

(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:

<u>Food Category</u>	<u>Number of Sample Units</u>
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

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

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.

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:

^aCategory II: Thirty 25-g samples.

^bCategory III: Fifteen 25-g samples.

SOURCE: Sillicker, 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*

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).

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, thermophilic, 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

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,

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

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.

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

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-

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

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.

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.