

MICRO- ORGANISMS IN FOODS 2

Sampling for microbiological analysis: Principles and specific applications

Second edition

Microorganisms in Foods, Volume 2

Sampling for Microbiological Analysis: Principles and Specific Applications

Second Edition

International Commission on Microbiological Specifications for Foods

This thoroughly revised, updated, and much expanded edition of *Microorganisms in Foods 2* retains the basic format and purpose of the first edition published in 1974. It preserves the statistical treatment, but Part I (Principles) now includes a discussion of the Hazard Analysis Critical Control Point concept and Part II (Specific Proposals for Sampling and Sampling Plans) has been reorganized into sixteen commodity categories: raw meats; processed meats; poultry and poultry products; feeds of animal origin and pet foods; milk and milk products; eggs and egg products; fish and shellfish; vegetables, fruits, and nuts; soft drinks, fruit juices, concentrates, and fruit preserves; cereals and cereal products; spices, condiments, and gums; fats and oils; sugar, cocoa, chocolate, and confectionery; formulated foods; natural mineral waters, other bottled waters, process waters, and ice; and shelf-stable canned foods. In addition, Part I has been revised to include microbiological hazards which have only recently come to light.

This new edition will be of even greater value than the first to food microbiologists and those responsible for food quality control and public health.

The International Commission on Microbiological Specifications for Foods, a standing commission of the International Union of Microbiological Societies, was formed in 1962 in response to the need for international microbiological specifications for foods. Its members are internationally known food microbiologists, drawn from government laboratories in public health, agriculture, and food technology, and from universities and the food industry.



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MICRO- ORGANISMS IN FOODS

2

Sampling for microbiological analysis: Principles and specific applications

Second edition

The International Commission on
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of the International Union of
Microbiological Societies

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Preface to the second edition

In the first edition of this book (ICMSF, 1974; reprinted 1978), a group of food microbiologists and statisticians discussed the statistical aspects of sampling foods for microbiological analysis, presented the concept of 2- and 3-class attribute sampling plans, and suggested microbiological criteria for a range of food products and ingredients that move in international trade.

In subsequent years, these concepts have been increasingly embraced by the food industries and by national and international food-control authorities. In related activities, ICMSF undertook a series of international collaborative and comparative trials on media and methods for the isolation and enumeration of microorganisms in foods (Appendix 4) and at the request of the World Health Organization an ICMSF committee prepared a document on the application to food processing of the Hazard Analysis and Critical Control Point (HACCP) concept (WHO/ICMSF, 1982). Also during this period the ICMSF's first volume on laboratory methods was revised (ICMSF, 1978) and its third book (ICMSF, 1980a, b) was published. The latter book presents the principles of food microbiology and discusses in detail microbiological ecology in relation to both food processes and individual foods. It includes treatment of microbial hazards in foods and the reasoning behind the selection of cases for attributes sampling plans.

The purposes and organization of this book are described in detail in the preface to the first edition (see pp. xix–xxii below). The present edition preserves the statistical treatment, but Part II has been reorganized to follow the commodity categories in the ecology book (ICMSF, 1980b). Consideration of the 'General Principles for the Establishment and Application of Microbiological Criteria for Foods' (Codex, 1981), accumulated microbiological data, and experience in the use of the

criteria cited in the first edition have resulted in either addition or deletion of criteria for some foods and modification of criteria for others.

These criteria are generally recommended for port-of-entry sampling and examination of foods. They are not necessarily appropriate to control of processing. However, guidelines are also suggested in some chapters to assist in process control in food plants.

The sampling plans suggested in this book are statistically based and derived from the best available microbiological data. In applying them, however, the microbiologist must make the final judgment based on experience and on the prevailing circumstances.

The Commission hopes that this edition will be of even greater value to food microbiologists than the first has been, and that they will continue to provide members of the Commission with advice and data on the microbiology of foods.

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The Commission is most grateful for advice and assistance from many scientists in the revision of this book, and in particular for the help of Mr D. Kilsby and Dr. G. Jarvis in statistical matters. Thanks are also due to the Editorial Committee chaired by Dr T.A. Roberts and to the chairmen of the chapter subcommittees.

This revision would have been impossible without financial sponsorship from many quarters, and the Commission is indebted to the World Health Organization and to many companies within the food industry for their generous support (see Appendix 3). Much of the revision was centred on workshops held in Stresa, Italy (1980), Chexbres, Switzerland (1981), and Anaheim, USA (1982) and on editorial discussions in Los Angeles, USA (1982), Montreux, Switzerland (1983), and Bedford, England (1983). Sincere thanks are extended to the hosts and organizers of these meetings.

Finally the Commission expresses its gratitude to various national governments, universities, and private companies for supporting the participation of their staff in the activities of the ICMSF.

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Preface to the first edition

Microbiological methods, no matter how accurate and reproducible, are inadequate to appraise the microbiological quality of food without a satisfactory sampling plan. Sampling plans in current use are often badly understood and highly unsatisfactory, and the level of safety they provide is generally not well known. At present, no comprehensive publication exists dealing with statistically based sampling plans, broadly applicable to the field of food microbiology. The facts that the production of foodstuffs is gradually being centralized in enlarging enterprises and that foodstuffs are moving in international commerce on a rapidly increasing scale make the need for such plans still more obvious. The Commission decided to try to fill this gap and, to that end, called upon expert statisticians and commodity specialists to supplement its own areas of competence.

The primary aim of this book is instructional: to draw attention to the unsatisfactory nature of casual sampling, and to provide information necessary to improve the situation. The immediate objectives are: to describe what different sampling plans can achieve in principle; to establish their significance for the interpretation of the results of microbiological testing of foods; and to offer guidance as to the choice of appropriate sampling plans in different situations.

The cost of sampling and testing and inadequate awareness of the principles involved nearly always preclude the use of an ideal sampling plan, and lead to the use of sampling procedures that are far from satisfactory in both nature and scope. Such a situation seems likely to produce an unjustified feeling of security in those responsible for the interpretation of the results. Improved sampling plans as indicated in this book will give a basis for statistically valid and realistic judgment of the microbiological quality of foods under test.

The Commission has limited its scope both in the previously published book and in the present text to the range of competence of its members and advisers. Thus neither includes the fields of parasitology, virology, and mycology. Incomplete survey data imposed additional limitations. The criteria proposed herein were based primarily on the knowledge of experts in the various commodity fields. They will apply to many situations, but must be tempered with good judgment in particular instances. The Commission intends to collect further information on these matters, which will probably make imperative a revision of this text in the relatively near future.

The scope and limitations, as outlined above, indicate that the book is intended primarily for people dealing with the microbiological safety of food moving in international and domestic commerce. National food control and public health authorities, food manufacturers, international organizations, and teachers in food microbiology should also find it useful.

The substance of the book falls into two parts: the principles of sampling (Part I), and the application of these principles to suggest sampling plans for various foods (Part II). Part I defines the statistical concepts and terms used in the book, describes the kind of sampling plans available and their purposes, outlines the procedures for selecting the best plan for the food and organism in question, and explains the principles of randomization. Part II describes practical applications of the principles set out in Part I and treats the procedures for collecting and handling sampling units for various food categories.

The text ends with general conclusions and a glossary of special terms.

The text is the result of five years of study by ICMSF members and consultants, involving workshops held in Dubrovnik, Yugoslavia (1969), Mexico City, Mexico (1970), Opatija, Yugoslavia (1971), Langford, England (1972), and Ottawa, Canada (1973). The project was proposed and planned by the chairman, F.S. Thatcher, after initial phases of collaboration with the chairman of the Statistics Committee, D.F. Bray. Major segments of the work were first studied by subcommittees and then discussed in plenary sessions. Results were compiled as minutes by the secretary, D.S. Clark, and later drafted into book form by the chairman, F.S. Thatcher. Subsequent compilation and rewriting was done by the various subcommittees. Editing was the responsibility of an editorial committee under Chairman M. Ingram.

The group represented a range of opinions and principles, whose

expression required constructive compromise. For example, the impracticability at present of insisting that *Salmonella* be undetectable in some raw meats had to be reconciled with the reluctance to sanction the presence of a pathogen in any food. The sampling plans described herein are not inflexible standards. If applied with increasing stringency they should permit improvement in microbiological quality without making necessary the condemnation, in prohibitive proportion, of important foodstuffs.

NOTICE

The main aims of this book are to show what sampling plans can do and what their advantages are over casual sampling procedures. The examples set out in Part II are only intended to illustrate the organisms important in the different foods and how, for each, limits might be set. The Commission has not decided whether there is a sufficient need to apply all these limits. Moreover, the actual limits chosen are based on information readily available to the Commission, which is mainly derived from a restricted range of countries and conditions; hence the suggested values are likely to need revision if applied to different circumstances. The values indicated are certainly not intended as hard and fast limits for universal application.

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Sincere thanks are extended to the many scientists who contributed to this book, in particular: Dr D.F. Bray, Professor I.W. Burr, and Dr E.F. Drion, who guided the Commission on statistical questions; Mr G.G. Anderson, Dr J. Liston, Dr C.F. Niven, and Dr J.M. Shewan, whose advice and assistance were much appreciated; the chairmen of the various subcommittees; and also the staff of the National Science Library of Canada, for confirming the accuracy of the reference citations.

The Commission is most grateful for generous financial sponsorship without which the work would have been impossible: from the United States Department of Health, Education and Welfare, Public Health Service, Health Services and Mental Health Administration, Center for Disease Control; the World Health Organization; Canada Department of National Health and Welfare, Health Protection Branch; and various companies within the food industry. This assistance does not, of course, constitute endorsement of the findings and views expressed

herein. Finally, thanks are also expressed to the respective national governments, universities, and private companies for supporting the participation of their staff in the work of the Commission, of which the present text is but one result.

Abbreviations of societies and agencies

AMI	American Meat Institute
AOAC	Association of Official Analytical Chemists
APHA	American Public Health Association
CEC	Commission on the European Communities
DHSS	Department of Health and Social Security (UK)
EEC	European Economic Community (now European Communities)
FAO	Food and Agriculture Organization of the United Nations
FDA	United States Food and Drug Administration
FPI	Food Processors Institute
HPB	Health and Protection Branch, Health and Welfare Canada
HWC	Health and Welfare Canada
IAMS	International Association of Microbiological Societies
ICMSF	International Commission on Microbiological Specifications for Foods
IDF	International Dairy Federation
IEC	International Egg Commission
IOCC	International Office of Cocoa and Chocolate
ISO	International Standards Organization
IUBS	International Union of Biological Societies
IUMS	International Union of Microbiological Societies
NAS	National Academy of Sciences of the United States
NCA	National Canners Association
NCDC	United States National Communicable Disease Center
NCI	National Cheese Institute
NFPA	National Food Processors Association
NRC	National Research Council of the United States

Concepts of probability and sampling

Consider a trial or a test the outcome of which is doubtful, such as a test for the presence of an organism in a food. After the standard procedure has been followed, the test either shows the presence of the organism or it does not; thus we have a positive or a negative result. We have resolved the pre-test uncertainty.

If there were relatively many of the organisms present in the food sampled, we would expect relatively many such tests to yield a positive result. But if there were relatively few organisms present, we would expect that relatively few tests would yield a positive result. In the two cases, the 'probability' of a positive result would be respectively high and low.

A. PROBABILITY

The probability of a positive result is, in fact, the 'long-run' proportion of times a positive result occurs out of all the times we test the food. Thus, if a positive result occurs 112 times in 1000 tests, we estimate the probability to be $112/1000 = 0.112$, while if it occurs 914 times in 1000 trials, we estimate the probability to be $914/1000 = 0.914$.

The word 'estimate' is used because, if we were to run 1000 trials again on the same material and using the same procedure, we could not be sure of observing 112 and 914 positive results, respectively. But the results should be close to these, because 1000 is a large number of trials. Thus the estimated probability of a positive result, or any other 'outcome in some other type of test, is the proportion of times the outcome did occur among the trials or tests actually made. A probability can be anywhere from 0 to 1. It will be zero if the organism

is absent from the food (assuming a test procedure that will detect any organism present), and 1 if every one of a large number of tests provides a positive result.

What does an observed proportion of trials such as 0.112 estimate? Suppose we divided the entire lot of food into small sample units, say perhaps 10,000,000 one-gram units, and then went through the test procedure on each of these sample units. Suppose 1,051,200 gave positive results. Then the ratio $1,051,200/10,000,000$ (the actual proportion of positives) = 0.10512 is the measure of the probability. But what kind of measure? This is no longer an 'estimate' of the probability of a positive result. Instead, it is the 'true probability' or 'population probability.' Of course, this approach is not practical, because of the test time needed, and because there would be no food left to eat! But it is useful to have this concept in mind. The 'population probability' determines the kind of sample probabilities or estimated probabilities we may expect from a given number of sample units examined. If that number is low, the estimated probability is not likely to be precise. In general, we never know the true or population probability, but have only estimates of it. But we do know that the larger the number of units included in the sample of the population, the closer the estimated probability is likely to be to the population probability.

B. POPULATION AND SAMPLE OF THE POPULATION

The preceding section introduced the two basic concepts: (i) population as a whole and (ii) sample of the population. In relation to results of an experimental test, these are, respectively, the whole set of results of the test made on each and every unit in the lot of food and the partial collection of such results, derived only from the group of sample units actually examined. In terms of standard plate counts, for example, these concepts would be represented by (i) all the counts that could be made by examining every unit in the lot and (ii) those counts actually made on the few sample units examined. Statisticians use the word 'sample' for the group of units which is withdrawn to estimate the character of a population, while an analyst or bacteriologist would call any one of these units a 'sample.' To try to minimize the confusion, we distinguish between 'the sample of the population' and the 'sample units' of which it is composed.

C. DISTRIBUTION OF COUNTS

Any series of measurements or counts can be analysed by tallying, that is, by taking each number in turn, and tallying it in whatever numerical interval it falls. For example, we might have classes for plate counts of 8000–9999, 10,000–11,999, 12,000–13,999, etc. Then we tally each count in the class to which it belongs. This arrangement of observed data into classes is called a ‘frequency distribution.’ In order to find the estimated probability of a count between, say, 10,000 and 14,000, we add the frequencies for those classes lying between these limits, namely 10,000–11,999 and 12,000–13,999, and then divide the sum of these two frequencies by the total frequency for all the classes. For example, this might be 15 divided by 300, which would be 0.050. In general, the larger the total number of counts tallied, the more the frequencies of the classes tend to smooth out on plotting and appear like a curve.

D. CHOOSING THE SAMPLE UNITS

Chapter 3 describes how to choose the material to be tested from the total amount in the lot or shipment. The important point is to avoid bias, so that the sample of the population may represent the lot as well as possible. Random choice is one way of achieving this. Thus, if we can think of the lot as made up of a population of 10-gram blocks called ‘sample units,’ and we decide upon a sample from this population of 10 such units, then we should choose these units in such a way that each sample unit in the lot has the same chance of being included among the sample units chosen. At the very least, we should try to draw test material from all parts of the lot.

E. THE SAMPLING PLAN

The sample units so drawn will, after examination, yield results which will be compared with certain criteria to reach a decision as to whether the entire lot should be accepted or rejected (see Section H below for explanation of rejection). The particular choice of sampling procedure and the decision criteria is called the ‘sampling plan.’ Proper drawing of samples is essential if the decision-making criteria of the sampling plan are to give unbiased results. By sampling randomly we are able to reduce the risk of making wrong decisions.

A simple example of a sampling plan follows. Take 10 sample units of a food from a lot and subject them to appropriate laboratory procedure to test for the presence or absence of a microorganism. If two or fewer of the 10 sample units show presence of the organism, that is, give a 'positive' result, then the whole lot of food is acceptable (relative to this organism). But if three or more give a positive result, the whole lot is to be rejected. This plan is described by $n = 10$ (number of sample units drawn) and $c = 2$ (maximum allowable number of positive results).

F. THE OPERATING CHARACTERISTIC CURVE

In section E we described what we mean by a sampling plan, and gave an example of a simple sampling plan based upon positive and negative indications of a microorganism. This plan was described by the two numbers $n = 10$, $c = 2$. If we are going to use this plan, we want to know what it will do for us. How discriminating is it? It is possible when using such a plan that it will sometimes, though rarely, accept a relatively poor lot; it is also possible, though rarely, for it to reject a relatively good lot. There is no way to avoid some degree of risk in each acceptance and in each rejection, unless we test the entire lot, in which case no edible food will be left. We can make these risks smaller by testing more sample units; that is, by using a larger number of samples (larger n). In fact, we can reduce the risks to any desired level by making n sufficiently large. But in practice we usually have to seek a compromise between (a) large n (many sample units) and small risks, and (b) small n (few sample units) and large risks.

Here we often use an 'operating characteristic' curve (abbreviated as OC curve). Such a curve has two scales. The vertical scale gives the probability of acceptance, P_a ; that is, P_a is the expected proportion of times that the results will indicate 'pass the lot' out of the number of times a lot of this given quality is sampled for a decision. The horizontal scale shows a measure of lot quality. The commonest measure of lot quality is the true probability or percentage of times that a test on a sample unit from a lot of this quality would show an unsatisfactory result (e.g., a 'positive,' or a count above some number m). This is called p , and might be anywhere between 0 and 100%. This probability is commonly expressed as percentage of 'defectives.' Let us see how the probability runs $n = 10$, $c = 2$ (the calculations are carried out by using the so-called binomial distribution):

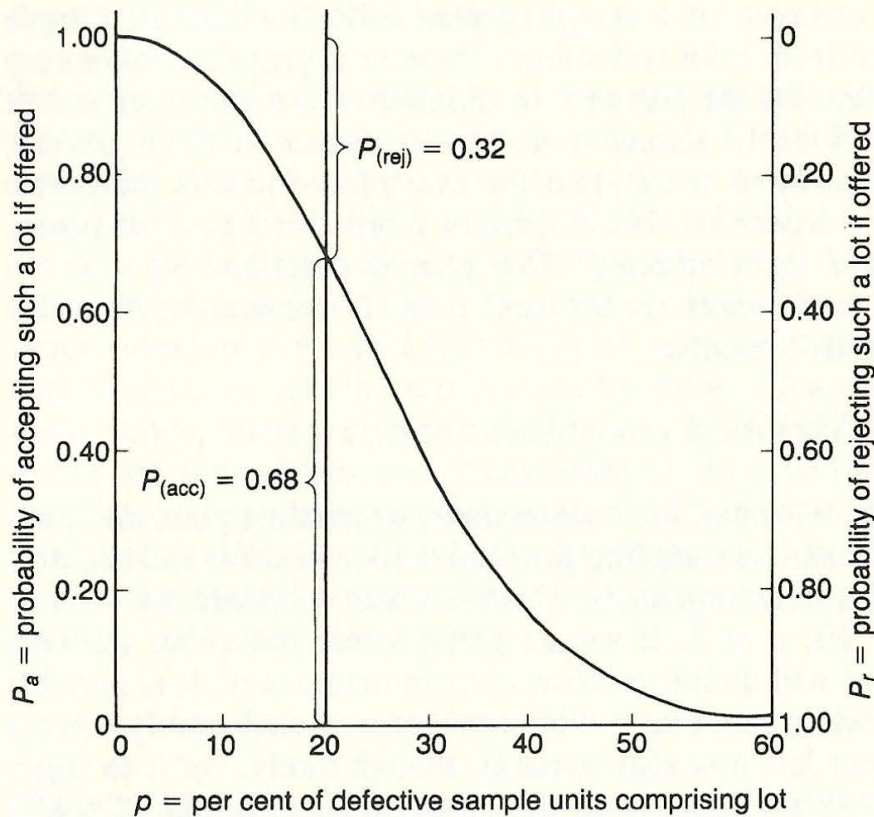


Figure 1. The operating characteristic curve for $n = 10$, $c = 2$, i.e., the probability of accepting lots, in relation to the proportion defective among the sample units comprising the lots

$p\%$	0	10	20	30	40	50	60
P_a	1.00	0.93	0.68	0.38	0.17	0.05	0.01

Figure 1 shows the full curve (cf. Table 3, p. 35). We see that the greater the probability (p) that a test unit from a given lot yields a positive result, the lower is the probability of acceptance (P_a) of that lot. If, for example, we set a limit of 20% defectives (i.e., $p = 20\%$), then $P_a = 0.68$. This means that on 68 of every 100 occasions when we sample a 20% defective lot, we may expect to have 2 or fewer of the 10 tests showing the presence of the organism and thus calling for 'acceptance,' while on 32 of every 100 there will be 3 or more positives, calling for non-acceptance. But if $p = 10\%$ (i.e., 10% positive units in the lot), such lots will be accepted 0.93 of the time; or if $p = 40\%$, such lots will be accepted 0.17 of the time. Thus lots with 10% of the sample units defective will be accepted most of the time, but with 40% defective, rather seldom.

G. CONSUMER RISK AND PRODUCER RISK

Since decisions to accept or reject lots are made on samples drawn from the lots, occasions will arise when the sample results do not reflect the true condition of the lot. The 'producer's risk' describes the probability that an 'acceptable' lot if offered will be falsely rejected. The 'consumer's risk' describes the probability that a 'bad' lot when offered will be falsely accepted. 'Consumer's risk,' for the purpose of this text, is considered to be the probability of accepting a lot whose actual microbial content is substandard as specified in the plan, even though the determined values indicate acceptable quality. This is expressed by the probability of acceptance (P_a) as given in Tables 2-5 in Chapter 4. The 'producer's risk' (the obverse of 'consumer's risk') is expressed by $1 - P_a$.

H. ACCEPTANCE AND REJECTION

We have been speaking of acceptance or rejection of a lot, on the basis of a sampling plan associated with some particular microbiological test. This judgment, of course, applies only to the purpose for which that test (or several such tests) was performed. A food unsuitable for one purpose may still be suitable for another; for example, if 'rejected' for humans it might still be suitable for animals. Or a rejected food might even, if sorted to remove objectionable material or if reprocessed, be so improved as to pass the test and become acceptable for the original purpose. Normally, therefore, a rejected lot will simply be withheld while the responsible authority decides what to do with it: to return it to the producer, order reprocessing, forbid its use for human consumption, or order its destruction, according to circumstances. Throughout this text, the terms 'accept' and 'reject' are used in this limited sense.

Principles of drawing samples

Sampling is necessary because it is not feasible to examine microbiologically an entire lot of food. Results from the portion of the lot represented by the sample are used to draw conclusions about the whole (the lot). The process involves the concepts of 'population,' 'sample' (made up of 'sample units'), and the associated 'probability,' discussed in Chapter 2.

A. WHAT IS A 'LOT'?

Ideally a lot is a quantity of food or food units produced and handled under uniform conditions. The implication is that there is a homogeneity within a lot, which, when considering microbial levels and distributions, rarely occurs in practice. In most instances the distribution of microorganisms within 'lots' of food is heterogeneous. Even in food factories this heterogeneity makes the interpretation of sample results difficult, and it becomes even more so in circumstances where a lot is less well defined, such as in a consignment of a very large quantity of food.

It is therefore helpful if suppliers can be persuaded to give identifiable code numbers to batches (lots) of food produced over short time periods (e.g., a day or part of a day), for particular processes. The choice of coding system will vary from process to process depending on the type of process and degree of homogeneity within the batch. For example, a continuous process may produce a relatively homogeneous product, in which case a lot could include units produced continuously over a relatively long time, whereas a batch process, such as batch retorting, may require the coding of relatively few product units as one lot (e.g., one retort load).

If a consignment consisting of a mixture of production batches is treated as one lot, the producer's risk (i.e., the risk that an acceptable lot will be rejected) can be high, even though relatively few of the production batches within the lot are of poor quality. Treating the individual production batches as lots, and coding appropriately, permits more precise identification of poor-quality food and, at the expense of more analyses, can result in the rejection of less units from the whole consignment.

A lot should be composed of food produced with as little variation as possible for a given process or commodity. Because of the uncertainties in identifying a lot commercially, however, the use of the word 'lot' in this book is usually in its 'statistical' sense, as a collection of units of a product, the acceptability of which is determined by examining a sample drawn from it.

B. WHAT IS A 'REPRESENTATIVE' SAMPLE?

A 'representative' sample reflects, as far as is possible, the composition of the lot from which it is drawn.

How then should a representative sample be drawn? It is important to avoid bias and to draw a sufficient number of sample units to confidently make a judgment about a lot. Sampling at random is the universally recognized way of avoiding bias and is more reliable than consciously trying to draw the sample units from the various parts of a lot. The units (cartons or containers, particular weights of solid, or volumes of liquid) are drawn by using random numbers. There is, of course, no guarantee that a random sample (see Section C below) has characteristics identical with those of the lot, but it is more likely to have than samples chosen non-randomly.

It is also possible, and may be desirable, to use a 'stratified' random sampling approach, drawing a random sample of a given number of sample units from each 'stratum' (e.g., each subplot or carton). The objective is to give each small bit of material within each stratum an equal chance to be in the total sample. Such stratification is a device for handling known sources of variation, and may be used where one has prior knowledge that the consignment is potentially not of uniform quality. A consignment might not be of uniform quality if portions of it are shipped in different vehicles or in different holds of a vessel, or if it is known that it is really composed of several lots, representing, for example, different days of production from the same plant or different plants of the same company. The results for different strata

should be assessed separately and then pooled if they appear to be homogeneous.

C. USE OF TABLE OF RANDOM NUMBERS

The generally accepted method of random sampling is to use a table of random numbers, comprising columns of single digits 0, 1, 2, ..., 9 in random order (Table 1). These have been generated randomly so that, in any column, any digit is completely independent of the preceding digits in this or other columns. (At each place the probability for each one of the ten digits to appear next is 0.1.)

To use a table of random numbers or digits, first give consecutive numbers to the packages, containers, or other units in the lot that is to be sampled, in any convenient order. Then pick a page of the table of random numbers (Table 1) – for example, by using numbered cards in a box. Next, without looking, bring a pencil point down on some place on the page. The digit nearest the point is the first digit of the number of the first sample package. Take as many columns to the right of that in which this digit appears as are needed to number all the packages in the lot. The digits in these columns in the same row as the first digit chosen complete the number of the first sample. The numbers of additional sample packages are the following numbers in the designated columns. Note that the column numbers are indicated at the top of the table and that each column consists of a vertical row of one-digit numbers. The columns are arranged in groups of five to facilitate identification.

To clarify this procedure, take the following example. Suppose a lot of 600 packages has been numbered 1, 2, ..., 600. Then one needs a random number consisting of three random digits in the chosen three consecutive columns, for each package to be sampled. Suppose the pencil hits row 48 and column 10, on the first page of Table 1. Then in row 48 take the three digits in columns 10, 11, and 12; these are 245. Then take package 245 for the sample. In row 49 in the same three columns one next finds 068. So, take package 68 for the sample. Then go to row 50 on the next double page and find 931 in columns 10, 11, and 12. This is outside the range of 1 to 600, so discard it and also the next number 842. Since the next one is 142, take package 142 for the sample. If selection at random yields a number corresponding to a package that has already been chosen, simply go to the next number, and so on, until the required number of sample packages has been assembled.

D. FUNDAMENTAL PRINCIPLES

The number of sample units n refers to the number of units that are chosen separately and independently. For food in small packages, the sample unit is often the individual package. For bulk materials, it is necessary to imagine a number of sample units within each large container, of a size equal to that subsequently subjected to individual analysis. The concepts of random sampling, stratification, and heterogeneity are relevant (see Section B above). A sample of 1000 g consisting of ten units of 100 g individually collected at random would consist of 10 sample units ($n = 10$), whereas, if all 1000 g are taken from one place, n would equal 1; or, drawing two independent sample units of 500 g, $n = 2$.

The effective sample of the population consists only of those sample units that are actually examined. If ten sample units are drawn, but only three are examined, the sampling plan is one in which $n = 3$, not $n = 10$, and the probability of accepting defective lots is correspondingly increased.

The governing factor is not the proportion of the lot sampled, but rather the total gross size of the random sample of the population (number and size of sample units) and the related acceptance/rejection criteria. A random sample of 100×5 g sample units does very nearly as well for a 500,000 g lot as it does for a lot of 10,000 g. The main reasons for drawing a somewhat smaller sample of the population (i.e., fewer sample units) from a small than from a large lot are economics and the greater importance of the decision on the large lot. Trying to sample a fixed proportion of the lot is not a sound concept.

The concept of frame vs consignment is applied whenever it is possible to take a random sample not from an entire consignment but only from some accessible portion of the consignment, this portion of the consignment being called the 'frame.' Sample units are then chosen randomly from the frame. After analysis the sampling results and conclusions technically apply only to the frame, not the consignment.

E. PRACTICAL CONSIDERATIONS

To use available resources to the best effect, all food cannot receive the same attention. The important foods, and lots, should receive the most time and effort, which means that they should be subjected to the most intensive sampling. What factors govern this decision?

(a) *Hazard*. The most important factor is the hazard involved. How

TABLE 1*

Ten thousand random digits

	00-04	05-09	10-14	15-19	20-24	25-29	30-34	35-39	40-44	45-49
00	88758	66605	33843	43623	62774	25517	09560	41880	85126	60755
01	35661	42832	16240	77410	20686	26656	59698	86241	13152	49187
02	26335	03771	46115	88133	40721	06787	95962	60841	91788	86386
03	60826	74718	56527	29508	91975	13695	25215	72237	06337	73439
04	95044	99896	13763	31764	93970	60987	14692	71039	34165	21297
05	83746	47694	06143	42741	38338	97694	69300	99864	19641	15083
06	27998	42562	63402	10056	81668	48744	08400	83124	19896	18805
07	82685	32323	74625	14510	85927	28017	80588	14756	54937	76379
08	18386	13862	10988	04197	18770	72757	71418	81133	69503	44037
09	21717	13141	22707	68165	58440	19187	08421	23872	03036	34208
10	18446	83052	31842	08634	11887	86070	08464	20565	74390	36541
11	66027	75177	47398	66423	70160	16232	67343	36205	50036	59411
12	51420	96779	54309	87456	78967	79638	68869	49062	02196	55109
13	27045	62626	73159	91149	96509	44204	92237	29969	49315	11804
14	13094	17725	14103	00067	68843	63565	93578	24756	10814	15185
15	92382	62518	17752	53163	63852	44840	02592	88572	03107	90169
16	16215	50809	49326	77232	90155	69955	93892	70445	00906	57002
17	09342	14528	64727	71403	84156	34083	35613	35670	10549	07468
18	38148	79001	03509	79424	39625	73315	18811	86230	99682	82896
19	23689	19997	72382	15247	80205	58090	43804	94548	82693	22799
20	25407	37726	73099	51057	68733	75768	77991	72641	95386	70138
21	25349	69456	19693	85568	93876	18661	69018	10332	83137	88257
22	02322	77491	56095	03055	37738	18216	81781	32245	84081	18436
23	15072	33261	99219	43307	39239	79712	94753	41450	30944	53912
24	27002	31036	85278	74547	84809	36252	09373	69471	15606	77209
25	66181	83316	40386	54316	29505	86032	34563	93204	72973	90760
26	09779	01822	45537	13128	51128	82703	75350	25179	86104	40638
27	10791	07706	87481	26107	24857	27805	42710	63471	08804	23455
28	74833	55767	31312	76611	67389	04691	39687	13596	88730	86850
29	17583	24038	83701	28570	63561	00098	60784	76098	84217	34997
30	45601	46977	39325	09286	41133	34031	94867	11849	75171	57682
31	60683	33112	65995	64203	18070	65437	13624	90896	80945	71987
32	29956	81169	18877	15296	94368	16317	34239	03643	66081	12242
33	91713	84235	75296	69875	62414	05197	66596	13083	46278	73498
34	85704	86588	82837	67822	95963	83021	90732	32661	64751	83903
35	17921	26111	35373	86494	48266	01888	65735	05315	79328	13367
36	13929	71341	80488	89827	48277	07229	71953	16128	65074	28782
37	03248	18880	21667	01311	61806	80201	47889	83052	31029	06023
38	50583	17972	12690	00452	93766	16414	01212	27964	02766	28786
39	10636	46975	09449	45986	34672	46916	63881	83117	53947	95218
40	43896	41278	42205	10425	66560	59967	90139	73563	29875	79033
41	76714	80963	74907	16890	15492	27489	06067	22287	19760	13056
42	22393	46719	02083	62428	45177	57562	49243	31748	64278	05731
43	70942	92042	22776	47761	13503	16037	30875	80754	47491	96012
44	92011	60326	86346	26738	01983	04186	41388	03848	78354	14964
45	66456	00126	45685	67607	70796	04889	98128	13599	93710	23974
46	96292	44348	20898	02227	76512	53185	03057	61375	10760	26889
47	19680	07146	53951	10935	23333	76233	13706	20502	60405	09745
48	67347	51442	24536	60151	05498	64678	87569	65066	17790	55413
49	95888	59255	06898	99137	50871	81625	42223	83303	48694	81953

*From *Principles and Procedures of Statistics* by R.G.D. Steel and J.H. Torrie (McGraw-Hill, 1960).
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TABLE 1 (continued)

	50-54	55-59	60-64	65-69	70-74	75-79	80-84	85-89	90-94	95-99
00	70896	44520	64720	49898	78088	76740	47460	83150	78905	59870
01	56809	42909	25853	47624	29486	14196	75841	00393	42390	24847
02	66109	84775	07515	49949	61482	91836	48126	80778	21302	24975
03	18071	36263	14053	52526	44347	04923	68100	57805	19521	15345
04	98732	15120	91754	12657	74675	78500	01247	49719	47635	55514
05	36075	83967	22268	77971	31169	68584	21336	72541	66959	39708
06	04110	45061	78062	18911	27855	09419	56459	00695	70323	04538
07	75658	58509	24479	10202	13150	95946	55087	38398	18718	95561
08	87403	19142	27208	35149	34889	27003	14181	44813	17784	41036
09	00005	52142	65021	64438	69610	12154	98422	65320	79996	01935
10	43674	47103	48614	70823	78252	82403	93424	05236	54588	27757
11	68597	68874	35567	98463	99671	05634	81533	47406	17228	44455
12	91874	70208	06308	40719	02772	69589	79936	07514	44950	35190
13	73854	19470	53014	29375	62256	77488	74388	53949	49607	19816
14	65926	34117	55344	68155	38099	56009	03513	05926	35584	42328
15	40005	35246	49440	40295	44390	83043	26090	80201	02934	49260
16	46686	29890	14821	69783	34733	11803	64845	32065	14527	38702
17	02717	61518	39585	72863	50707	96115	07416	05041	36756	61065
18	17048	22281	35573	28944	96889	51823	57268	03866	27658	91950
19	75304	53248	42151	93928	17343	88322	28683	11252	10355	65175
20	97844	62947	62230	30500	92816	85232	27222	91701	11057	83257
21	07611	71163	82212	20653	21499	51496	40715	78952	33029	64207
22	47744	04603	44522	62783	39347	72310	41460	31052	40814	94297
23	54293	43576	88116	67416	34908	15238	40561	73940	56850	31078
24	67556	93979	73363	00300	11217	74405	18937	79000	68834	48307
25	86581	73041	95809	73986	49408	53316	90841	73808	53421	82315
26	28020	86282	83365	76600	11261	74354	20968	60770	12141	09539
27	42578	32471	37840	30872	75074	79027	57813	62831	54715	26693
28	47290	15997	86163	10571	81911	92124	92971	80860	41012	58666
29	24856	63911	13221	77028	06573	33667	30732	47280	12926	67276
30	16352	24836	60799	76281	83402	44709	78930	82969	84468	36910
31	89060	79852	97854	28324	39638	86936	06702	74304	39873	19496
32	07637	30412	04921	26471	09605	07355	20466	49793	40539	21077
33	37711	47786	37468	31963	16908	50283	80884	08252	72655	58926
34	82994	53232	58202	73318	62471	49650	15888	73370	98748	69181
35	31722	67288	12110	04776	15168	68862	92347	90789	66961	04162
36	93819	78050	19364	38037	25706	90879	05215	00260	14426	88207
37	65557	24496	04713	23688	26623	41356	47049	60676	72236	01214
38	88001	91382	05129	36041	10357	55558	89979	58061	28957	10701
39	96648	70303	18191	62404	26558	92804	15415	02865	52449	78509
40	04118	51573	59356	02426	35010	37104	98316	44602	96478	08433
41	19317	27753	39431	26996	04465	69695	61374	06317	42225	62025
42	37182	91221	17307	68507	85725	81898	22588	22241	80337	89033
43	82990	03607	29560	60413	59743	75000	03806	13741	79671	25416
44	97294	21991	11217	98087	79124	52275	31088	32085	23089	21498
45	86771	69504	13345	42544	59616	07867	78717	82840	74669	21515
46	26046	55559	12200	95106	56496	76662	44880	98457	84209	01332
47	39698	05999	92290	79024	70271	93352	90272	94495	26842	54477
48	83265	89573	01437	43786	52986	49041	17952	35035	88985	84671
49	15128	35791	11296	45319	06330	82027	90808	54351	43091	30387

TABLE 1 (continued)

	00-04	05-09	10-14	15-19	20-24	25-29	30-34	35-39	40-44	45-49
50	54441	64681	93190	00993	62130	44484	46293	60717	52039	76319
51	08573	52937	84274	95106	89117	65849	41356	65549	78787	50442
52	81067	68052	14270	19718	88499	63303	13533	91882	51136	60828
53	39737	58891	75278	98046	52284	40164	72442	77824	72900	14886
54	34958	76090	08827	61623	31114	86952	83645	91786	29633	78294
55	61417	72424	92626	71952	69709	81259	58472	43409	84454	88648
56	99187	14149	57474	32264	85424	90378	34682	47606	89295	02420
57	13130	13064	36485	48133	35319	05720	76317	70953	50823	06793
58	65563	11831	82402	46929	91446	72037	17205	89600	59084	55718
59	28737	49502	06060	52100	43704	50839	22538	56768	83467	19313
60	50353	74022	59767	49927	45882	74099	18758	57510	58560	07050
61	65208	96466	29917	22862	69972	35178	32911	08172	06277	62795
62	21323	38148	26696	81741	25131	20087	67452	19670	35898	50636
63	67875	29831	59330	46570	69768	36671	01031	95995	68417	68665
64	82631	26260	86554	31881	70512	37899	38851	40568	54284	24056
65	91989	39633	59039	12526	37730	68848	71399	28513	69018	10289
66	12950	31418	93425	69756	34036	55097	97241	92480	49745	42461
67	00328	27427	95474	97217	05034	26676	49629	13594	50525	13485
68	63986	16698	82804	04524	39919	32381	67488	05223	89537	59490
69	55775	75005	57912	20977	35722	51931	89565	77579	93085	06467
70	24761	56877	56357	78809	40748	69727	56652	12462	40528	75269
71	43820	80926	26795	57553	28319	25376	51795	26123	51102	89853
72	66669	02880	02987	33615	54206	20013	75872	88678	17726	60640
73	49944	66725	19779	50416	42800	71733	82052	28504	15593	51799
74	71003	87598	61296	95019	21568	86134	66096	65403	47166	78638
75	52715	04593	69484	93411	38046	13000	04293	60830	03914	75357
76	21998	31729	89963	11573	49442	69467	40265	56066	36024	25705
77	58970	96827	18377	31564	23555	86338	79250	43168	96929	97732
78	67592	59149	42554	42719	13553	48560	81167	10747	92552	19867
79	18298	18429	09357	96436	11237	88039	81020	00428	75731	37779
80	88420	28841	42628	84647	59024	52032	31251	72017	43875	48320
81	07627	88424	23381	29680	14027	75905	27037	22113	77873	78711
82	37917	93581	04979	21041	95252	62450	05937	81670	44894	47262
83	14783	95119	68464	08726	74818	91700	05961	23554	74649	50540
84	05378	32640	64562	15303	13168	23189	88198	63617	58566	56047
85	19640	96709	22047	07825	40583	99500	39989	96593	32254	37158
86	20514	11081	51131	56469	33947	77703	35679	45774	06776	67062
87	96763	56249	81243	62416	84451	14696	38195	70435	45948	67690
88	49439	61075	31558	59740	52759	55323	95226	01385	20158	54054
89	16294	50548	71317	32168	86071	47314	65393	56367	46910	51269
90	31381	94301	79273	32843	05862	36211	93960	00671	67631	23952
91	98032	87203	03227	66021	99666	98368	39222	36056	81992	20121
92	40700	31826	94774	11366	81391	33602	69608	84119	93204	26825
93	68692	66849	29366	77540	14978	06508	10824	65416	23629	63029
94	19047	10784	19607	20296	31804	72984	60060	50353	23260	58909
95	82867	69266	50733	62630	00956	61500	89913	30049	82321	62367
96	26528	28928	52600	72997	80943	04084	86662	90025	14360	64867
97	51166	00607	49962	30724	81707	14548	25844	47336	57492	02207
98	97245	15440	55182	15368	85136	98869	33712	95152	50973	98658
99	54998	88830	95639	45104	72676	28220	82576	57381	34438	24565

SOURCE: Prepared by Fred Gruenberger, Numerical Analysis Laboratory, University of Wisconsin, Madison, Wis., 1952

TABLE 1 (concluded)

	50-54	55-59	60-64	65-69	70-74	75-79	80-84	85-89	90-94	95-99
50	58649	85086	16502	97541	76611	94229	34987	86718	87208	05426
51	97306	52449	55596	66739	36525	97563	29469	31235	79276	10831
52	09942	79344	78160	11015	55777	22047	57615	15717	82639	36578
53	83842	28631	74893	47911	92170	38181	30416	54860	44120	73031
54	73778	30395	20163	76111	13712	33449	99224	18206	51418	70006
55	88381	56550	47467	59663	61117	39716	32927	06168	06217	45477
56	31044	21404	15968	21357	30772	81482	38807	67231	84283	63552
57	00909	63837	91328	81106	11740	50193	86806	21931	18054	49601
58	69882	37028	41732	37425	80832	03320	20690	32653	90145	03029
59	26059	78324	22501	73825	16927	31545	15695	74216	98372	28547
60	38573	98078	38982	33078	93524	45606	53463	20391	81637	37269
61	70624	00063	81455	16924	12848	23801	55481	78978	26795	10553
62	49806	23976	05640	29804	38988	25024	76951	02341	63219	75864
63	05461	67523	48316	14613	08541	35231	38312	14969	67279	50502
64	76582	62153	53801	51219	30424	32599	49099	83959	68408	20147
65	16660	80470	75062	75588	24384	27874	20018	11428	32265	07692
66	60166	42424	97470	88451	81270	80070	72959	26220	59939	31127
67	28953	03272	31460	41691	57736	72052	22762	96323	27616	53123
68	47536	86439	95210	96386	38704	15484	07426	70675	06888	81203
69	73457	26657	36983	72410	30244	97711	25652	09373	66218	64077
70	11190	66193	66287	09116	48140	37669	02932	50799	17255	06181
71	57062	78964	44455	14036	36098	40773	11688	33150	07459	36127
72	99624	67254	67302	18991	97687	54099	94884	42283	63258	50651
73	97521	83669	85968	16135	30133	51312	17831	75016	80278	68953
74	40273	04838	13661	64757	17461	78085	60094	27010	80945	66439
75	57260	06176	49963	29760	69546	61336	39429	41985	18572	98128
76	03451	47098	63495	71227	79304	29753	99131	18419	71791	81515
77	62331	20492	15393	84270	24396	32962	21632	92965	38670	44923
78	32290	51079	06512	38806	93327	80086	19088	59887	98416	24918
79	28014	80428	92853	31333	32648	16734	43418	90124	15086	48444
80	18950	16091	29543	65817	07002	73115	94115	20271	50250	25061
81	17403	69503	01866	13049	07263	13039	83844	80143	39048	62654
82	27999	50489	66613	21843	71746	65868	16208	46781	93402	12323
83	87076	53174	12165	84495	47947	60706	64034	31635	65169	93070
84	89044	45974	14524	46906	26052	51851	84197	61694	57429	63395
85	98048	64400	24705	75711	36232	57624	41424	77366	52790	84705
86	09345	12956	49770	80311	32319	48238	16952	92088	51222	82865
87	07086	77628	76195	47584	62411	40397	71857	54823	26536	56792
88	93128	25657	46872	11206	06831	87944	97914	64670	45760	34353
89	85137	70964	29947	27795	25547	37682	96105	26848	09389	64326
90	32798	39024	13814	98546	46585	84108	74603	94812	73968	68766
91	62496	26371	89880	52078	47781	95260	83464	65942	91761	53727
92	62707	81825	40987	97656	89714	52177	23778	07482	91678	40128
93	05500	28982	86124	19554	80818	94935	61924	31828	79369	23507
94	79476	31445	59498	85132	24582	26024	24002	63718	79164	43556
95	10653	29954	97568	91541	33139	84525	72271	02546	64818	14381
96	30524	06495	00886	40666	68574	49574	19705	16429	90981	08103
97	69050	22019	74066	14500	14506	06423	38332	34191	82663	85323
98	27908	78802	63446	07674	98871	63831	72449	42705	26513	19883
99	64520	16618	47409	19574	78136	46047	01277	79146	95759	36781

hazardous is the type (or types) or microorganisms present? and how hazardous are the numbers present? These questions are discussed more fully in Chapter 6. The probability of accepting a lot which should be rejected should be reduced with increasing hazard.

(b) *Uniformity*. If the food is well mixed as a result of the manufacturing process (e.g., a mobile liquid), relatively few sample units can be used. If, however, there is likely to be relatively heavy contamination in a few small places in the lot of food, relatively large numbers of sample units may be needed to identify it.

(c) *Stratification*. If it is known that there is stratification within lots of the food (see Section B above), a corresponding stratification can be used in selecting sampling units.

(d) *Record of consistency*. A consistently good record for a food from a specific source indicates that its control is good, and reliable, and hence may justify reduced sampling or even omission of sampling on occasional lots. Discretion must be used in making this decision, with increasing confidence as the record accumulates. Confidence will be maintained if the producer provides detailed records of control procedures.

(e) *Practical limitations*. Since regulatory agencies never have the resources to test all imported lots, they must reduce the sampling plans to a feasible level. Most microbiological tests are laborious and slow; yet regulatory agencies cannot hold highly perishable foods pending results of analysis. Political or administrative pressures to reduce sampling will increase the probability of error.

In considering the above factors, it must be remembered that the ability to distinguish between good and bad lots often improves relatively little with increase in the number of sample units constituting the population sample. Indeed, in many instances reliability only increases roughly as the square root of the number of sample units, so that multiplying the sample number by four will only halve the likelihood of making wrong decisions.

Appropriate sampling plans

This text is concerned primarily with plans that may be applied to lots of food presented for acceptance at ports or other points of entry. Often little or no information is available to the receiving agency about the method by which the food was processed or the record of previous performance by the same processor. Under these circumstances attributes plans are appropriate. Variables sampling plans, which depend upon the nature of the frequency distribution of organisms within lots of foods, are suitable only if this distribution is known. This limits severely their usefulness in port-of-entry sampling, but they may be particularly helpful to food producers monitoring their own production.

A. TWO-CLASS ATTRIBUTES PLANS

A simple way to decide whether to accept or reject a food lot may be based on some microbiological test performed on several (n) sample units. This will usually be a test for the presence (positive result) or absence (negative result) of an organism. Concentrations of microorganisms can be assigned to a particular attribute class by determining whether they are above (positive) or below (negative) some preset concentration.

As explained in Chapter 2, the decision-making process is defined by two numbers. The first is represented by the letter n , and defines the number of sample units required for testing. The second number, denoted c , is the maximum allowable number of sample units yielding unsatisfactory test results: for examples, the presence of the organism, or a count above the defined concentration denoted by m , which in a 2-class plan separates good quality from defective quality. Thus, in a presence/absence decision on a lot, the sampling plan $n = 10, c = 2$

means that 10 sample units are taken and a test made on each; if 2 or fewer show the presence of the organisms, the lot is accepted (with respect to this characteristic); but if 3 or more of the 10 show the presence of the organism, the lot is rejected, although not necessarily destroyed (see Chapter 2, Section H, for an explanation of rejection).

The stringency of the sampling plan depends upon n and c (see Chapter 2, Section E). The larger the value of n at a given value of c , the better the food quality must be to have the same chance of being passed. Conversely, for a given sample size n , if c is increased the plan becomes more lenient and will more often pass food lots of a given quality whenever offered for test (i.e., there is a higher probability of acceptance, P_a). Thus, compared with $n = 10$, $c = 2$, the plans $n = 15$, $c = 2$ and $n = 10$, $c = 1$ are more stringent, while the plans $n = 5$, $c = 2$ and $n = 10$, $c = 3$ are more lenient. Probabilities of acceptance for a set of plans are given in Tables 2 and 3. Figure 2 displays the operating characteristic (OC) curves for a few of these plans to illustrate the characteristics of various 2-class attributes plans.

In foods that are intimately mixed, it is possible that the distribution of microorganisms within them may approach uniformity. Under those circumstances, data obtained from the application of a 2-class plan based on presence/absence of an organism may give an approximate guide to the likely concentration of that microbe within the lot. Such techniques should only be applied when the analyst is confident that there is a uniform distribution of the microorganisms of concern.

B. THREE-CLASS ATTRIBUTES PLANS

Three-class attributes plans (see Bray, Lyon, and Burr, 1973) were devised for the situation where the quality of the product can be divided into three attribute classes depending upon the concentration of microorganisms within the sample units. A count above a concentration M for any sample unit is unacceptable, and if any count for the n sample units from a lot exceeds M , that lot is rejected. Counts above m , which in a 3-class plan separates good quality from marginally acceptable quality, and up to and including M are undesirable but some can be accepted, the number acceptable being denoted by c .

Accordingly, in the 3-class plans there are again only two numbers, n and c , from which it is possible to find the probability of acceptance,

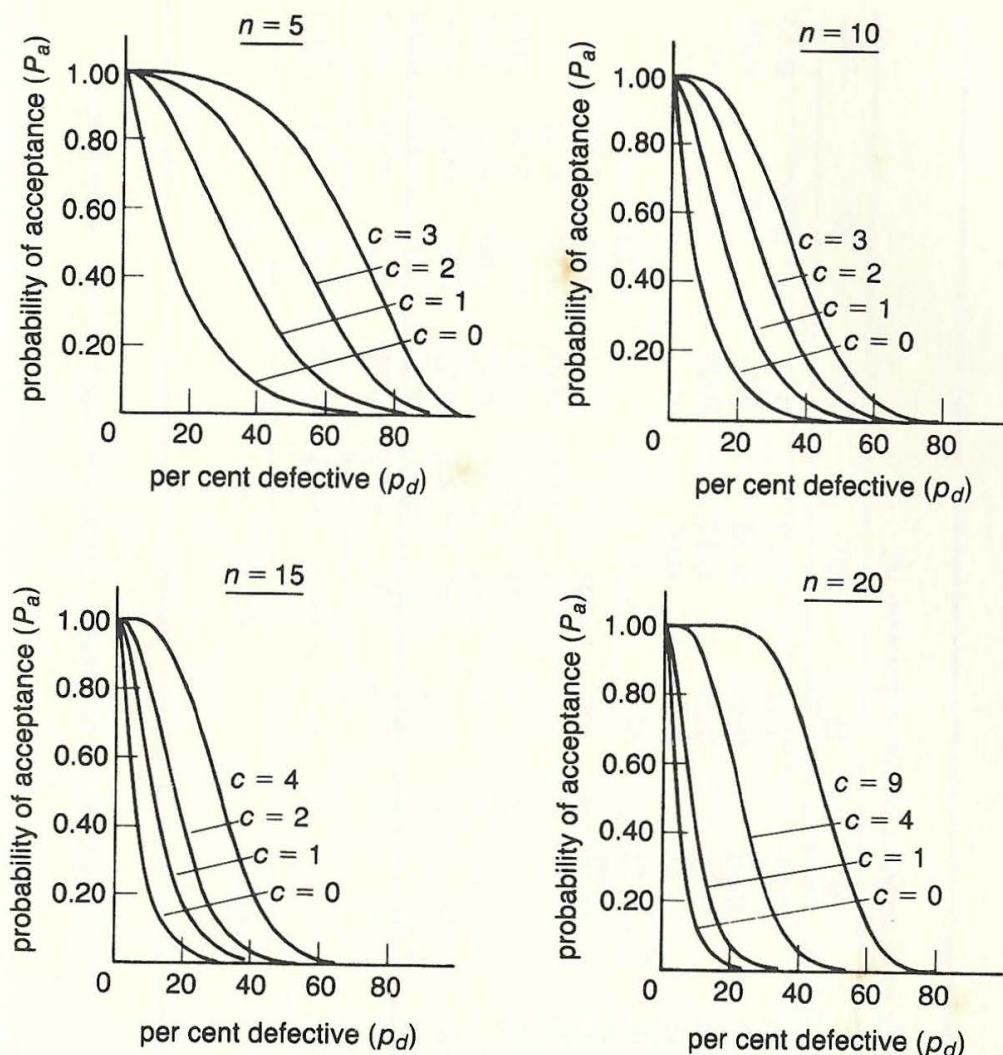


Figure 2 Operating characteristic curves for different sample sizes (n) and different criteria of acceptance (c) for 2-class attributes plan

P_a , for a food lot of given microbiological quality. To describe the lot quality we consider all sample units which could be drawn from the lot, which must yield counts in three classes; 0 to m , m to M , and above M . Since the proportions in the lot for the three classes must total 1, one need only specify *two* of them in describing lot quality. We might call these proportions the per cent 'defective,' i.e. above M (P_d), and the per cent 'marginally acceptable,' i.e. m to M (P_m). The per cent 'acceptable,' equal to or less than m , must be 100% minus the sum of P_d and P_m . By appropriate calculations, we can find the probability of acceptance, P_a , for a given lot quality for any specified sampling plan. For example, for the plan $n = 10$, $c = 2$, P_a will be

TABLE 2

Two-class plans ($c=0$): probabilities of acceptance (P_a) of lots containing indicated proportions of acceptable and defective sample units*

Composition of lot		Number of sample units tested from the population (n)							
% acceptable ($100-p$)	% defective (p)	3	5	10	15	20	30	60	100
98	2	0.94	0.90	0.82	0.74	0.67	0.55	0.30	0.13
95	5	0.86	0.77	0.60	0.46	0.36	0.21	0.05	0.01
90	10	0.73	0.59	0.35	0.21	0.12	0.04	<	<
80	20	0.51	0.33	0.11	0.04	0.01	<		
70	30	0.34	0.17	0.03	<	<			
60	40	0.22	0.08	0.01					
50	50	0.13	0.03	<					
40	60	0.06	0.01						
30	70	0.03	<						
20	80	0.01							
10	90	<							

* '<' means $P_a < 0.005$.

TABLE 3

Two-class plans (selected c values): probabilities of acceptance (P_a) of lots containing indicated proportions of acceptable and defective sample units*

Composition of lot		$n = 5$			$n = 10$			$n = 15$			$n = 20$		
% acceptable ($100 - p$)	% defective (p)	$c = 3$	$c = 2$	$c = 1$	$c = 3$	$c = 2$	$c = 1$	$c = 4$	$c = 2$	$c = 1$	$c = 9$	$c = 4$	$c = 1$
98	2	1.00	1.00	1.00	1.00	1.00	0.98	1.00	1.00	0.96	1.00	1.00	0.94
95	5	1.00	1.00	0.98	1.00	0.99	0.91	1.00	0.96	0.83	1.00	1.00	0.74
90	10	1.00	0.99	0.92	0.99	0.93	0.74	0.99	0.82	0.55	1.00	0.96	0.39
80	20	0.99	0.94	0.74	0.88	0.68	0.38	0.84	0.40	0.17	1.00	0.63	0.07
70	30	0.97	0.84	0.53	0.65	0.38	0.15	0.52	0.13	0.04	0.95	0.24	0.01
60	40	0.91	0.68	0.34	0.38	0.17	0.05	0.22	0.03	0.01	0.76	0.05	<
50	50	0.81	0.50	0.19	0.17	0.05	0.01	0.06	<	<	0.41	0.01	<
40	60	0.66	0.32	0.09	0.05	0.01	<	0.01	<	<	0.13	<	<
30	70	0.47	0.16	0.03	0.01	<	<	<	<	<	0.02	<	<
20	80	0.26	0.06	0.01	<	<	<	<	<	<	<	<	<
10	90	0.08	0.01	<	<	<	<	<	<	<	<	<	<
5	95	0.02	<	<	<	<	<	<	<	<	<	<	<

* n = number of sample units tested from the population; '<' means $P_a < 0.005$.

0.21 for a lot distribution for which 20% of the sample counts are marginally acceptable ($P_m = 20\%$) and 10% 'defective' ($P_d = 10\%$). That is, on the basis of the particular values decided upon for m and M , only about 21 lots out of 100 of that quality will be accepted, because they have no defective counts and two or fewer 'marginally acceptable' counts out of the 10 samples chosen from the lot. The other lots will all be rejected.

Probabilities associated with a collection of 3-class plans are shown in Table 4 for various lot qualities. The scheme depends for acceptance or rejection not only on the proportion of 'defective' material (P_d) but also on the proportion of 'marginally acceptable' product (P_m); that is, on the frequency distribution of microorganisms within the lot. For example, a lot with 20% of 'marginal quality' and 10% 'defective' quality with a sampling plan based on $n = 10$, $c = 2$ will, on average, be accepted 21% of the times it is put forward for testing. Using the identical plan ($n = 10$, $c = 2$) a lot containing 0% 'defective' material but 40% of 'marginal quality' has a lower chance of acceptance (17%). Thus the 3-class attributes scheme is affected to some extent by the frequency distribution of microorganisms within the batch, but the advantages of the scheme are its simplicity and general applicability, which make it particularly relevant to port-of-entry sampling.

C. COMPARISON OF TWO- AND THREE-CLASS PLANS

Table 5 compares the operating characteristics of the two types of plans recommended in this text, on the basis of equal sample sizes n , acceptance numbers c , and lot qualities. To facilitate comparison, lot quality is measured as the proportion of the lot worse than level m and, correspondingly, the same value of c is taken for the 2-class plan as the c of marginally acceptable quality for the 3-class plan.

The 2-class plans do not distinguish values between m and M from those above M . If not more than c sample units give results above m , the lot is acceptable, regardless of how far individual results exceed m . But the corresponding 3-class plan does make a distinction, by including an extra subdivision of lot quality since the limit M separates marginally acceptable from defective quality.

D. THE INFLUENCE OF SIZE OF LOT

A sample size of, say, $n = 30$ sample units might be taken at random from a lot of any size (or consignment if appropriate – see Chapter 3,

Section A) for use in a 2-class plan with $c = 0$. If the lot contains a very large number of sample units, one obtains an OC curve such as that shown in Figure 5 (p. 82). There it is apparent that a lot with one defective unit out of 40 (proportion defective, $p = 0.025$) will be accepted about half the time ($P_a = 0.50$) when using the plan $n = 30$, $c = 0$. If, however, the lot contains a smaller number of sample units, the probabilities of acceptance P_a for various values of p would be only slightly smaller than those shown in Figure 5, despite the fact that the 30 sample units might now constitute an appreciable fraction of the whole lot. This effect is only really important when one begins to take a quarter to a half of the lot as a sample, a condition rarely occurring in bacteriological analysis of food lots.

Suppose that instead of $n = 30$, $c = 0$, we use $n = 5$, $c = 0$. The latter plan is quite indiscriminating. But the associated probabilities of acceptance (see Figure 2, p. 33) are again nearly independent of the consignment size.

In summary, a sampling plan of the form described gives nearly the same degree of protection against acceptance of 'bad' lots as against rejection of 'good' ones, regardless of lot size.

The attributes schemes given in this book do not increase stringency as lot size increases. The sampling plan is therefore independent of lot size if the lot is large in comparison to sample size. If the important criterion is the actual number of defective units, rather than the proportion of the batch that is defective, then the sampling plans given are not appropriate.

E. VARIABLES SAMPLING

Under certain circumstances, it has been shown that the logarithms of the counts from a batch of food are likely to be normally distributed (Baird-Parker, 1980; Kilsby and Baird-Parker, 1983 [their Table 2]; Ingram and Roberts, 1976). Knowledge of this 'log-normal' distribution would rarely exist in port-of-entry sampling. For this reason it is not dealt with to any great degree in this book. However, such knowledge may be available to a food producer, particularly when the production process is stable and the microbiological distribution has been carefully studied. Under these circumstances, variables plans are an alternative to attributes plans. Since variables plans may be of use to the food producer in his internal quality control program, they are discussed briefly in Chapter 8.

TABLE 4

Three-class plans: probabilities of acceptance (P_a) of lots containing indicated proportions for selected numbers of sample units and c values (P_d = per cent defective, P_m = per cent marginal)*

P_d	P_m									
	10	20	30	40	50	60	70	80	90	
$n=5, c=3$										
50	0.03	0.03	0.02	0.01	<	<	<	<	<	
40	0.08	0.07	0.06	0.04	0.02	0.03	0.04	0.06	<	
30	0.17	0.16	0.15	0.12	0.07	0.12	0.18	0.26	0.02	
20	0.33	0.32	0.31	0.27	0.20	0.32	0.47	0.66	0.08	
10	0.59	0.58	0.56	0.52	0.43	0.60	0.81	0.97	1.00	
5	0.77	0.77	0.75	0.69	0.60	0.81	0.97	1.00	1.00	
0	1.00	0.99	0.97	0.91	0.81	0.66	0.47	0.26	0.08	
$n=5, c=2$										
50	0.03	0.02	0.01	<	<	<	<	<	<	
40	0.08	0.06	0.04	0.02	0.02	0.03	0.05	0.06	<	
30	0.16	0.14	0.11	0.06	0.09	0.12	0.16	0.20	<	
20	0.32	0.29	0.24	0.16	0.23	0.32	0.47	0.66	0.01	
10	0.58	0.55	0.47	0.36	0.23	0.43	0.60	0.81	0.02	
5	0.77	0.72	0.63	0.50	0.35	0.60	0.81	0.97	1.00	
0	0.99	0.94	0.84	0.68	0.50	0.32	0.16	0.06	0.01	
$n=5, c=1$										
50	0.02	0.01	<	<	<	<	<	<	<	
40	0.06	0.04	0.01	<	<	<	<	<	<	
30	0.14	0.09	0.05	0.02	0.07	0.12	0.16	0.20	<	
20	0.29	0.21	0.13	0.06	0.20	0.32	0.47	0.66	0.01	
10	0.53	0.41	0.27	0.16	0.07	0.43	0.60	0.81	0.02	
5	0.70	0.55	0.38	0.23	0.12	0.60	0.81	0.97	1.00	
0	0.92	0.74	0.53	0.34	0.19	0.09	0.03	0.01	0.01	

TABLE 4 (concluded)

P_d	P_m									
	10	20	30	40	50	60	70	80	90	
$n=10, c=3$										
40	0.01	<								
30	0.03	0.02	0.01	<						
20	0.10	0.08	0.05	0.02	<					
10	0.34	0.29	0.20	0.10	0.03	0.01	<			
5	0.59	0.51	0.36	0.20	0.08	0.02	<			
0	0.99	0.88	0.65	0.38	0.17	0.05	0.01	<		
$n=10, c=2$										
30	0.02	0.01	<							
20	0.09	0.06	0.02	0.01	<					
10	0.32	0.21	0.10	0.04	0.01	<				
5	0.55	0.39	0.20	0.08	0.02	<				
0	0.93	0.68	0.38	0.17	0.05	0.01				
$n=10, c=1$										
30	0.02	<								
20	0.07	0.03	0.01	<						
10	0.24	0.11	0.04	0.01	<					
5	0.43	0.21	0.08	0.02	<					
0	0.74	0.38	0.15	0.05	0.01	<				

* Each of these blocks of numbers, relating P_a to P_m and P_d , represents a three-dimensional relation called an OC surface, corresponding to the two-dimensional OC curve.
 '<' means $P_a < 0.005$.

TABLE 5

Probabilities of acceptance (P_a) for 2- and 3-class attributes sampling plans when the lot examined contains 5%, 20%, or 50% of sample units $> m^*$

Sampling plan	n	c	5% $> m$				20% $> m$				50% $> m$			
			2-class plan		3-class plan		2-class plan		3-class plan		2-class plan		3-class plan	
			0% $> M$	5% $> M$	0% $> M$	5% $> M$	0% $> M$	5% $> M$	0% $> M$	5% $> M$	0% $> M$	5% $> M$	0% $> M$	5% $> M$
5	0	0	0.77	0.77	0.77	0.77	0.33	0.33	0.33	0.33	0.03	0.03	0.03	0.03
5	1	1	0.98	0.98	0.98	0.77	0.74	0.74	0.53	0.33	0.19	0.19	0.11	0.03
5	2	2	1.00	1.00	1.00	0.77	0.94	0.94	0.58	0.33	0.50	0.50	0.19	0.03
5	3	3	1.00	1.00	1.00	0.77	0.99	0.99	0.59	0.33	0.81	0.81	0.23	0.03
10	0	0	0.60	0.60	0.60	0.60	0.11	0.11	0.11	0.11	<	<	<	<
10	1	1	0.91	0.91	0.91	0.60	0.38	0.38	0.24	0.11	0.01	0.01	0.01	<
10	2	2	0.99	0.99	0.99	0.60	0.68	0.68	0.32	0.11	0.05	0.05	0.02	<
10	3	3	1.00	1.00	1.00	0.60	0.88	0.88	0.34	0.11	0.17	0.17	0.03	<
15	0	0	0.46	0.46	0.46	0.46	0.04	0.04	0.04	0.04	<	<	<	<
20	0	0	0.36	0.36	0.36	0.36	0.01	0.01	0.01	0.01	<	<	<	<
60	0	0	0.05	0.05	0.05	0.05	<	<	<	<	<	<	<	<

* Note that any % $> M$ is included in the % $> m$; e.g., for the case where 20% $> m$ and 10% $> M$, it follows that 10% is between m and M .

'<' means $P_a < 0.005$.

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