers of a variety of pathogens such as *Salmonella, Yersinia, Campylobacter*, and *Vibrio* may be associated particularly with raw animal foods such as fresh raw meats, poultry, milk, or fish. For example, *Salmonella* with raw meats and poultry; *Yersinia* with raw meats, particularly pork; *Campylobacter* with raw milk and poultry; *V. parahaemolyticus* with seafood; and *V. cholerae* with shellfish. *S. aureus* can be readily transferred to foods as they are handled by people.

In most instances, foodborne illness resulting from the above-mentioned pathogens has its genesis in the occurrence of these organisms in raw foods of animal origin. For example, man becomes infected with *Salmonella*, in the vast majority of cases, because the potential occurrence of *Salmonella* in raw foods of animal origin is not taken into account although the routes and circumstances leading to human infection from such raw foods are fairly well understood. The incidence of foodborne illness caused by these pathogens will be reduced only if the potential presence of these organisms in raw foods of animal origin is taken into account and raw and processed animal foods are not mishandled. This involves application of the HACCP system at the food-processing plant and food service establishment (see Chapter 10). Thus, everyone throughout the entire food chain has to recognize the potential problems that these organisms can pose. Control of these organisms and hence elimination of public health hazards usually can be achieved (a) by proper heat processing of the food, and (b) by avoiding recontamination of the heat-processed food with the same or other pathogens from contaminated surfaces of equipment or utensils and through poor hygienic practices of food handlers. Application of proper refrigeration also is important in minimizing the hazard because in many foodborne disease outbreaks there is not only a history of contamination but also one of time-temperature abuse. Though low numbers of some pathogens may lead to illness, the likelihood of disease is greatly increased with increasing dosage.

In summary, a variety of pathogens can be expected as part of the normal flora of various raw foods of animal origin. They do pose definite health hazards in the entire food chain if proper preventive and control measures are not applied. Meat and poultry are the most important sources of foodborne illness in the United States, and failure to handle the raw and cooked materials properly in food-processing plants, food service operations, and in the home is the major cause of foodborne disease involving these foods in the U.S. Contamination of seafoods with pathogens of similar heat resistance as *Salmonella* do not cause, generally, the same foodborne disease problem in the United States as do red meat and poultry—though shellfish are not an insignificant source of other types of foodborne disease.

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Additional information related to this contract item can be found in Chapters 4 and 9.

VIII. The contractor will define the purposes for microbiological criteria and will make cost vs. benefit assessment for their use in regulatory control of raw and heat-processed foods.

The overall purposes of microbiological criteria for foods have been discussed in Chapter 2. This contract item requests that purposes of criteria for (1) raw and (2) heat-processed foods be defined. The subcommittee's response to this contract item is presented in Chapters 2, 3, 10, and particularly in Chapter 9. No summary response can do justice to this contract item; thus only a few isolated examples are given below.

Raw Foods

The usefulness of criteria for raw foods will vary depending upon food type (see Chapters 3 and 9). For example, sound raw fruits and vegetables may harbor high populations of microorganisms. Within reason, however, these numbers have little relationship to quality or production practices. Even when eaten raw, they have not presented a serious health problem in the United States. The routine testing of these foods for viable microorganisms offers few benefits. Microbiological standards for raw meat and poultry would prevent neither spoilage nor foodborne illness. On the other hand, the application of criteria to raw foods such as shellfish can be extremely useful. Shellfish harvested from polluted waters present a potential public health problem because they often are eaten raw. Criteria that include limits on fecal indicator organisms provide a very necessary safeguard for this class of food.

Heat-Processed Foods

There are a variety of thermal processes for foods ranging from the pasteurization of wines at relatively low temperatures to the use of retorts for the commercial sterilization of low-acid canned vegetables. The usefulness of microbiological criteria for regulatory control will vary with the process and the type of food. The application of criteria to foods such as pasteurized milk and egg products aids in assessing adequacy of the process and in the detection of contamination following heat treatment (see Chapter 9, parts A and F). Guidelines are useful for frozen vegetables to detect poor manufacturing practices following blanching. If proper action is taken, application of microbiological criteria to precooked ready-to-eat products can lead to rejection of product that has the potential to

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cause a public health problem. Criteria based on microscopic mold counts for certain canned fruits and vegetables aid in detecting poor quality raw materials and insanitary processing lines.

Cost/Benefits

Foods most amenable to microbiological criteria are those that have relatively stable microbial populations such as certain dried, heat-processed, and frozen products.

Benefits to be derived from microbiological criteria and appropriate actions on test results include:

1. An improvement in food safety by rejecting unsafe product on the basis of detection of pathogens or toxins.
2. Results indicating poor manufacturing practices may lead to action resulting in good manufacturing practices (better sanitation, improved process control, and monitoring of critical control points).

A disadvantage to the expanded use of microbiological criteria for finished products is increased costs that undoubtedly would be passed on to the consumer. Two of the sources of the costs are:

1. The costs of conducting a greater number of analyses by the processor and by regulatory agencies.
2. An increased holding time becomes a disadvantage when the manufacturer must delay shipments pending availability of test results.

It is extremely difficult to make an accurate assessment of the cost/benefit of the use of microbiological criteria. A few attempts have been made to establish the economic losses of foodborne illness. For example, some information has been presented relative to the economic losses of human salmonellosis (NRC, 1969).

Additional information related to this contract item can be found in Chapters 2, 3, 9, and 10.

IX. The contractor will evaluate at which level in the food chain microbial pathogens should be tested for in foods, by food class.

As indicated previously, small numbers of certain pathogens can be expected on part of our raw foods of animal origin. With few exceptions there is little merit in testing these foods for pathogens. In some instances raw imported foods (shrimp and frog legs, for example) are tested for *Salmonella* to detect gross mismanagement of these foods or the harvesting from fecal-polluted waters. In the case of shellfish, the water and the product are checked for either coliform or fecal coliform bacteria, which are used as an index of potential fecal contamination. In processed foods,

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relevant tests for pathogens are best conducted at the processing level, before the foods leave the processing plant, or at least before control of the product is lost by the manufacturer in trade channels. In addition to microbiological tests to check for effective processing at critical control points, "control at source" requires that control be exercised over inspection and maintenance of equipment and practice of sanitation in the processing plant, i.e., HACCP supplemented with appropriate finished product testing. When conditions related to a food after it has left the processing plant result in the introduction of pathogens and/or growth of pathogens, and in some cases production of toxin, then tests for pathogens might be necessary during transportation, warehousing, or at the retail level. Tests for pathogens might even be appropriately made in food service establishments such as a large food preparation and catering establishment where mishandling may result in growth of pathogenic organisms and in some cases attendant toxin production. In most cases, "control at source" will be most effective, but for certain foods and in certain uses of foods it may be necessary to conduct tests for pathogenic microorganisms at other points in the food chain. Regulatory agencies might appropriately test foods at any point along the food chain.

The presence and growth of pathogens in a food depends upon many factors, including the nature and source of the food, the physical-chemical properties of the food, and the conditions of processing, packaging, storage, and distribution. Therefore, only those pathogens should be tested for that are of public health relevance in a particular food. Chapter 9 of this report presents the relevant pathogens for which specific groups of foods should be tested and at which level in the food chain tests should be applied.

X. The contractor will examine relationships between food quality and microbiological characteristics and criteria of foods.

Food quality in the broad sense includes flavor, color, texture, nutritional value, and safety. At some point sufficient microbial growth will occur on a perishable food to affect its organoleptic properties, usually adversely. Volatile compounds may be generated that change flavor; pigments may be degraded or new colors produced; texture may be altered due to the activity of microbial proteases, pectinases, cellulases, and other hydrolytic enzymes; the utilization of food constituents and the release of metabolic products may influence nutritive properties.

The numbers needed to produce detectable changes will be influenced by food type and the predominant microorganisms. In terms of criteria established according to the principles of this report, the value of m represents levels consistent with Good Manufacturing Practices and is set

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at a level below that at which these characteristics become evident. The value of M relates to a point, and approaches to it, where the changes are or soon will be evident. Foods meeting these criteria will not show manifestations of quality deterioration (see Chapters 6 and 9).

When high microbial populations originate from contaminated equipment only, rather than from actual microbial growth on the food, fewer changes, either detectable or nondetectable, will occur. The types of microorganisms also can be important. Growth of lactic acid bacteria on meats, for example, produces less flavor change than comparable growth of certain pseudomonads.

While high counts may reflect lower quality or poor processing conditions, the opposite is not necessarily true. Low counts may result because the food was given a lethal treatment at a stage near the end of the process, or because many of the contaminating microorganisms had died off during storage of the food. The presence of pathogenic microorganisms, especially on ready-to-eat foods, is of course evidence of poor quality. The finding of excessive numbers of mold mycelia in certain foods such as catsup is evidence that it was made from raw materials containing rots. Additional information related to this contract item can be found in Chapters 2, 6, and 9.

XI. The contractor will evaluate at which level during harvesting, processing, storage, and distribution needed microbiological criteria can be best applied.

The objective of the criterion will determine when microbiological analyses should be performed.

If the criterion is a purchase specification that, for example, limits the number of heat-resistant mold spores in an ingredient, analyses usually are conducted by the purchaser when the shipment is first received at the plant. Frequently, the supplier analyzes the product before it is shipped to the purchaser.

If the criterion is a guideline designed to monitor a critical control point in a process, samples collected immediately after the unit operation might be analyzed.

If the objective is to assess good manufacturing practices, the level(s) at which microbiological testing should be conducted depends upon the processes to which such food is subjected. For some foods, microbiological testing of finished product after packaging may be appropriate to assess good manufacturing practices. With certain processes the analysis of the finished product would not be particularly useful to assess good manufacturing practices, for example, with a product subjected to a heat treatment. There are many situations where evaluating manufacturing practices would require microbiological testing at points other than finished products, for example, sanitary conditions of equipment.

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If the concern is abuse or contamination during transport of the food or while it is held in the marketplace or food service establishment, samples collected at the retail level should be analyzed. Furthermore, samples may be collected to monitor critical control points in food service establishments as well as in processing plants. Additional information related to this contract item can be found in Chapters 2 and 9.

XII. The contractor will determine the validity of aerobic and coliform plate counts as indicators of insanitation and of time-temperature abuse of foods.

High aerobic plate counts (APCs) in finished products or in products during processing may be caused by either poor sanitation or time-temperature abuse or both. Several other conditions, however, may be involved, such as the quality of raw materials and ingredients and adequacy of a heat-processing procedure if one is used. Hence, the APC can be a valid indicator of insanitation or of time-temperature abuse (primarily in perishable foods) if other potential causes are eliminated. The relationship of APC to insanitation or to time-temperature abuse can be determined best by a thorough understanding of the microbiology of the product (hazard analysis) and examination of line samples taken at critical control points. For example, a high APC of packaged ground beef may have resulted from (a) poor-quality trimmings, (b) poor sanitation of equipment (for example, grinder), and (c) holding of the product for too long or at marginal temperatures at which normal aerobic, psychrotrophic, gram-negative rods continue to multiply.

Coliform bacteria are particularly valuable as indicators of postprocessing contamination of foods treated for safety. The validity of coliform counts as an indicator of insanitation and of time-temperature abuse requires a thorough understanding of the microbiology of a food. In some foods they have little relationship to the above-mentioned conditions, in others they have more. Coliforms can be a valid indicator of poor sanitation if it can be shown that their presence at a particular point in the processing and handling of a food is not expected or their numbers are at a level beyond what is considered normal. For example, small numbers of coliforms are common in raw milk, vegetables, and meats. Large numbers in raw milk indicate insanitation and likely time-temperature abuse. Even small numbers of coliforms in pasteurized milk indicate postpasteurization contamination. In heat-processed foods, the presence of coliforms indicates most likely contamination (poor sanitation) after heating that may be accentuated by time-temperature abuse of the food.

Additional information related to this contract item can be found in Chapter 5.

XIII. The contractor will determine the validity of aerobic and coliform counts as significant or useful indices as one facet of food "quality."

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This question has been discussed extensively in Chapter 2 of this report. Appropriate sections are repeated here to emphasize certain aspects of this question.

The term quality as commonly applied to food summarizes its desirable characteristics. Quality of a food as perceived by the public can be described as a value related to flavor (taste and odor), color, and texture. It also includes imperceptible traits such as nutritional value and safety. Excluding safety and utility from this discussion, from the microbiological viewpoint quality includes: (a) shelf-life, as perceived by attributes such as flavor and appearance, and (b) adherence to Good Manufacturing Practices.

Each of these attributes is measurable to some extent microbiologically; the decisive question, however, is to what extent.

The ultimate shelf-life of a perishable food can be estimated to some degree through the application of microbiological criteria. Assuming that storage conditions are the same, a perishable food with a low number of spoilage microorganisms will have a longer shelf-life than the same product with larger numbers of such organisms. However, relationships between common microbiological parameters such as aerobic plate counts and coliform counts and the shelf-life of a food are inexact. Some types of microorganisms, because of enzyme systems acting upon the constituents of a food, cause marked changes in perceptible quality characteristics of a food while others are relatively inert biochemically and thus produce little change. In addition, the effect of certain levels and/or types of microorganisms on perceptible quality characteristics often differs from food to food and is also subject to changes in environmental conditions such as temperature and gaseous atmosphere.

Lack of adherence to Good Manufacturing Practices often can be related to APC and/or coliform counts in excess of those present in a food produced under good conditions. The use of poor-quality materials, inadequate heat processing, careless handling, or insanitation may result in a higher bacterial count in the finished product. This relationship may not always be valid, however, because a heat treatment or other lethal treatment in the process can cover up the grossest evidence of malpractice, and organisms may die off during storage of frozen, dried, or fermented foods. Low counts in a finished product or ingredient, therefore, do not necessarily indicate good manufacturing practices or even food safety. High aerobic plate counts, on the other hand, do not necessarily mean careless handling or lack of wholesomeness. For example, ground beef prepared from the trimmings from carcasses may yield a high aerobic plate count, but this may merely reflect the growth of harmless psychrotrophic bacteria during refrigerated storage. On the other hand, it could also represent poor sanitary conditions and/or time-temperature abuse.

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The relationship between the microbiology of a food and adherence to good manufacturing practices must be established by conducting repeated surveys of processing lines to obtain statistically valid data. The critical control points must be identified and the microbiology of the food at the different stages of processing must be determined. Through these studies one can arrive for some foods at numbers and types of organisms that characterize the flora of a food produced under a given set of conditions, and thus provide a basis for the establishment of a microbiological criterion. Even then an allowance has to be made for variations because of differences in processing procedures and equipment. Finished foods that exceeded the criterion might reasonably be expected to have been mishandled somehow during production and/or storage.

In recent years microbiological quality standards (APC and coliform counts) have been proposed for various foods under Section 401 of the Food, Drug and Cosmetic Act. Recently, they have been recommended for frozen fish sticks, fish cakes, and crab cakes. This has been discussed extensively in Chapter 2.

Additional information related to this contract item can be found in Chapters 2 and 5.

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