Comparison of Three-Class Attributes Sampling Plans and Variables Sampling Plans for Lot Acceptance Sampling in Food Microbiology

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ABSTRACT

Lot acceptance sampling is an established method of assessing the microbiological quality and safety of batches or consignments of food, but the choice between three-class attributes plans and variables plans is not always clear. Application of variables plans requires that the microorganism of concern be distributed normally, or log normally. When such is not true, variables plans may place either the consumer or the producer at increased risk. Validation of normality is therefore essential when using variables plans. However, with small numbers of sample units as are typically analyzed in microbiological testing of food, statistical tests are unlikely to detect non-normality. Three-class attributes plans do not require strong distributional assumptions for correct application, and as well they have several practical and operational advantages over variables plans. Moreover, three-class attributes plans assess lot quality in a fashion fundamentally different from variables plans, and this difference precludes the usual statistical comparisons based on relative discriminatory ability. We conclude that when selecting acceptance sampling plans for microbiological testing of food, whether the plans be for regulatory, port-of-entry or in-plant purposes, three-class plans are generally preferable to variables plans.

Three-class attributes plans (1) were adopted by the International Commission on Microbiological Specifications for Foods (ICMSF) in 1974 (3) for use in food microbiology lot acceptance sampling. More recently, Kilsby et al. (6) described a system for setting microbiological specifications based on the application of a variables plan to production lots in which the microorganism of interest is assumed to be normally (or log normally) distributed. Both approaches offer a statistical decision criterion by which a lot is either accepted or rejected, according to pre-specified microbiological quality and/or safety standards.

Comparisons between variables plans and three-class plans have been attempted, but only in a limited and somewhat intuitive fashion (4,5,6). However, objective statistical comparisons are encumbered by fundamental differences in the way these two approaches assess lot acceptability. Variables plans view items in the lot in relation to a single value beyond which items are considered defective. Lot acceptability is determined by the proportion of the lot estimated to be defective. Three-class attributes plans, on the other hand, view each item in relation to two values which together create three classes of quality - acceptable, marginally acceptable and defective. Lot acceptability depends on the proportion of the lot estimated to be marginally acceptable as well as the proportion estimated to be defective. This recognition of three classes of quality may yield decisions which are more meaningful in the context of food microbiology, since it is possible to restrict the proportion of the lot which is permitted to have counts close to, but below, the defective level.

In acceptance sampling, n sample units are drawn at random from the lot and measurements are made on these units. For three-class plans, the measurements are in turn compared to two values, denoted m and M, which are specific to the application. If a measurement is less than or equal to m, the corresponding sample unit is acceptable. If a measurement is greater than m but not greater than M the corresponding sample unit is marginally acceptable, and if a measurement exceeds M, the corresponding sample unit is defective. Each of the sample units is thus assigned to one of three classes. The lot is accepted when the number of marginals and the number of defectives in the sample do not exceed pre-specified limits. In food microbiology applications with which the authors are familiar, zero defectives are permitted in the sample. The lot is therefore accepted only when there are zero defectives and no more than a pre-specified number, 'c', of marginals in the sample. This special case, where no defectives are permitted in the sample, is the only type of three-class plan we consider in this paper.

In the variables plan, the sample mean, \( \bar{x} \), the sample standard deviation, s and the quantity \( \bar{x} + ks \), where k is a pre-specified constant chosen for a particular plan, are calculated. The lot is then accepted if \( \bar{x} + ks \) does not ex-
ceed a critical value $C$. $C$ may be similar to $M$ in meaning and hence in its assigned value. The constant $k$ is chosen such that the plan will reject a lot with a desired probability $P$ when a specified proportion $p$ of the lot exceeds $C$. Values for $k$ were calculated by Kilsby et al. (6) and revised by Malcolm (8) for $n = 3, 4, ..., 10$ and numerous combinations of $p$ and $P$.

Failure to accept a lot indicates that the lot is, temporarily at least, unfit for its intended use. It may be released after a more thorough investigation, or it may require reconditioning, reprocessing, diversion to another use, or destruction.

The purpose of this paper is to examine some of the factors which should be considered when choosing between the three-class plan and the variables plan approach. We show that the variables plans described by Kilsby et al. (6) are unreliable when the normality assumption fails, and that statistical tests of normality stand little chance of detecting non-normality with the small sample sizes typically used in microbiological testing. In the discussion, we enumerate some of the operational advantages enjoyed by the attributes approach, and illustrate the perils of attempting to compare the two approaches on objective statistical grounds.

**METHODS**

*Consequences of non-normality on variables plans*

Since the variables plans discussed in this paper require that the underlying distribution be normal, we examine the consequences of applying these plans to some non-normal distributions. Non-normal distributions were mathematically created by combining two normal distributions with identical variances but different means, to obtain distributions which were either skewed or bimodal. Three non-normal distributions are shown in Fig. 1. Probabilities of rejection for these distributions were based on the observed rates of rejection when computer-simulated random samples of $n = 5$ were repeatedly drawn from each non-normal distribution and subjected to the rejection criteria of variables plans selected from (6). These probabilities of rejection were compared to the probabilities expected under normality.

**Validation of normality**

One thousand random samples of size $n = 5$ and 1,000 ran-

![Figure 1](http://meridian.allenpress.com/jfp/article-pdf/49/9/724/1657470/0362-028x-49_9_724.pdf)

**TABLE 1. Expected vs. actual probabilities of rejection for $n = 5$.**

<table>
<thead>
<tr>
<th>Distribution</th>
<th>$k$</th>
<th>Proportion of distribution exceeding $C$</th>
<th>Expected*</th>
<th>Actual</th>
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</thead>
<tbody>
<tr>
<td>Fig. 1(a)</td>
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<td>.1</td>
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<td>.86</td>
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<td>2.7</td>
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<td>Fig. 1(b)</td>
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<td>Fig. 1(c)</td>
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*Expected probability of rejection is that which would occur if the distribution were normal.

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dom samples of size \( n = 10 \) were drawn via computer simulation from each non-normal distribution described above. Each sample was tested for normality at a significance level of \( \alpha = .05 \) and \( \alpha = .01 \), using the probability plot correlation coefficient test described by Filliben (2). At this level the test will falsely declare non-normality 5% and 1% of the time, respectively. This particular test compares favorably to other tests for normality (2,9) and has been used in (5) and (7) to test for the normality of the logarithms of concentrations of total viable counts obtained from batches of food. From these simulations, the actual rate of detection of non-normality was determined.

RESULTS

Consequences of non-normality on variables plans

The three non-normal distributions studied are shown in Fig. 1. In Table 1 are the expected (assuming normality) and actual probabilities of rejection for each of the distributions shown in Fig. 1 and for various \( k \) values, when sample size \( n = 5 \). For distribution 1(a), actual probabilities of rejection tend to be slightly lower than expected, placing the consumer at a somewhat greater risk than intended. With more severe departures from normality (distributions 1(b) and 1(c)), discrepancies between expected and actual probabilities of rejection are greater. Actual probabilities are in some instances drastically lower than expected, and in other instances somewhat higher than expected. For example, with distribution 1(b) and \( k = 2.7 \), the actual probability of rejection is .62 when it is expected to be .90. This places the consumer at much greater risk than intended. On the other hand, with distribution 1(c) and \( k = 2.7 \), the actual probability of rejection of .97 is higher than the expected probability of .90. In this instance the producer will unknowingly be faced with a plan considerably more stringent than intended. Even from the consumer’s viewpoint this situation may be detrimental since the increased cost of meeting specifications stricter than intended may ultimately reach the marketplace.

The preceding examples demonstrate that variables plans based on small sample sizes can be quite sensitive to non-normality. The actual probabilities of rejection may be higher or lower than intended. Thus when normality is not assured, application of a variables plan may place the consumer or the producer at higher risk than planned.

<table>
<thead>
<tr>
<th>TABLE 2. Probability of declaring a distribution to be non-normal using the probability plot correlation coefficient test.</th>
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<tbody>
<tr>
<td>Distribution</td>
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<td>Fig. 1(a)</td>
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<td>Fig. 1(c)</td>
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Validation of normality

Using the probability plot correlation coefficient test (2), the probabilities of detecting the non-normality depicted in Fig. 1 are shown in Table 2. It is apparent from this table that even the extremely non-normal distributions 1(b) and 1(c) would escape detection most of the time, even with sample size \( n = 10 \). With \( n = 5 \), the probability of declaring distribution 1(c) to be non-normal is only .148, indicating that with a small sample this particular test barely distinguishes this distribution from the normal distribution. Similar results should be expected using other statistical tests for normality.

DISCUSSION

The three-class plan is easier to understand and easier to apply than the variables plan. It requires minimum quality control training for correct administration, since it requires neither ‘complex’ computations nor the validation of the normality assumption.

Three-class plans have the potential to reduce the amount of analytical work required to reach a decision. For example, it is not necessary to complete the analytical work on all sample units if one defective unit or more than \( c \) marginally acceptable units have already been found, since further work cannot alter the decision to reject. As well, it is not necessary to obtain a definite count for a defective sample unit; it is sufficient to establish that it is greater than \( M \). Similarly, methods with sensitive limits of detection are not necessary as long as the method is capable of accurately determining counts close to \( m \).

None of the above advantages is enjoyed by the variables plan approach. This approach relies on strong distributional assumptions which are not easily validated. The computations for \( \bar{x} \) and \( s \), although relatively easy, are nevertheless more complex than those required by the three-class plan and for some would be an insurmountable obstacle. Finally, all analytical determinations must be completed, and the methodology must be capable of detecting very low values as well as very high values, so that \( \bar{x} \) and \( s \) can be calculated.

Thus, from an operational viewpoint, three-class plans have several advantages over variables plans.

It is a widespread belief that variables plans, where applicable, are to be preferred over attributes plans since for a given sample their discriminatory abilities are greater. That is, for a given sample size, variables plans should have a relatively lower probability of rejection for lots of good quality, and a relatively higher probability of rejection for lots of poor quality, where quality is measured by the proportion \( p \) of the lot exceeding the limit value \( C \). This belief is well-founded when considering attributes plans with two classes, and has been demonstrated by Wallis (10) and others. However, such comparisons are not possible with three-class plans. This is because, for a fixed proportion \( p \) of the lot exceeding the limit \( C \), the variable plan has a unique probability of acceptance whereas the three-class plan does not.
defective but different variances.

the same probability. But the proportion of marginally ac-
ceptable product is quite different in these two distribu-
tions. For any three-class plan with fixed $\pi$, $c$, $m$ and
$M = C$, the probability of acceptance for the narrower dis-
tribution will be lower due to the higher proportion of
marginals. This is the crux of the difference between the
variables plan and the three-class plan: for a given propor-
tion defective, the probability of acceptance of the vari-
bles plan is independent of the spread of the distribu-
tion. No distinction is made between the situation where
much of the product is well below the limit $C$ (i.e. large
spread) and the situation where most of the product is
very close to, but not in excess of $C$ (i.e. small spread).
For the three-class plan, even with the same fixed propor-
tion defective, the probability of acceptance depends
heavily on this spread (and the resulting proportion mar-
ginal), as demonstrated. For a fixed proportion defective
$\pi$, the probability of acceptance for the three-class plan
may be less than or greater than the corresponding proba-
bility of acceptance for the variables plan, depending on
the spread of the distribution. Thus it is futile to compare
the discriminatory abilities of the two approaches using
traditional statistical methods.

The variables plans discussed in this paper are based
on the assumption that the underlying distribution is nor-
mal. However, if this is not true, departures from norm-
ality will result in probabilities of acceptance different
from those expected. We have examined these conse-
quences when the underlying distribution is in fact a mix-
ture of two normal distributions. Such non-normal distri-
butions can readily occur in food microbiology, either
from the practice of combining food or ingredients from
different batches into a single lot, or from process fail-
ures in which an otherwise homogeneous lot is contami-
nated by a production irregularity or by post-processing
contamination. We have shown that with small samples
under these conditions the use of variables plans can place
the consumer or producer at an unknown but greater risk
than intended. Variables plans are not ‘fail-safe’ from
anyone’s point of view.

When using variables plans with small $n$, therefore, it
is essential that the normality assumption be valid. A for-
mal statistical test for normality is the most objective way
to detect non-normality, but some care must be exercised
when using such a procedure. The sample must be drawn
randomly and a sufficiently large number $n$ of sample
units must be withdrawn and examined. If the sample
size is not large enough, the test will have little chance
doing so. Of particular note is the pos-
sibility that these tests may be misconstrued as verifica-
tion when the test result is not significant. Lack of sig-
ificance is not synonymous with normality, but simply
indicates failure to detect non-normality.

In food microbiology, sample analysis is usually costly
and destructive, and hence sample sizes are generally
small. Thus it is pointless to routinely perform statistical
tests of normality, since with the small sample sizes typi-
cally encountered such tests will fail to detect non-nor-
mality much of the time. The routine application of vari-
bles plans to food microbiology, therefore, requires that
the normality assumption be justified on theoretical or
historical grounds. For example, some well-monitored
production processes may safely be assumed to be nor-
mally distributed if they have been statistically declared
so in the past using appropriately large sample sizes, as-
suming no event has since occurred which casts doubt
on the continuing validity of the assumption. In receiver
and regulatory oriented situations, very little is usually
known about the conditions under which the lot was pro-
duced and handled, and small sample sizes prevent prop-
er statistical assessment of the normality assumption.
Moreover, in these situations a lot may be a shipping
consignment or a day’s production which may be made
up of several batches, each with its own particular distri-
bution, the combination of which may be non-normal.
The consequence is that variables plans are rarely appli-
cable to regulatory, receiver, port-of-entry and other simi-
lar types of food microbiology acceptance sampling.
Three-class plans, on the other hand, do not require the
assumption of underlying normality and are ideal under
these circumstances.

The food manufacturer is in a better position to pro-
perly investigate the normality assumption since he has de-
tailed information about the lot and can, on occasion at least, draw and analyze a random sample large enough for adequate statistical analyses. However, even under these ideal circumstances the choice between a variables plan and a three-class plan is not obvious. We contend that three-class plans, by virtue of their limited tolerance of a 'grey' area of product quality, may in fact provide a more meaningful decision on the acceptability of the lot. This, coupled with the potential savings in analytical work discussed earlier may give three-class sampling plans a decided advantage in many industrial applications.

REFERENCES