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



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Criteria for Foods and Food Ingredients



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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

National Research Council



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This report has been reviewed by a group other than the authors according to procedures approved by a Report Review Committee consisting of members of the National Academy of Sciences, the National Academy of Engineering, and the Institute of Medicine.

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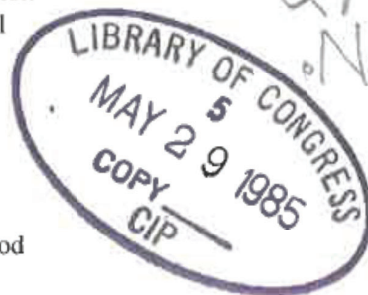
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Appendix A

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.

I. 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

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

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

Type of Food	Hazard characteristic ^a			Category
	A	B	C	
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

^aA = 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.

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

^aAccuracy of Attribute Sampling, USDA Consumer and Marketing Service, March 1966.

^bNot normally applicable.

SOURCE: NRC, 1969.

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*