Acceptance Sampling for Food Quality Assurance

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Dedicated to my mother, Carmen Fernández Ferrer
A ti madre querida, por ser ejemplo de dedicacion y amor.

"In God we trust, all others bring data.[1]"

[1] Attributed to W. Edwards Deming.

Declaration

I hereby declare that except where specific reference is made to the work of others, the contents of this dissertation are original and have not been submitted in whole or in part for consideration for any other degree or qualification in this, or any other university. This dissertation is my own work and contains nothing which is the outcome of work done in collaboration with others, except as specified in the text and Acknowledgements. This dissertation contains fewer than 65,000 words including appendices, bibliography, footnotes, tables and equations and has fewer than 150 figures.

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Abstract

Acceptance sampling plays a crucial role in food quality assurance. However, safety inspection represents a substantial economic burden due to the testing costs and the number of quality characteristics involved. This thesis presents six pieces of work on the design of attribute and variables sampling inspection plans for food safety and quality. Several sampling plans are introduced with the aims of providing a better protection for the consumers and reducing the sample sizes. The effect of factors such as the spatial distribution of microorganisms and the analytical unit amount is discussed. The quality in accepted batches has also been studied, which is relevant for assessing the impact of the product in the public health system. Optimum design of sampling plans for bulk materials is considered and different scenarios in terms of mixing efficiency are evaluated. Single and two-stage sampling plans based on compressed limits are introduced. Other issues such as the effect of imperfect testing and the robustness of the plan have been also discussed. The use of the techniques is illustrated with practical examples. We considered numerous probability models for fitting aerobic plate counts and presence-absence data from milk powder samples. The suggested techniques have been found to provide a substantial sampling economy, reducing the sample size by a factor between 20 and 80% (when compared to plans recommended by the International Commission on Microbiological Specification for Food (ICMSF) and the CODEX Alimentarius). Free software and apps have been published, allowing practitioners to design more stringent sampling plans.

Keywords:

Bulk material, Composite samples, Compressed limit, Consumer Protection, Double sampling plan, Food safety, Measurement errors, Microbiological testing, Sampling inspection plan.

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This thesis complies with the 'Guidelines for Doctoral Thesis by Publications' and with the requirements from the Handbook for Doctoral Study by the Doctoral Research Committee (DRC), Massey University. January 2011. Version 7.

Disclaimer

The opinions, findings and conclusions in this thesis are solely those of the author(s). Under no circumstances will the author(s) be responsible for any loss or damage of any kind resulted from the use of these techniques. The software codes and the apps produced by this research are licensed under GPL$\geqslant$ 2.0 and it comes without warranty of any kind.

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Chapter 1

Introduction

1.1 Food safety and assurance

The food industry comprises the activities of farming, manufacturing, preserving and distribution of foods and beverages. According to the World Bank, there are more people involved in agricultural and food production than in any other primary activity and this sector accounts for 4% of the global GDP.

The major challenge is not only to produce enough food to feed more than seven billion people, but also to ensure that food is essentially safe. From the food microbiology perspective, the term 'safe' refers to the near absence of harmful microorganisms or toxins. As stated by European Commission (2005), "foodstuffs should not contain microorganisms or their toxins or metabolites in quantities that present an unacceptable risk for human health".

The consumption of contaminated food with bacteria or viruses causes foodborne illness, burdening the public health and individuals. Food Safety as a discipline refers to the activities carried out during the food production chain to prevent foodborne diseases (Motarjemi et al., 2014)

Disease-causing microorganisms are generally referred to as pathogens. Some of the most concerning pathogens in food are *Salmonella*, *Cronobacter* spp. (formerly *Enterobacter* sakazakii), *Listeria monocytogenes* and *E.coli*. These are generally known as safety quality characteristics and they cause outright rejection of the product when detected in food samples. Microbiological methods for pathogens aim to determine their presence or absence status rather than enumeration. Traditional pathogen identification techniques are generally known as culturing tests, which normally involve enrichment, allowing the multiplication of cells so that colonies becomes visible and identifiable. These tests are time-consuming; requiring from several hours to a few days for a result.

Another important group of microorganisms is the sanitary/hygiene 'indicators'. Indicator organisms generally refer to non-pathogenic bacteria whose excessive presence might indicate pathogens contamination. They are primarily used to reflect the sanitary and hygienic conditions of the food production plants. Generally, tests for indicator organisms are aimed at a group or family of microorganisms e.g. aerobic plate counts (APC) and *Enterobacteriaceae*. These

microorganisms do not cause harm when they are present in small concentrations and therefore the acceptability of a batch is based on a non-zero microbiological specification limit. Tests for safety quality characteristics are based on the enumeration or count of colony forming units (CFUs).

The occurrence of pathogens in foodstuffs is considered stochastic and it may happen at any stage of the food production chain. The risk is expressed by the probability of occurrence and it cannot be completely eliminated but can be minimized with Good Manufacturing Practices (GMP) and the Hazard Analysis and Critical Control Point system (HACCP). These systems involve programs and principles designed to reduce risks and prevent hazards.

International bodies such as the Codex Alimentarius, the Food and Agriculture Organization of the United Nations (FAO), the International Commission on Microbiological Specification for Foods (ICMSF) provide standards, recommendations and good practices in relation to food safety and consumer protection. The New Zealand Food Safety Authority (NZFSA) within the Ministry for Primary Industries (MPI) is the body responsible for issues related to food safety in New Zealand (Lee and Hathaway, 2000).

1.2 Acceptance sampling

Acceptance sampling is one of the main areas of statistical quality control. Sampling inspection plans are used to assess the "fitness for use" of batches of products. This technique provides protection to the consumers and motivates producers to keep processes free of special causes. The most commonly used single sampling plan consists of a sample of size (n) and an acceptance criterion. The decision of acceptance or rejection is made based on the information obtained from the sample. Sampling plans are used when 100% inspection is impossible due to technical limitations, the destructive nature of some testing methods, the costs associated with the measuring, workload, etc. The weak point of acceptance sampling is the risk that batches of acceptable quality may be rejected and lots of bad quality may be accepted. Hence, sampling plans are designed in such a way that batches with poor (good) quality will have a low (high) probability of being accepted.

By increasing the sample size, the risk of accepting or rejecting a batch erroneously is reduced, but at the same time, it raises the costs. Consequently, acceptance sampling is a trade-off between risks and costs. Inspection plans allow producers to assess whether batches satisfy the specifications and to verify that only common causes of variation are acting in the manufacturing process. For a theoretical justification of acceptance sampling, see Wiel and Vardeman (1994).

The formal development of sampling inspection plans can be traced back to the creation of the inspection department at Bell Telephone Laboratories in the 1920s. This department was integrated among others by Walter A. Shewhart and Harold F. Dodge. The publication of the inspection tables for single and double plans by attributes (Dodge and Romig, 1941) marked a milestone in acceptance sampling. Other significant contributions were the publication of the

principles of the sequential sampling (Wald, 1945), the introduction of the approach of variables plan for the normal distribution given two points in the OC curve by Wallis (1947) and the design of the variables plan for the proportion nonconforming by Lieberman and Resnikoff (1955). Since then, a considerable amount of literature has been published in this field.

Classifications of acceptance sampling techniques are diverse. Fig 1.1 shows a grouping of various acceptance sampling methods commonly used. The first branch summarizes the plans based on the quality characteristic measured:

- attribute plan: the characteristic is classified on a go/no go or pass/fail basis using a specification or a regulatory limit. See for instance Dodge and Romig (1941); Hald (1967b).
- variables plan: the characteristic is measured on a continuous scale (Duncan, 1958; Govindaraju and Balamurali, 1998; Lieberman and Resnikoff, 1955; Pearn and Wu, 2006; Wallis, 1947; Wu and Pearn, 2008).
- mixed or combined plan: is the result of the combination of attributes and variables plans (Govindaraju and Kissling, 2015; Schilling and Neubauer, 2010; Wilrich, 2015).

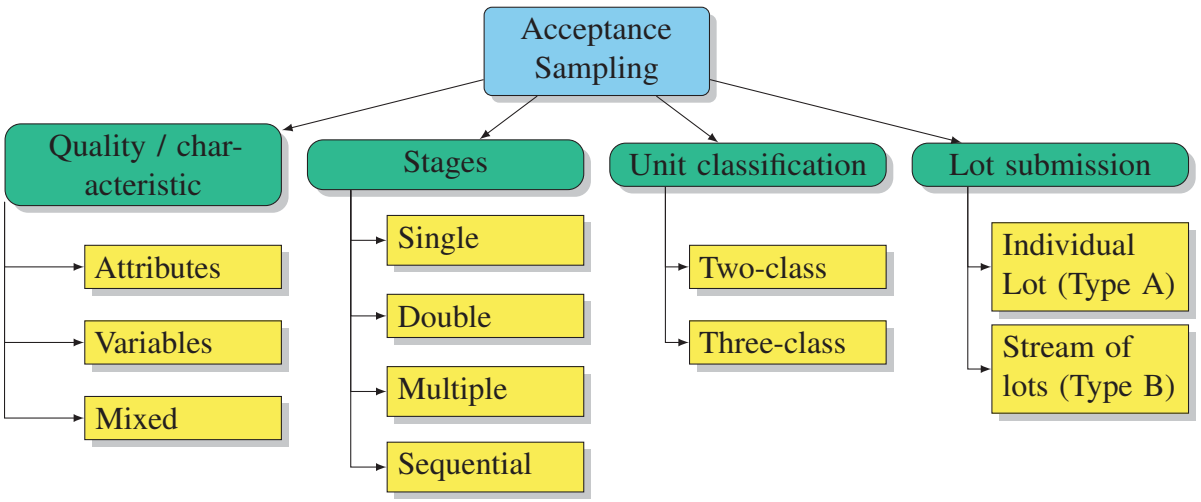


Fig. 1.1 Types of acceptance sampling schemes

The advantages of using the attributes plan is that (1) it does not require the knowledge of the statistical model, (2) easier to administer and that (3) classifying items as go/no go requires less specialization and workload. However, plans for variables require lower sample sizes since the whole information is used in the decision making process.

The second branch in Fig 1.1 is according to the number of stages (that might be) required to sentence a batch:

- single: a sample is drawn from the batch and the decision is made according to the information obtained from the individual sample. This is the most common sampling inspection procedure.

- double: after taking the first sample, the batch might be disposed (accepted or rejected) or a second sample is taken and combined with the initial one to make the final decision.
- multiple: more than two samples may be drawn from the batch.
- sequential: the units are drawn one-by-one until the decision is made.

Moreover, primary units can be classified into two or more categories:

- two-class plan: when using attributes plans each sample is classified as pass/fail (two categories), while in variables plan only one upper (lower) specification limit is used e.g. $U = 100$ CFU/g.
- three-class plan: for the attributes plan each sample is classified as good, marginal or bad (three categories), using two limits (Bray et al., 1973b). For a plan of inspection by variables two limits are required and the decision criterion involves two restrictions, (Newcombe and Allen, 1988).

The application of the plans may be by lot-by-lot (isolated lot) or focused on controlling the risks in the stream of batches. Skip-lot and chain sampling schemes are cost-effective inspection procedures that are applied to the stream of batches (Dodge, 1955a,b; Perry, 1973).

Several alternatives arise from combining characteristics from the branches of Fig 1.1. The options substantially increase when different statistical distributions are considered e.g. binomial, lognormal, exponential distribution. Lot-by-lot, single, two-class attributes and variables plan are the most widely used inspection procedures. The other procedures are known as 'special purpose' plans (Dodge, 1969), which are intended for specific applications. This thesis focuses on special purpose plans for food control. Most of the categories from Fig 1.1 apart from mixed, multiple and sequential sampling plans are studied in this thesis. Several statistical distributions that have been used to describe the frequencies of microorganisms will be considered in the design of sampling plans, e.g.: binomial, Poisson, normal, lognormal, Weibull, gamma, negative binomial, Poisson-lognormal, Poisson-gamma, Dirichlet and multivariate hypergeometric.

Hamaker (1960) summarized the most important objectives when designing sampling plans / schemes. However, he pointed out that it is not possible to accomplish all of them.

1. 'To strike a proper balance between the consumer's requirements, the producer's capabilities and the inspector's capacity.'
2. 'To separate bad lots from good.'
3. 'Simplicity of procedures and administration.'
4. 'Economy in number of observations.'
5. 'To reduce the risk of wrong decisions with increasing lot size.'
6. 'To use accumulated sample data as a valuable source of information.'

7. 'To exert pressure on the producer or supplier when the quality of the lots received is unreliable or not up to standard.'

8. 'To reduce sampling when the quality is reliable and satisfactory.'

1.3 Microbiological sampling plans

In food safety and food microbiology, acceptance sampling techniques are commonly used for quality assurance purposes. Some of the first sampling plans for microbiological applications were suggested by Kilsby and Baird-Parker (1983); Kilsby et al. (1979). Kilsby et al. (1979) seminal paper suggested the use of variables plans for bacterial log counts. The design in this plan is basically obtained from fixing the consumer's risk point and the sample size. Malcolm (1984) showed later that Kilsby et al. (1979) approximate method gives an imprecise batch probability of acceptance and suggested the computation of the risk based on the non-central t-distribution. Later on, Smelt and Quadt (1990) studied variables plans for the cases in which the standard deviation is calculated using historical data.

Since 1980s the International Commission on Microbiological Specifications for Foods (ICMSF) has been publishing regularly recommendations and guidelines on microbiological sampling plan. Some of the most relevant are ICMSF (1986, 2002, 2011). Simultaneously, guidelines, policies, recommendations and standards on food safety and particularly on the use of inspection plans for food trade have been given by the Codex Alimentarius. See for instance CAC (1997, 2004).

The Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) regularly promote joint experts meeting and publish recommendations on sampling plans for different microorganisms of interest e.g. FAO/WHO (2006, 2007, 2012, 2014).

Several special purpose sampling plans have been suggested for safety problems. A crucial advance was the development of the three-class attributes plan theory, firstly proposed by Bray et al. (1973b). Other important contributions to the applications of these plans to food safety issues were made by Dahms and Hildebrandt (1998); Hildebrandt et al. (1995); Wilrich and Weiss (2009). Today three-class attributes plan are widely-used for the inspection of different commodities and especially for sanitary quality characteristics. See for instance European Commission (2005); Food Standards Australia New Zealand (2001); ICMSF (2002).

Legan et al. (2001) suggested the use of plans in which the batch probability of acceptance is based on the concentration of microorganisms rather than the traditional proportion nonconforming. This approach was later on enhanced by Van Schothorst et al. (2009). They suggested the use of the Poisson-lognormal distribution to describe the frequencies of microorganisms.

More recently numerous authors have studied a range of statistical models to describe the frequencies of microorganisms. Several methods that allow a better characterization of the risk for the consumers have been suggested and several recommendations on the design of sampling

plans have been given. See for instance Gonzales-Barron and Butler (2011a,b); Gonzales-Barron et al. (2010a, 2013); Hoelzer and Pouillot (2013); Jarvis (2007, 2008); Jongenburger (2012a,b); Jongenburger et al. (2012a,b, 2011a,b, 2012c); Kiermeier et al. (2011); Mussida et al. (2013a,b); Powell (2014); Whiting et al. (2006); Zwietering (2009).

Composite sampling

For bulk materials, testing composite or pooled samples is possible but not for discrete items. Composite sampling is employed in a wide range of disciplines e.g.: mining, food microbiology. Compositing is defined as "the physical mix of individual sample units or a batch of unblended individual sample units that are tested as a group"(Patil, 2006). This technique is basically a physical averaging process, which allows the use of more representative samples for testing and hence achieves sampling economy.

Silliker and Gabis (1973) and Gabis and Silliker (1974) are among the first authors that showed the potential of composite sampling in food microbiology. They found that a smaller number of samples was equally effective to detect pathogens if they contained a larger analytical amount. Jarvis (2007) discussed the effectiveness and demerits of several pooling alternatives for pathogen detection. Ross et al. (2011) examined several factors which need to be considered when compositing, such as the number of increments, the limit of detection and the growing rate.

A fundamental limitation of pooling is the risk of dilution. This has motivated authors like Jongenburger (2012b) to recommend testing primary units instead of composite samples. So far, the use of pooled samples in food safety remains contradictory.

1.4 Scientific problem and research objectives

The use of inspection techniques in food safety is restricted by the nature and characteristics of microbiological testing. Food safety testing is:

1. destructive: the portion of material cannot be reused. Often the whole item or product has to be sent to the laboratory.
2. costly: the test requires several operations and time in the laboratory, which result in a substantial expense. For example, a test for parasite identification might cost 180 USD (7 CFR, 2000) in the United States and 30 analytical tests might be required for every pathogen in order to sentence a batch.
3. mandatory: testing to determine the acceptability of the batch is compulsory.
4. several quality characteristics are simultaneously measured.
5. focused totally on consumer's protection.
6. batch is rejected when at least one pathogen cell is found in the sample(s).

7. often the frequencies of microorganisms does not often fit traditional statistical models e.g. normal.
8. heterogeneity and localized contamination.
9. the concentration of bacteria generally increase over the time.
10. time-consuming test (mainly for culture-based test), but also time-constrained (the decision need to be made in few days). These makes continuous and sequential plans inappropriate.
11. pathogens appear in small concentrations, yet this might cause serious outbreaks.
12. the target microorganisms might be present but below the limit of detection (LOD).
13. numerous sources of errors including imperfect sensitivity and specificity.
14. simplicity in the sampling procedure is required since inspection is mostly carried out by food safety professionals and microbiologists.

One of the main challenges in food safety is that the actual inspection procedures cannot produce the desired and the required levels of protection. For example, 1% of the analytical units containing target pathogens would have massive consequences in the public heath system. Detecting this level of bacterial contamination using a single attributes plan under homogeneity will require a sample size of 230 units, which is far higher than any of the sampling plans used in the industry. Fortunately, a 1% contamination is a rarity in manufactured food products, and hence small sample sizes are considered adequate.

This research aims to design *special purpose* sampling plans for microbiological applications with better performance in terms of sampling economy, consumer's protection and robustness. The specific objectives are:

1. To investigate plans that provide better consumer's protection and require smaller sample sizes.
2. To propose optimum plans for bulk materials using composite samples under different sampling alternatives.
3. To design plans with a robust performance when the underlying statistical distribution departs from the assumed model.
4. To provide a better characterization of the risk for the consumers using frequentist and Bayesian methods, considering measurement errors.

The study investigates the use of more effective sampling plan techniques in food microbiology allowing food producers, regulatory agencies, food importers and consumers to reduce the inspection costs, increase the effectiveness of the sampling procedures and provide higher protection and assurance. The research will produce online applications to design sampling inspection plans and to estimate the risks.

1.5 List of publications/manuscripts

The forthcoming chapters contain the research outputs (papers) in peer-reviewed international journals of this research, in a non-chronological order. The chapters dealing with attributes and concentration based sampling plans are firstly presented (Chapters 2-5). The last two chapters (6 and 7) discuss variables plans.

- Chapter 2: Santos-Fernández, E., Govindaraju, K., and Jones, G. (2016a). Quantity-based microbiological sampling plans and quality after inspection. *Food Control*, 63:83–92.
- Chapter 3: Santos-Fernández, E., Kondaswamy, G., and Jones, G. (2016c). Compressed limit sampling inspection plans for food safety. *Applied Stochastic Models in Business and Industry*, 32(4):469–484.
- Chapter 4: Santos-Fernández, E., Govindaraju, K., Jones, G., and Kissling, R. (2016b). New two-stage sampling inspection plans for bacterial cell counts. *Food Control. In Press*.
- Chapter 5: Santos-Fernández, E., Govindaraju, K., and Jones, G. (Submitted). Effects of imperfect testing on presence-absence sampling plans. *Quality and Reliability Engineering International*.
- Chapter 6: Santos-Fernández, E., Govindaraju, K., and Jones, G. (2014). A new variables acceptance sampling plan for food safety. *Food Control*, 44:249–257.
- Chapter 7: Santos-Fernández, E., Govindaraju, K., and Jones, G. (2015). Variables sampling plans using composite samples for food quality assurance. *Food Control*, 50:530–538.

Chapter 2

Quantity-Based Microbiological Sampling Plans and Quality after Inspection

Edgar Santos-Fernández, K. Govindaraju, Geoff Jones
Food Control, 2016, 63:83–92
http://www.sciencedirect.com/science/article/pii/S0956713515303005

2.1 Abstract

Sampling inspection plans are principally used to determine whether a batch of food is contaminated or not. In this theoretical research, we study the effect of increasing the analytical unit amount on the performance of microbiological sampling plans, and on the resulting quality after inspection. We discuss several scenarios of homogeneous and inhomogeneous contamination for assessing the consumer's risk. Several statistical approaches to describe the effect of an increase in analytical amount are studied. We provided a procedure for designing of the sampling plan for a given consumer's risk and according to different dispersion parameters and contamination levels.

Keywords

analytical unit amount; composite samples; heterogeneity; Poisson-lognormal; quality after inspection; safety sampling plan

2.2 Introduction

Sampling inspection plans for microbiological characteristics seldom allow the acceptance of a batch when test samples fail on a safety parameter. Even for sanitary characteristics, only one or two test samples are allowed to fail. The performance of microbiological inspection plans

largely depends on the number of test samples (n). The adequacy of n can be assessed using the Operating Characteristic (OC) curve of the plan to ensure that batches of unsafe or limiting concentration levels are mostly rejected. In addition to ensuring the rejection of unsafe/poor quality batches, focus must also be placed on the (outgoing) concentration levels in accepted batches. The amount of material to be tested, called the analytical unit amount (w) in FAO/WHO (2014) and expressed in weight/volume/area, is an important factor that affects the operating characteristics of the plan and hence the concentration levels in a series of accepted batches.

When sampling plans are used by regulatory authorities, they deal with many suppliers whose submitted quality can vary from batch to batch. Regulatory risk assessment cannot ignore possible batch to batch variation in microbiological concentration levels. Because of sampling inspection, the overall quality in the accepted batches is expected to be improved because poor quality batches are mostly rejected. Moderate quality batches may still be accepted and hence the concentration levels in a series of accepted batches are of interest, for example for evaluating the expected number of individuals contracting food poisoning.

The analytical unit amount w is an important leverage factor when a higher level of protection is desired without increasing the number of tests. Even though the size of w is restricted by the capacity of the analytical method, a small w may lead to a misleading conclusion regarding the distribution of cells, see the warning given by Jarvis (2008, pp.63). It is reasonable to assume that the sampled material w is sufficient to capture the local distribution of cells. That is, the size of the cluster of microorganisms is generally smaller than w.

In this paper, we mainly study the effect of increasing w on the probability of detection and batch acceptance under a sampling plan. Protection against a poor quality individual batch as well as the overall concentration level in a series of batches are important. An individual or isolated batch needs not necessarily be homogeneous which will also affect the protection to the consumer. Hence we discuss the following four cases:

- Case 1: Contamination within a batch is homogenous (i.e. case of an individual but homogeneous batch).
- Case 2: Contamination within a batch is inhomogeneous (i.e. case of an individual but inhomogeneous batch).
- Case 3: Contamination in a series of batches which are homogenous within the batch but the concentration level fluctuates from batch to batch.
- Case 4: Contamination in a series of batches which are inhomogeneous within as well as the concentration level fluctuates from batch to batch.

Throughout this paper, C is the observed concentration of microorganisms per gram. The random variable X represents the number of microorganisms in w. The notations $\mathrm{E}[X]$, $\mathrm{Var}[X]$ and $\mathrm{S}[X]$ are used to refer to the within batch mean concentration (or expected value), the variance and standard deviation of the concentration respectively. Notations of μ and σ are

specifically used for the parameters of the lognormal distribution on the base 10 logarithmic ($\log_{10}$) scale. The log notation without a subscript refers to the natural logarithm ($\log_e$ or ln). A summary of the symbols used is presented in the Appendix.

The paper is structured in the following way. We start the discussion with concentration-based sampling plans in section 2.3. Cases 1 and 2 are studied in subsection 2.3.1 focusing on the quality assurance of on every batch intended for individual buyers and importers (who in turn represent the ultimate consumers). The sampling plan design issues are discussed in subsection 2.3.1. In subsection 2.3.2, we consider Cases 3 and 4 which are important for regulatory purposes wherein the focus is on a broader population dealing with issues such as the rate of cases of food-borne disease. Finally, a variables version of the inspection plan is studied in section 2.4.

2.3 Concentration-based sampling plan

2.3.1 Single batch microbial risk assessment.

In this section we focus the analysis on presence-absence tests and particularly for safety characteristics. Safety inspection is carried out when microorganisms pose a significant risk for human health even when these are unknowingly consumed in minute quantity. Ideally all accepted batches must be free of pathogens. Safety inspection results are often qualitative because the batch disposition is based on whether the target microorganism is present in any of analytical samples or not.

Inspection of a homogeneous batch (Case 1)

In a homogeneous batch , the concentration of pathogen will not differ within it. In other words, if the batch is split into sublots, no sublot is expected to contain either high or low concentration when compared to any other sublot. Homogeneity is often assumed in well-mixed bulk materials. The Poisson distribution is commonly used to model the count (X) of pathogens found in random samples drawn from a homogeneous batch. For the Poisson distribution, $\mathrm{E}[X]$ and $\mathrm{Var}[X]$ are equal to λ, the underlying concentration rate in a fixed amount (mass) such as $w = 5$g of material. The Poisson function

$$P(x|\lambda) = \frac{\lambda^x e^{-\lambda}}{x!} \tag{2.1}$$

gives the probability of obtaining x cells for a given λ. While the concentration C gives the actual contamination level, λ is a measure of the risk of contamination. The parameter λ must be defined for a fixed constant mass or amount, and without loss of generality λ can be assumed to be associated with smallest amount that can be tested (such as 5g). Suppose that the analytical method is also capable of analysing an amount larger than the unit amount of material, say $w_y = 25$g. Let $m = w_y/w$. Let the random variable Y represents the number of microorganisms in w_y. The rate parameter λ_y for the larger amount w_y will then be $\lambda_y = \lambda w_y/w = \lambda m$. In

presence-absence tests, an analytical sample is declared as positive when at least one target microorganism is found. Hence the probability of detection $P_d(\lambda|w)$ in a single analytical sample is given by $P(x>0) = 1 - P(x=0) = 1 - e^{-\lambda}$ for the size w. The probability of detection is greater for the analytical sample of size w_y because $P(y>0) = 1 - e^{-\lambda_y} = 1 - e^{-\lambda w_y/w}$. This means that an increase in the analytical amount will always lead to a higher the probability of detection. We assume that the analytical test has perfect sensitivity and specificity and thereby avoid the complications of false positives and/or false negatives.

Let n be the number of analytical samples tested. For the inspection of a homogeneous batch, FAO/WHO (2014) provided sets of amount w and n fixing the total $T = nw$. For a zero acceptance number $(c = 0)$ plan, the OC function giving the batch probability of acceptance is $P_a(\lambda|n,w) = (1-P_d)^n = \left(e^{-\lambda}\right)^n$ which is the probability of n analytical samples failing to detect any pathogen. For a homogeneous batch, $P_a = e^{-T\lambda}$ depends on the underlying rate parameter λ, and the total amount tested T (because $T = nw$), see FAO/WHO (2014). For example, for a fixed total amount of material of 50g, testing 10 samples of 5g is similar to testing 2 samples of 25g each. In this case, the second alternative is preferable since it would involve less testing.

Inspection of an inhomogeneous batch (Case 2)

Microorganisms grow in colonies, clusters or clumps resulting in batch inhomogeneity for the cell counts. It is well established in food control literature that the Poisson law fails to apply when pathogen counts are over dispersed ($\mathrm{Var}[X] > \mathrm{E}[X]$). The family of Poisson mixture distributions , which combines the Poisson distribution with another continuous distribution to account for varying λ, is adopted for modelling over-dispersed cell counts. Consider-

$$P(\lambda,x) = \int_0^\infty \frac{\lambda^x e^{-\lambda}}{x!} f(\lambda)\, d\lambda \tag{2.2}$$

where $f(\lambda)$ is the mixing distribution. Popular Poisson mixture distributions are the Poisson-gamma (Anscombe, 1950) and the Poisson-lognormal (Bulmer, 1974a). Both models have been used extensively in the food safety literature, e.g. Toft et al. (2006), Teunis et al. (2008), Jarvis (2008), Van Schothorst et al. (2009), Zwietering (2009), Gonzales-Barron and Butler (2011b), Gonzales-Barron and Butler (2011a), Jongenburger et al. (2012b), Jongenburger et al. (2012c), Williams and Ebel (2012), Gonzales-Barron et al. (2013), Mussida et al. (2013a) and Haas et al. (2014).

We particularly focus on the Poisson-lognormal (PLN) distribution because it is common to study the effect of the amount w using this mixture distribution. The PLN arises as a Poisson process in which the rate parameter λ is lognormally distributed (with parameters μ and σ) with probability density function:

$$P(x|\dot{\mu},\dot{\sigma}) = \int_0^\infty \frac{\lambda^x e^{-\lambda}}{x!} \frac{1}{\lambda\dot{\sigma}\sqrt{2\pi}} e^{\left(-\frac{(\ln(\lambda)-\dot{\mu})^2}{2\dot{\sigma}^2}\right)} d\lambda \tag{2.3}$$

The above integral has no analytical solution. Hence the probability of detection is also evaluated numerically. Notice that the notations $\dot{\mu}$ and $\dot{\sigma}$ in Eq. 2.3 are specifically used to assert that these are on the natural logarithmic scale ($\log_e$) and obtained from the $\log_{10}$ base parameters as $\dot{\mu} = \ln(10)\,\mu$ and $\dot{\sigma} = \ln(10)\,\sigma$.

Consider the zero acceptance number plans with $n = 10$ and 30 for the underlying PLN distribution with unknown parameters μ and σ and a unit amount w. Ideally, the performance of these plans must be assessed using the OC or P_a contours for given (μ, σ) pairs. The traditional two dimensional OC curve of P_a vs λ is suitable for the Poisson case but not for the PLN case because it involves two parameters for a fixed amount w. The PLN distribution approaches the Poisson distribution for $\sigma < 0.10$, and only in such cases can the two-dimensional OC curve plotting P_a against μ be useful. Fig. 2.1 gives the OC contour plot of the plans ($n = 10$ and 30, $c = 0$) which shows the P_a contours against μ and σ (both in $\log_{10}$ scale). This plot clearly shows that the higher the inhomogeneity within a batch, the smaller the batch probability of acceptance will be.

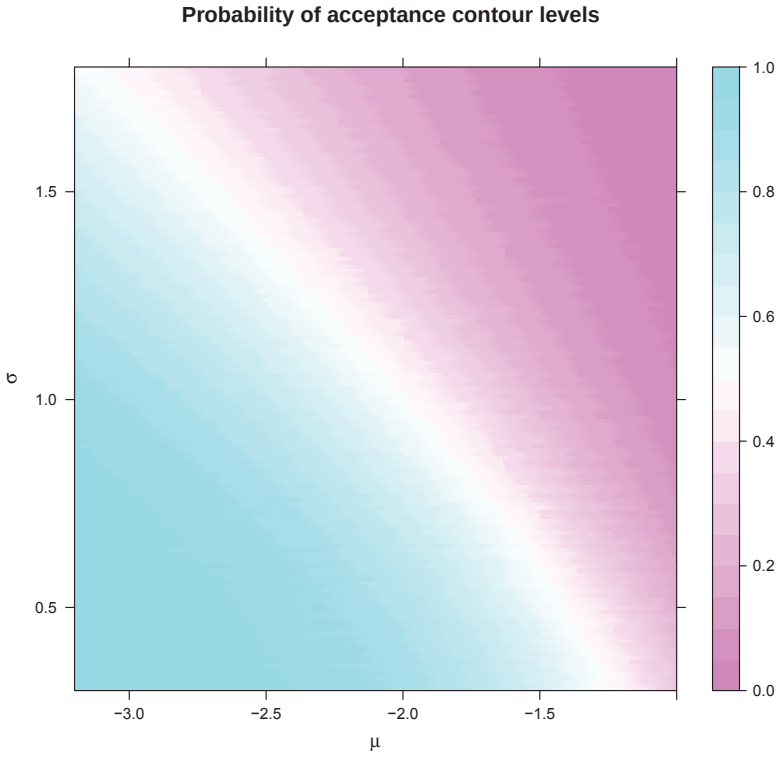
In order to compare the sampling plans based on the Poisson and PLN models, P_a can be plotted against the respective expectations $\mathrm{E}[X]$ for a fixed σ (Fig. 2.2). $\mathrm{E}[X]$ is referred to as the *arithmetic* mean of the discrete cell counts in food control literature, but it should be noted that $E[X] = \lambda = 10^{\mu+\log(10)\sigma^2/2}$ is not computed using sample data but rather is an unknown population value. Under a heterogeneous spatial distribution of cells, the probability of detecting contamination is smaller. The higher the dispersion of cells, the smaller the chances of detecting contamination.

Using composite samples

Composite sampling aims to provide more representative samples with a reduced variability in the test results. Therefore, this technique might lower the risk while keeping the analytical costs. See e.g. ICMSF (2002). Compositing is a natural averaging process in which n_I primary units or increments of size w are physically combined forming n composite or pooled samples. The composite samples are then well mixed and a subsample of size w is obtained from each one for testing purposes. In this section, we show how composite sampling is another important strategy to take into account in the design of microbiological sampling plans.

There are several recommendations on how compositing should be used. For example, Jarvis (2007) discussed three methods of compositing. For the purpose of this paper we only analyse the composite that was formed before the laboratory test so that compositing does not conflict with the test procedure. The case in which the samples are firstly incubated as in Jarvis (2007) third alternative, would yield better probability of detection. We need to mention that the number of increments to be used depends on the specific test protocol. For the purpose of this discussion we use $n_I = 4$ increments. Moreover, the efficiency of this technique depends on the quality of the mixing of the primary units. Perfect composite means that every individual sample will equally contribute to the final subsample. However, this is rarely achievable in practice. For the development of the theory, we assume perfect mixing and our results are expected to hold

$n = 10$



$n = 30$

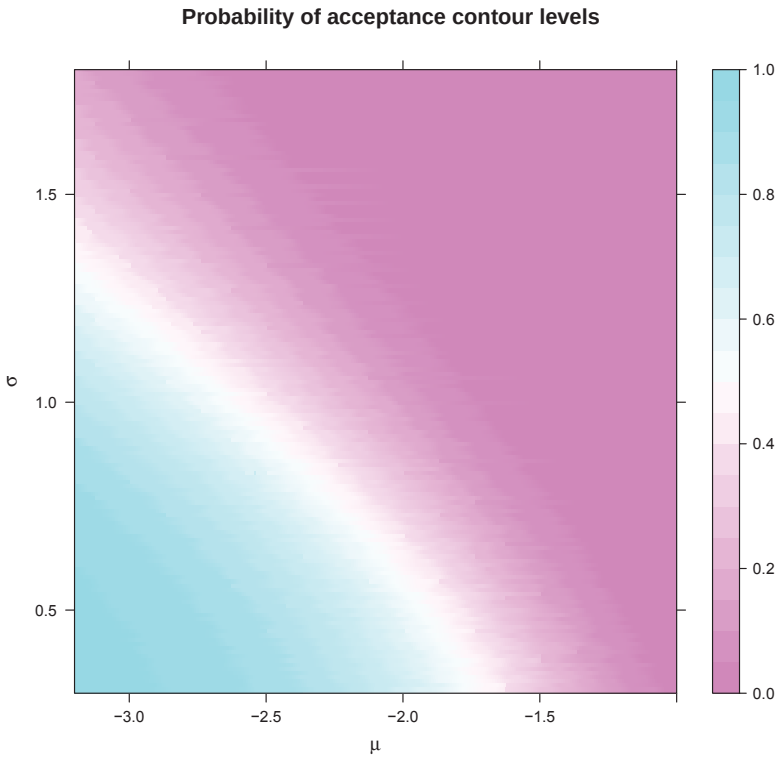


Fig. 2.1 OC contour plots of two-class concentration-based sampling plans with $n = 10$ and 30. The batch probability of acceptance is obtained from the Poisson-lognormal distribution.

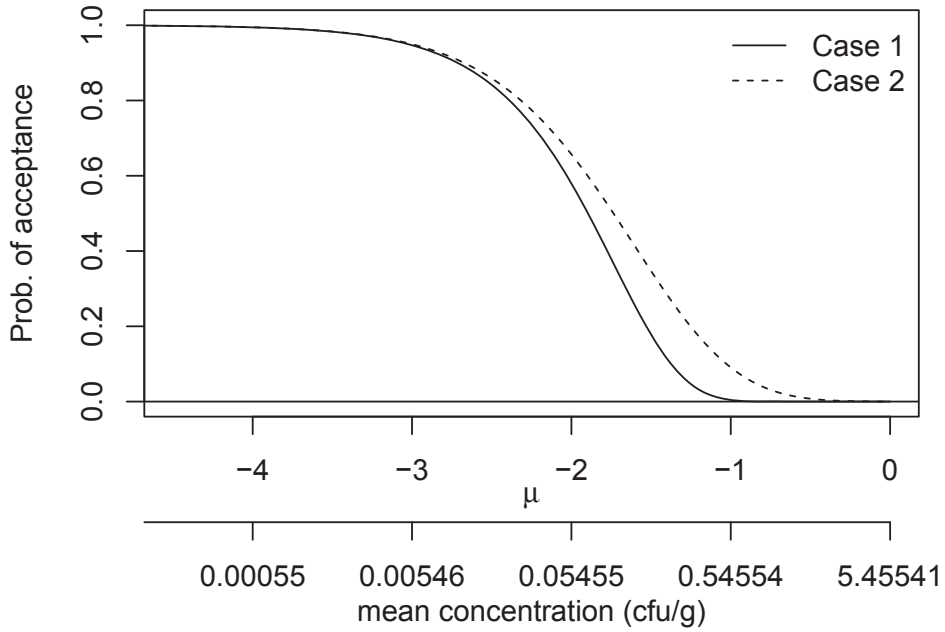


Fig. 2.2 Effect of batch inhomogeneity on the OC curve ($n = 10$, $c = 0$). Cases 1 and 2 refer to homogenous and inhomogeneous contamination respectively.

as long as the mixing is not too imperfect. Various scenarios of imperfect mixing have been discussed by Nauta (2005) and Santos-Fernández et al. (2015).

In Fig. 2.3 we compare sampling plans using composite samples and using the primary samples directly (without pooling primary samples). Compositing has little effect when microorganisms are homogenously distributed, which is given by the difference between the black and grey solid lines (Case 1 vs. Case 1, $n_I = 4$). However, for heterogeneous contamination the use of composite samples provides higher stringency and lower consumer's risk. Notice the difference between the dashed black and dashed grey lines (Case 2 vs. Case 2, $n_I = 4$). Since the spatial distribution of cells is commonly unknown, it seems to be convenient to test pooled samples. Compositing can reduce the risk difference associated with both homogenous and inhomogeneous distributions of microorganisms. In subsequent sections we are not using composite samples.

Effect of increasing the analytical amount

In this section we examine the risk when the analytical amount is increased m-fold using three methods (designated as **a**, **b** and **c**), corresponding to three different spatial levels of inhomogeneity.

In the first approach (**a**), the effect of w_y is incorporated via the parameters of the population of the bigger unit (μ_y and σ_y). The distribution parameters are obtained using the arithmetic moments $E(Y) = mE(X)$ and $V(Y) = mV(X)$. The expected number of microorganisms in the bigger unit is m times the expected number in the small unit. The same is true for the arithmetic

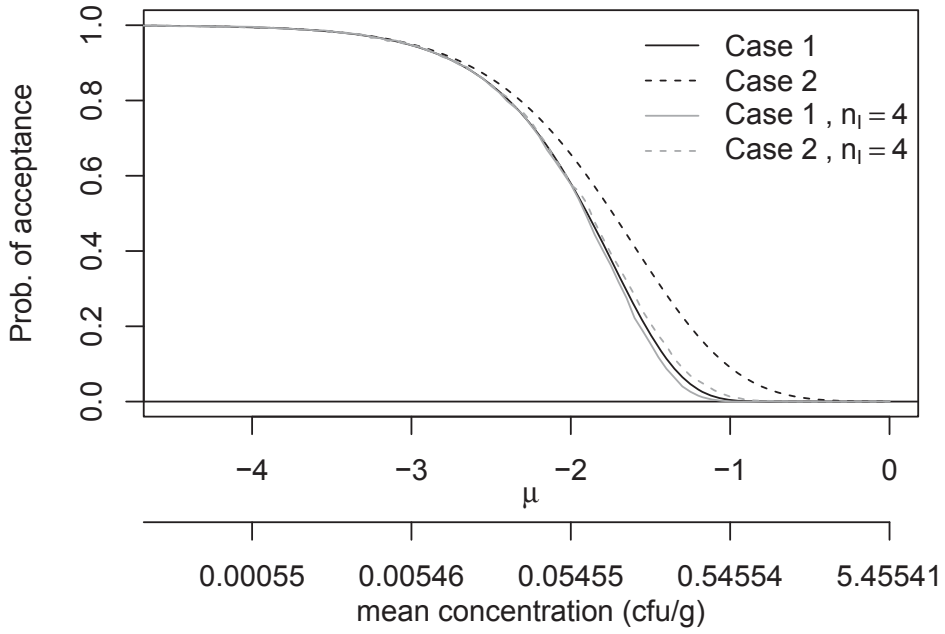


Fig. 2.3 Effect of using composite samples with $n_I = 4$ increments using the plan ($n = 10$, $c = 0$) for the cases of homogeneity and inhomogeneity.

variance. These relationships are based on the assumption that there is no spatial correlation in the (contamination) rate. Using this method, Mussida et al. (2013b) recently demonstrated how an increase in w leads to a reduction in the risks. This approach, known as convolution, is briefed in 2.B.

The second method (**b**) is obtained using the probability mass function given by Haas et al. (2014, pp.193) for a given m value.

$$P(x|\dot{\mu},\dot{\sigma},m) = \int_0^\infty \frac{(\lambda m)^x e^{-\lambda m}}{x!} \frac{1}{\lambda\dot{\sigma}\sqrt{2\pi}} e^{\left(-\frac{(\ln(\lambda)-\dot{\mu})^2}{2\dot{\sigma}^2}\right)} d\lambda \tag{2.4}$$

This method assumes that λ is locally constant, equivalently that there is a high spatial correlation locally. That is, adjacent small units in the batch are assumed to have similar numbers of cells. Since Eq.2.4 depends on m, this form of the distribution is different from the usual two-parameter PLN distribution based on a fixed w. This equation clearly shows that m affects the probability of detection $P_d = P(0|\mu,\sigma,m)$ and hence batch probability of acceptance $P_a(\mu,\sigma|m) = (1-P_d)^n$ for the $c = 0$ plan. For fixed μ and σ, an increase in w will decrease P_a.

The degree of spatial correlation in the contamination is commonly unknown. Our third method (**c**) represents the scenario in which the contamination is most likely to be present in one cluster. The P_d in this alternative is obtained via Monte Carlo simulations using the following algorithm:

- Step 0. Define the parameters μ_x, σ_x in the small analytical unit X of size w_x.

- Step 1. Set the increased analytical unit w_y and obtain m.
- Step 2. Set the number of iterations I. Using $I = 50,000$ gives a good estimate.
- Step 3. Generate the number of microorganisms in w_x using random numbers from the PLN(μ, σ), creating a two dimensional grid N_{ij} with I rows and m columns.
- Step 4. Sort (ascending) N_{ij} so that the contaminated small units form a unique cluster in one extreme of the grid.
- Step 5. Sum by rows ($\sum_{j=1}^{m} N_{ij}$) to obtain the number of microorganisms in the bigger unit Y.
- Step 6. Obtain the P_d as the proportion of Y units with one or more microorganisms.

This contamination is likely to occur when a highly contaminated external source enters to the stream of product. ICMSF (2002, pp.193) describes this type of contamination as "comet like". Other examples of this type contamination can be found in the literature. See for example the study of the contamination of beef with *E. coli* O157 by Kiermeier et al. (2011). This case is also described by Jongenburger et al. (2011b) as localized contamination .

In Table 2.1 we compare the detection probabilities for Case 2 using the three types of clustering described above. The scale parameter is fixed ($\sigma = 0.8$) and different values of μ and w are considered.

Table 2.1 Detection probability according to different methods for $\sigma = 0.8$.

$E(X)$	$V(X)$	μ	m	Case 2a	Case 2b	Case 2c
0.055	0.37	-2	2	0.08	0.07	0.04
0.055	0.37	-2	5	0.18	0.14	0.04
0.055	0.37	-2	10	0.32	0.21	0.04
0.546	3.01	-1	2	0.35	0.31	0.22
0.546	3.01	-1	5	0.62	0.47	0.22
0.546	3.01	-1	10	0.83	0.59	0.22

Case 2a of no clustering gives the highest probability of detection being therefore the most optimistic scenario. The most conservative approach is Case 2c because it gives the lowest P_d. This is the worst case scenario increasing the consumer's risk because there is a high correlation between the contaminated units, and hence the contaminated units form a large cluster with the rest of the batch cluster free of pathogens. Hence, it may be appropriate to design microbial sampling plans based on this conservative supposition for some product types relying on the empirical knowledge on the frequency of large contaminated clusters to improve consumer protection. This, however, will undoubtedly require higher sample effort involving additional testing costs.

Sampling plan design

In this section we provide the required sample size for a given μ, σ, P_d and w for Cases 2a and 2b. We consider that the typical unit amount tested is lognormally distributed with $\sigma = 0.8$. From Table 2.2, it should be noted that for small μ, say -3 log10 cfu/g, using a small unit amount of 5g is simply not viable since it requires an enormous sample size. Testing 107 samples of 10g provides the same level of protection as 43 samples of 25g each for Case 2a. Case 2b requires higher sample sizes because this alternative lowers the probability of detection.

Table 2.2 Number of analytical samples (n) to be tested when the contamination is modelled by the Poisson-lognormal distribution for a desired probability of detection given μ, σ and analytical portion (in g).

			Case 2a			**Case 2b**			**Case 2c**		
			$\sigma = 0.8$			$\sigma = 0.8$			$\sigma = 0.8$		
m	w	P_d	μ=-3	μ=-2	μ=-1	μ=-3	μ=-2	μ=-1	μ=-3	μ=-2	μ=-1
1	5	0.67	213	27	5	213	27	5	213	27	5
1	5	0.90	446	55	10	446	55	10	446	55	10
1	5	0.95	580	72	13	580	72	13	580	72	13
1	5	0.99	891	110	20	891	110	20	891	110	20
			$\sigma = 0.5$			$\sigma = 0.5$			$\sigma = 0.5$		
			μ=-1.56	μ=-0.56	μ=0.44	μ=-1.56	μ=-0.56	μ=0.44	μ=-1.56	μ=-0.56	μ=0.44
2	10	0.67	107	14	3	111	15	3	213	27	5
2	10	0.90	224	29	6	231	32	7	446	55	10
2	10	0.95	291	37	7	301	41	9	580	72	13
2	10	0.99	447	57	11	462	63	13	891	110	20
			$\sigma = 0.38$			$\sigma = 0.38$			$\sigma = 0.38$		
			μ=-1.03	μ=-0.03	μ=0.97	μ=-1.03	μ=-0.03	μ=0.97	μ=-1.03	μ=-0.03	μ=0.97
5	25	0.67	43	6	2	48	8	2	213	27	5
5	25	0.90	90	12	3	101	16	4	446	55	10
5	25	0.95	117	16	4	131	21	5	580	72	13
5	25	0.99	180	24	5	201	31	8	891	110	20

2.3.2 Average quality in accepted batches

Highly contaminated batches are most likely rejected by the inspection process. Similarly good quality batches are likely to be accepted and cleared to the consumers. As a result, the overall quality in the population (or series) of accepted batches is expected to be superior when compared to the quality in the submitted or uninspected batches. This property is clearly established in the literature for physically discrete units, mainly when screening for defective units and correcting them are possible. In bulk materials, the quality after inspection is more complex to derive compared to the traditional inspection of units in parts manufacturing. In the microbial risk assessment context, several authors have shown the need for models accounting for variability from batch-to-batch. See e.g. Paoli and Hartnett (2006), Zwietering (2009), Gonzales-Barron et al. (2013), Mussida et al. (2013b).

The impact of pathogenic microorganisms in public health is often assessed for a single batch. Given that the probability of illness is a function of the intake dose (number of microorganisms), the computation of metrics like the expected annual number of illnesses is a function of the quality of the accepted batches. For example, FAO/WHO (2007) provides a web-based tool for risk assessment for *Enterobacter sakazakii* in powdered infant formula. This tool gives the quality after inspection for a given log concentration. It considers within batch heterogeneity as well as between batch variability. The main limitation of this tool is that it requires knowledge of the incoming log concentration, which is generally unknown. Moreover, the computation of the risk for increasing the analytical amount is obtained from Eq.2.4 (Haas et al., 2014). Mussida et al. (2013b) instead used the convolution approach that gives the most optimistic scenario. However, both methods underestimate the risk when the contamination is localized in a specific part of a batch (Case 4c).

In the next subsection, we discuss the measurement of a limit for the average quality after inspection . This limit gives the peak average level of contamination in accepted batches and portrays realistic picture of the quality received by the consumer. We also discuss the scenario of a series of homogenous batches with variation in the contamination rate from batch to batch.

Simulation algorithm

We opted for Monte Carlo simulation in this section since the analytical solution is intractable when batch to batch variability is additionally involved. The following algorithm allows the computation of the outgoing concentration levels in accepted batches for Cases 3 and 4:

- Step 0. Set a sample size (n) and an analytical unit amount (w), e.g. $n = 10$ and $w = 5$.
- Step 1. Homogeneity within the batch is modelled with the Poisson distribution with rate λ. We first assumed that the batch is homogenous, but allow the contamination rate to vary from batch to batch. The inhomogeneous case is then modelled with the Poisson-lognormal distribution with parameters μ and within batch standard deviation σ_w. Similarly, μ changes from batch to batch.

  For a given contamination level, the parameters under batch homogeneity and inhomogeneity are matched using the mean of the original counts $E[X] = \lambda = 10^{\mu+\log(10)\sigma^2/2}$. Notice that if we use the mean log concentration, the risk is underestimated. Define the within and between batch standard deviations, say $\sigma_w = 0.8$ (Legan et al., 2001) and $\sigma_b = 0.8$ (Mussida et al., 2013b).
- Step 2. Set the number of batches N to be simulated. For instance, $N = 50,000$ gives a good estimate.
- Step 3. Suppose that μ_i changes from batch to batch and that the normal distribution with standard deviation (σ_b) is suitable to describe it. Generate N values μ_i with mean μ and standard deviation σ_b. Compute the corresponding $\lambda_i = 10^{\mu_i+\log(10)\sigma^2/2}$.

- Step 4. For each μ_i (inhomogeneous case) and the matching λ_i (homogenous case), obtain the probability of detecting contamination and batch probability of acceptance P_a.
- Step 5. Determine the concentration of microorganisms after inspection as the weighted arithmetic mean of λ_i using the batch P_a as weights.
- Step 6. For the incoming and accepted batches, estimate the population prevalence (p) for the homogeneous and inhomogeneous scenarios. The prevalence p is the proportion of analytical units in the population with at least one microorganism. The prevalence before inspection is $p = \sum_{i=1}^{N} P_{d_i}/N$. For accepted batches, it becomes $p = \sum_{i=1}^{N} P_{d_i} \times P_{a_i} / \sum_{i=1}^{N} P_{a_i}$.
- Step 7. Compute the proportion of accepted batches out of N.
- Step 8. Repeat Steps 1-7 for various μ in the interval $-7 \leqslant \mu \leqslant 0$. The bigger the μ value, the lower the proportion of accepted batches would be.

We considered that every batch is inspected only once and no resampling is carried out when a nonconforming batch is found. The concentration of microorganisms and the associated prevalence are treated as measures of quality for the incoming and accepted batches and calculated in the above steps.

Results

Fig. 2.4 compares several metrics for the submitted as well as the accepted batches using the sampling plan $n = 10$, $c = 0$, $w = 5$g, $\sigma_w = \sigma_b = 0.8$. In Fig. 2.4(a), we compare the contamination levels of the incoming batches with those in accepted batches. The average concentration is substantially lower in the accepted batches when compared to the concentration before inspection. The concentration in Case 4 is higher when compared with Case 3, since batches with high and localized contamination are more difficult to detect.

Fig. 2.4(b) shows the prevalence before and after inspection. Notice that Case 2 presents a lower prevalence than Case 1 for the same concentration rate. However, the prevalence is similar in accepted batches irrespective of whether the submitted batches are homogeneous or not. For the range of μ we studied, the prevalence was found to be monotonically increasing with μ. The prevalence after inspection does not decrease (see the right-hand part of this graph) because a contaminated batch cannot be replaced with a batch guaranteed to be completely free of contamination (which can occur in screening a batch of discrete units with non-destructive testing). A newly produced batch is subjected to inspection and upon acceptance; it can take the place of a rejected batch to form part of the series of batches released to the consumers. Fig. 2.4 (a) represents the contamination for hygiene characteristics, where the conformance depends on the level of the contamination. While (b) is more relevant for safety characteristics, where non-conformance as well as noncompliance is caused by the presence of a single cell or more in the sample.

In Fig. 2.4(c) we show the proportion of accepted batches in our simulation for Cases 3 and 4 along with the batch probability of acceptance for Cases 1 and 2. An increase in μ means a higher contamination and higher probability of detection in the incoming batches. Notice that the risk is higher when considering between batch variation because the OC curve for Cases 3 and 4 is less steeper when compared with Cases 1 and 2. Consider the sampling plan $(n = 10, c = 0)$ with more than 50% free of contamination in the submitted batches. The mean contamination in the batches received by the consumers is 0.07 cfu/5g. An increase in n is needed to lower down the mean contamination in the accepted batches.

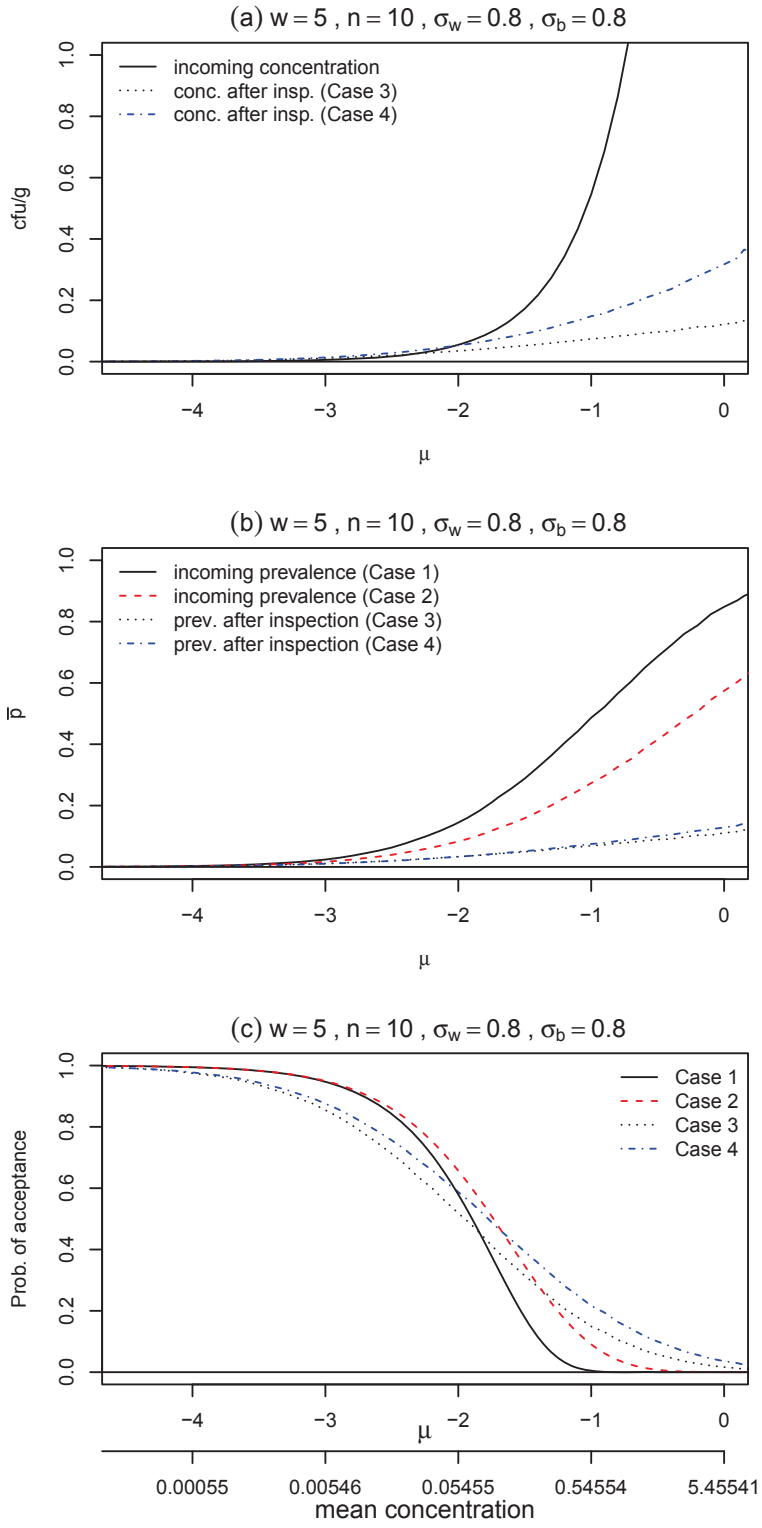


Fig. 2.4 (a) Incoming concentration (λ) is represented by the solid line. The mean concentration after the inspection for Cases 3 and 4 are shown as dashed and dotdashed lines. (b) Estimates of prevalence in the incoming and in the accepted batches. (c) Probability of acceptance for the homogeneous and inhomogeneous batches, before and after inspection.

Effect of increasing the analytical amount

Assume that the analytical amount w is increased five-fold (from 5 to 25 g). The probability of detection for the heterogeneous case in Step 4 is obtained using the three methods described in the last section. The simulation results shown in Fig. 2.5 reveal the following:

1. the concentration after inspection in the bigger analytical unit is more than the concentration in the smaller unit ($\mathrm{E}[Y] > \mathrm{E}[X]$). However, the *relative* concentration (at the same w) is smaller for the bigger analytical unit because $\mathrm{E}[Y] < \mathrm{E}[X] \times w$. Consequently, the overall contamination is reduced in the accepted batches when using a bigger w.

2. the prevalence in the bigger analytical unit increases, since the probability of observing at least one cell is increased. However, the *relative* prevalence (at the same w) is smaller since $p_y < p_x \times w$.

3. the proportion of accepted batches is reduced because of the increased probability of detection for the analytical sample.

4. as expected the Case 4 becomes closer to Case 3 with increased analytical unit amount.

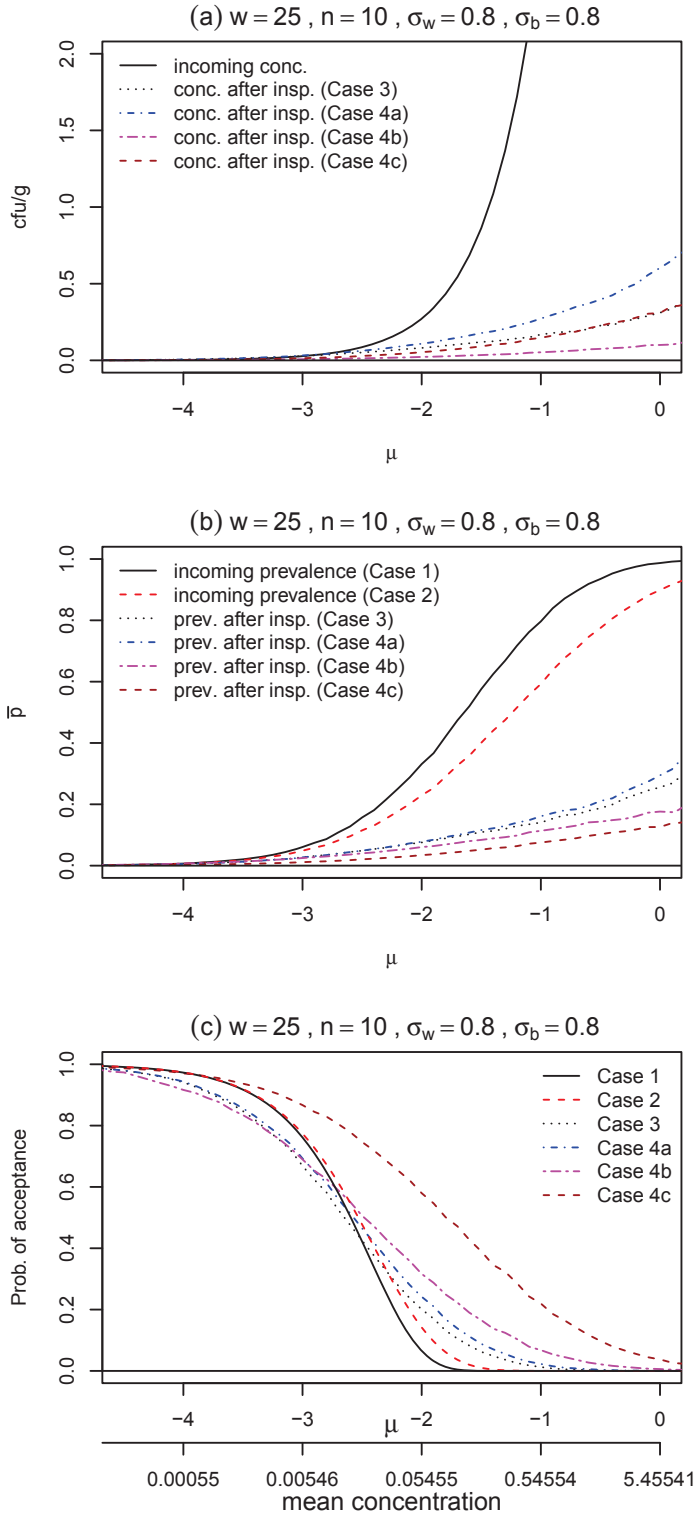


Fig. 2.5 Increased analytical unit amount $w = 25$g. (a) Incoming concentration (λ) is represented by the solid line. The mean concentrations after inspection for Cases 3 and 4 are shown as dashed and dotdashed lines. (b) Estimate of the prevalence of the contamination in the incoming and in the accepted batches. (c) Probability of acceptance for the homogeneous and inhomogeneous batches, before and after inspection.

2.4 Variables sampling plan

Variables plan are mainly employed for hygienic indicators where the background concentration level is low but not necessarily absent, e.g. *Enterobacteriaceae* in meat. The lognormal distribution is the *de facto* model for estimating the risk in this case. This distribution is easily transformed to normal after applying $\log_{10}$ and the traditional variables plan is then used. Let $V = \log_{10}(X)$ and $m_v = \log_{10}(m)$. The batch is accepted if $\bar{v} + k\sigma_v \leqslant m_v$, otherwise rejected, where $\bar{v} = \sum_{i=1}^{n} v_i/n$ is the mean of the $\log_{10}$-transformed count, σ_v is the known standard deviation of V and k is the critical distance. If the left part in the acceptance criterion ($\bar{v} + k\sigma_v$) is large, the prevalence is higher than expected and hence the batch should be rejected.

Effect of increasing the analytical amount

In this plan, increasing the analytical amount also increases the chances of finding contamination and therefore it also increases the probability of rejecting poor quality. The effect of w on the performance of the variables plan is not reported in the literature. Consider the following example. Suppose that the contamination in the small analytical unit X of 5g is lognormally distributed with $\sigma_w = 0.8$, $X \sim LN(\mu, \sigma_w = 0.8)$. Consider a microbiological limit $m = 2.5$ $\log_{10}$ cfu/5g. Consider that the analytical method is also capable of analysing a greater amount, $w_y = 25$g. In order to obtain the parameters of the bigger unit (μ_y and σ_y), we used the convolution approach previously described. In Fig. 2.6 we show the OC curve of the plan $n = 10$ for $w = 5$ & 25. We notice the substantial reduction in the limiting quality level when increasing w.

2.4.1 Sampling plan design

In Table 2.3 we show the required sample size for given values of w, μ, σ_w for the case of an individual batch. From this table, it can be noted that the sample size is significantly reduced with a higher analytical amount. For example, using 30 samples of 5g each is equivalent in terms of consumers protection to using 11 samples of 25g each.

Table 2.3 Number of analytical samples to be tested n and the critical distance k given μ, σ_w and w values. $T = w \times n$ represents the total amount to be tested.

m	w	n	T	μ	σ_w	LQL	k
1	5	10	50	0.00	0.80	1.6	1.89
2	10	6	60	0.44	0.72	1.6	1.47
5	25	3	75	1.02	0.60	1.6	0.84
1	5	20	100	0.00	0.80	1.2	2.19
2	10	15	150	0.44	0.72	1.2	1.85
5	25	6	150	1.02	0.60	1.2	1.20
1	5	30	150	0.00	0.80	1.0	2.31
2	10	24	240	0.44	0.72	1.0	2.02
5	25	11	275	1.02	0.60	1.0	1.46

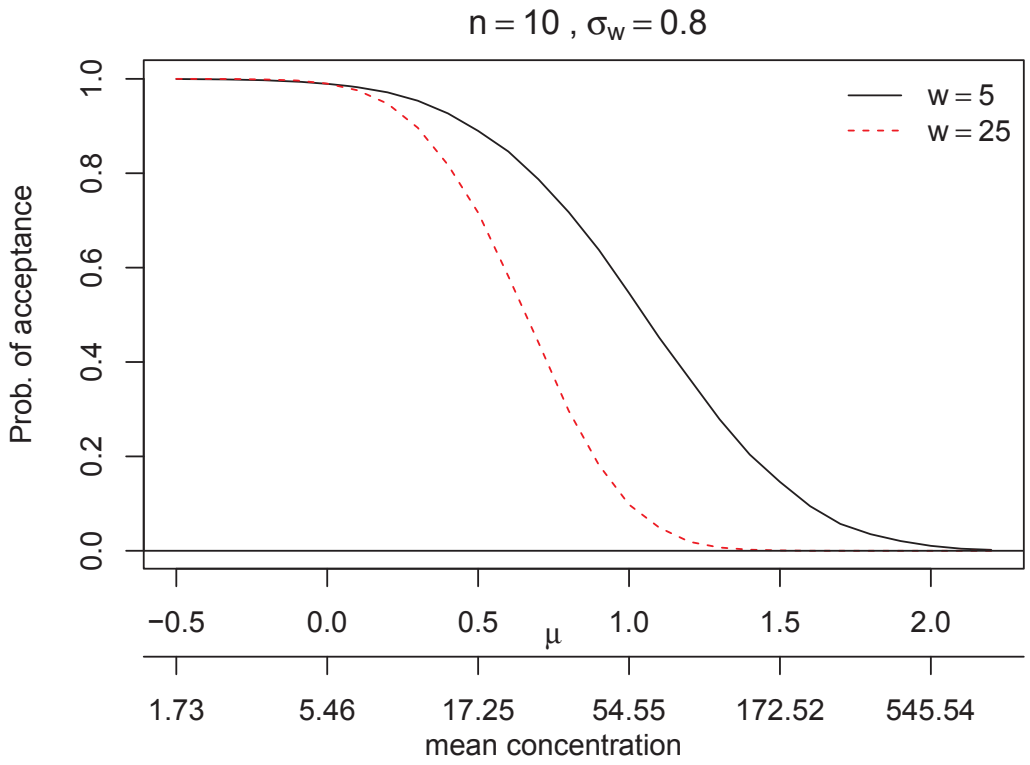


Fig. 2.6 OC curve of the variables plan with $n = 10$ and $\sigma_w = 0.8$ for $w = 5$ and 25g. This figure shows that an increased analytical unit amount reduces the consumer's risk.

2.4.2 Average quality in accepted batches using variables plan

In this section, we explore the microbiological quality in accepted batches when the inspection is based on a variables plan. In the population of accepted batches, the distributional parameters of the contamination cannot be obtained analytically. We resorted to the simulation procedure previously discussed to obtain the probability of acceptance.

In Fig. 2.7 (a), we compare the concentration in the submitted as well as in the accepted batches for the sampling plan $n = 10$, $w = 5$g when $\sigma_w = \sigma_b = 0.8$. A substantial reduction in the concentration is achieved after sampling inspection. In Fig. 2.7 (b), we show the probability of acceptance for a single batch and for a series of batches allowing for batch to batch variation. The OC curve becomes less stringent after allowing for variability between the batches. For example, at a limiting concentration level $\mu = 1.5$, the consumer's risk of accepting a single poor quality batch is only half of the risk when batch to batch variation of the order $\sigma_b = 0.8$ is present even though the average concentration level for these batches is also at $\mu = 1.5$.

2.5 Discussion and conclusions

Microbiological sampling plans under a wide range of scenarios including concentration-based and variables plans are discussed in earlier sections. We provided a broad range of factors which can affect quality including the spatial distribution of microorganisms, the use of composite

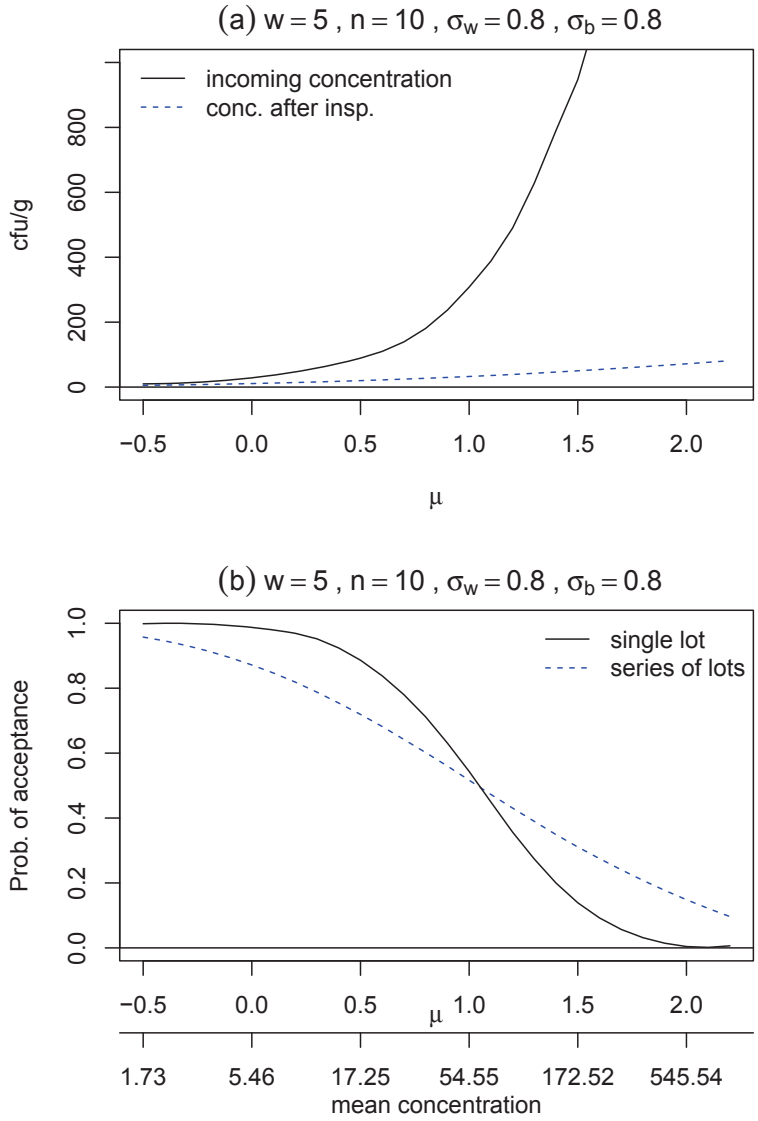


Fig. 2.7 (a) Incoming concentration of the contamination (represented by the solid line) in relation to μ. The concentration after the inspection is given by the dashed line. (b) It compares the batch probability of acceptance for a single batch and for the series of batches.

samples, the amount of material used for testing purposes and then assessed quality after inspection in a series of batches. We listed the merits and limitations of methods found in the bibliography (e.g. FAO/WHO, 2007; Mussida et al., 2013b) which incorporate the analytical unit amount in the computation of the consumer's risk. In both, concentration-based and variables inspection plans, the contamination in the accepted batches is considerably smaller when compared with the contamination in the batches submitted for inspection. This means a reduction of the risk of contamination is achieved by sampling inspection, and therefore assures quality received by the consumers.

In the convolution approach, the analytical test units are considered to be uncorrelated. Therefore, the aggregated unit is assumed to be the sum of independent and identically distributed random variables. Increasing the unit analytical amount, allows undoubtedly a higher proba-

bility of detection. However, this strategy should be employed with caution. It brings further complications because correct parameter estimation for the bigger unit is difficult. The size of the contamination is often bigger than the size of the analytical unit resulting in non-ignorable spatial correlation. In this scenario, the current methods may fail to provide a good estimate of the probability of detection. However, the convolution theory used by Mussida et al. (2013b) has proven to be satisfactory under certain conditions, for example, when considering a small increase in w and for a limited range of standard deviations. The results of this study indicate that highly localized contamination (Case 4c) warrants further increased sampling in the absence of empirical knowledge on the spatial nature of potential contamination.

We should mention that the main limitation of compositing is the risk of dilution. For example, suppose that one of the increments contains the pathogen. If we mix this increment with other non-contaminated samples, then the concentration will be reduced. This would yield a negative result for concentration values below the limit of detection. Hence, the sensitivity might be affected; see the comments of Jarvis (2007). Also, the extra laboratory manipulation while preparing and mixing the composite might increase the risk of cross-contamination. Therefore, the risk of false positives might be increased, affecting the test specificity. However, this is factor is often considered as less relevant and is assumed to be negligible.

Finally, statistical models accounting for spatial distribution, such as Log-Gaussian Cox Process model, should be investigated in order to provide a better characterization of the risk in the food safety area.

Appendix 2.A Table of symbols

n	sample size or the number of analytical samples tested
w	analytical unit amount
C	concentration of microorganisms
λ	rate parameter in the Poisson distribution
P_a	probability of acceptance
P_d	probability of detection
p	prevalence
n_I	number of primary samples or increments that are combined to form a composite sample
LN	lognormal distribution
PLN	Poisson-lognormal distribution
μ	location parameter (mean log) of the LN and PLN distributions on the $\log_{10}$ scale
σ_w	within-batch scale (standard deviation) of the LN and PLN distributions on the $\log_{10}$ scale
σ_b	between batches scale (standard deviation) on the $\log_{10}$ scale
LQL	Limiting Quality Level
β	consumer's risk
X	number of microorganisms in the small unit
$Y = \sum X$	number of microorganisms in the bigger unit
$\mathrm{E}[X]$	expected value
$\mathrm{Var}[X]$	variance in the arithmetic scale
$\mathrm{S}[X]$	standard deviation in the arithmetic scale
Case 1	individual but homogeneous batch
Case 2	individual but heterogeneous batch
Case 3	series of homogenous batches
Case 4	series of heterogeneous batches
a	convolution method
b	Haas et al. (2014) Eq.2.4 method
c	simulation method for the case of one cluster

Appendix 2.B The convolution theory

If the cell cluster size is expected to be small compared to analytical unit amount for low contamination levels, the spatial correlation between the analytical units can be considered negligible. In other words, the analytical amounts can be treated as independent. Suppose that the analytical method is also capable of analysing a greater amount of material. For the bigger amount, the process of aggregation of the small analytical samples can be treated as the convolution or sum operation done on random variables. The sum of independent log-normally distributed random variables does not have a closed-form solution, but it can be approximated by another lognormal distribution under certain conditions, (Johnson et al., 1994, pp. 217). That is, if Y be the sum of independent and identically distributed (i.i.d.) lognormal random variables X, then the approximate distribution of Y is $LN(\mu_y, \sigma_y)$ where $E(Y) = mE(X)$ and $V(Y) = mV(X)$. The mean and variance for the larger amount is obviously bigger when several small amounts are aggregated. This approach of approximating the sum of lognormals is known as the Fenton-Wilkinson (Fenton, 1960) method. In the log10 scale, the parameters μ_y and σ_y of the population using a bigger unit Y become

$$\mu_y = \log_{10}(\mathrm{E}[Y]) - \log(10)\,\sigma_y^2/2 \tag{2.5}$$

$$\sigma_y = \sqrt{\log_{10}\left(1 + \frac{\mathrm{Var}[Y] - \mathrm{E}[Y]}{(\mathrm{E}[Y])^2}\right)/\log(10)} \tag{2.6}$$

Chapter 3

Compressed Limit Sampling Inspection Plans for Food Safety

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3.1 Abstract

The design of attribute sampling inspection plans based on compressed or narrow limits for food safety applications is covered. Artificially compressed limits allow a significant reduction in the number of analytical tests to be done while maintaining the risks at predefined levels. The design of optimal sampling plans is discussed for two given points on the Operating Characteristic curve and especially for the zero acceptance number case. Compressed limit plans matching the attribute plans of the International Commission on Microbiological Specifications for Foods are also given. The case of unknown batch standard deviation is also discussed. Three-class attribute plans with optimal positions for given microbiological limit M and Good Manufacturing Practices limit m are derived. The proposed plans are illustrated through examples. R software codes to obtain sampling plans are also given.

Keywords

attribute inspection; compressed limits; GMP limit; microbiological sampling plan; three-class plan

3.2 Introduction

Microbiological assurance of food quality is commonly carried out using sampling inspection plans. The sampling procedure comprises the number of samples (n) to be drawn and the lot acceptance criterion includes the upper microbiological limits. Section 3.A lists further symbols and definitions employed in the paper.

Microbiological attribute plans are divided into two groups FAO/WHO (2014):

1. plans for presence-absence response, intended for microorganisms that in small quantities represent a serious risk for the human health;

2. plans for concentration response, which are mainly used for hygiene characteristics. In this case, every analytical sample is classified as conforming if the concentration is below the set microbiological limit.

This paper deals with compressed limit plans for concentration and/or hygiene characteristic type responses such as the Aerobic Plate Count (APC). Compressed specification limits cannot be set to safety characteristics because the specification limit is generally equal to zero and this limit cannot be compressed. Microbiological risk assessment is commonly based on a one-sided specification such as an upper regulatory limit or food safety criterion e.g. $m = 100$ colony forming units per gram (CFU/g) of *Listeria monocytogenes* in "ready-to-eat foods other than those intended for infants and for special medical purposes" European Commission (2005). Microbiological limits included in the microbiological criteria could be either established by food safety authorities, defined by food operators or are the result of best practices.

The performance of a sampling plan is revealed by its Operating Characteristic (OC) curve . The OC curve gives the batch probability of acceptance for a given proportion nonconforming. The vertical axis of the OC curve gives the consumer's risk (β) for a given Limiting Quality Level (LQL). The OC curve also shows the probability of acceptance at a given Acceptance Quality Limit (AQL) from which the producer's risk (α) of rejecting AQL quality batches can be found. High analytical testing costs may force the use of smaller sample sizes, which can lead to lower protection for the consumer. The aim of this paper is to discuss the use of compressed specification limits in order to provide better consumer protection even with smaller sample sizes.

The paper is organized in the following way. An overview of the Good Manufacturing Practices (GMP) limits is given in Section 3.3. Section 3.4 discusses the use of two-class compressed limit plans when the standard deviation is known as well as unknown. Section 3.5 introduces a new compressed limit (CL) approach for three-class plans and Section 3.6 presents some numerical results including a discussion on the optimum two-class plans of the International Commission on Microbiological Specifications for Foods (ICMSF), ICMSF (2002, 2011). Finally, the last part discusses the case in which the underlying concentration distribution is other than lognormal.

All the calculations and figures were obtained using the R programming language R Core Team (2015). For some computations we borrowed functions from the R-packages **AcceptanceSampling** (Kiermeier, 2008) and **MFSAS** (Childs and Chen, 2011).

3.3 Good Manufacturing Practices (GMP) limits

It is common that food producers use an additional (self-imposed) limit or a compressed or warning limit during process control. The use of GMP limits in variables plans as described by Kilsby et al. (1979) allows producers to correct the production process immediately after exceeding the GMP warning limit, avoiding significant deviations from the process target. GMP limits when employed for lot-by-lot disposition can also lower the consumer's risk. GMP limits are used in three-class attribute plans (Bray et al., 1973b; Dahms and Hildebrandt, 1998) as well as in variables inspection plans as a warning limit (Kilsby et al., 1979).

Three-class plans by attributes involve two safety specifications namely the regulatory limit (M) and the GMP limit (m). Here m is defined as the maximum allowable frequency of pathogens under GMP conditions (Dahms and Hildebrandt, 1998) and this limit is set conservatively well below M. While the use of M results in the proportion nonconforming (p_M), m defines a proportion marginally acceptable (p_m) , see Figure 3.1.

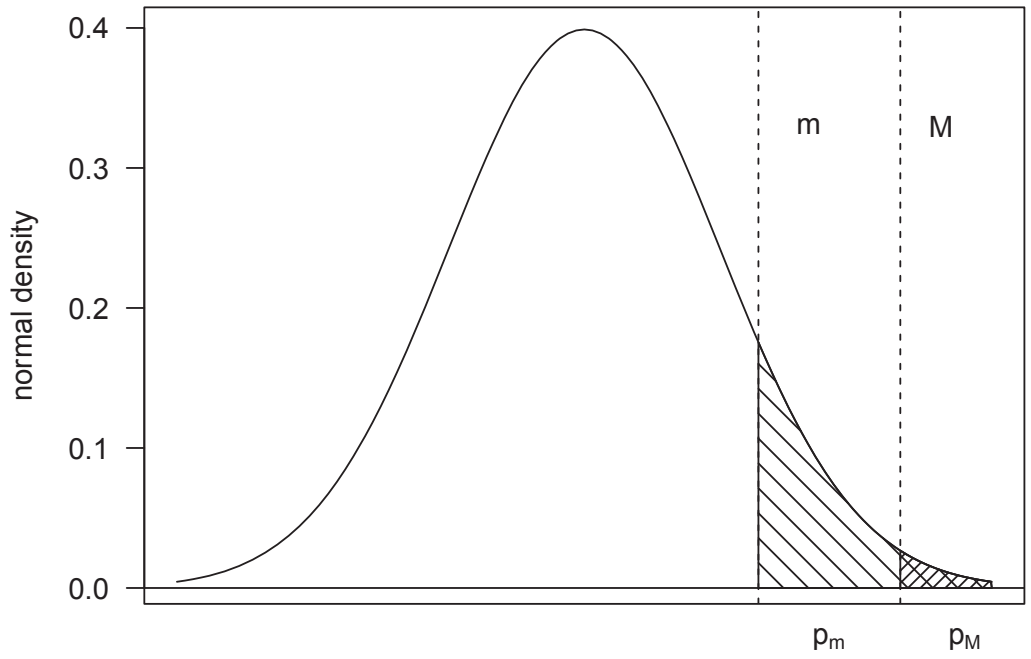

Fig. 3.1 Illustration of the GMP limit (m) in relation to the regulatory limit (M) for the normal distribution.

The traditional "known sigma" variables plan based on the normal distribution involves the decision (lot acceptance) criterion:

$$\bar{X} + k_1 \sigma \leqslant M \tag{3.1}$$

where $\bar{X}$ and σ are the sample mean and the batch standard deviation respectively and k_1 is the critical distance. If a compressed GMP limit is employed, the lot acceptance becomes $\bar{X} + k_2\sigma \leqslant m$. The new critical distance k_2 ($< k_1$) is obtained for the original sample size, the desired reduced LQL and β risk under GMP conditions. See Kilsby et al. (1979) or Malcolm (1984) for more details.

Having $\bar{X} + k_2\sigma \geqslant m$ but $\bar{X} + k_1\sigma < M$ means that the batch is acceptable but corrective actions must be taken to lower the mean level of the process. A very small m will lead to an increase in the producer's risk. Hence the choice of m requires risk evaluation. The relationship between GMP limits and compressed limits has not been explicitly studied in the literature.

3.4 Two-class compressed limit attribute plans for known σ

The term *compressed limit* is synonymous with terms such as pseudo-specification, tightened limit, and narrow limit. A compressed limit is an artificial limit which is fixed well below the regulatory or specification limit. Sampling plans based on compressed limits have been studied by Ott and Mundel (1954), Beja and Ladany (1974), Schilling and Sommers (1981) and Evans and Thyregod (1985) and others.

The traditional compressed limit sampling plans are based on the normal distribution and the standard deviation is assumed to be known and stable. Log transformed microbial counts are generally assumed to be normally distributed with a known standard deviation on the $\log_{10}$ scale $\sigma = 0.8$ (Dahms, 2004; Legan et al., 2001). This assumed batch standard deviation is larger than usually expected and therefore the consumers risk is not adversely affected. Compressed limit plans use the same decision criterion as the two-class attribute plans namely $d \leqslant c$; where d is the observed number of nonconforming analytical results beyond the tightened limit and c is the acceptance number. Compressed limit plans partly take advantage of the underlying continuous probability distribution of the variable of interest and hence require smaller sample sizes. Compressed limit plans may achieve a reduction in the sample size of about 80% when compared to using uncompressed specification limit (Schilling and Neubauer, 2010).

The procedure of setting a compressed limit for the normal distribution is described below. Let Z_p be the quantile in the normal distribution associated with a proportion nonconforming p. See Figure 3.2. By compressing the specification by t standard deviations (σ), an artificial proportion nonconforming g results. The normal distribution quantile corresponding to this artificial proportion nonconforming Z_g yields the compressed limit. Therefore,

$$Z_g = Z_p - \sigma t \tag{3.2}$$

In the literature t is known as the compression constant , and the value $t = 1$ is often employed for the sake of simplicity. However, $t = 1$ compressed limit plans may not be optimal for controlling the producer's and consumer's risks at desired levels.

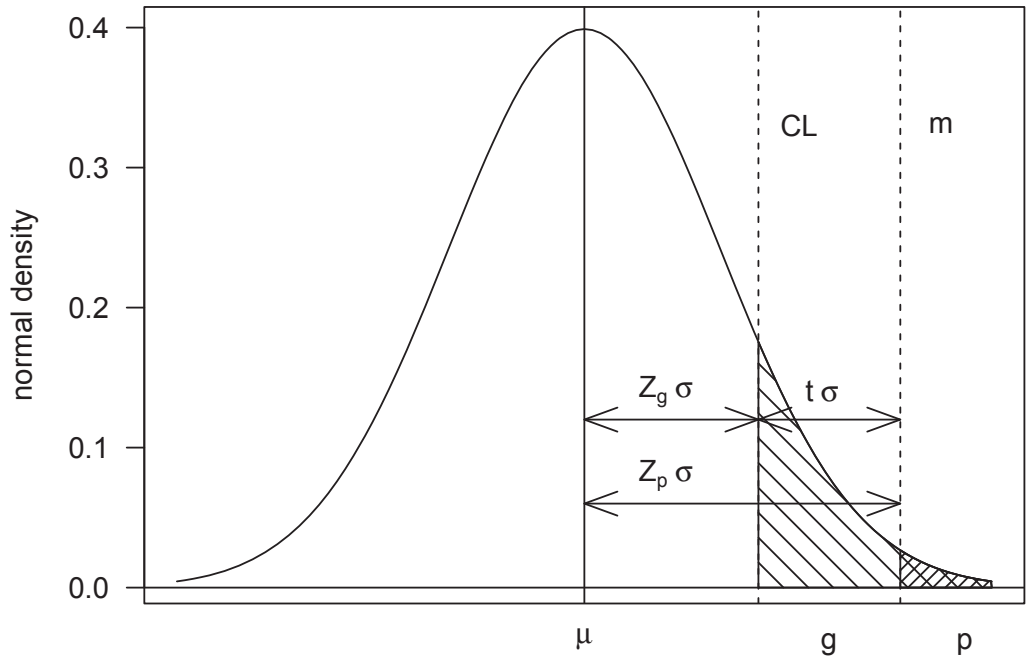

Fig. 3.2 Illustration of the compressed limit approach in the normal distribution.

For determination of the optimum t value, Ladany (1976) proposed an iterative graphical method based on the nomograph of the cumulative binomial distribution given by Larson (1966). An approximate heuristic approach was later proposed by Schilling and Sommers (1981) who provided the following formulae for the compressed limit plan parameters:

$$\begin{aligned} n_t &= 1.5 n_v \\ t &= k \\ c_t &= 0.75 n_v - 0.67 \end{aligned} \tag{3.3}$$

where n_v is the sample size of the variables plan and k the critical distance obtained for the traditional variables plan, see Duncan (1986); Schilling and Neubauer (2010). Another approximate optimal solution was suggested by Evans and Thyregod (1985). This method is based on the normal approximation to the binomial distribution and yields better results. The formulae for the design of compressed limit plans are

$$\begin{aligned} n_t &= \frac{\pi}{2}\left(\frac{Z_\alpha + Z_\beta}{Z_{AQL} - Z_{LQL}}\right)^2 \\ t = k &= \frac{Z_\alpha Z_{LQL} + Z_\beta Z_{AQL}}{Z_\alpha + Z_\beta} \\ c_t &= (n_t - 1)/2 \end{aligned} \tag{3.4}$$

Sampling plans published in Schilling and Sommers (1981) are not exact since the risks were relaxed by allowing tolerances $\alpha + 0.005$ and $\beta + 0.005$ which leads to smaller sample sizes. Other approaches obtained by approximation to the binomial model lead to slightly different results. Hence we provide below a new algorithm to obtain the exact optimal compressed limit plans.

1. Given two points (AQL, α) and (LQL, β), compute the corresponding standard normal quantiles Z_{AQL} and Z_{LQL}.

2. For the sequence of $t = 0(0.01)4$, calculate the normal quantiles $Z_{g_1} = Z_{AQL} - t$ and $Z_{g_2} = Z_{LQL} - t$.

3. Obtain the artificial proportions nonconforming p_{g_1} and p_{g_2} as the right tail areas of the standard normal distribution corresponding to Z_{g_1} and Z_{g_2}.

4. For given pair of points (p_{g_1}, α) and $(p_{g_2}, \beta)$of the OC curve, obtain n_t and c_t by solving the binomial inequalities:

$$\begin{aligned} 1 - \alpha^{'} &= \sum_{d=0}^{c} \binom{n}{d} p_{g1}^{d} \left(1 - p_{g1}\right)^{n-d} \geqslant 1 - \alpha \\ \beta^{'} &= \sum_{d=0}^{c} \binom{n}{d} p_{g2}^{d} \left(1 - p_{g2}\right)^{n-d} \leqslant \beta \end{aligned} \tag{3.5}$$

   where $\binom{n}{d} = n!/(d!(n-d)!)$ is the binomial coefficient, ! is the factorial and n, c and d are nonnegative integers. α and β are the predefined producer's and consumer's risks and $\alpha^{'}$ and $\beta^{'}$ are the achieved producer's and consumer's risks. Note that Eq.3.5 implies $\alpha^{'} \leqslant \alpha$ and $\beta^{'} \leqslant \beta$. Guenther (1969), for instance, provides an algorithm to solve these inequalities.

5. Select the t value that minimizes the sample size.

6. When more than one sampling plan exists, a second optimality criterion has to be employed. We propose the criterion [1] of the maximum absolute risk difference (MARD) $\max\left[\left|\alpha - \alpha^{'}\right| + \left|\beta - \beta^{'}\right|\right]$. The MARD criterion provides a slightly tighter OC curve than desired when $\alpha > \alpha^{'}$ and $\beta > \beta^{'}$, and hence the designed plan is more stringent .

Other alternatives to the MARD criterion are available in the literature, for instance, the minimum absolute risk difference (MIRD) $\min\left[\left|\alpha - \alpha^{'}\right| + \left|\beta - \beta^{'}\right|\right]$ Schilling and Sommers (1981). The method proposed in Schilling and Sommers (1981) does not impose the conditions $\alpha > \alpha^{'}$ and $\beta > \beta^{'}$ and hence it gives the closest OC curve to the points (AQL, α) and (LQL, β). Evans and Thyregod (1985) suggested the use of the midpoint between all the possible t values.

Appendix 3.C gives the compressed limit plans based on two points on the OC curve. The sampling design is also given for the MIRD criterion. The LQL values correspond to the selected

[1] If the MARD solution is not found to be unique, the plan with the smaller t can be chosen.

operating ratios $R = LQL/AQL$ equal to 20 and 40. For very small AQL values, t tends to be large which may cause a conflict with the specification limit. 3.B contains the R codes to obtain the optimal sampling design for other combinations of risks. We have also built an easy-to-use web application (app) using the *R* package **shiny** (Chang et al., 2015) for those practitioners unfamiliar with *R*. This tool is available at https://edgarsantosfdez.shinyapps.io/compress. As seen in Appendix 3.C, when both AQL and LQL are very low, the usual uncompressed attribute plans require large sample sizes such as $n = 313$. We show that a substantial reduction in the sample size can be achieved using the optimum compressed limit.

The following step-by-step guide illustrates the design and operation of the compressed limit attribute plan:

1. Assess the fit to a normal distribution and the stability of the variance using control charts.
2. Using two points (AQL, α) and (LQL, β), obtain the number of samples to be drawn (n_t), the acceptance number (c_t) and the quantile (q_t) from 3.C. For other quality levels and/or risks, use the R codes given in 3.B.
3. Obtain the artificial limit CL as the q_t quantile of the normal distribution.
4. Inspect the n_t items and determine the number of artificially nonconforming items (d_t) for the CL limit.
5. If $d_t \leqslant c_t$, accept the batch; otherwise reject.

Zero acceptance number sampling plans

Zero acceptance number ($c = 0$) inspection plans are desired in several industrial applications. In food safety, the plans are generally designed using one point in the OC curve (LQL, β) plus the restriction $c = 0$. Here, the producer's point (AQL, α) is not relevant because for food safety assurance the batch is expected to be free of pathogens. In the inspection of pathogenic microorganisms, it is not possible to release a lot when one of the samples fails the microbiological limit. Therefore the compressed limit plans introduced earlier should be limited to $c_t = 0$. The algorithm to find the compressed limit zero acceptance number plan for the known σ case is described below.

1. Given the point (LQL, β) and $c_t = 0$ compute the standard normal quantile Z_{LQL}.
2. Select a reasonable value for t, say $t = 1$ and obtain the normal quantile $Z_{g_2} = Z_{LQL} - t$.
3. Obtain the artificial proportion nonconforming p_{g_2} corresponding to Z_{g_2} (right tail area of the standard normal distribution).
4. Use p_{g_2} and β obtain n_t

$$n_t = \frac{\log(\beta)}{\log(1 - p_{g2})}. \tag{3.6}$$

Two-class compressed limit for unknown σ

For the traditional variables inspection plans, the sample size for the unknown σ case is approximately $\left(1+k^2/2\right)$ times the sample size of the known σ plan, see Wallis (1947) or Schilling and Neubauer (2010). The compressed limit attribute plan is also expected to be sensitive to the uncertainty of the population variance. However, the design of compressed limit attribute plans when the condition of known σ is not satisfied needs to be considered. We developed the following Monte Carlo simulation procedure to obtain the optimal compressed attribute plans for unknown σ.

1. For the normal distribution, there exists a one-to-one relationship between AQL and m. That is, for given producer's point (AQL, α), obtain the specification limit as the $(1-AQL)$-quantile of the standard normal distribution.
2. Generate a random sample of size n from the standard normal distribution $(\mu = 0, \sigma = 1)$.
3. Obtain the compressed limit CL as $m-t$.
4. Obtain the number of artificial nonconforming items (d) as the number of observations of the sample greater than CL.
5. Obtain empirically the probability of acceptance as the proportion of cases in which $d \leqslant c$ using at least 5000 iterations.
6. Consider select $\mu > 0$ values. Obtain the probability of acceptance P_a for a range of μ values.
7. To determine whether a given combination of n, c and t produces an OC curve restricted to the given two points, the following conditions need to be satisfied: $P_a \geqslant 1-\alpha$ and $P_a \leqslant \beta$ at AQL and LQL respectively.
8. The optimum plan is the one that minimizes the sample size and satisfies the two point restrictions.
9. When more than one sampling design exists obtain the plan applying MARD or MIRD criterion.

The sampling plans designed for common combinations of quality levels are also shown in Appendix 3.C (matched with other sampling plans). The operation of this sampling plan is similar to the two-class compressed limit plan for known σ discussed earlier.

3.5 Three-class compressed limit attribute plan

For food hygiene variables, analytical test results can be classified in more than two classes such as good, marginal and bad. The three-class attribute plan of Bray et al. (1973b) is the most

commonly used multi-class plan. Three class variables plans were introduced by Newcombe and Allen (1988). Three-class plans are convenient compared to two-class alternatives since they provide a greater protection when the assumptions are violated, for example, when the underlying distribution departs from the assumed model or the standard deviation is higher than expected (Wilrich and Weiss, 2009). In three-class attribute plans, both GMP and regulatory limits (m and M) are used simultaneously for classifying the inspected item as "acceptable", "marginally acceptable" or "unacceptable" instead of classifying them as just "conforming" or "non-conforming" for the two-class attribute plans. The population proportion nonconforming, p_M, is based on the M limit while the proportion marginally acceptable, p_m, is the population fraction of items between the m and M limits. Let d_M be the number of nonconforming items found in the sample. Also let d_m be the number of marginally acceptable sample units. Denote c_m and c_M as the acceptance numbers for marginally acceptable and nonconforming items found in the sample. The three-class compressed limit plan accepts the lot when both $d_m \leq c_m$ and $d_M \leq c_M$. If $d_m > c_m$ and/or $d_M > c_M$, the lot is rejected.

Since every trial now has three possible outcomes, the probabilities are obtained from the trinomial distribution . This model is a particular case of the multinomial distribution (Jarvis, 2008; Johnson et al., 1997). The trinomial distribution is relevant when the batch is considered sufficiently large. For isolated and small batches, the trivariate hypergeometric distribution should be employed to obtain the risks. The performance of the three class plan is revealed by a three-dimensional OC surface or by OC contours.

Three-class microbiological plans are widely used in practice. For instance, it is recommended in ICMSF (2002, pp. 163) as cases 1-9, and regulated by European Commission (2005) for sampling in food categories such as meats, fishery products, milk and dairy products, vegetables and fruits. These plans use $c_M = 0$. Dahms and Hildebrandt (1998) and Wilrich and Weiss (2009) showed that the performance of three-class plans depends on the distance between m and M. Dahms and Hildebrandt (1998) derived this difference between both limits as:

$$M - m = Z_{1-AQL}\sigma \tag{3.7}$$

This condition cannot be ignored since the performance of three-class plans is significantly affected when using arbitrary m and M values. If the difference between m and M is very large or very small, the performance of the three-class plan will clearly approach to a two-class plan. See Wilrich and Weiss (2009) for more details.

The use of artificial or compressed limits in three-class plans can reduce the sample size while keeping the risks at the same level. However, the use of artificial limits in multi-class attribute plans has not been considered in the literature. In this section we discuss the three-class compressed limit approach for the normal distribution with known σ achieving the maximum absolute risk difference. This method requires the underlying (or log-transformed) distribution to be normal with stable and known σ, and the batch size to be sufficiently large.

This approach is not easily extended to the case of unknown σ due to various complex issues involved. Three-class compressed plans can also be designed for a fixed $c_M = 0$, which is an

extension of the zero acceptance number compressed plan discussed above. This alternative, however, is not discussed in this research.

Consider the proportion nonconforming p_M and the proportion marginally acceptable p_m determined by the limits M and m. Setting two compression constants t_M and t_m creates an artificial nonconforming proportion g_M and an artificial marginally acceptable proportion g_m as illustrated in Figure 3.3.

$$\begin{aligned} Z_{g_M} &= Z_{p_M} - t_M \\ Z_{g_m} &= Z_{p_m} - t_m \end{aligned} \tag{3.8}$$

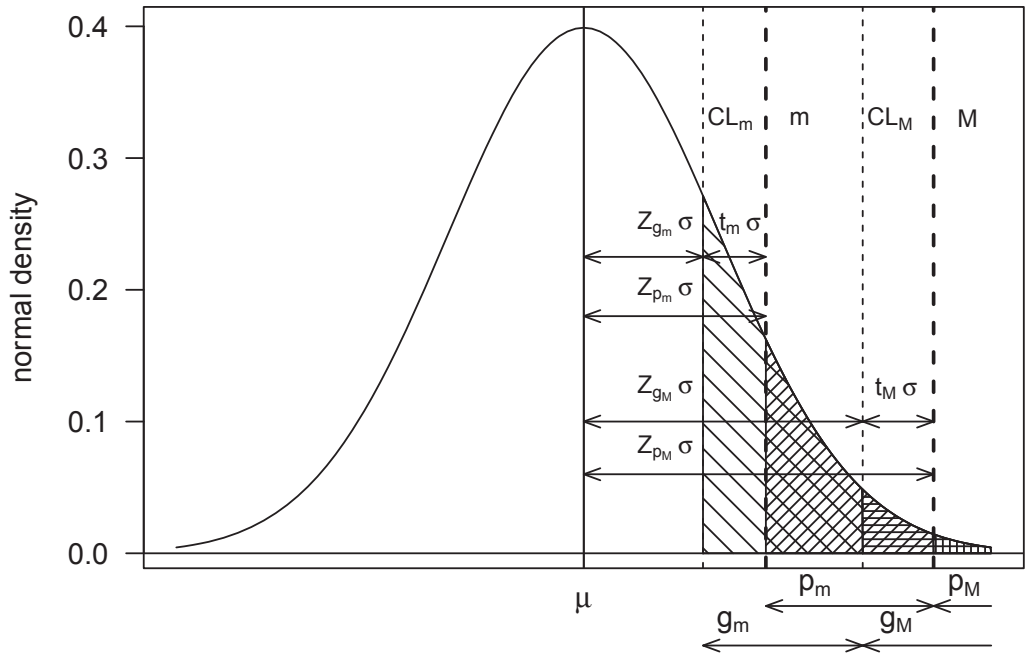

Fig. 3.3 Illustration of the three-class compressed limit approach for the normal distribution.

For the nonconforming classification, let AQL_M and LQL_M (with $AQL_M < LQL_M$) be the given AQL and LQL values. Also let the corresponding quality levels for the marginally acceptable cases be AQL_m and LQL_m (with $AQL_m < LQL_m$, $AQL_m > AQL_M$ and $LQL_m > LQL_M$). Here AQL_M and AQL_m are the fractions of nonconforming and marginally acceptable items respectively that will be accepted with high probability $(1-\alpha)$ while LQL_M and LQL_m are the fraction nonconforming and fraction marginally acceptable that will be accepted with low probability β. The three class plan can be designed using the following procedure which is an extension of the design procedure discussed in Section 3.4.

1. Given two points in the OC surface (AQL_M, AQL_m, α) and (LQL_M, LQL_m, β), obtain the quantiles of the standard normal distribution Z_{AQL_M},Z_{AQL_m},Z_{LQL_M} and Z_{LQL_m}.

2. Calculate the quantiles associated with the compressed limits as:

$$\begin{aligned} Z_{g_{1M}} &= Z_{AQL_M} - t_M \\ Z_{g_{1m}} &= Z_{AQL_m} - t_m \\ Z_{g_{2M}} &= Z_{LQL_M} - t_M \\ Z_{g_{2m}} &= Z_{LQL_m} - t_m \end{aligned} \tag{3.9}$$

3. Obtain the artificial proportions nonconforming ($p_{g_{1M}}$ and $p_{g_{2M}}$) and proportions marginally acceptable ($p_{g_{1m}}$ and $p_{g_{2m}}$) as the right tail areas corresponding to $Z_{g_{1M}}$, $Z_{g_{1m}}$, $Z_{g_{2M}}$ and $Z_{g_{2m}}$ of the normal distribution.

4. Using the pairs $(p_{g_{1M}}, p_{g_{1m}}, \alpha)$ and $(p_{g_{2M}}, p_{g_{2m}}, \beta)$ obtain n_t, c_M and c_m by solving the trinomial distribution inequalities:

$$\begin{aligned} \sum_{d_M=0}^{c_M} \sum_{d_m=0}^{c_m} \frac{n_t}{d_M!\, d_m!\, d_o!} p_{g_{1M}}^{d_M} p_{g_{1m}}^{d_m} p_{g_{1o}}^{d_o} &\geqslant 1-\alpha \\ \sum_{d_M=0}^{c_M} \sum_{d_m=0}^{c_m} \frac{n_t}{d_M!\, d_m!\, d_o!} p_{g_{2M}}^{d_M} p_{g_{2m}}^{d_m} p_{g_{2o}}^{d_o} &\leqslant \beta \end{aligned} \tag{3.10}$$

   where d_M, d_m, c_M and c_m are nonnegative integers and $d_o = n_t - (d_M + d_m)$. The algorithm described in Guenther (1969) helps to solve these inequalities.

5. The optimum t_M and t_m are found as a pair in order to minimize n_t. If there is more than one pair for the same sample size, the optimum pair is chosen corresponding to maximize absolute risk difference. Alternatively, the MIRD criterion can be used instead. However, for simplicity we only used the MARD criterion.

Optimum sampling plans found for various combinations of risks are shown in 3.D. It can be noted that a considerable reduction in the sample size can be achieved with optimum artificial limits.

The design and operation of the compressed three-class plans are given below:

1. Given two points in the OC surface (AQL_M, AQL_m, α) and (LQL_M, LQL_m, β) obtain from 3.D the number of samples to be drawn n_t, the acceptance numbers c_{t_M} and c_{t_m}, and the quantiles q_{t_M} and q_{t_m}.

2. Compute the artificial limits CL_M and CL_m as the q_{t_M} and q_{t_m} normal quantiles.

3. Obtain the number of artificially nonconforming items d_{t_M} and the number of artificially and marginally conforming items d_{t_m}.

4. Accept the batch if $d_{t_M} \leq c_{t_M}$ and $d_{t_m} \leq c_{t_m}$; otherwise reject.

The three-class approach is illustrated briefly in following example. Let $AQL_M = 0.005$, $AQL_m = 0.01$, $LQL_M = 0.10$ and $LQL_m = 0.20$ and the producer's and consumer's risks are $\alpha = 0.05$ and $\beta = 0.10$. To achieve the desired level of protection, 14 items must be drawn. The maximum allowed number of nonconforming items (c_M) is one and the maximum allowed marginally acceptable items c_m is one. From 3.D the optimum design is obtained for the compression constants $t_M = 1.0$ and $t_m = 0.8$, the sample size $n_t = 4$ and the acceptance constants $c_M = 1$ and $c_m = 1$. Figure 3.4 shows the OC contour plot for the three-class compressed plan that satisfied the restrictions given by the two points.

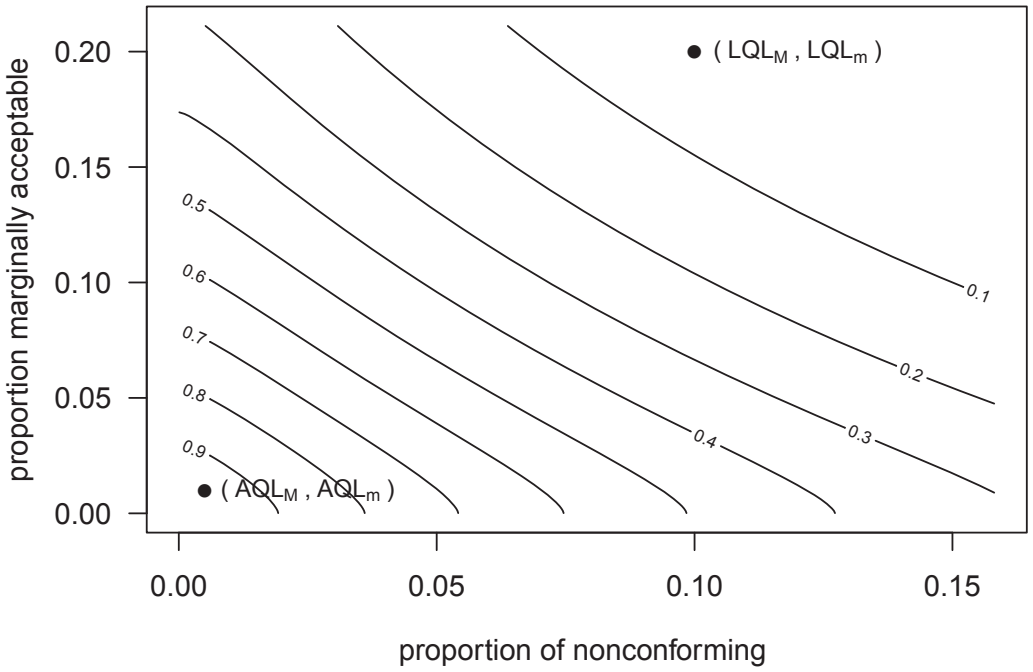

Fig. 3.4 OC contour plot of the three-class compressed limit approach.

3.6 Numerical results

The international body ICMSF ICMSF (2002, pp. 163) and ICMSF (2011, pp. 68) recommend 15 cases of two or three-class attribute plan for food quality inspection. The two-class alternatives (Cases 10-15) involve acceptance constants equal to zero and therefore these plans have very stringent OC curves. In this section, we provide the matching plans to Cases 10-15 using optimum compressed limits for σ known and unknown, matched at two points in the OC curve (AQL, α and LQL, β) or matched at (LQL, β) with $c = 0$. For a given plan, say Case 12, ($n = 20, c = 0$), the producer's and consumer's points in the OC curve can be found fixing the commonly used producer's and consumer's risks of $\alpha = 0.05$ and $\beta = 0.10$ respectively. The optimum t-value minimizing n_t was obtained using the procedure discussed in Section 3.4. Table 3.1 gives the optimum compressed limit plans matching the AQL, α, LQL and β values of the ICMSF plans. Table 3.2 contains the zero acceptance number plans matching with the ICMSF plans using

compression constant $t = 0.5$ and 1. These plans are relevant for compliance related applications where $c = 0$ is often mandatory. As a result, the control of the producer's risk α becomes less critical for these $c = 0$ plans.

Table 3.1 Compressed limit alternatives for σ known and unknown matching *AQL* and *LQL* of two-class ICMSF plans.

							matched compressed plans					
ICMSF plan			Quality levels and risks				σ known			σ unknown		
	n_a	c_a	*AQL*	*LQL*	α	β	t	n_t	c_t	t	n_t	c_t
Case 10	5	0	0.0102	0.3690	0.05	0.10	1.20	3	1	–	–	–
Case 11	10	0	0.0051	0.2057	0.05	0.10	1.68	5	2	1.91	9	5
Case 12	20	0	0.0026	0.1087	0.05	0.10	2.18	6	3	1.76	13	5
Case 13	15	0	0.0034	0.1423	0.05	0.10	1.82	5	2	2.55	11	8
Case 14	30	0	0.0017	0.0739	0.05	0.10	2.32	6	3	2.64	15	10
Case 15	60	0	0.0009	0.0376	0.05	0.10	2.56	8	4	2.34	22	10

Table 3.2 Zero acceptance number compressed limit alternatives to the two-class ICMSF plans for the known σ case.

ICMSF plan					matched plans					
	n_a	c_a	*LQL*	β	t	n_t	c_t	t	n_t	c_t
Case 10	5	0	0.3690	0.10	0.50	3	0	1.00	2	0
Case 11	10	0	0.2057	0.10	0.50	5	0	1.00	3	0
Case 12	20	0	0.1087	0.10	0.50	9	0	1.00	5	0
Case 13	15	0	0.1423	0.10	0.50	7	0	1.00	4	0
Case 14	30	0	0.0739	0.10	0.50	13	0	1.00	6	0
Case 15	60	0	0.0376	0.10	0.50	22	0	1.00	10	0

It can be appreciated from Table 3.1 that the number of analytical tests will be reduced significantly, by a factor of between 40 and 87% for the known σ case. Similarly, the compressed approach for unknown σ should be used for Cases 12-15 where the sample size is reduced by 27-63%. In the zero acceptance number plans of Table 3.2 the sample size is reduced by 40-83%.

Figure 3.5 shows the OC curve of Case 12 attribute plan of the ICMSF and matching the optimum compressed limit plan when σ is known and unknown. Notice that the known σ compressed limit plan also reduces the consumer's risk (lower part of the OC curve) due to the MARD criterion employed for the design. Figure 3.5 also shows the OC curve of the zero acceptance number plan is given. This plan does not satisfy the producer's point restriction and hence the producer's risk is increased.

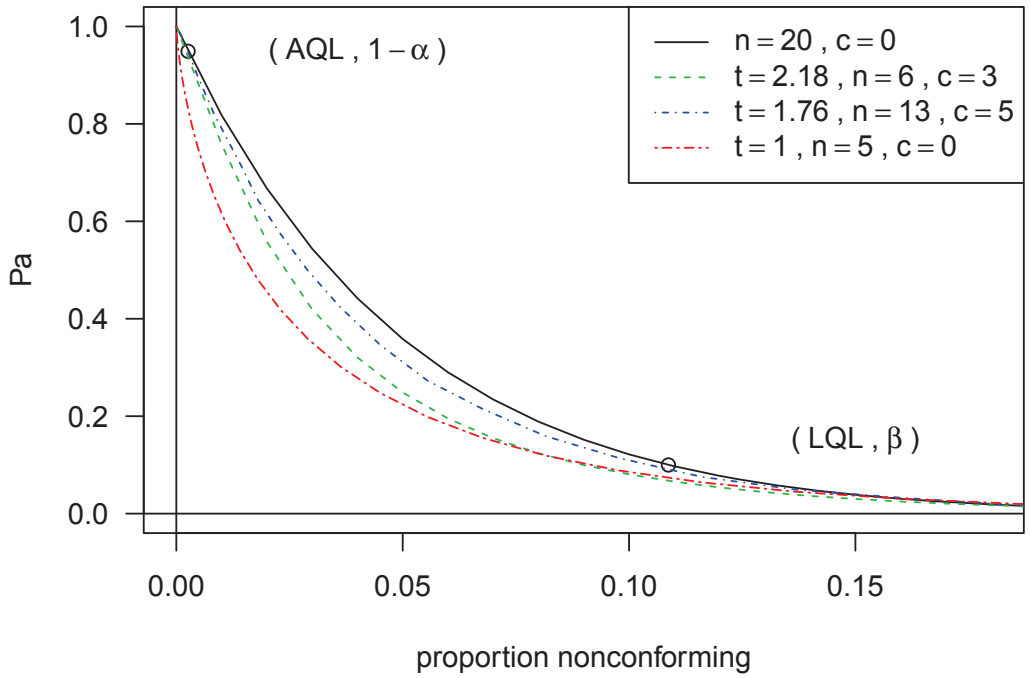

Fig. 3.5 Compressed limit OC curves for Case 12 plan of the ICMSF. The dark solid OC curve represents attribute plan with $n = 20, c = 0$.

3.7 Economic evaluation

From an economic point of view, the decision to apply a plan by variables or attributes is a trade-off between the sample sizes and costs.

$$n_v C_v < n_a C_a \tag{3.11}$$

where n_v and n_a are the required sample size associated with the variables and the attribute plan respectively. C_v and C_a are the cost of obtaining a measurement in a continues scale and classifying as pass or not pass respectively. Commonly $C_v > C_a$ since measurements such as cell enumeration in food testing requires more time, resources and specialization than just assessing whether the contamination is below the microbial limit. The same argument applies to the compressed limit plans. According to Schilling and Sommers (1981) the known σ compressed plan is preferable when $C_v/C_t < 1.5$ since $n_t = 1.5n_v$ while Evans and Thyregod (1985) set this condition as $C_v/C_t < \pi/2$. The MARD criterion requires $C_v/C_t < 1.65$. This condition is similar to the one set in Schilling and Sommers (1981).

A full economic design of a sampling inspection plan requires the costs of incorrect decisions to be considered in addition to the inspection and testing costs. The cost of rejecting a good quality batch is usually known. However the cost of accepting an unsafe batch is not only very large for food products but also unknown. For instance, the brand image of a product may be tarnished due to a single catastrophic incident involving food safety. Due to the difficulty in estimating the costs of accepted unsafe batches, economical designed microbiological sampling

plans are rarely used in practice. International bodies such as ICMSF, FAO and Codex do not advocate any cost driven sampling inspection plans. A small LQL specification indirectly controls the cost of unsafe batches reaching the customers. Various preferred small LQL values are set on empirical grounds by the international bodies depending on the severity of the microbiological characteristics involved. The compressed limit plans proposed in this paper are matched to the traditional plans and hence the decision related costs are equal. The main saving achieved is only in the testing costs.

3.8 Robustness and nonnormal-based compressed limit plans

Compressed limit plans require the knowledge of the underlying probability distribution. Departure from this assumption will result in biased estimation of the proportion nonconforming. Schilling and Sommers (1981) pointed out that this bias increases proportionally to t. It has been well documented that multiplicative processes such as cell aggregation lead to right-skewed distributions and particularly lognormal. Empirical evidence suggests that the lognormal distribution fits satisfactorily the frequencies of microorganisms in foodstuff, see ICMSF (2002); Jarvis (2008); Kilsby and Baird-Parker (1983). This model is advantageous because the log transformation leads to a normal distribution.

The robustness of the compressed limit plan for the distributional assumption is discussed using the following example. Suppose that the CFU per gram of a certain pathogen is assumed to follow a lognormal distribution with mean $\mu = 0$ and standard deviation $\sigma = 1$ (both on the natural logarithmic scale). The resulting expected value is 1.64 CFU/g and the dispersion is 2.16 CFU/g. The lognormal density and the cumulative distribution function are shown in Figures 3.6 (a) and (b).

The standard procedure is to apply log transformation to the sample measurements. Suppose that the Case 12 ICMSF attribute plan with $n = 20$ and $c = 0$ is used. Form Table 3.1, the equivalent compressed limit plans are $t = 2.18$, $n_t = 6$ and $c_t = 3$ for known σ and $t = 1.76$, $n_t = 13$ and $c_t = 5$ unknown σ. At $\alpha = 0.05$ and $\beta = 0.10$, the quality levels are $AQL = 0.0026$ and $LQL = 0.1087$. Figure 3.7 shows the corresponding OC curves for both cases.

Other right skewed distributions like gamma and Weibull have also been considered to describe the distribution of pathogens in food e.g. Chen et al. (2003); Corradini et al. (2001); Jarvis (2008); Jongenburger et al. (2012b,c). The identification of probability distribution such as lognormal, gamma and Weibull requires large sample sizes (Marshall et al., 2012). However, microbiological risk assessment is usually done with small sample sizes. To investigate the robustness of the plans, consider that the true distribution follows a gamma or Weibull model instead of lognormal. The parameters of the gamma and Weibull distributions matching the $LN(0,1)$ distribution are obtained so that the modes and their density values are equivalent. The gamma distribution with shape $d = 1.5$ and scale $b = 0.75$; and the Weibull distribution with shape $\kappa = 1.3$ and scale $\lambda = 1.14$ match the $LN(0,1)$. Both densities and cumulative distribution functions are also presented in Figure 3.6. Applying the same plan based on the lognormal

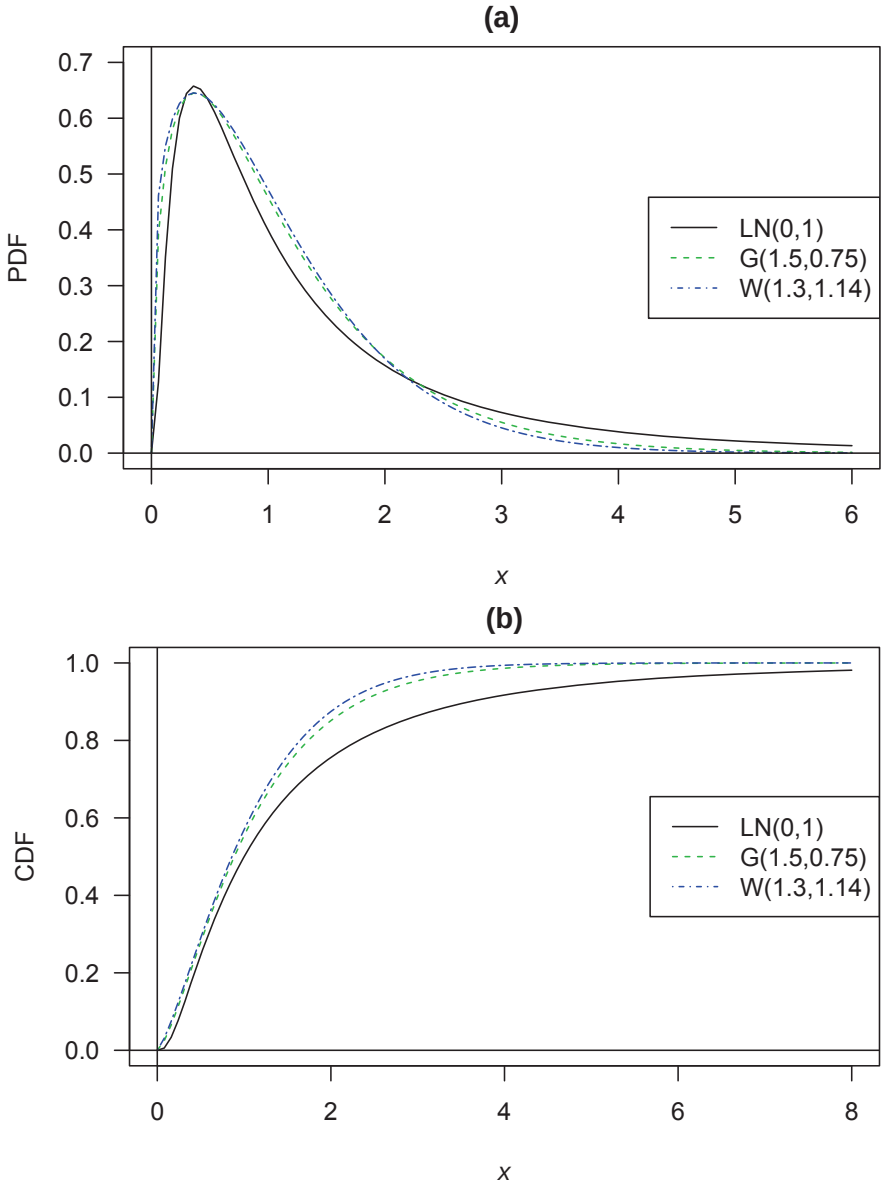

Fig. 3.6 Lognormal, gamma and Weibull (a) probability density functions and (b) cumulative distribution functions matched by the mode and the density.

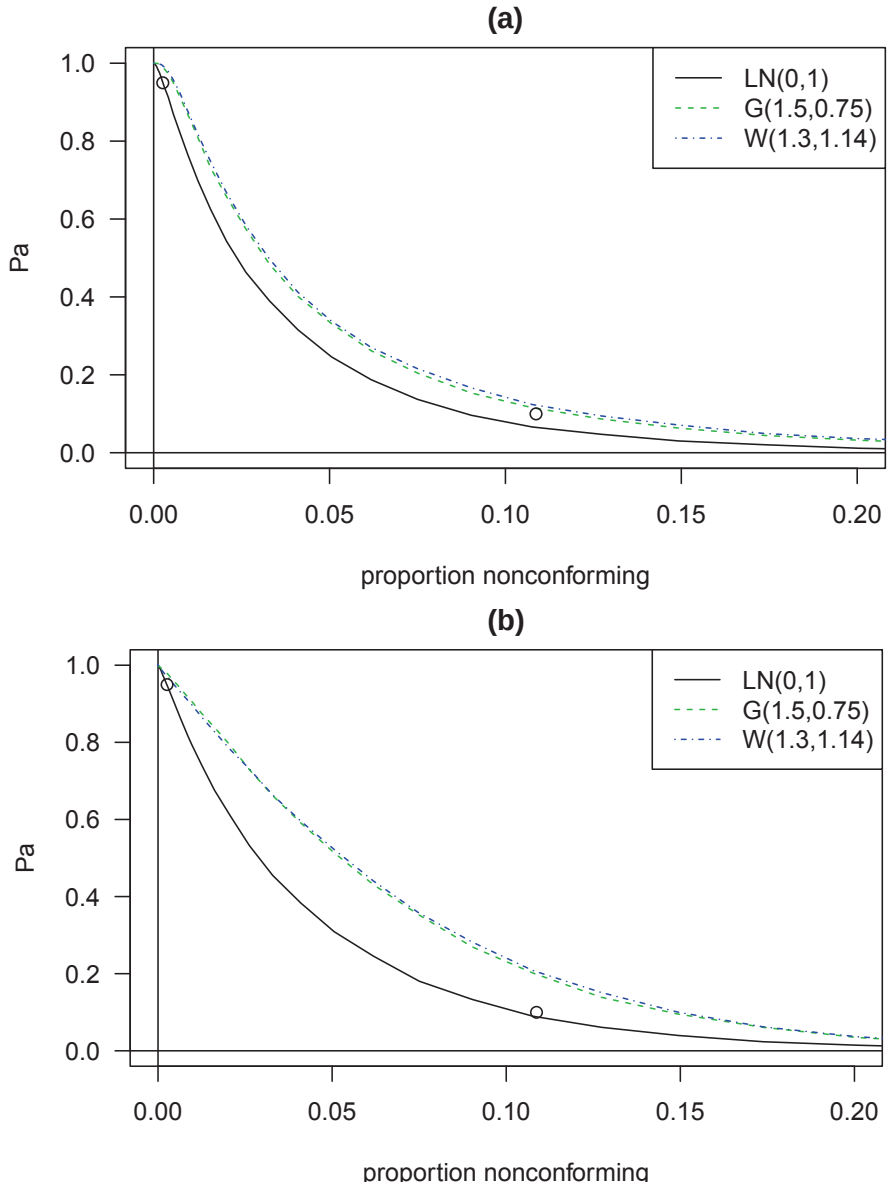

Fig. 3.7 Compressed limit OC curves equivalent to the ICMSF (2002) Case 12 ($n = 20, c = 0$) for known σ (a) and unknown (b). The assumed distribution is lognormal when the true underlying model is lognormal, gamma and Weibull.

assumption yields the OC curves shown in Figure 3.7. It can be appreciated that the quality levels at the producer's and consumer's risks differ considerably when the true distribution is gamma or Weibull. This example illustrates that compressed limit plans are not robust to departures from normality.

When the base-line distribution is known the compressed limit can be recomputed. The specific compressed limit design for known parameters is obtained by replacing the quantile and the distribution function of the normal for the true distribution in Steps 1 and 3 of the procedure given in Section 3.4. The R codes of 3.B also deal with design of the plans for gamma and Weibull distributions.

3.9 Summary and conclusions

A standard practice in food trade is to use ICMSF attribute sampling plans. By using variables plans, the number of analytical units tested can be reduced considerably. Nonetheless, the cost associated with taking a measurement in a continuous scale is generally higher than just classifying a sample on a go/no-go basis. For lognormally distributed quality characteristics, variables plans pose problems in administration because the test outcome can be a zero value. For example, a batch of food product may not be totally free of microorganisms but the observed number of microorganisms in the samples can be below the limit of detection. This results in zero counts.

Compressed limit plans combine the features of attribute and variables plans. Therefore, this approach can achieve the benefits of both alternatives: a reduced sample size and simpler classification of the tested items as conforming/non-conforming. However, compressed limit plans also inherit the lack of robustness of variables plans. Previous publications such as Ladany (1976), Schilling and Sommers (1981) and Evans and Thyregod (1985) are limited to the normal distribution with known standard deviation. However, in most practical cases the process sigma is unknown and commonly a conservative (large) standard deviation value is used to protect the consumer's interest. For food safety applications, a value of $\sigma = 0.8$ is used in the ICMSF plans. This paper introduces an approach for the normal distribution when σ is unknown and it discusses compressed limit plans for other right-skewed models such as gamma and Weibull. Three-class compressed limits are introduced as alternatives to the ICMSF plans. This research as well as Govindaraju and Kissling (2015) accomplish a reduced sample size, but by different means. The former uses a compressed limit and assumes knowledge of the underlying distribution, while the latter consists of a variables plan with an additional restriction. Compressed limit plans are suitable for pre-shipment inspection by producers, since this method requires the knowledge of the underlying distribution. From the consumer perspective, compressed limit plans should be used when the batches come from food suppliers with proven reputation. In this case, the analytical tests carried out from previous batches must show lognormality for frequencies of microorganisms. If a departure from the assumed model is suspected, say the lognormality assumption is not satisfied, a smaller compression constant such as $t = 1$ may be used. This

approach will increase the required sample size, but can provide increased consumer protection. In the case of the zero acceptance number compressed plans, using values of $t > 1$ might compromise the accuracy of this technique even when the assumptions are marginally violated. Further research might explore other sampling plan alternatives based on the compressed limits theory.

Appendix 3.A Glossary of symbols and definitions.

$f(x\|\sigma,\mu)=\frac{1}{\sigma\sqrt{2\pi}}\exp\left(-\frac{(x-\mu)^2}{2\sigma^2}\right)$	normal density function
$f(d\|n,p)=\binom{n}{d}p^d(1-p)^{n-d}$	binomial probability function
$f(d_1,d_2,d_3\|n;p_1,p_2,p_3)=\frac{n}{d_1!d_2!d_3!}p_1^{d_1}p_2^{d_2}p_3^{d_3}$	trinomial probability function
m	microbiological limit in two-class plans or GMP limit in three-class plans
M	second microbiological limit
$CL=m-t\sigma$	compressed limit
$\bar{X}$	sample mean
$S=\sqrt{\sum(X_i-\bar{X})^2/(n-1)}$	standard deviation
p	proportion nonconforming
g	artificial proportion nonconforming
α	producer's risk
β	consumer's risk
AQL	Acceptance Quality Limit
LQL	Limiting Quality Level
n_a	sample size of attribute plan
n_v	sample size of variables plan
n_t	sample size of compressed limit plan
k	critical distance
d	number of observed nonconforming items
c	attribute acceptance number
c_t	acceptance number for compressed limit
t	compression constant
$MARD=\max\left[\left\|\alpha-\alpha'\right\|+\left\|\beta-\beta'\right\|\right]$	maximum absolute risk difference
$MIRD=\min\left[\left\|\alpha-\alpha'\right\|+\left\|\beta-\beta'\right\|\right]$	minimum absolute risk difference

Appendix 3.B R Software code

The R function given below obtains the optimum compressed limit plans for given two-points on the OC curve using normal, gamma and Weibull distributions. The function depends on the R-package **AcceptanceSampling** Kiermeier (2008) to solve Eq.3.5 by trial and error.

A straightforward shiny app is also developed and made available at https://internal.shinyapps.io/edgarsantosfdez/compress/ for the practitioners. A reference sampling plan such as ($n=5$, $c=0$) needs to be input. The app will then return the optimum matching compressed sampling plan for the specified underlying distribution.

```
### The R code computes the optimum compressed-limit plan.
### Edgar Santos-Fernandez, K. Govindaraju, Geoff Jones
### July/29,2014
# AQL    # Acceptance Quality Limit
# alpha  # producer's risk
# LQL    # Limiting  Quality  Level
# beta   # consumer's risk
# t      # compression constant
# dist   #  statistical   distribution  (normal, gamma or Weibull)

compress <-function(AQL = 0.02, LQL = 0.08, alpha = 0.05, beta = 0.10, distr = "normal",  ...  ){
 library ("AcceptanceSampling")
 t = seq(0, 4, 0.01)
 plan <-matrix(NA, nrow = length(t), ncol = 3)
 condition <-function(code) {tryCatch(code, error = function(c) NA, # Exception handling
     warning = function(c) NA, message = function(c) NA)}

 if ( distr == "normal"){
  Zaql <-qnorm(AQL,lower.tail = 0)
  Zlql <-qnorm(LQL,lower.tail = 0)
  for (i in 1:length(t )){
   Zgaql <-Zaql - t[i]
   Zglql <-Zlql - t[i]
   p.gaql <-pnorm(Zgaql, lower.tail = 0)
   p.glql <-pnorm(Zglql, lower.tail = 0)
   plan[i,1]<-condition(find.plan(PRP=c(p.gaql,1-alpha),CRP=c(p.glql,beta),type="binomial")$n)
   plan[i,2]<-condition(find.plan(PRP=c(p.gaql,1-alpha),CRP=c(p.glql,beta),type="binomial")$c)
   plan[i,3]<- 1 -p.gaql }}

 if ( distr == "gamma"){
  Zaql <-qgamma(AQL, shape = shape, scale = scale, lower.tail = 0)
  Zlql <-qgamma(LQL, shape = shape, scale = scale, lower.tail = 0)
  for (i in 1:length(t )){
   Zgaql <-Zaql - t[i]
   Zglql <-Zlql - t[i]
   p.gaql <-pgamma(Zgaql, shape = shape, scale = scale, lower.tail = 0)
   p.glql <-pgamma(Zglql, shape = shape, scale = scale, lower.tail = 0)
   plan[i,1]<-condition(find.plan(PRP=c(p.gaql,1-alpha),CRP=c(p.glql,beta),type="binomial")$n)
   plan[i,2]<-condition(find.plan(PRP=c(p.gaql,1-alpha),CRP=c(p.glql,beta),type="binomial")$c)
   plan[i,3]<- 1 -p.gaql }}

 if ( distr == "Weibull"){
  Zaql <-qweibull(AQL, shape = shape, scale = scale, lower.tail = 0)
  Zlql <-qweibull(LQL, shape = shape, scale = scale, lower.tail = 0)
  for (i in 1:length(t )){
   Zgaql <-Zaql - t[i]
   Zglql <-Zlql - t[i]
   p.gaql <-pweibull(Zgaql,shape=shape,scale=scale,lower.tail = 0)
   p.glql <-pweibull(Zglql,shape=shape,scale=scale,lower.tail = 0)
   plan[i,1]<-condition(find.plan(PRP=c(p.gaql,1- alpha),CRP=c(p.glql,beta),type="binomial")$n)
   plan[i,2]<-condition(find.plan(PRP=c(p.gaql,1- alpha),CRP=c(p.glql,beta),type="binomial")$c)
   plan[i,3]<- 1 -p.gaql }}

 plan <-cbind(t,plan); colnames(plan) <-NULL
 a <-plan[which(plan[,2] == min(plan[,2][plan[,2] != 1], na.rm = TRUE)),]
 fd <-seq(0, 0.995, 0.0001)
 madr <-rep(NA, nrow(a))

 for (j in 1 : nrow(a)){
  t = a[j,1]; n <-a[j,2]; c <-a[j,3]
  if ( distr == "normal"){ zp <-qnorm(fd,lower.tail = 0)
   zg <-zp - t; pr <-pnorm(zg, lower.tail = 0)}
```

```
  if  ( distr  == "gamma"){
   zp <-qgamma(fd, shape = shape, scale = scale, lower.tail = 0)
   zg <-zp - t ;  pr  <-pgamma(zg, shape = shape, scale = scale, lower.tail = 0)}

  if  ( distr  == "Weibull"){
   zp <-qweibull(fd ,  shape = shape, scale = scale, lower. tail  = 0)
   zg <-zp - t ;  pr  <-pweibull(zg,  shape = shape, scale = scale, lower. tail  = 0)}

  Op <-cbind(fd, pbinom(q = c, size  = n,  prob = pr))
  madr[j]<-abs(Op[which(abs((Op[,1]-AQL)) == min(abs((Op[,1]-AQL)))),2]-(1-alpha))+
  abs(Op[ which(abs((Op[,1]-LQL)) == min(abs((Op[,1]-LQL)))) ,2]-beta)}

 opt  <-a[which(madr == max(madr)),]
 return( list (t  = opt [1],  n = opt [2],  c  = opt [3],  q_t =  round(opt [4],3)  ))
}

# Example 1 normal distribution
compress(AQL=0.01, LQL=0.2, alpha=0.05, beta=0.10, distr="normal")
# Example 2 gamma distribution, Case 11 ICMSF
shape = 1.50; scale = 0.75
compress(AQL=0.0051, LQL=0.2057, alpha=0.05, beta=0.10, distr="gamma",
 shape=shape, scale=scale)
# Example 3 Weibull distribution
shape = 1.30; scale = 1.14
compress(AQL=0.02, LQL=0.08, alpha=0.05, beta=0.10, distr="Weibull",
 shape=shape, scale=scale)
```

Appendix 3.C Optimum compression constants (t), sample size (n_t), acceptance number (c_t) and the corresponding quantile (q_t) for given two points of the OC curve

						compressed limit plan σ known								compressed limit plan σ unknown							
Quality levels and risks				attr plan		using MARD				using MIRD				using MARD				using MIRD			
AQL	*LQL*	α	β	n	c	t	n_t	c_t	q_t	t	n_t	c_t	q_t	t	n_t	c_t	q_t	t	n_t	c_t	q_t
0.001	0.02	0.01	0.05	313	2	2.48	23	11	0.729	2.59	23	12	0.692	2.36	66	29	0.767	2.97	66	45	0.548
0.001	0.02	0.01	0.10	265	2	2.56	19	10	0.702	2.29	19	8	0.788	2.60	54	30	0.688	2.92	54	37	0.567
0.001	0.02	0.05	0.05	236	1	2.65	16	8	0.670	2.81	16	9	0.610	2.85	47	29	0.594	3.42	47	37	0.370
0.001	0.02	0.05	0.10	194	1	2.52	13	6	0.716	2.90	13	8	0.575	2.12	36	12	0.834	2.12	36	12	0.834
0.001	0.04	0.01	0.05	117	1	2.41	14	7	0.752	2.03	14	5	0.855	2.16	37	16	0.823	3.14	37	29	0.480
0.001	0.04	0.01	0.10	96	1	2.36	12	6	0.767	2.77	12	8	0.626	1.93	30	11	0.877	2.91	30	22	0.570
0.001	0.04	0.05	0.05	117	1	2.30	10	4	0.785	2.03	10	3	0.855	1.93	30	11	0.813	3.30	28	22	0.417
0.001	0.04	0.05	0.10	96	1	2.53	8	4	0.712	1.85	8	2	0.893	2.30	22	10	0.785	2.40	22	11	0.755
0.01	0.2	0.01	0.05	30	2	1.46	11	5	0.807	1.46	11	5	0.807	1.40	20	9	0.823	0.50	20	3	0.966
0.01	0.2	0.01	0.10	25	2	1.37	9	4	0.831	1.65	9	5	0.751	1.70	15	9	0.734	1.70	15	9	0.734
0.01	0.2	0.05	0.05	22	1	1.43	8	3	0.815	2.07	8	5	0.601	0.90	14	3	0.923	0.90	14	3	0.923
0.01	0.2	0.05	0.10	18	1	1.71	6	3	0.731	1.28	6	2	0.852	1.30	11	4	0.848	1.30	11	4	0.848
0.01	0.4	0.01	0.05	10	1	1.38	6	3	0.828	0.87	6	2	0.927	1.30	8	4	0.848	1.30	8	4	0.848
0.01	0.4	0.01	0.10	9	1	1.07	5	2	0.896	0.47	5	1	0.968	3.70	2	1	0.085	3.70	2	1	0.085
0.01	0.4	0.05	0.05	10	1	0.99	4	1	0.909	1.64	4	2	0.754	1.30	7	3	0.848	2.70	7	6	0.354
0.01	0.4	0.05	0.10	5	0	1.22	3	1	0.866	1.12	3	1	0.886	3.70	2	1	0.085	3.70	2	1	0.085

Appendix 3.D Optimum compression constant (t_1), (t_2), sample size (n_t) and acceptance numbers (c_{t_M}) and (c_{t_m}) for three-class compressed limit plan.

Quality levels and risks						three-class plan			three-class compressed limit plan						
AQL_1	AQL_2	LQL_1	LQL_2	α	β	n	c_M	c_m	t_M	t_m	n_t	c_{t_M}	c_{t_m}	q_{t_M}	q_{t_m}
0.001	0.01	0.05	0.15	0.01	0.05	33	1	2	1.5	1.0	7	2	3	0.944	0.908
0.001	0.01	0.05	0.15	0.01	0.10	29	1	2	1.6	1.0	5	2	2	0.932	0.908
0.001	0.01	0.05	0.15	0.05	0.05	21	0	1	1.6	1.0	3	1	1	0.932	0.908
0.001	0.01	0.05	0.15	0.05	0.10	17	0	1	1.6	1.0	3	1	1	0.932	0.908
0.001	0.01	0.05	0.20	0.01	0.05	26	1	2	1.5	0.8	6	2	2	0.944	0.937
0.001	0.01	0.05	0.20	0.01	0.10	22	1	2	1.5	0.8	6	2	2	0.944	0.937
0.001	0.01	0.05	0.20	0.05	0.05	17	0	1	1.5	0.8	4	1	1	0.944	0.937
0.001	0.01	0.05	0.20	0.05	0.10	14	0	1	1.5	0.8	4	1	1	0.944	0.937
0.001	0.01	0.10	0.15	0.01	0.05	26	1	2	1.1	1.0	6	1	3	0.977	0.908
0.001	0.01	0.10	0.15	0.01	0.10	22	1	2	1.2	1.0	4	1	2	0.971	0.908
0.001	0.01	0.10	0.15	0.05	0.05	16	0	1	1.1	1.0	4	1	1	0.977	0.908
0.001	0.01	0.10	0.15	0.05	0.10	13	0	1	1.2	1.0	3	1	1	0.971	0.908
0.001	0.01	0.10	0.20	0.01	0.05	22	1	2	1.1	0.8	5	1	2	0.977	0.937
0.001	0.01	0.10	0.20	0.01	0.10	14	1	1	1.2	0.8	4	1	2	0.971	0.937
0.001	0.01	0.10	0.20	0.05	0.05	13	0	1	1.2	0.8	4	1	1	0.971	0.937
0.001	0.01	0.10	0.20	0.05	0.10	11	0	1	1.2	0.8	3	1	1	0.971	0.937
0.001	0.02	0.05	0.15	0.01	0.05	40	1	3	1.6	1.0	9	3	4	0.932	0.854
0.001	0.02	0.05	0.15	0.01	0.10	35	1	3	1.6	1.0	8	3	4	0.932	0.854
0.001	0.02	0.05	0.15	0.05	0.05	27	0	2	1.6	1.0	4	1	2	0.932	0.854
0.001	0.02	0.05	0.15	0.05	0.10	22	0	2	1.6	1.0	4	1	2	0.932	0.854
0.001	0.02	0.05	0.20	0.01	0.05	31	1	3	1.5	0.8	7	2	3	0.944	0.895
0.001	0.02	0.05	0.20	0.01	0.10	22	1	2	1.6	0.8	6	2	3	0.932	0.895

...Continued

Quality levels and risks						three-class plan			three-class compressed limit plan						
AQL_1	AQL_2	LQL_1	LQL_2	α	β	n	c_M	c_m	t_M	t_m	n_t	c_{t_M}	c_{t_m}	q_{t_M}	q_{t_m}
0.001	0.02	0.05	0.20	0.05	0.05	22	0	2	1.5	0.8	5	1	2	0.944	0.895
0.001	0.02	0.05	0.20	0.05	0.10	14	0	1	1.6	0.8	3	1	1	0.932	0.895
0.001	0.02	0.10	0.15	0.01	0.05	30	1	3	1.2	1.0	8	2	4	0.971	0.854
0.001	0.02	0.10	0.15	0.01	0.10	22	1	2	1.2	1.0	6	2	3	0.971	0.854
0.001	0.02	0.10	0.15	0.05	0.05	19	0	2	1.2	1.0	5	1	2	0.971	0.854
0.001	0.02	0.10	0.15	0.05	0.10	13	0	1	1.2	1.0	4	1	2	0.971	0.854
0.001	0.02	0.10	0.20	0.01	0.05	22	1	2	1.1	0.8	6	1	3	0.977	0.895
0.001	0.02	0.10	0.20	0.01	0.10	19	1	2	1.2	0.8	4	1	2	0.971	0.895
0.001	0.02	0.10	0.20	0.05	0.05	13	0	1	1.1	0.7	4	1	1	0.977	0.912
0.001	0.02	0.10	0.20	0.05	0.10	11	0	1	1.2	0.8	3	1	1	0.971	0.895
0.005	0.01	0.05	0.15	0.01	0.05	37	2	2	1.2	1.0	13	4	4	0.916	0.908
0.005	0.01	0.05	0.15	0.01	0.10	32	2	2	1.1	1.0	11	3	4	0.930	0.908
0.005	0.01	0.05	0.15	0.05	0.05	26	1	1	1.1	1.0	8	2	2	0.930	0.908
0.005	0.01	0.05	0.15	0.05	0.10	22	1	1	1.2	1.0	7	2	2	0.916	0.908
0.005	0.01	0.05	0.20	0.01	0.05	26	1	2	1.0	0.8	11	3	3	0.942	0.937
0.005	0.01	0.05	0.20	0.01	0.10	22	1	2	0.8	0.8	10	2	3	0.962	0.937
0.005	0.01	0.05	0.20	0.05	0.05	20	1	1	0.8	0.8	8	1	2	0.962	0.937
0.005	0.01	0.05	0.20	0.05	0.10	17	1	1	0.8	0.8	5	1	1	0.962	0.937
0.005	0.01	0.10	0.15	0.01	0.05	26	1	2	1.2	1.0	8	3	3	0.916	0.908
0.005	0.01	0.10	0.15	0.01	0.10	22	1	2	1.0	1.0	7	2	3	0.942	0.908
0.005	0.01	0.10	0.15	0.05	0.05	21	1	1	1.1	1.0	5	1	2	0.930	0.908
0.005	0.01	0.10	0.15	0.05	0.10	18	1	1	1.2	1.0	3	1	1	0.916	0.908
0.005	0.01	0.10	0.20	0.01	0.05	22	1	2	1.0	0.8	8	2	3	0.942	0.937
0.005	0.01	0.10	0.20	0.01	0.10	19	1	2	1.0	0.8	6	2	2	0.942	0.937
0.005	0.01	0.10	0.20	0.05	0.05	17	1	1	1.0	0.8	4	1	1	0.942	0.937

...Continued

Quality levels and risks						three-class plan			three-class compressed limit plan						
AQL_1	AQL_2	LQL_1	LQL_2	α	β	n	c_M	c_m	t_M	t_m	n_t	c_{t_M}	c_{t_m}	q_{t_M}	q_{t_m}
0.005	0.01	0.10	0.20	0.05	0.10	14	1	1	1.0	0.8	4	1	1	0.942	0.937
0.005	0.02	0.05	0.15	0.01	0.05	51	2	4	1.5	1.0	15	6	6	0.859	0.854
0.005	0.02	0.05	0.15	0.01	0.10	39	2	3	1.5	1.0	12	5	5	0.859	0.854
0.005	0.02	0.05	0.15	0.05	0.05	33	1	2	1.5	1.0	8	3	3	0.859	0.854
0.005	0.02	0.05	0.15	0.05	0.10	29	1	2	1.5	1.0	8	3	3	0.859	0.854
0.005	0.02	0.05	0.20	0.01	0.05	34	2	3	1.3	0.8	12	4	4	0.899	0.895
0.005	0.02	0.05	0.20	0.01	0.10	30	2	3	1.3	0.8	11	4	4	0.899	0.895
0.005	0.02	0.05	0.20	0.05	0.05	26	1	2	1.3	0.8	8	2	3	0.899	0.895
0.005	0.02	0.05	0.20	0.05	0.10	17	1	1	1.2	0.8	7	2	2	0.916	0.895
0.005	0.02	0.10	0.15	0.01	0.05	36	2	3	1.2	1.0	9	3	4	0.916	0.854
0.005	0.02	0.10	0.15	0.01	0.10	26	1	3	1.2	1.0	9	3	4	0.916	0.854
0.005	0.02	0.10	0.15	0.05	0.05	26	1	2	1.1	1.0	6	2	2	0.930	0.854
0.005	0.02	0.10	0.15	0.05	0.10	22	1	2	1.2	1.0	4	1	2	0.916	0.854
0.005	0.02	0.10	0.20	0.01	0.05	25	1	3	1.2	0.8	8	3	3	0.916	0.895
0.005	0.02	0.10	0.20	0.01	0.10	21	2	2	1.0	0.8	7	2	3	0.942	0.895
0.005	0.02	0.10	0.20	0.05	0.05	17	1	1	1.2	0.8	6	2	2	0.916	0.895
0.005	0.02	0.10	0.20	0.05	0.10	14	1	1	1.2	0.8	4	1	2	0.916	0.895

Chapter 4

New two-stage sampling inspection plans for bacterial cell counts

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4.1 Abstract

The inspection of a batch of food generally relies on testing a small number of samples. Yet, this low rate of testing still results in a significant expenditure for the producer as well as a substantial laboratory workload due to the large number of safety and sanitary characteristics involved. A new double sampling methodology employing a compressed limit in the first stage of inspection is introduced. The proposed double sampling plan provides the same or better consumer protection with substantially smaller average sample size and hence it reduces the testing cost and the laboratory workload. This plan is intended for sanitary characteristics where the bacterial count generally fits a Poisson or a mixed-Poisson distribution, resulting in a high proportion of zero values. Optimum determination of the compressed limit, which is set well below the regulatory or specification limit, is addressed. The application of the new plan is validated using a large empirical dataset of aerobic plate counts observed in milk powder samples. For this dataset the Poisson-gamma was found to be the best fitting distribution. An interactive web-based tool (*shiny* app) that allows the design of the new sampling plan is also provided for practitioners and food safety professionals.

[1] An abridged version of this Chapter has been published in Food Control.

Keywords

double sampling plan; compressed limit; hygiene indicator; consumers protection; Poisson-gamma distribution

4.2 Introduction

Sampling inspection plans are generally used to assess the acceptability of a batch of foodstuffs and to determine whether the food safety systems are working free of special causes of variation. Guidance and regulations on microbiological sampling plans are given by European Commission (2005); FAO/WHO (2014); Food Standards Australia New Zealand (2001); ICMSF (2002) and by other country-specific regulatory agencies. The inspection of a batch generally relies on small sample sizes, typically $n = 5$ or 10 (Hoelzer and Pouillot, 2013; ICMSF, 2002). Yet, these testing levels lead to a significant expenditure and a substantial laboratory workload. Several recent publications have focused on quantitative risk assessment of food products using statistical models. Their focus is mainly on reducing the consumer's risk, increasing the sampling plan stringency and robustness, as well as reducing the testing costs (e.g. Dahms and Hildebrandt, 1998; ICMSF, 2002; Powell, 2014).

Both attribute and variables type inspection plans are recommended in the safety literature e.g. FAO/WHO (2014). Concentration-based attribute sampling plans are generally used for sanitary characteristics, where the batch probability of acceptance is expressed as a function of sanitary quality parameter(s) rather than the proportion nonconforming to specifications; see for instance FAO/WHO (2014). In the first two alternative plans of FAO/WHO (2014), the test statistic is the number of individual samples that fail to satisfy the microbiological or the specification limit m. However, in variables plans the test statistic is obtained from the mean and standard deviation of the log transformed bacterial count. Variables plans provide similar protection with smaller sample sizes compared to attribute type concentration-based plans. However, the application of variables plans is generally limited to the case of high cell counts only because the discontinuity in large cell counts is not critical. A reduction in sample size can also be achieved using a compressed limit plan. This technique inherits the benefits of both variables and attribute plans: a reduced sample size and individual cell counts being classified as pass or fail. However, the theory of compressed limit plans is limited in the literature, mainly employing this technique to single inspection plans; see Schilling and Neubauer (2010).

A double sampling plan allows for a second stage of inspection and achieves sampling economy when compared to taking a single large sample; see Alonzo and Pepe (2003) for an application of the double sampling approach to inspection. For food product inspection, a two stage procedure might be convenient because the microorganism indicators are often low (well below the regulatory limit). The sampling plans as recommended by ICMSF (2002) mostly involve zero acceptance numbers $(c = 0)$. Under this restriction, a sample size reduction cannot be achieved by the traditional double sampling plan where the same regulatory limit is employed

for the assessment of conformance in the two stages of inspection. However, a double sampling plan with compressed limit in the first stage of inspection will be able to match the performance of a $c = 0$ plan. In this research we introduce a new two-stage compressed plan based on the discrete distributions generally used to describe microbial counts. The proposed plans are intended for sanitary characteristics with nonzero microbiological limit $m > 0$ such as an Aerobic Plate Count (APC). A compressed limit $CL < m$ is used for the first stage, while the regular specification m is applied in the second stage of sampling. In the common cause situations (good quality batches), the proposed plans will operate mostly as a single sampling plan but with lower average sample size. The second stage of sampling will only be reached in special cause situations. Hence the proposed plan is not expected to cause operational management issues (such as delaying the batch disposition) under normal circumstances. The plan is not applicable to safety characteristics because no pathogens can be tolerated for samples in accepted batches: this regulatory limit of $m = 0$ cfu obviously cannot be compressed further.

In this paper, the following concepts and abbreviations are used. The parameters μ and σ in the Poisson-lognormal (PLN) distribution are expressed in the $\log_{10}$ scale. The Poisson-gamma is abbreviated as PG. The symbols α and β refer to the producer's and consumer's risks. The terms *AQL* and *LQL* stand for Acceptance Quality Limit and Limiting Quality Level respectively. The term Indifference Quality (p_0) refers to the point in the x-axis of the Operating Characteristic (OC) curve corresponding to a probability of acceptance (P_a) of 50%. The indifference quality zone is the region of the OC curve around this point. By the term 'matching sampling plans', we mean plans having very similar OC curves. Since the OC curves of two plans are seldom exactly identical, the matching sampling plans are required to satisfy two restrictions such as the OC curves coinciding well at two points (*LQL*,β and *AQL*, α) while differing elsewhere. The point (*AQL*, α) is not commonly used in microbial risk assessment but can be used for matching purposes to compare the performance of sampling plans. An alternative approach to matching sampling plans is to ensure that the two plans achieve the same indifference quality point p_0 and same slope value h_0 of the OC at this point. We consider both alternatives in our discussion. Finally, most of the computations and figures were developed using **R** (R Core Team, 2015).

4.3 Materials and methods

4.3.1 Statistical models

Consider a random variable X representing the observed number of microorganisms or cfu in a sample of size w subjected to a limit m. Suppose that the contamination (in cfu/g) is homogenous in the batch and let λ be the rate of the contamination. Then X follows a Poisson distribution with probability mass function:

$$P(X = x|\lambda) = \frac{\lambda^x e^{-\lambda}}{x!}, \qquad x = 0, 1, 2, \cdots \tag{4.1}$$

Microorganisms tend to form clusters or colonies in certain commodities, in which case the homogeneity assumption cannot be satisfied. Several models for overdispersed counts ($\mathrm{E}[X] << \mathrm{Var}[X]$) have been used for modelling microorganisms in food. For low bacterial count, compounded Poisson-lognormal (Bulmer, 1974b) and Poisson-gamma (Anscombe, 1950) models are generally employed. See for example, Van Schothorst et al. (2009), Gonzales-Barron and Butler (2011b), Gonzales-Barron and Butler (2011a), Jongenburger et al. (2012b), Jongenburger et al. (2012c), Williams and Ebel (2012), Gonzales-Barron et al. (2013), Mussida et al. (2013a).

The mixed Poisson-lognormal model is a Poisson process with parameter λ lognormally distributed with location μ and scale σ (i.e. $\lambda \sim \mathscr{LN}(\mu,\sigma)$). The probability mass function for the PLN case is

$$P(X=x|\mu,\sigma) = \int_0^\infty \frac{\lambda^x e^{-\lambda}}{x!} \frac{1}{\lambda\sigma\sqrt{2\pi}} e^{\left(-\frac{(\ln(\lambda)-\mu)^2}{2\sigma^2}\right)} \mathrm{d}\lambda, \qquad x=0,1,2,\cdots \tag{4.2}$$

where μ and σ are on the natural logarithmic scale (ln or $\log_e$), hence obtained from the $\log_{10}$ parameters as $\mu = \ln(10)\,\mu_{10}$ and $\sigma = \ln(10)\,\sigma_{10}$.

Poisson-gamma is another popular mixture distribution. The mass function for this case is parameterized via the mean concentration $m = \mathrm{E}[X]$ and the dispersion parameter K.

$$P(X=x|K,m) = \frac{\Gamma(K+x)}{\Gamma(K)x!}\left(\frac{K}{K+m}\right)^K\left(\frac{m}{K+m}\right)^x \tag{4.3}$$

where Γ is the gamma function.

4.3.2 Compressed limit plans

A compressed or narrow limit is a limit that is set well below the regulatory specification. Compressed limits are often regarded as good manufacturing practice (GMP) limits. Sampling plans based on compressed limits are used to achieve a reduction in sample size; see Ott and Mundel (1954), Beja and Ladany (1974), Schilling and Sommers (1981) and Evans and Thyregod (1985). Traditional compressed plans are based on a continuous distribution, generally the normal distribution. The general procedure to obtain a compressed plan is as follows. Let $CL = m - t$ be the compressed limit where t is the compression constant. Given the points AQL, α and LQL, β, obtain the standard normal quantiles Z_{AQL} and Z_{LQL} and then compute the compressed normal quantiles $Z_{g_1} = Z_{AQL} - t$ and $Z_{g_2} = Z_{LQL} - t$ for a given t. Obtain right tail areas of the standard normal distribution p_{g_1} and p_{g_2} associated with Z_{g_1} and Z_{g_2} respectively. Using the pairs p_{g_1}, α and p_{g_2}, β obtain the required sample size n and the acceptance constant c using the traditional algorithm suggested by Guenther (1969). For other non-normal models, the assumed non-normal distribution quantiles are used. Compressed limit plans require knowledge of the underlying distribution, and the batch proportion nonconforming is incorrectly estimated when the actual

distribution departs from the assumed model. Schilling and Sommers (1981) demonstrated that small compression constants are preferred in this case.

4.3.3 Double sampling plans

The double sampling plan (Dodge and Romig, 1959) allows for a second sample to be taken when the evidence for acceptance or rejection is not conclusive with the inspection of the first sample. Double sampling plans are in general more complex to administer because they cause larger decision times and operational costs when compared with a single attribute plan. However the double sampling approach is advantageous because the average sample number (ASN) is reduced while maintaining the same producer's and consumer's risks. Double sampling plans are generally chosen to match a given single plan at two designated points on the curve; see Schilling and Neubauer (2010) for further exposition. The efficiency of double sampling plans was discussed by Hamaker and Strik (1955) comparing two different plans having the same indifference point. Hamaker and Strik (1955) further imposed a second constraint involving the slope of the OC curve measured at the indifference point p_0. The quantity h_0, defined as the 'relative' slope of the OC curve at p_0 by Hamaker and Strik (1955), is given by:

$$h_0 = -2p\frac{dP_a}{dp}\Big|_{p=p_0} \tag{4.4}$$

where P_a is the OC function whose first derivative (slope) is evaluated at $p = p_0$. A strong theoretical argument for using the pair (p_0, h_0) is given in Wetherill and Kollerstrom (1979).

While a single plan is defined by the pair (n, c), a double plan requires five parameters (n_1, n_2, a_1, r_1, $a_2 = r_2$), where n_1 and n_2 are the sample sizes for the first and second stages of inspection respectively. The constants a_1 and a_2 stand for the acceptance numbers while r_1 and r_2 stand for the rejection numbers for first and second stages respectively. Let d_1 be the observed number of nonconforming test results in the first stage. The batch is accepted in the first stage when $d_1 \leqslant a_1$. Similarly the batch is rejected if $d_1 \geqslant r_1$. If instead $a_1 < d_1 < r_1$, a second sample of size n_2 is drawn and d_2, the number of nonconforming test results for the second sample, is observed. Let $D = d_1 + d_2$ be the combined or total number of nonconforming test results in both samples (n_1 $+n_2$). If $D \leqslant a_2$, the batch is accepted; otherwise ($D \geqslant r_2$), the batch is rejected.

4.3.4 Two-stage sampling plan based on compressed limit.

The zero acceptance number plan used in the safety area is the most stringent sampling alternative for a fixed sample size n. The OC of this $c = 0$ plan drops rapidly close to the vertical axis, allowing the use of very small values of rejectable or limiting quality level. Using the traditional matching theory, plans such as double or multiple plans cannot be matched to the $c = 0$ single sampling plan: see the tables given in Schilling and Johnson (1980). However, we have discovered that by using a compressed limit under a two-stage (also multistage) inspection procedure, the double plan can be matched to the $c = 0$ plan. In this research, we present two

variants of this two-stage sampling inspection plan where a compressed limit is used for decision making in the first stage.

First approach

Our first alternative is a double sampling procedure that uses only the *CL* in place of *m* in stage 1. In this plan we obtain d_1 as the artificial number of nonconforming test results in n_1 for given *CL*. That is, the number of test samples in the first stage of inspection that fail to conform with the *CL*. In the second stage, the regular specification limit *m* will be applied to obtain d_2, the number of test results that exceed *m* in the second stage of inspection of n_2 samples. The operation of the plan is illustrated in Fig 4.1.

The batch probability of acceptance is equal to the combined probability of acceptance in stages 1 and 2,

$$P_a = P_{a_1} + P_{a_2} \tag{4.5}$$

where

$$P_{a_1} = P\left(d_1 \leqslant a_1\right) \tag{4.6}$$

$$P_{a_2} = P\left(a_1 < d_1 < r_1 \cap D \leqslant a_2\right). \tag{4.7}$$

The probabilities P_{a_1} and P_{a_2} are obtained from the binomial probability function

$$f\left(d|n,p\right) = \binom{n}{d} p^d \left(1-p\right)^{n-d} \tag{4.8}$$

where *p* is the fraction nonconforming or prevalence, which depends on the set limit.

The average sample number (ASN) depends on the probability of proceeding to the second stage of inspection. The ASN function is obtained as follows:

$$ASN = n_1 + n_2\left[P\left(d_1 < r_1\right) - P\left(d_1 \leqslant a_1\right)\right] \tag{4.9}$$

Second approach

We also propose a second alternative that does not allow any test result to be over *m* in the first stage of inspection, as shown in Fig 4.2. This alternative uses not only *CL* but also *m* in the first stage. We obtain d_1 as the number of samples with count between *CL* and *m*. Therefore it gives the number of marginally acceptable samples, which is different from the first proposed plan. Also, we obtain d_{1m} as the number of samples with microbiological count over *m* or the number of nonconforming samples. The second stage is reached only when none of the sample counts is

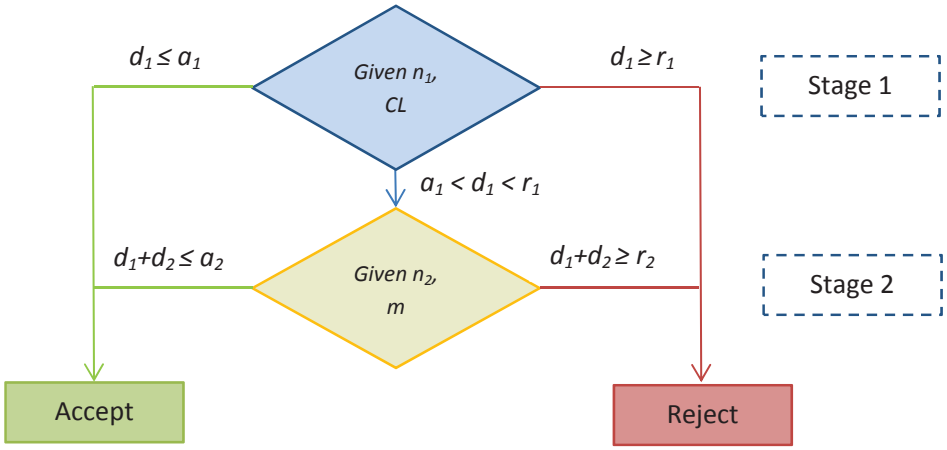


Fig. 4.1 Operation of the proposed two-stage sampling plan: first approach

over m ($d_{1m} = 0$) and $a_1 < d_1 < r_1$. The batch sentencing in the second stage is similar to the first approach.

The probability of acceptance P_{a_2} is obtained from the binomial probability distribution. However, the P_{a_1} is computed using two binomial distributions or by using the trinomial probability function (Jarvis, 2008; Johnson et al., 1997).

$$f(d_1, d_{1m}, d_0 | n_1; p_1, p_{1m}, p_0) = \frac{n_1}{d_1! d_{1m}! d_0!} p_1^{d_1} p_{1m}^{d_{1m}} p_0^{d_0} \tag{4.10}$$

where $d_0 = n_1 - d_1 - d_{1m}$ and $p_0 = 1 - p_1 - p_{1m}$.

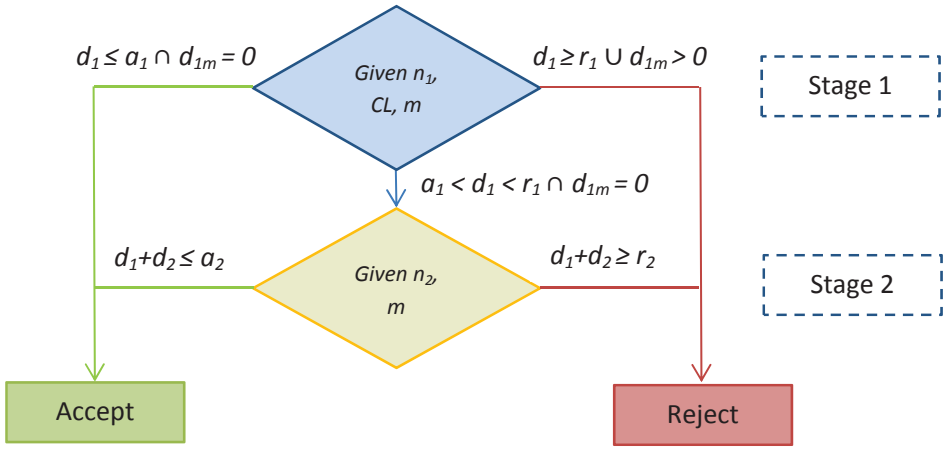


Fig. 4.2 Operation of the proposed two-stage sampling plan: approach two.

The traditional compressed-limit plans are based on the assumption of normality and the compression constant is obtained using the standard normal distribution. Since the assumed distribution is symmetric, the compression constant t (along with n and c) is enough to define the compressed limit plan. However, for discrete right-skewed distributions used in food control inspection, the optimum compression constant depends not only on the parameters of the assumed distribution but on the set specification limit m. Its calculation is considered in the next section.

4.4 Evaluation of double sampling plan with compressed limit in the first stage

4.4.1 The homogeneous case

Consider for example the zero acceptance number reference plan $n = 5$, $c = 0$. For the purpose of this discussion, let us assume a regulatory limit $m = 50$ cfu. Fig.4.3 shows the OC curves of this and the two newly introduced double plans when the count distribution of microorganisms in a homogenous batch is Poisson.

We now illustrate the use of the compressed limit in the first stage. This plan will require six parameters: five from the double sampling plan, plus CL. Suppose that we decide $n_1 = 2$ samples are to be taken in the first stage and then employ the set compressed limit of $CL = 41$ cfu (say). Let us define that a batch is accepted in the first stage when no nonconforming samples are obtained ($a_1 = 0$), which is a justifiable assumption for food quality problems. Further, that the batch is going to be rejected when two or more nonconforming samples are observed in stage one ($r_1 = 2$). We obtain d_1 the number of samples failing the compressed limit CL in n_1. Notice that d_1 is the number of *artificial* nonconforming samples since we use CL rather than m. A second sample of size $n_2 = 3$ will be drawn if $d_1 = 1$. The batch will be rejected in the second stage when the total number of nonconforming samples ($d_1 + d_2$) equals or exceeds two ($r_2 = 2$). The OC curve of this double compressed plan (Approach 1) is shown in Fig.4.3.

It is also justifiable on grounds of caution to use a plan that does not allow any sample over m in the first stage ($r_{1m} = 1$), which is Approach 2. Consider the plan $n_1 = 2$, $n_2 = 3$, $a_1 = 0$, $r_1 = 2$, $r_{1m} = 1$, $r_2 = 2$ and $CL = 42$. The OC curve for this plan is also shown in Fig.4.3. Notice how similar the OC curves of these three sampling plans are. The double plans match at two points of the OC curve based on $\alpha = 0.05$ and $\beta = 0.10$. Also, both double plans have slightly higher relative OC slope h_0 as well as smaller IQ value p_0 when compared with the reference single sampling plan. This means that the double sampling plans are discriminating between good and bad quality batches in a slightly better way when compared to the single plan.

In Fig.4.4 we compare the ASN of the single and double plans. It is clear that the two double plan alternatives will lower the sample sizes on the average for a series of lots. The metric $\max(ASN)$ gives the worst case scenario in terms of the ASN. As a general rule, the second method tends to provide smaller $\max(ASN)$. For larger sample sizes as considered by the ICMSF, say $n = 10$ to 60, we found that the reduction in ASN for the double plans is in the range 22 to 72%.

It is expected that the microbiological quality in some food products may decrease over time. Therefore, a factor to be considered in food quality assessment is the time frame between the collection of the samples and the test result being obtained. Our two-stage procedure involves additional time for testing the second sample and batch disposition. Consider the following example. Suppose that we are dealing with a quality characteristic for which enumeration requires the use of the traditional culture method. Let the inspection time of the traditional

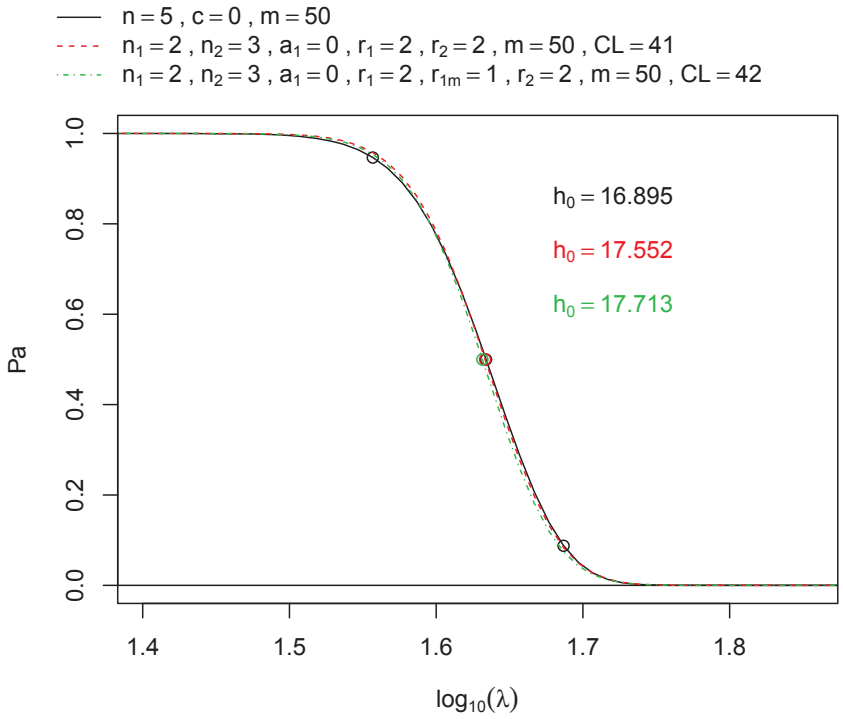


Fig. 4.3 Operating Characteristic (OC) curve of the reference single plan $n = 5$, $c = 0$ (solid line). The dashed and dotdash line gives the double plan with compressed limit in Stage 1.

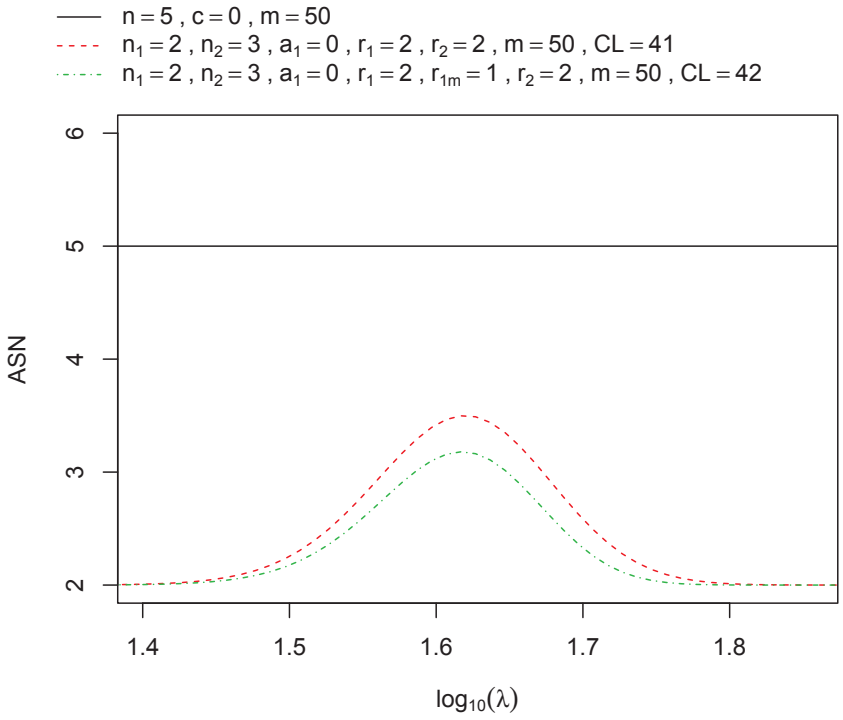


Fig. 4.4 Average sample number (ASN) of the plans $n = 5$, $c = 0$, $n_1 = 3$, $n_2 = 2$, $a_1 = 0$, $r_1 = 2$, $r_2 = 2$ and $n_1 = 2$, $n_2 = 5$, $a_1 = 0$, $r_1 = 2$, $r_{1m} = 1$, $r_2 = 2$.

sampling plan be 1 (certain known unit length of time). We can then compute the Average Inspection Time (AIT) for the two-stage plans as

$$AIT = 1 + [P(d_1 < r_1) - P(d_1 \leqslant a_1)] \tag{4.11}$$

In Fig.4.5 we compare the plans' AITs. In the worst case scenario, the the first and second approaches of double sampling will require 1.5 and 1.39 more decision time when compared to the single plan.

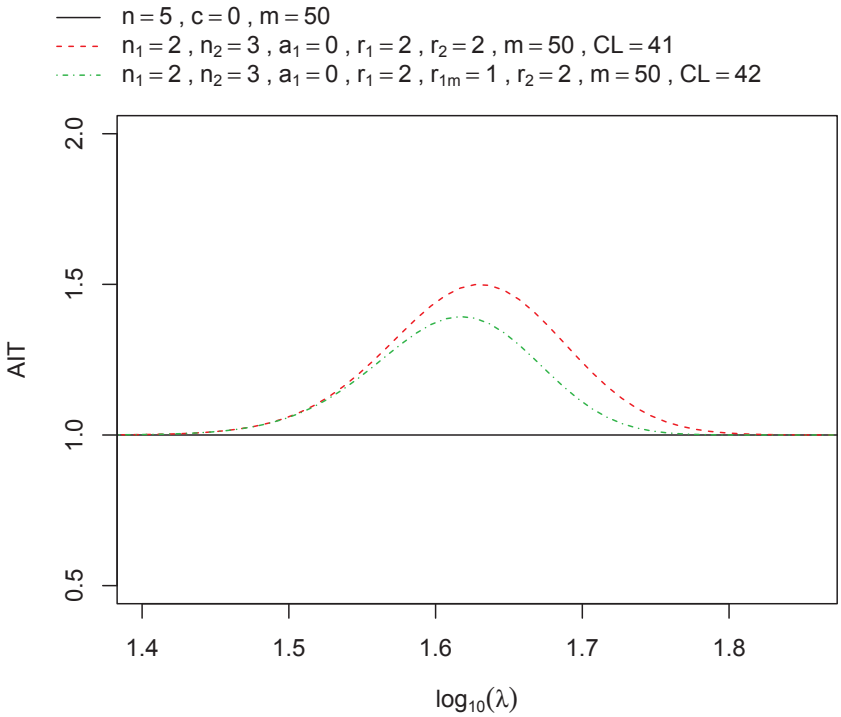


Fig. 4.5 Average Inspection Time (AIT) of the plans $n = 5$, $c = 0$, $n_1 = 3$, $n_2 = 2$, $a_1 = 0$, $r_1 = 2$, $r_2 = 2$ and $n_1 = 2$, $n_2 = 5$, $a_1 = 0$, $r_1 = 2$, $r_{1m} = 1$, $r_2 = 2$.

4.4.2 The heterogeneous case modelled with the PLN distribution

It is well established in the food safety literature that the probability of detection is smaller in the presence of a heterogeneous spatial distribution of microorganisms in the batch for a given average level of contamination. Hence, the consumer's risk increases when batches are not completely homogeneous. In this section we match double plans with compressed limits based on the Poisson-lognormal distribution with $\sigma = 0.8$. This value for σ has been found appropriate in several empirical studies; see for instance Legan et al. (2001). In the presence of heterogeneity, bigger sample sizes and a tightened CL will be required to match the single sampling plan. We compare the plans in Fig.4.6. In this graph the probability of acceptance is given as a function of $\log_{10}$ of the mean concentration and as a function of the parameter μ. The parameters λ and μ are connected through the first moment $\lambda = 10^{\mu + \log(10)\sigma^2/2}$.

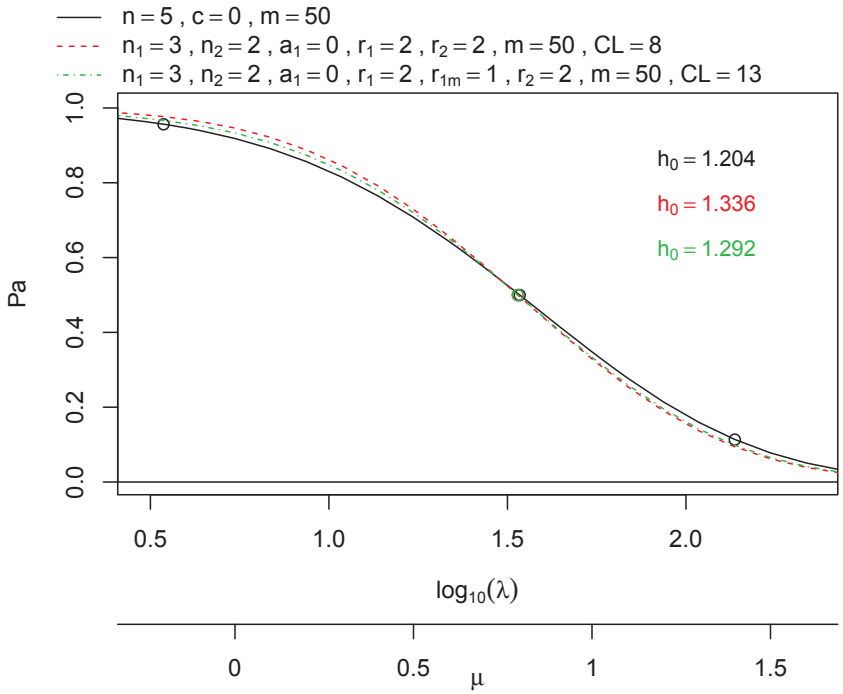


Fig. 4.6 Operating Characteristic (OC) curve of the reference single plan $n = 5$, $c = 0$ (solid line) assuming heterogeneity, with $\sigma = 0.8$. The dashed and dotdash lines give double plans with compressed limit in Stage 1.

4.4.3 The heterogeneous case modelled with the PG distribution

In this section we match the OC curves of the concentration based single and the double sampling plans using the Poisson-gamma distribution. Gonzales-Barron and Butler (2011b) found dispersion parameters K between 0.044 and 0.401 while fitting the Poisson-gamma distribution to the plate counts in different datasets. For discussion purposes in this work, we use $K = 0.25$. The OC curves of two matching plans are shown in Fig.4.7.

4.4.4 Iterative algorithm to obtain the optimum sampling plan

The two-stage sampling plan studied here involves several parameters. Hence, just two points of the OC curve are not sufficient to design and fix a unique sampling plan so further optimization condition involving the ASN is required. In this section we provide an iterative algorithm to obtain the optimum matching plan to a two-class single plan achieving minimum *ASN* values. The proposed procedure slightly differs from the Guenther (1970) method, since the compressed plan has an extra parameter.

1. Given the single plan (n, c) and the limit m, obtain the points $(AQL, 1-\alpha)$ and (LQL, β), generally setting $\alpha = 0.05$ and $\beta = 0.10$.

2. Set $a_1 = 0$ since this is a requirement in food safety inspection in particular, and also this setting involves the minimum sample size. Start with the minimum rejection numbers $r_1 = 2$ and $r_2 = 2$.

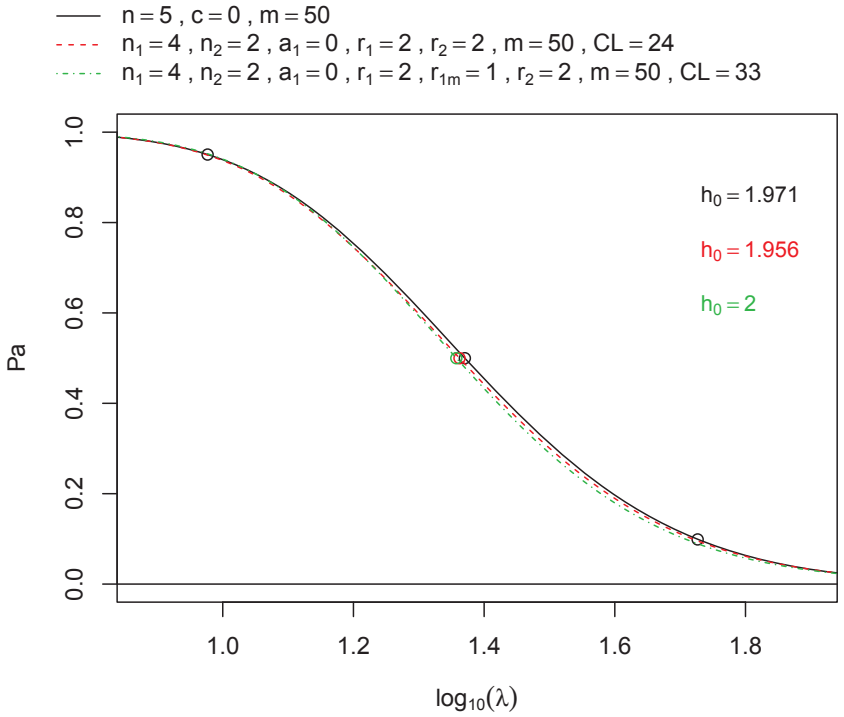


Fig. 4.7 Operating Characteristic (OC) curve of the reference single plan $n = 5$, $c = 0$ (solid line) assuming heterogeneity, modelled with the Poisson-gamma distribution with dispersion parameter $K = 0.25$. The dashed and dotdash lines give double plans with compressed limit in Stage 1.

3. For the sequence of $t = 0(1)m$, obtain the compressed limits $CL = m - t$. Notice that t is a non-negative integer because the underlying distribution is discrete.

4. Start with $n_2 = 1$. Obtain the largest n_1 namely n_{1_L} that satisfies $P_a(AQL, n_1, n_2) \geqslant 1 - \alpha$.

5. Check all the combinations $2 \leqslant n_1 \leqslant n_{1_S}$, $2 \leqslant n_2 \leqslant n - n_1$ that satisfy the two OC curve point restrictions.

6. If a plan is not found satisfying the stipulated conditions, then let $r_1 = r_1 + 1$ and $r_2 = r_2 + 1$ and go to Step 4.

7. Repeat Steps 4-7 for every t value.

8. When more than one plan exists at the end of the exhaustive searches, use either of the following optimality criteria: (i) smaller $\max(ASN)$ or (ii) $\min \int_{\lambda=0} ASN \, d\lambda$. For simplicity, we used the first (*minimax*) optimality criterion throughout the paper. The second criterion computes the area under the ASN curve which produced very similar results in the cases we examined.

The above design procedure can be easily modified when the pair (p_0, h_0) is used for matching plans.

4.4.5 Comparison with the single compressed limit plan

A compressed limit single plan based on a continuous distribution offers flexibility when finding a matching plan with a smaller sample size. This is because the compression constant could theoretically take any positive value. Many combinations of t and c can result in closely matching OC curves to the single sampling plan. In contrast, when the underlying distribution is discrete, only a finite and limited number t values can be used. This might limit the ability of the compressed limit single plan to exactly satisfy the two OC curve point restrictions. On the other hand, the double plan has more parameters and hence slightly more discriminating plans can be found. We illustrate this finer matching with an example. In Fig.4.8, the single plan $(n = 5, c = 0)$ is treated as the reference plan for matching assuming a regulatory limit of $m = 50$. We found

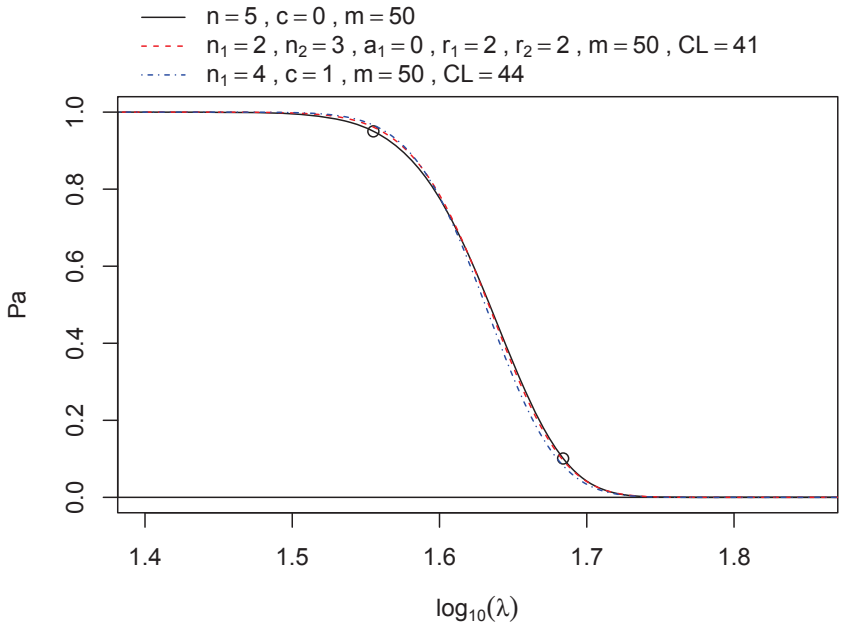


Fig. 4.8 Operating Characteristic (OC) curve of the reference single plan ($n = 5$, $c = 0$, $m = 50$) (in solid line). The dashed line gives the double plan with compressed limit in Stage 1 while the dotdash line represents the single compressed limit plan ($n = 4$, $c = 1$, $m = 50$, $t = 44$).

that the single compressed limit plan ($n = 4$, $c = 1$, $CL = 44$) equally satisfies the producer's and consumer's points. However, it can be noticed from Fig.4.9 how the double compressed plan provides a lower *ASN*. Another advantage of the double compressed limit plan is that the decision in not solely made based on the compressed limit as in the single alternative. However, for bigger sample sizes it would be possible to find an approximate single compressed plan, with lower ASN, relaxing the producer's point.

4.4.6 Assessing the robustness of the plans

Compressed plans are in general non-robust to departures from the assumed model; see the warning given in Schilling and Neubauer (2010). In this section we assess the consumers' risk when the distribution changes from Poisson to Poisson-lognormal with $\sigma = 0.8$. We compare

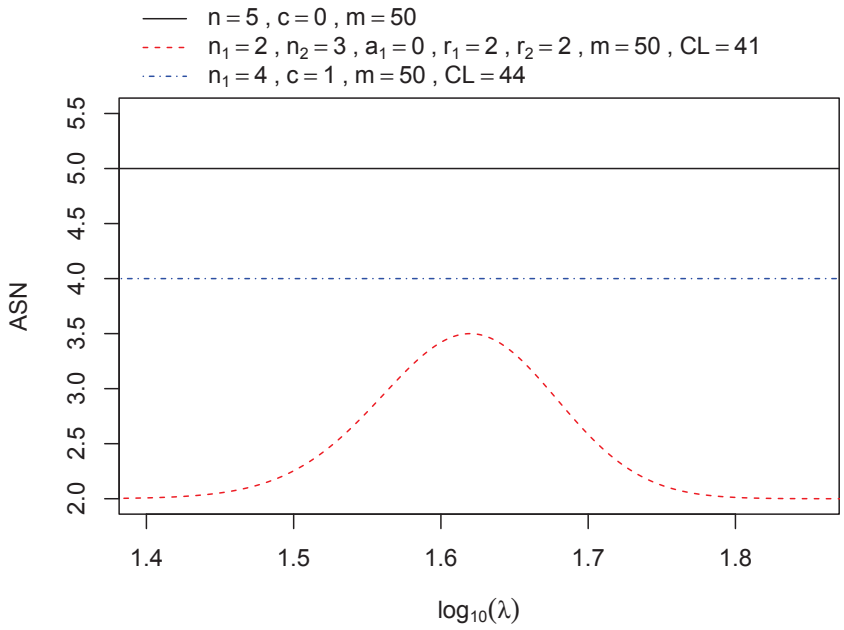


Fig. 4.9 Average sample number (ASN) of the plans $n = 5$, $c = 0$; $n_1 = 2$, $n_2 = 3$, $a_1 = 0$, $r_1 = 2$, $r_2 = 2$, $CL = 41$ and $n = 4$, $c = 1$, $CL = 44$.

in Table 4.1 the regular single sampling plan ($n = 5$, $c = 0$), the single compressed limit plan ($n = 4$, $c = 1$, $CL = 44$) and the compressed limit double plans discussed earlier. For the Poisson assumption, we show the LQL_P at $\beta = 0.10$, expressed in $log_{10}(\lambda)$. Notice that these plans have similar LQLs as seen in Fig.4.8. We then compute the corresponding values under the Poisson-lognormal assumption and show the achieved limiting quality levels as LQL_{PLN}. The single plan gives the lowest LQL_{PLN}, which suggest that the single plan provides slightly better consumer protection when batches are less homogeneous.

Table 4.1 Comparison in terms of LQL between the proposed plans, the regular single sampling plan and the single compressed limit plan. The quality is expressed in terms of $log_{10}(\lambda)$

Plan	LQL_P	LQL_{PLN}
Single plan	1.69	2.14
Approach 1	1.69	2.74
Approach 2	1.68	2.74
Single compressed plan	1.68	2.74

4.5 Practical results

We validated the application of the proposed double sampling procedures using a large amount of real cfu data of Aerobic Plate Counts in milk powder. The dataset consists of 2470 observations from 494 batches with 5 test results per batch. A considerable proportion (47%) of the APC values were zero. The arithmetic mean of the counts is 1.41 cfu and the standard deviation is 3.89 cfu which suggest over-dispersion ($\mathrm{Var}[X] > \mathrm{E}[X]$). The total variation can be partitioned into 'within batch' and 'between batch' variation. The single plan $(n = 5, c = 0)$ was employed in practice and most of the observed counts were well below the specification limit of 50 cfu/0.1g. A well managed process such as this allows a wide range compressed limit *CL* to be trialled.

The test samples were prepared according to the ISO standard 6887 (ISO 6887-1, 1999), where every analytical sample of 10g of milk powder was diluted up to 100mL. Subsequently 1mL inoculum was plated onto plate count agar previously poured according to the ISO standard 4833 (ISO 4833-1, 2003). The dish was incubated aerobically for 72 h at 30 °C. It was assumed that every cell forms a visible cfu after incubation and the cells are locally homogeneous in the small plated amount of 1mL. The practice is to multiply the observed cell counts in 1mL by 100 to obtain the approximate number of cells in the original 10g unit amount for which the specification is 5,000 cfu/10g. We opted to analyze the original observed count in 1mL unit directly because the direct use of raw data is more appropriate for statistical modelling.

We first assessed how well the three statistical models previously described fitted the empirical data. The models were fitted by Markov chain Monte Carlo (MCMC) using the **OpenBUGS** package (Lunn et al., 2000). Details of the simulations and the codes are given as 4.A and 4.B.

We assessed the fit in terms of Deviance Information Criterion (DIC), see Spiegelhalter et al. (2002). The smaller the DIC, the better the fit of the statistical model. In Table 4.2, we show a summary of the estimated posterior parameters and the DIC. The medians (point estimates) and 95 % intervals are also given. The parameters of the lognormal distribution are in natural log scale (ln). It can be noted that the Poisson-gamma distribution with $R = 0.4599$ (or alternatively $K = 2.1744$) was the model that produced the best fit the APC data. As expected the Poisson model does not fit well this data since it has no model parameter to allow for over dispersion.

Table 4.2 Estimated parameters and fitting metrics for the Poisson, PLN and PG distributions.

Distribution	DIC	Parameters	Mean	SD	MC error	2.5%	Median	97.5%
Poisson	7384	μ_0	-0.2255*	0.0528	7.30E-04	-0.3313	-0.2256	-0.1214
		σ_b	0.9927	0.0432	7.43E-04	0.9131	0.9910	1.0810
PLN	6462	μ_0	-0.3892	0.0528	8.40E-04	-0.4942	-0.3884	-0.2869
		σ_w	0.6622	0.0308	8.04E-04	0.6039	0.6616	0.7245
		σ_b	0.9240	0.0438	8.40E-04	0.8411	0.9228	1.0140
PG	6430	$R(1/K)$	0.4599	0.0427	0.0021	0.3807	0.4584	0.5467
		μ_0	-0.1807	0.0531	0.0016	-0.2870	-0.1790	-0.0785
		σ_b	0.9481	0.0453	0.0017	0.8635	0.9464	1.0410

* Note: The parameters of the lognormal distribution are in natural log scale (ln). The MC error refers to the Monte Carlo standard error of the mean.

Using the web-based tool described in Section 4.6, the double plan $n_1 = 3$, $n_2 = 3$, $a_1 = 0$, $r_1 = 2$, $r_2 = 2$, $m = 50$, $CL = 28$ can be found as the Approach 1 plan matching $(n = 5, c = 0)$ single plan. The matching Approach 2 double plan is with $n_1 = 3$, $n_2 = 3$, $a_1 = 0$, $r_1 = 2$, $r_{1_m} = 0$, $r_2 = 2$, $m = 50$, $t = 33$. This plan also better satisfies the restrictions involving both two points in the OC curve and the IQ value p_0 with relative slope h_0.

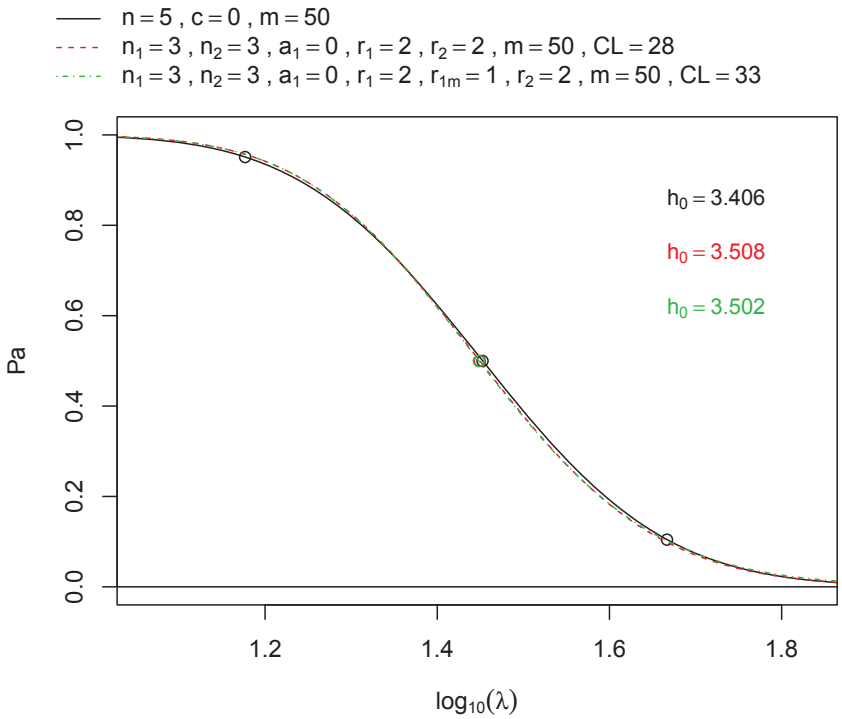


Fig. 4.10 Operating Characteristic (OC) curve of the reference single sampling plan $n = 5$, $c = 0$, $m = 50$ modelled with the negative binomial distribution with $K = 2.17$. The dashed line represents the double plan $n_1 = 3$, $n_2 = 3$, $a_1 = 0$, $r_1 = 2$, $r_2 = 2$, $m = 50$, $CL = 28$. The dotdash line represents the plan $n_1 = 3$, $n_2 = 3$, $a_1 = 0$, $r_1 = 2$, $r_{1_m} = 0$, $r_2 = 2$, $m = 50$, $CL = 33$.

Three batches out of 494 were rejected under the traditional sampling plan ($n = 5$, $c = 0$), because at least one observation was over the specification limit $m = 50$ cfu. In Table 4.3 we summarize the batch sentencing results for the MCMC simulation of a large series of batches using the APC dataset we studied. Since the double plans require $n_1 = 3$ in the first stage, three observations out of five are randomly selected without replacement. By considering all possible selections we obtain a probability of rejection by the double plans.

A particular batch with sample counts (33, 20, 35, 44, 13) was accepted under the single plan but this lot will be rejected under Approach 1 with a probability of at least 0.7 mainly because three of the values are over the $CL = 28$. Using Approach 2 where $CL = 33$ the same batch will be rejected with probability of at least 0.4. This particular batch exhibits marginal sanitary quality. From Table 4.3 we notice that the total saving when using the double plans is around 40%. In general we found that the second approach performs better than the first one in terms of the expected number of rejected nonconforming batches. For example, the following three batches were rejected under the traditional plan: (1) 2, 4, 4, 69, 58, (2) 11, 85, 15, 23, 2 and (3) 0, 0, 1, 0, 56. They will have probabilities of at least 0.9, 0.6 and 0.6 of being rejected by the

second approach. By contrast, the probability of rejection of these batches under Approach 1 is much lower.

Table 4.3 Results of applying the double sampling plans to the APC dataset. The comparison is done in relation to the decision using the reference single sampling plan with ($n = 5$, $c = 0$).

Decision	Approach 1	Approach 2
Batches correctly accepted	99.25%	99.33%
Batches correctly rejected	0.18%	0.43%
Batches incorrectly rejected	0.14%	0.08%
Batches incorrectly accepted or non detected	0.43%	0.16%
Batches reaching 2nd stage	0.43%	0.24%
Saving in inspection	39.74%	39.85%

4.6 A web-based application

In order to provide flexible solutions for practical problems, we provide an interactive web-based tool made with Shiny (Chang et al., 2015). This free tool is hosted at https://edgarsantosfdez.shinyapps.io/Double, which is multiplatform and therefore can be accessed from PCs, smartphones or any other device via a web browser. In Fig.4.11 we show a screenshot. The three statistical models previously described are included. The tool allows the user to interactively see the effect of each parameter on the batch probability of acceptance and the *ASN*. It also allows the user to find the optimum matching plan following the steps given in Section 4.4.4. The app source codes are available from the first author upon request.

4.7 Discussion and conclusions

In this paper we introduce two new double sampling procedures for bacterial cell counts. The efficiency of double sampling is achieved by compressing the specification limit in the first stage, while keeping the regular specification limit for the second stage.

The purpose of the study was to assess the performance of double plans using several statistical models accounting for homogeneity and for clumping in foodstuffs. The proposed double plans were found to provide similar protection to the consumers when compared to the single sampling plan, while reducing the sample size on an average for a series of batches. The double plans will reduce the laboratory workload and testing cost. Our second approach to double sampling is slightly more complex to administer but it achieves a lower *ASN*. Moreover, it ensures that no batch will be accepted with an observation over the regulatory limit.

We opted for the smaller *ASN* design criterion as a strategy to reduce the testing cost. Double plans can also be found so that for indifference quality batches $ASN > n$, but still $\min \int_{\lambda=0} ASN \, d\lambda < n \times \lambda_{max}$. This means that a part of the *ASN* curve will be over n, but the

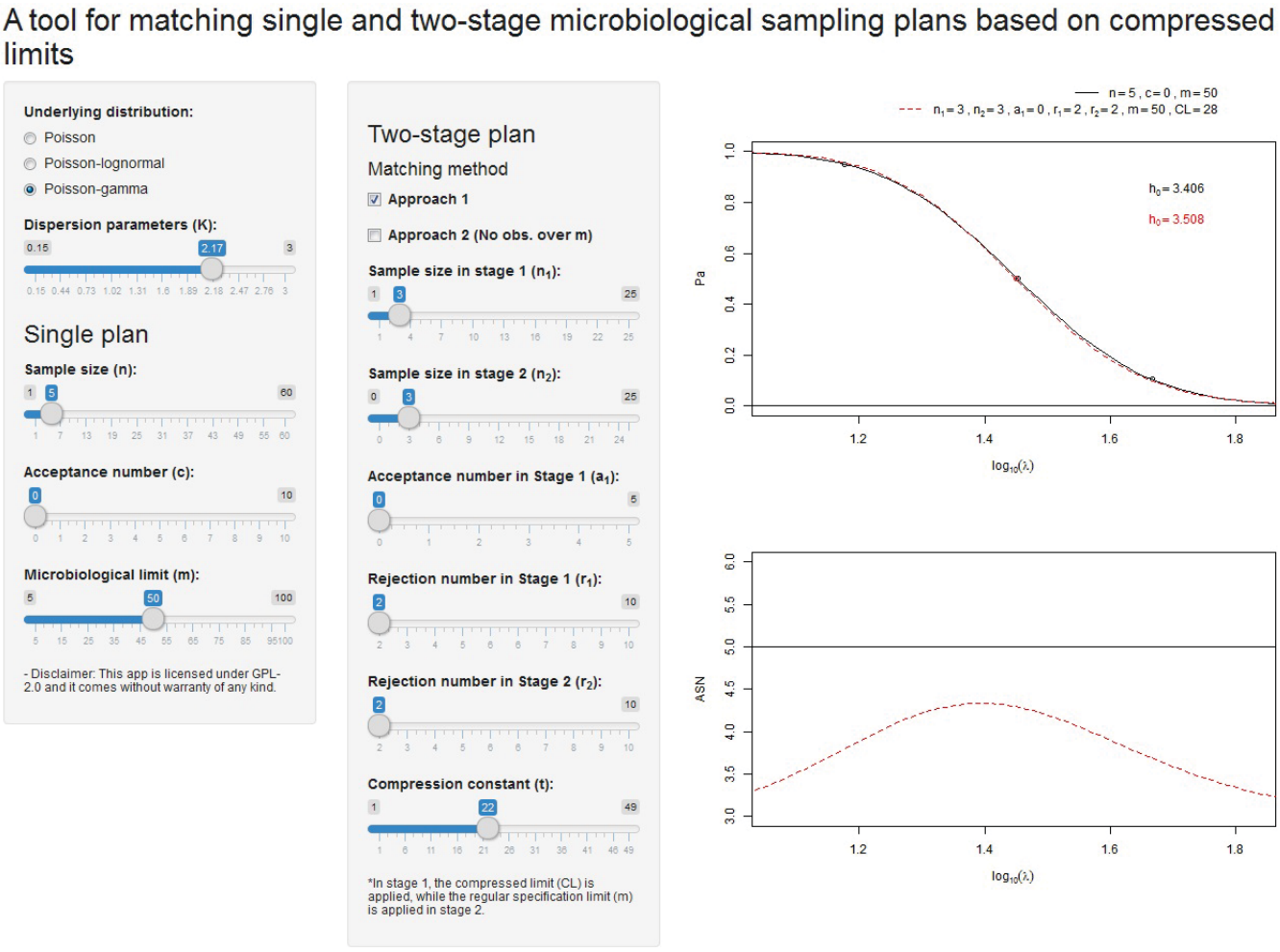


Fig. 4.11 Screenshot of the online app for matching single concentration-based sampling plan and double sampling plans based on compressed limit in stage 1.
Online at: **https://edgarsantosfdez.shinyapps.io/Double**

area underneath this curve will be smaller than the area below n. The double plan can also provide consumer protection against over-dispersed contamination and marginal quality batches as described in Section 4.5.

Any two-stage sampling plan must be predefined before the actual inspection is carried out. The proposed plan should not be used as a way of giving another chance to a rejected batch using a single plan; see the warning given by ICMSF (2002).

Quoting Earl Wiener's 29^{th} law: *"Whenever you solve a problem, you usually create one. You can only hope that the one you created is less critical than the one you eliminated."* The trade-off in our procedure is the delayed decision time whenever the second stage is reached. This, however, will not affect the normal operation as long as the process is well maintained and is kept in a state of statistical control. Under the proposed plan, most poor quality batches will be sentenced in the first stage of sampling itself. A second stage is mostly required around the indifference quality levels, which often corresponds to marginal quality batches. The batch probability of acceptance is more complex to derive for the proposed double plans. However, this difficulty is overcome using the online app that allows visual matching of sampling plans. Finally, this technique might be extended to three-class sanitary characteristics based on two stages, but with obvious detriment to the simplicity of the inspection protocols.

Appendix 4.A Markov chain Monte Carlo (MCMC) method

The fitting of the statistical models was done in **OpenBUGS** package using MCMC. We simulated three chains each with 10,000 iterations, checked convergence and discarded a 'burn-in' of 500 samples. In the Poisson-lognormal case, the within and between standard deviations (σ_w and σ_b) were considered as constant across batches, while μ is a random effect that varies from batch to batch. Therefore,

$$\lambda \sim \mathscr{LN}(\mu, \sigma_w) \tag{4.12}$$

where is normally distributed with μ_0 and σ_b.

$$\mu \sim \mathscr{N}(\mu_0, \sigma_b) \tag{4.13}$$

For priors we used $\mu_0 \sim \mathscr{N}(0, 0.01)$, $\sigma_w \sim \mathscr{U}(0, 10)$ and $\sigma_b \sim \mathscr{U}(0, 50)$, which are all largely uninformative. In the negative binomial (or Poisson-gamma) case, we assumed the mean concentration m as a random batch effect, while the dispersion parameter or shape K was considered as constant. For convenience, we used $R = 1/K$, with prior $R \sim \text{Exp}\left(10^{-7}\right)$ to allow for the possibility of no over-dispersion ($R = 0$). For m we used the prior $m \sim \mathscr{LN}(\mu_0, \sigma_b)$. Finally, in the Poisson distribution case, we assumed that the rate λ changes from batch-to-batch, lognormally distributed $\lambda \sim \mathscr{LN}(\mu_0, \sigma_b)$ since it can take only positive values.

The posterior densities of every parameter for the negative binomial distribution case are shown in Fig.4.12.

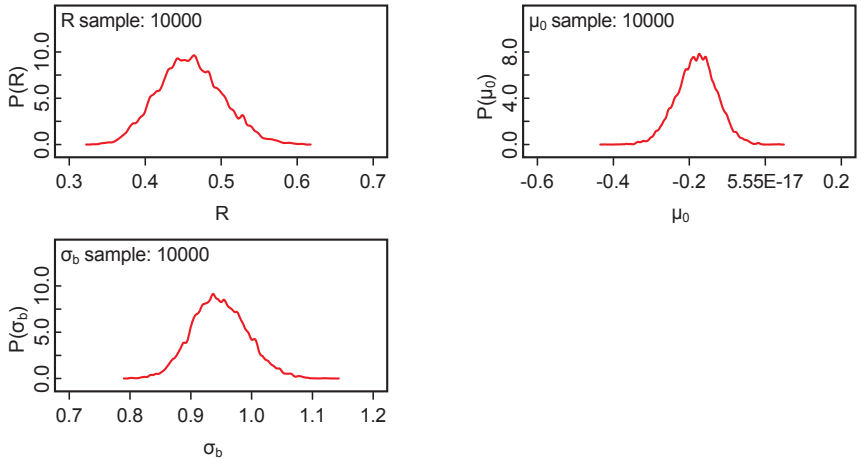


Fig. 4.12 Posterior densities of the fit to the negative binomial distribution. The parameter R is the reciprocal of the dispersion parameter K ($R = 1/K$.)

Appendix 4.B OpenBUGS codes used for the simulations

4.B.1 Negative binomial

```
model{
    for (i in 1:2470) {
        Count[i] ~ dpois(lambda[i])
        lambda[i] ~ dgamma(r, b[Batch[i]])
    }

    for (j in 1 : 494) {
        mu[j] ~ dlnorm(mu0,tau0)
        b[j] <-r / mu[j]
    }

    tau0 <-1 / (sig0 * sig0)
    r <-1 / R

    #Priors distributions :
    mu0 ~ dnorm(0,0.01)
    R ~ dexp(0.0000001)
    sig0 ~ dunif(0,50)
}

#chain inits :
 list (mu0 = 0, R = 2, sig0 = 0.01)
 list (mu0 = -0.2, R = 1, sig0 = 0.05)
 list (mu0 = 0.2, R = 0.5, sig0 = 0.1)
```

4.B.2 Poisson-lognormal

```
model{
```

```
    for (i in 1 : 2470) {
        Count[i] ~ dpois(lambda[i])
        lambda[i] ~ dlnorm(mu[Batch[i]], tau)
    }

    for (j in 1 : 494) {
        mu[j] ~ dnorm(mu0,tau0)
    }

    tau <-1 / (sig * sig)
    tau0 <-1 / (sig0 * sig0)

    #Priors:
    mu0 ~ dnorm(0,0.01)
    sig ~ dunif(0,10)
    sig0 ~ dunif(0,50)
}

#chain inits :
 list (mu0 = 0, sig = 2, sig0 = 0.1)
 list (mu0 = -1, sig = 0.1, sig0 = 0.5)
 list (mu0 = 1, sig = 0.5, sig0 = 2)
```

4.B.3 Poisson

```
model{
    for (i in 1 : 2470) {
        Count[i] ~ dpois(mu[Batch[i]])
    }

    for (j in 1 : 494) {
        mu[j] ~ dlnorm(mu0,tau0)
    }

    tau0 <-1 / (sig0 * sig0)

    #Priors:
    mu0 ~ dnorm(1,0.01)
    sig0 ~ dunif(0,50)
}

#chain inits :
 list (mu0 = 0, sig0 = 0.1)
 list (mu0 = 0.5, sig0 = 0.5)
 list (mu0 = 1, sig0 = 2)
```

Chapter 5

Effects of imperfect testing on presence-absence sampling plans

Edgar Santos-Fernández, K. Govindaraju, Geoff Jones
Quality and Reliability Engineering International, Submitted [1]

5.1 Abstract

Test performance measures such as sensitivity and specificity are generally ignored in microbiological risk assessment. In this research we examine the impact of imperfect analytical tests on sampling inspection plans for presence-absence characteristics. We discuss several plausible scenarios and assess the risk for the consumers. The method is illustrated using collected data over two years for *Cronobacter* spp. (formerly *Enterobacter* sakazakii) in skimmed milk powder. The probability of contamination and the test sensitivity and specificity, are estimated using Bayesian inference. We examine the sampling plans proposed by the Codex Alimentarius and by New Zealand's Ministry of Primary Industries for this pathogen. A cost analysis is carried out to show the economic loss due to measurement errors. We describe the strengths and limitations of these plans under different conditions and propose a plan that could provide better protection to the consumers as well as to the producers.

Keywords

presence-absence tests; sensitivity; specificity; sampling inspection plan; Bayesian inference; measurement errors; *Cronobacter* spp.

[1] An abridged version of this paper was presented at the European Network for Business and Industrial Statistics (ENBIS) 2016 Annual Conference in Sheffield, UK. http://www.enbis.org/activities/events/current/424_ENBIS_16_in_Sheffield/programmeitem/2164_Effects_of_Imperfect_Testing_on_Presence_Absence_Sampling_Plans

5.2 Introduction

Binary or presence/absence tests aim to classify items, samples or individuals into two classes, e.g. positive or negative, pass or fail. The efficacy of these tests is expressed by metrics like sensitivity (*se*) and specificity (*sp*). Sensitivity refers to the test's ability to detect the true positives (TP). The sensitivity is computed as the number of true positives divided by the total number of positives (P). P = TP + FN, where FN is the number of false negatives. By contrast, the specificity expresses the ability of the test to detect true negatives (TN). It is obtained as the number of true negatives divided by the number of negatives, where N = TN + FP.

The test sensitivity and specificity are assumed to be independent of the prevalence in the population. Perfect sensitivity and specificity are desirable but not achievable in practice. Generally, *se* and *sp* over 95% are considered appropriate. See for instance Eijkelkamp et al. (2009). Commonly, there is a trade-off between sensitivity and specificity, which can be illustrated in the receiver operating characteristic (ROC) curve. The symbols used in this paper are listed in 5.A.

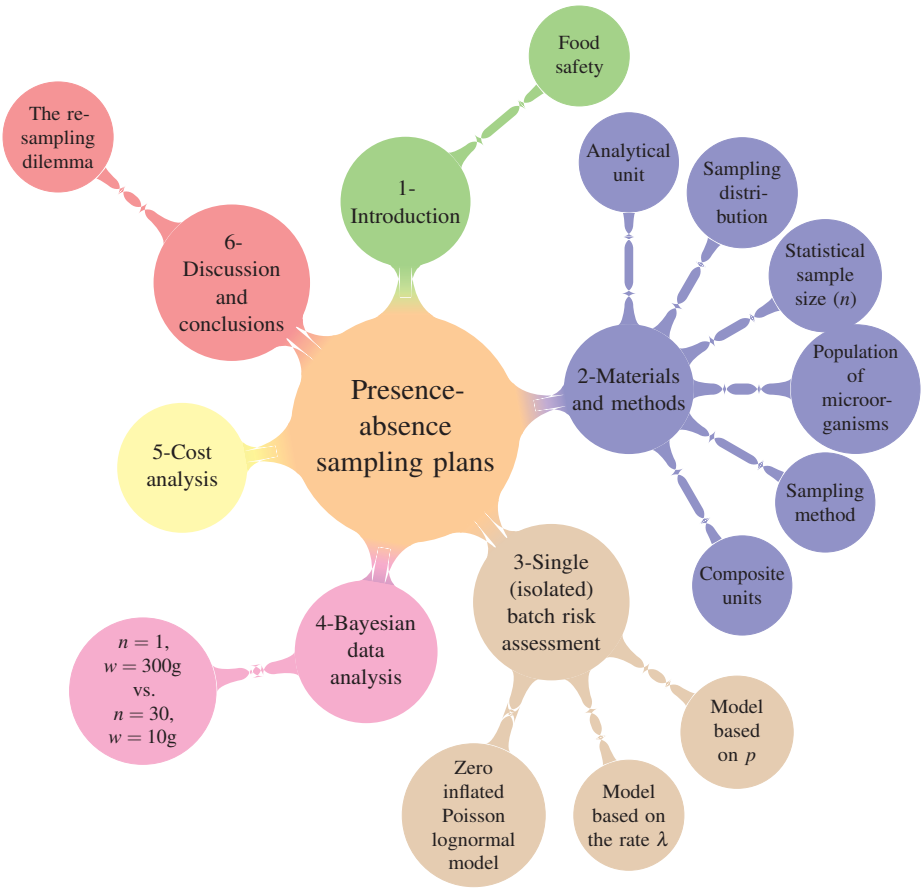
In the food safety area

FAO/WHO (2014) defines the probability of detecting a target microorganism for a supposedly perfect specificity and sensitivity. The ICMSF (2002, pp.9) has pointed out that microbial testing "often lacks sensitivity and specificity" and that usually the sensitivity is sacrificed to reduce the laboratory time. In practice, tests are usually assumed to be perfectly sensitive and specific (Pouillot et al., 2013) and microbial sampling plans are based on that assumption. In this regard ICMSF (2002, pp.120) suggest that when sensitivity and specificity are known for a particular microbiological method the computation of the risk should be adjusted. This is partially possible thanks to the FAO/WHO (2012) tool that incorporates into the model the test sensitivity. Hoelzer and Pouillot (2013) also studied the impact of imperfect test sensitivity in microbial risk assessment using low sample sizes.

In the traditional culture methods the specificity is generally high and commonly assumed 100% (Gardner, 2004; Hoelzer and Pouillot, 2013; Powell, 2014).

Empirical studies suggest that perfect specificity is seldom attained, independent of the detection methods. For instance, the cross-contamination risk cannot be completely eliminated. 5.B shows the reported performance indicators of several detection methods (culture, PCR, immunological, etc.) for different commodities and type of microorganisms. Iversen et al. (2008) using the FDA (2002) method for *Cronobacter* spp. detection in powdered infant formula showed as low as 52.2% sensitivity and 73.5% specificity. In this research we discuss the effect of imperfect classifiers on the performance of microbiological presence-absence sampling plans. Our purpose is to reduce the risks and the costs due to sampling and measurement errors. The remainder of the paper is summarized in Fig. 5.1.

Fig. 5.1 Mindmap of the structure of the article (clockwise)



5.3 Materials and methods

5.3.1 Discretization and the analytical unit

Bulk materials are generally studied by splitting into supposedly 'discrete units' for analysis. These analytical units can be conceptualized by supposing that an imaginary two or three-dimensional square grid is unfolded over the batch. The size of the grid defines the analytical unit amount.

Let p be the analytical unit probability of contamination for a perfect classifier. That is, p is the probability of finding one or more microorganisms in the analytical unit. We should mention that generally in the inspection of discrete items, p denotes a population parameter, which does not dependent on sampling. However, in bulk materials p is subject to the grid size used to discretize the lot and hence it will be conditioned by the sampling method.

Discretization is a complex issue and it is known in some disciplines as the Modifiable Areal Unit Problem (MAUP). See e.g. Wong (2009). To illustrate how the use of different grid structures leads to different probability of detection, consider the following hypothetical example. Fig. 5.2 depicts a section of a batch under two different grids. Suppose that the smaller grid in (a) splits the material into 1 g units, while the larger into 4 g units. The mean concentration is independent of the grid, being equal to 1 colony-forming unit per gram (cfu/g). However, the standard deviations are 1.21 cfu/g and 0 respectively. Also the proportion nonconforming is 0.5 in the first case and 1 in the second one.

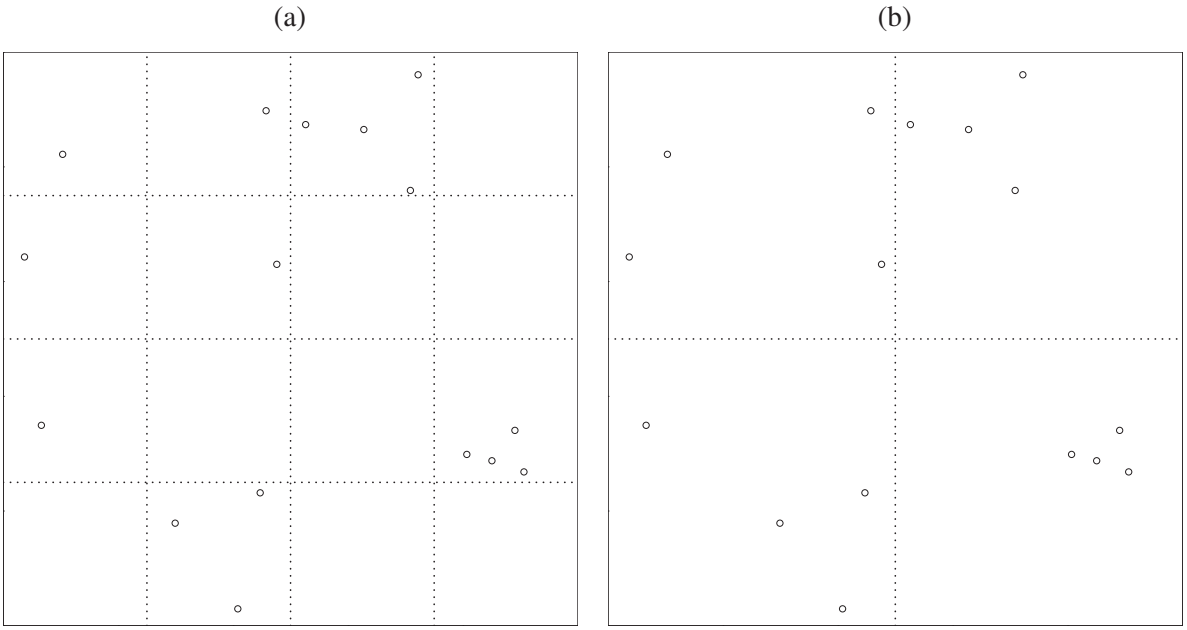


Fig. 5.2 Effect of the grid size in the standard deviations and the proportion nonconforming. The grids split the batch into 1 g (a) units and 4 g (b) units respectively.

5.3.2 The sampling distribution

The probability of accepting a batch (P_a) based on n samples is obtained from the binomial mass function

$$f(d;p,n) = \binom{n}{d} p^d (1-p)^{n-d} \tag{5.1}$$

where d represents the possible number of samples with the characteristic. For pathogens the acceptance number is generally zero ($c = 0$), so the probability of acceptance becomes

$$P_a = (1-p)^n \tag{5.2}$$

The value p in Eq.5.2 assumes that the classifier or test is perfect. The apparent probability of contamination p_e is the proportion of units that are classified as contaminated using an imperfect test. See for instance Vose (2008).

$$p_e = se \times p + (1-sp) \times (1-p) \tag{5.3}$$

Lavin (1946) and Johnson et al. (1991) give a similar expression for the apparent probability of contamination but as a function of the misclassification errors $e_1 = 1 - sp$ and $e_2 = 1 - se$. Substituting Eq.5.3 in Eq.5.2 we obtain the batch probability of acceptance as a function the proportion nonconforming, the sample size, the test sensitivity and the specificity.

$$P_a = P(d = 0|p, se, sp, n) = [(1-se)\,p + sp\,(1-p)]^n \tag{5.4}$$

5.3.3 Statistical sample size (n)

By rearranging Eq.5.4 we obtain the required sample size for a given probability of acceptance when using an imperfect classifier as

$$n = \frac{\log(\beta)}{\log[(1-se)\,p + sp\,(1-p)]} \tag{5.5}$$

Notice that P_a has been replaced by the consumer's risk (β), which is the most relevant point in the OC curve in food safety assurance and represents the probability of accepting rejectable quality.

The following hypothetical example shows the impact of an imperfect microbial test on the required sample size. Suppose that we want to accept a batch with $p = 0.2056$ with low probability $\beta = 0.10$, and let $c = 0$. Using a perfectly specific and sensitive microbiological test the required sample size is $n = \log(\beta)/\log(1-p) = 10$. Consider now that the test is imperfect with $se = sp = 0.95$. In this case from Eq.5.5 the required sample size is nine, which might seem contradictory at first. In Fig. 5.3 we show both Operating Characteristic (OC) curves, which match at the point p, β. Notice the massive impact of sp on the producers' risk when the batch is non-contaminated ($p = 0$).

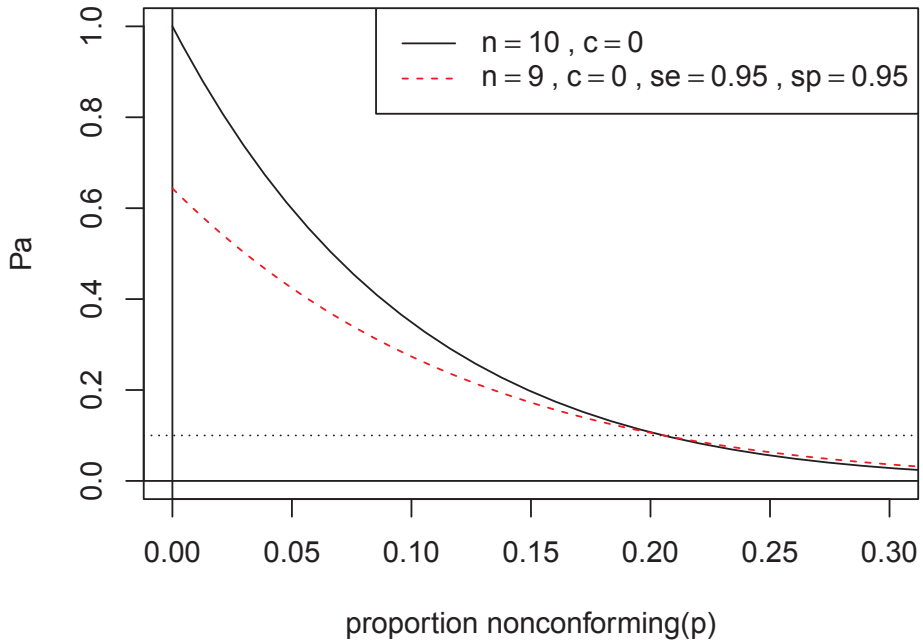


Fig. 5.3 Operating Characteristic (OC) curves of the plans $n = 10$, $c = 0$ and $n = 9$, $c = 0$, $se = sp = 0.95$.

For a fixed β value the apparent probability of contamination is smaller than the true probability of contamination when $p > (1 - sp)/[(1 - sp) + (1 - se)]$.

5.3.4 The population of microorganisms

Often, microorganisms are considered to be distributed homogeneously within a batch when the concentration is low, and the risk is generally obtained from the Poisson distribution. The Poisson probability mass function (Eq.5.6) gives the probability of obtaining x microorganisms in a sample given a contamination rate λ.

$$P(x|\lambda) = \frac{\lambda^x e^{-\lambda}}{x!} \tag{5.6}$$

By contrast, when the contamination is high the microorganisms tend to form clusters and groups. The risk in this case is assessed using right-skewed models like lognormal, gamma, Poisson-lognormal (PLN), Poisson-gamma (PG) (e.g. Gonzales-Barron and Butler, 2011b; Jongenburger et al., 2012a; Van Schothorst et al., 2009). The PLN model is the result of a Poisson distribution in which the rate λ is lognormally distributed with parameters μ and σ, and the density function is

$$P(x|\mu,\sigma) = \int_0^\infty \frac{\lambda^x e^{-\lambda}}{x!} \frac{1}{\lambda\sigma\sqrt{2\pi}} e^{\left(-\frac{(\ln(\lambda)-\mu)^2}{2\sigma^2}\right)} d\lambda \tag{5.7}$$

Poisson-gamma instead arises when the rate (λ) follows a gamma distribution. The density as a function of mean concentration $m = \mathrm{E}[X]$ and the dispersion parameter K is:

$$P(X = x|K,m) = \frac{\Gamma(K+x)}{\Gamma(K)x!}\left(\frac{K}{K+m}\right)^{K}\left(\frac{m}{K+m}\right)^{x} \tag{5.8}$$

where Γ is the gamma function.

Another useful mixed distribution is the Conway-Maxwell-Poisson (CMP) distribution (Shmueli et al., 2005). This model allows both underdispersion and overdispersion by including an extra parameter (ν).

$$P(x) = \frac{\lambda^{x}}{(x!)^{\nu}}\frac{1}{Z(\lambda,\nu)} \tag{5.9}$$

where $\lambda > 0$, $\nu \geqslant 0$ and the normalizing constant $Z(\lambda,\nu)$ is

$$Z(\lambda,\nu) = \sum_{j=0}^{\infty}\frac{\lambda^{j}}{(j!)^{\nu}} \tag{5.10}$$

Other models such as zero-inflated Poisson (ZIP) or zero-inflated negative binomial (ZINB) can be used as well when the frequency of zero values is very high. See e.g. Lambert (1992) and Hall (2000). Both models were considered by Gonzales-Barron et al. (2010a) to model *E. coli* and coliforms counts in beef carcasses.

In Eq.5.7 λ is lognormal distributed and therefore it does not allows for complete absence of the pathogen in the batch ($\lambda = 0$). To solve this issue we propose the use of a zero inflated Poisson-lognormal distribution. This model comprises two parts. The first one is a binary process governed by a Bernoulli law defining the proportion of zero values or the inflation probability (θ). The second part will contain the realization being Poisson-lognormally distributed. Hence λ is a semi-continuous variable. The probability mass function is:

$$\begin{aligned}\Pr(y_i = 0) &= \theta + (1-\theta)\,g(0)\,; x_i = 0\\ \Pr(y_i = x_i) &= (1-\theta)\,g(x_i)\,; x_i \geqslant 1\end{aligned} \tag{5.11}$$

where g is a discrete probability mass function, PLN in this case.

5.3.5 The sampling method

The spatial distribution of the contamination needs to be considered when deciding the sampling method to be used. Random or systematic sampling will not make any difference in the probability of detection for a perfectly homogenous contamination. However, under heterogeneity (specifically under localized contamination) systematic sampling has been found more suitable to detect pathogens in food. See e.g. Jongenburger et al. (2011b).

5.3.6 Testing pooled or composite units

Microbiological testing generally deals with bulk materials, which allows the use of composite samples. Compositing might increase the informative level and the stringency without increasing the number of analytical tests.

There are various ways of making composite samples. In this research we consider the following case. Several primary units or increments are aggregated forming a composite that is subsequently subsampled for testing. See Fig. 5.4

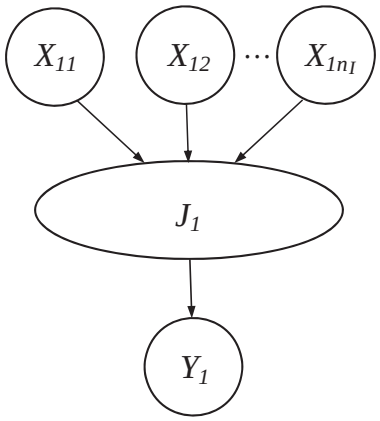


Fig. 5.4 Process of forming a composite sample (Y_1) by subsampling a big composite (J_1) composed by several primary units ($X_{1.}$).

In particular the use of composite samples in *Salmonella* testing has proved to be more cost-effective without a significant sacrifice of the sensitivity of the analytical test. Silliker and Gabis (1973) and Gabis and Silliker (1974) for instance studied the detection probability using composite samples of different sizes in commodities with high contamination levels. However, ICMSF (2002, pp.188) recommends validation of the methods when compositing due to the dilution effect and the risk of false negatives. Overall, assessing the sensitivity and specificity of the analytical method is of paramount importance if it is desired to test a higher analytical amount (Jarvis, 2007).

Let us consider independence between the primary units and that if at least one cell is present in the composite sample it will be detected. The probability of contamination in the composite sample p_c is then

$$p_c = 1 - (1-p)^{n_I} \tag{5.12}$$

Eq.5.12 is appropriate when pre-enrichment or incubation is applied before subsampling the composite sample. Here, it is assumed that if at least one cell is present it will multiply making the probability of detection very close to one.

Substituting Eq.5.12 in 5.4 we obtain

$$P_a = P(X=0|p,se,sp,n_I,n) = [(1-se)(1-(1-p)^{n_I}) + sp(1-p)^{n_I}]^n \tag{5.13}$$

Imperfect composite samples

Often the contribution of the primary units towards composite Y_1 is random. For instance, an automatic sampler collects a big composite during the production process, aggregating units of 10g each at systematic intervals of 10 minutes. The whole composite is sent to the laboratory, where a 300g subsample is drawn after thoroughly mixing the material. In this case, it is very unlikely that every unit will contribute equally towards the 300g subsample. Hence, the unit contribution can be assumed as random and it can be described with a statistical model e.g. Dirichlet.

5.4 Single (isolated) batch risk assessment

5.4.1 Building a hierarchical model based on p

Bayesian design of sampling inspection plans has been studied by Chiu (1974); Guenther (1971); Hald (1967a, 1968) and others. Brush (1986) and Graves et al. (1996) provided a discussion on Bayesian producer's and consumer's risks.

In recent years, there has been an increased interest in Bayesian analysis in Quantitative Microbial Risk Assessment (QMRA). See for instance Gonzales-Barron et al. (2010b) and Ranta et al. (2015). The Bayesian approach for the risk assessment is described as follows. Let us assume that the batch probability of contamination in Eq.5.1 is a random variable. Specifically, consider that $p \sim \text{Beta}(a,b)$ with density function

$$f(x) = \frac{1}{B(a,b)} x^{a-1} (1-x)^{b-1} \tag{5.14}$$

where B is the beta function, which is

$$B(a,b) = \frac{\Gamma(a)\Gamma(b)}{\Gamma(a+b)} \tag{5.15}$$

and Γ is the gamma function, $\Gamma(a) = (a-1)!$. Generally, the beta shapes are denoted as α and β rather than a and b. We opted for a and b to avoid confusion with the producer's and consumer's risks.

In Bayesian inference, the distribution of p is known as the *prior* distribution. The knowledge that we have about p will define the type of distribution to be used. For example, *noninformative* priors are used when there is vague or insufficient knowledge. The most popular noninformative beta prior is the Bayes-Laplace's Beta($a = 1, b = 1$), which is equivalent to the uniform distribution on the interval $(0,1)$. Other so-called noninformative priors are the Jeffrey's Beta($a = 0.5, b = 0.5$) (Jeffreys, 1946) and the Haldane's Beta($a \to 0, b \to 0$) (Haldane, 1932). For more details see the discussion in Tuyl et al. (2009) and also in Zhu and Lu (2004). The Haldane's Beta($a \to 0, b \to 0$) is chosen to express total ignorance and its density is completely concentrated at 0 and 1.

In the Bayesian inference, today's *posterior* is tomorrow's prior. Usually, some relevant knowledge is available from previous analysis and research. We might consider *a priori* that pathogens are rarely present in foodstuffs and that the probability of contamination is very low. Then we could opt for an *informative* prior, say a beta distribution with small a and large b. For example, $a = 1$, $b = 199$ yields mean and standard deviation equal to 0.005.

Substituting the prior (Eq.5.14) in the sampling distribution (5.1) we obtain the beta-binomial distribution

$$f(d|n,a,b) = \binom{n}{d} \frac{B(d+a, n-d+b)}{B(a,b)} \tag{5.16}$$

The test's sensitivity and specificity are generally unknown and they can also be considered as random variables. In this case, we could describe them with beta distributions as well. Let us denote the shape parameters for the distribution of the sensitivity as a_{se} and b_{se}. Equally, we will denote the shapes for the distribution of the specificity as a_{sp} and b_{sp}. As seen from 5.B both metrics are generally close to one. Therefore, it seems reasonable to use informative beta distributions with mass concentrated around one and therefore with values $a >> b$. If *se* and *sp* are included in the model, the probability distribution of P_a is obtained from the triple integral of Eq.5.13 with respect to p, *se* and *sp*. This function has no closed form. See for instance Rahme et al. (2000). Therefore, we resort to numerical integration to obtain the batch probability of acceptance. We have developed a *shiny* application (app), which is available at: https://edgarsantosfdez.shinyapps.io/PreAbs to obtain the P_a given different priors. In 5.D we present a screenshot. In 5.C.1 we show the model codes we used.

Let us consider the following four scenarios in order to show how the parameters affect the probability of acceptance and the risk for the consumers.

- Scenario 1: Beta prior ($a = 1$, $b = 99$), high the test sensitivity and specificity ($a_{se} = a_{sp} = 99, b_{se} = b_{sp} = 1$).
- Scenario 2: Beta prior ($a = 1$, $b = 99$) , moderate sensitivity and specificity ($a_{se} = a_{sp} = 19, b_{se} = b_{sp} = 1$).
- Scenario 3: Prior distribution of p is Haldane-type ($a = b = 0.005$), high test sensitivity ($a_{se} = 99, b_{se} = 1$) and specificity ($a_{sp} = 99, b_{sp} = 1$).
- Scenario 4: Haldane-type ($a = b = 0.001$) prior distribution for p, moderate sensitivity and specificity ($a_{se} = a_{sp} = 19, b_{se} = b_{sp} = 1$).

In Table 5.1 we show the mean of the proportion nonconforming (p), the apparent proportion nonconforming (p_e) and the batch probability of acceptance (P_a), for different sample sizes and parameters for the prior distributions. This table gives the four scenarios previously described. We notice that the *sp* has a major effect on P_a. It can be noticed that the selection of the prior distribution for p has a critical impact on the risk as well. The *se* seems much less important that the other two factors even with a small sample size.

Table 5.1 Batch probability of acceptance (P_a), proportion nonconforming (p) and apparent proportion nonconforming (p_e).

a	b	a_{se}	b_{se}	a_{sp}	b_{sp}	p	p_e	$Pa_{(n=1)}$	$Pa_{(n=5)}$	$Pa_{(n=30)}$
1	99	19	1	19	1	0.010	0.059	0.941	0.756	0.302
1	99	19	1	99	1	0.010	0.019	0.981	0.908	0.596
1	99	99	1	19	1	0.010	0.059	0.941	0.754	0.298
1	99	99	1	99	1	0.010	0.020	0.980	0.907	0.590
1	199	19	1	19	1	0.005	0.054	0.946	0.773	0.339
1	199	19	1	99	1	0.005	0.015	0.985	0.930	0.671
1	199	99	1	19	1	0.005	0.055	0.945	0.772	0.337
1	199	99	1	99	1	0.005	0.015	0.985	0.929	0.668
0.001	0.001	19	1	19	1	0.500	0.499	0.501	0.396	0.193
0.001	0.001	19	1	99	1	0.500	0.480	0.520	0.475	0.382
0.001	0.001	99	1	19	1	0.500	0.519	0.481	0.395	0.193
0.001	0.001	99	1	99	1	0.500	0.500	0.500	0.475	0.382
0.001	0.01	19	1	19	1	0.091	0.132	0.868	0.718	0.351
0.001	0.01	19	1	99	1	0.091	0.095	0.905	0.864	0.695
0.001	0.01	99	1	19	1	0.091	0.135	0.865	0.718	0.351
0.001	0.01	99	1	99	1	0.091	0.099	0.901	0.863	0.695

We might consider that the testing is done using composite samples. These samples are obtained by aggregating several primary units. Let us assume that the primary unit probability of detection is p. Consider that a positive result will be produced when at least one of the primary units is contaminated according to Eq.5.12. The model to obtain the batch probability of acceptance is given in 5.C.2.

Often in food safety it is convenient to estimate the quality of the accepted batches. The concentration level of the contamination after inspection is relevant to estimate the number of people contracting food poisoning. Also the batch probability of acceptance and the apparent probability of contamination in the accepted batches might be of interest. These metrics are also given in the *shiny* app.

5.4.2 Hierarchical model based on the rate λ

In the above Bayesian inference it was assumed that $p \sim \text{Beta}(a,b)$. However, for some characteristics the batch acceptance is conveniently expressed as a function of the concentration of the contamination rather than for the proportion nonconforming. This is because the concentration is often more relevant for the risk assessment. Eq.5.6 gives the probability of obtaining x microorganisms under the Poisson law given the contamination rate λ. The probability of detecting one or more cells in one sample reduces to $1-\exp(-\lambda)$. We might assume that $\lambda \sim LN(\mu,\sigma)$. A Bayesian model can be built to obtain the batch probability of acceptance given μ, σ, se and sp. See 5.C.4. In Table 5.2 we illustrate several scenarios for the distribution of λ and show the effect on the probability of acceptance.

Table 5.2 Means of the batch probability of acceptance (P_a), proportion nonconforming (p), apparent proportion nonconforming (p_e) and rate (λ) as a function of μ and σ.

μ	σ	a_{se}	b_{se}	a_{sp}	b_{sp}	λ	p	p_e	$Pa_{(n=1)}$	$Pa_{(n=5)}$	$Pa_{(n=30)}$
-2	0.5	99	1	99	1	0.153	0.139	0.147	0.853	0.477	0.033
-3	0.5	99	1	99	1	0.056	0.054	0.063	0.937	0.727	0.189
-4	0.5	99	1	99	1	0.021	0.020	0.030	0.970	0.860	0.434

5.4.3 Hierarchical model for semi-continuous data based on the zero inflated lognormal (ZILN) distribution

The JAGS (Plummer, 2016; Plummer et al., 2003) model considering Eq.5.11 is shown in 5.C.5. We computed the risk under different scenarios using the zero inflated model and considering several sample sizes. See Table 5.3.

Table 5.3 Means of the batch probability of acceptance (P_a), proportion nonconforming (p), apparent proportion nonconforming (p_e) and rate (λ) as a function of θ, μ and σ.

θ	μ	σ	a_{se}	b_{se}	a_{sp}	b_{sp}	λ	p	p_e	$Pa_{(n=1)}$	$Pa_{(n=5)}$	$Pa_{(n=30)}$
0.5	-2	0.5	99	1	99	1	0.077	0.070	0.078	0.922	0.715	0.400
0.5	-3	0.5	99	1	99	1	0.028	0.027	0.037	0.963	0.840	0.478
0.5	-4	0.5	99	1	99	1	0.010	0.010	0.020	0.980	0.906	0.600

5.5 Bayesian data analysis

In this section, we illustrate the risk assessment methods using a presence-absence dataset from *Cronobacter* spp. (formerly *Enterobacter* sakazakii) in skimmed milk powder. This pathogenic bacterium has been associated with cases of meningitis, especially in infants. Contamination with *Cronobacter* spp. is rare, but represents a serious risk due to the high mortality rate. Hence, a batch will be rejected if any cell is found in the analytical sample.

We will use a dataset detect/non-detect binary data from 270 batches. For each batch, a detection test was done using a single test sample, and two samples tested positive. These two batches with positives results were not released to consumers.

The test samples were prepared according to ISO 22964 (2006) standard. The microbiological criterion for this product in New Zealand is regulated by the Ministry for Primary Industries (formerly Ministry of Agriculture and Forestry). See the criteria in Ministry of Agriculture and Forestry (2011). It establishes the test to be done using a 300g composite sample resulting from mixing several increments or primary sample units. Hence, the composite sample is representative of the quality in the batch. It is relevant to mention that this composite is basically the result of aggregation of several primary units until 300g are accumulated and no subsample

is done or indicated. We should also point out that the Codex (CAC, 2008), instead, establishes for powdered infant formula the following criteria: $n = 30$, $c = 0$, $w = 10g$.

We assume that every cell will be recovered and will form a visible colony-forming unit after incubation. Let us also assume that the competitive micro flora will not affect the growth of *Cronobacter* spp.

We used the following Bayesian hierarchical model to describe the contamination. Since the sample size $n = 1$, the sampling distribution is Bernoulli, $\text{Bern}(p_e, 1 - p_e)$. The artificial proportion nonconforming and the proportion nonconforming are related by the following expression $p_e = se \times p + (1 - sp) \times (1 - p)$. Let us consider the test sensitivity and specificity as random variables. The priors for the test sensitivity and specificity are $se \sim \text{Beta}(a_{se} = 199, b_{se} = 1)$ and $sp \sim \text{Beta}(a_{sp} = 199, b_{sp} = 1)$.

The proportion nonconforming $p = 1 - \exp(-m\lambda)$, where λ is the rate of the contamination in 10g and $m = 30$. Therefore p is the probability of contamination in 300g. We considered λ as zero inflated according to Eq.5.11 with $\theta \sim \text{Beta}(a = 2, b = 20)$. The positive realization of λ is lognormally distributed with μ and σ_w, where σ_w is the within-batch standard deviation. The mean μ changes from batch to batch being normally distributed with μ_0 and σ_b. We considered two scenarios for the within and between-batch standard deviation and for the mean of the lognormal distribution of contaminated batches:

- Scenario 1: $\mu_0 = -4$, $\sigma_w = 0.8$ and $\sigma_b = 0.8$.
- Scenario 2: $\mu_0 = -2$, $\sigma_w = 1$ and $\sigma_b = 1$.

The values for σ in the first scenario have been considered among others by FAO/WHO (2006).

The codes of the model for the MCMC simulations (Scenario 1) are shown in 5.C.6. We obtained the posterior distributions using the package **rjags**. For plotting densities we adapted the function **diagMCMC** from Kruschke (2015). We simulated three chains each with 30,000 iterations and discarded a burn-in of 5,000 samples.

Results of the MCMC simulations for Scenario 1

Based on our prior beliefs about contaminated batches in Scenario 1, the probability that a batch that tested negative was truly free of the pathogen is estimated as 0.987. Conversely, the probability that a batch that tested positive was really contaminated is estimated as 0.715. The mean of the posterior density for the rate in the batches that tested positive is $\lambda = 0.0626$. Finally, the mean of the marginal posterior sensitivity and specificity are 98.9% and 99.6% respectively.

In Fig. 5.5-5.6 we show the posterior densities for the proportion nonconforming in the batches that tested negative (p_0) and positive (p_1), and also the posterior densities for *se* and *sp*. We also did MCMC convergence diagnostics. The posterior densities show the highest density intervals (HDI) in line with our prior beliefs and the values reported in the literature.

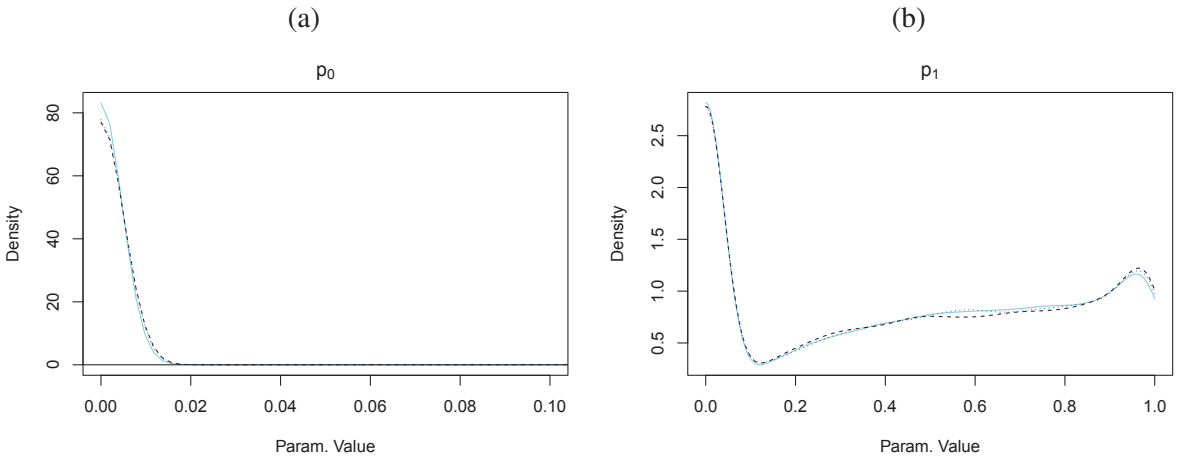


Fig. 5.5 Marginal posterior densities of the proportion nonconforming for the batches where the pathogen was not detected (p_0) and detected (p_1).

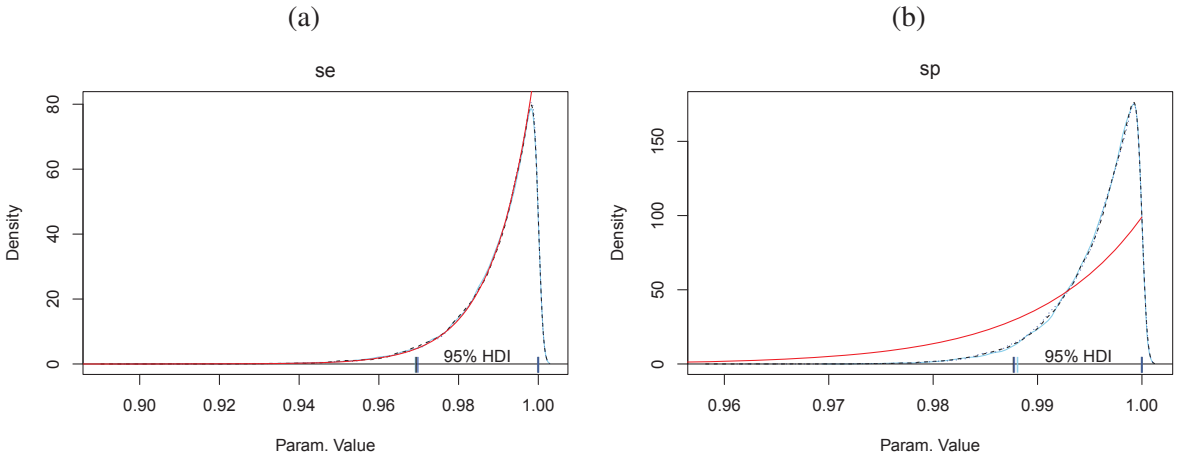


Fig. 5.6 (a) Marginal posterior density of every chain of the sensitivity (*se*). The red solid line represents the density of the prior beta distribution, Beta($a = 99$,$b = 1$). (b) Marginal posterior density of every chain of the specificity (*sp*). The red solid line represents the density of the prior beta distribution, Beta($a = 99$,$b = 1$).

Results of the MCMC simulations for Scenario 2

In the second scenario, we obtained that on average 99.78% of the batches that tested negative were free of contamination. Our posterior belief is that 72.8% of the batches that tested positive were truly contaminated. We obtained similar marginal posterior probabilities for the sensitivity and specificity.

5.5.1 One sample of 300g vs. 30 samples of 10g each

We mentioned before that the microbiological criterion established in New Zealand for *Cronobacter* spp. is $n = 1$, $c = 0$ and $w = 300$g. It was also noted that the Codex recommends $n = 30$, $c = 0$ and $w = 10$g. Under the assumption of homogeneity and perfect sensitivity and specificity, both alternatives will provide the same protection for the consumers. However, when the micro-

biological test is imperfect the sampling plans might have different performance. Suppose that the batch is split into 10g units and the probability of contamination is a function of this unit. The 300g sample for the first plan is formed by aggregating 30 random samples of 10g. Fig. 5.7 show the OC curves of both plans under the assumption of heterogeneity. We assumed that the small unit of 10g is Poisson-lognormally distributed with $\sigma = 0.8$. We use the means of the *se* and *sp* obtained from the MCMC simulations.

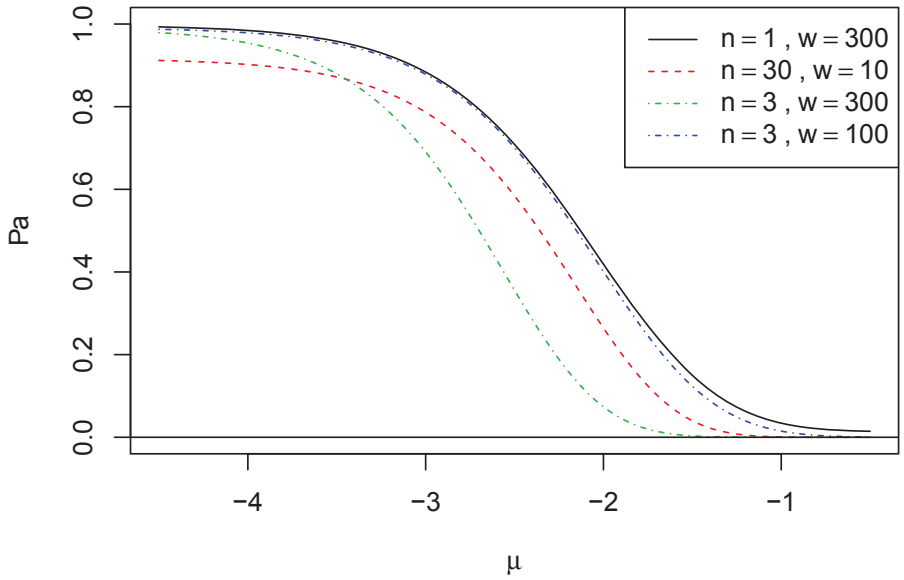


Fig. 5.7 Operating Characteristic (OC) curves of the plans $n = 1$, $c = 0$, $w = 300$g and $n = 30$, $c = 0$, $w = 10$g. The OC curve of the proposed plans $n = 3$, $c = 0$ with $w = 100$g and $w = 300$g are also shown. The contamination is assumed heterogeneous and it is described using the Poisson-lognormal distribution.

The Codex's plan (dotted line) will have a substantial proportion of rejection when the bacterium is absent in the batch ($p = 0$) due to the large n and the imperfect *sp*. The batch probability of acceptance $P_a(p = 0) = 0.825$ and hence, the performance in the left hand of the OC is not very satisfactory. The plan $n = 1$, $c = 0$, $w = 300$ represented by the solid line, would have a poor performance for other lower sensitivity values when the concentration of the contamination is high, due to the false negatives and the minimum sample size $n = 1$.

A compromise between both inspection plans could be a good alternative in order to provide better protection for consumers and producers. The dot dashed line in Fig. 5.7 represents the plan $n = 3$, $c = 0$, $w = 300$g. This plan requires a larger amount ($3 \times 300 = 900$g). The proposed plan will protect the producer during the food safety situation ($p = 0$) and at the same time will substantially reduce the consumer's risk for other values of $p > 0$. We also show the plan $n = 3$, $c = 0$, $w = 100$g. Notice that this plan is not substantially different from $n = 1$, $c = 0$, $w = 300$g.

This example shows that: (1) increasing the sample size n does not necessarily translate into a better sampling plan performance and protection to the consumers; (2) the plan $n = 1$

even under the assumption of perfect composite sampling might not be effective when the test is subject to false negatives.

Suppose that we use an automatic sampler, which collects a large composite, by combining hundreds or even thousands of individual units. After thoroughly mixing the composite sample we take a 300g-subsample for testing. In theory, this alternative might provide higher probability of detection than taking 300g directly from the batch. The efficiency of compositing increases proportionally to the quality of the mixing. This alternative also allows for retesting in case a false positive is suspected.

5.6 Cost analysis

Most of food safety sampling optimization studies fail to consider the effect of the cost constraints (Powell, 2014; Whiting et al., 2006). Generally, the sampling plan stringency is chosen based on the severity of the hazard for the consumers rather than optimization of the overall cost function. Powell (2014), for example, studied the impact of economic constraints in microbiological sampling plan. In this approach, however, the misclassification errors are considered negligible.

Research in quality control dealing with costs and misclassification errors is diverse. For instance, Hald (1964, 1968) considered the economical aspect of numerous sampling plans using prior distributions for p. Ferrell and Chhoker (2002) discussed several alternatives (from 100% inspection to sampling with/without errors) for continuous quality characteristic. Avinadav and Perlman (2013) proposed a cost effective plan for stream of batches based on total cost function.

In this section the discussion centers on the producers' economic burden due to measurement errors and sampling. The economic loss due to sampling is the result of the sampling cost plus the loss derived from wrong decisions (Wetherill and Chiu, 1975). The sampling cost is the analytical test cost (C) times the sample size (n). The sample testing cost is generally high and is specific to the type of microorganisms, the analytical method, the laboratory, etc. See, for instance, 7 CFR (2000, 91.37) for detailed list of laboratory fees from the U.S. Code of Federal Regulations; and New Zealand Parliamentary Counsel Office (2008) for food safety fees and charges by New Zealand Food Safety Authority.

The loss from making a wrong decision depends on the following probabilities and costs:

- Pr_1 [one or more false positives | all samples are free of microorganisms]
- Pr_2 [the test(s) produces false negative and no false positives | one or more samples are contaminated]
- C_c: the costs associated with a poor quality batch sentenced as acceptable. This includes the cost of recalling a product from the market, costs associated with food-borne diseases and compensations, damage to the company's image, etc. This cost is generally very high.
- C_p: the costs per lot incurred by the producer reprocessing, downgrading, destroying, etc. a non-contaminated batch due to false positives.

The total sampling cost function is

$$T = n \times C + Pr_1 \times C_p + Pr_2 \times C_c \tag{5.17}$$

where

$$Pr_1 = \{1 - [(1-p)(1-sp)]^n\}(1-p)^n \tag{5.18}$$

$$Pr_2 = \sum_{d=1}^{n} \binom{n}{d} (1-se)^d p^d (1-p)^{n-d} sp^{n-d} \tag{5.19}$$

and d is the observed number of nonconforming samples out of n.

Let us illustrate the impact of imperfect classifiers and sample sizes on the costs using the following hypothetical example. Consider that the testing cost $C = \$20$/test, that $C_p = 20,000\$$/batch and $C_c = 1,000,000\$$/batch. We consider the se and sp values obtained from the MCMC simulations. In Fig. 5.8 we show the total cost as a function of p for different sampling plans. When $p \to 1$ the cost function converges to the testing cost. The larger n, the faster the convergence. Under the food safety situation where p is very small, opting for high sample sizes will have a higher overall cost for the producer.

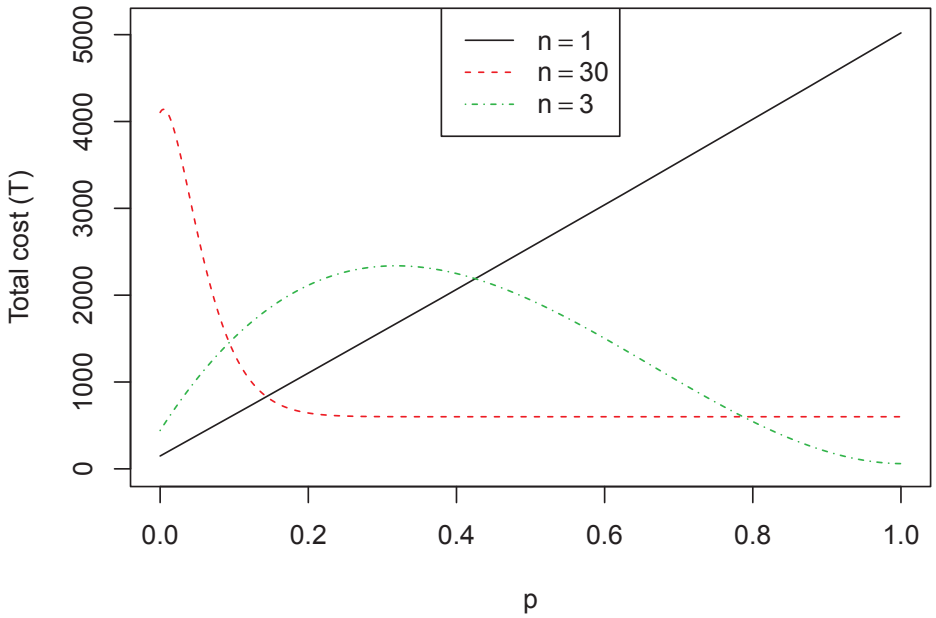


Fig. 5.8 Sampling cost function of the plans $n = 1$, $n = 3$ and $n = 30$ assuming $se = 0.995$ and $sp = 0.996$.

Fig. 5.9 illustrates the sampling cost as a function of the $\log_{10}$ concentration of the contamination, $\log_{10}(\lambda)$. The proportion nonconforming p is related to concentration λ via the Poisson distribution. We compare the sampling plans $n = 1$, $c = 0$, $w = 300$, $n = 30$, $c = 0$, $w = 10$ and $n = 3$, $c = 0$, $w = 300$. Notice that the worst case scenario when using the plan $n = 3$, $c = 0$,

$w = 300$ is when $\log_{10}(\lambda) = -1.9$ which yields \$2338. The maximum cost for the other two plans is much higher.

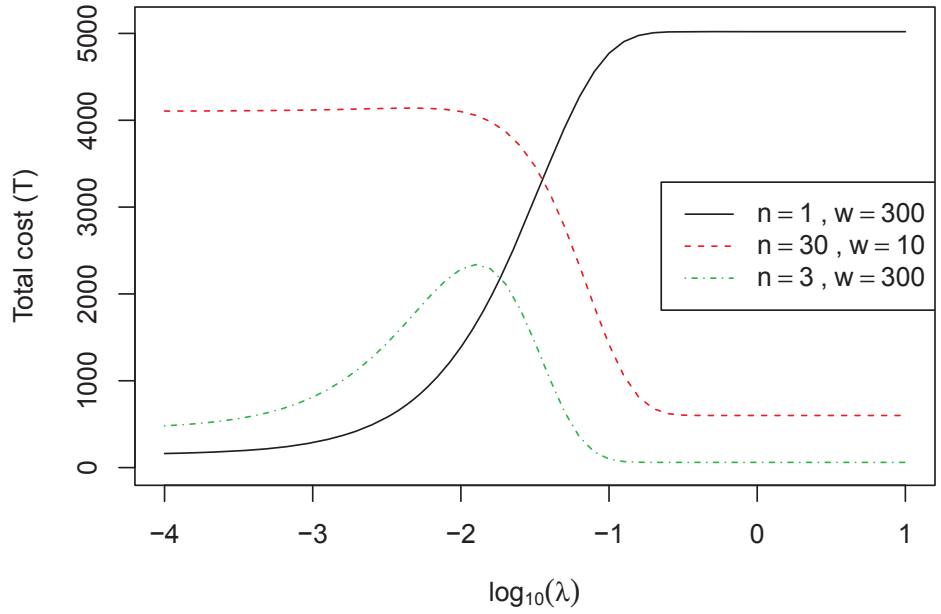


Fig. 5.9 Sampling cost function vs the $\log_{10}$ concentration of the contamination in 10mL assuming $se = 0.995$ and $sp = 0.996$. The black solid line represents the plan $n = 1$, $c = 0$, $w = 300$ and the dashed line gives the $n = 30$, $c = 0$, $w = 10$. The proposed plan $n = 3$, $c = 0$, $w = 300$ is also shown.

5.7 Discussion and conclusions

Test performance measures are often reported in the literature. However, in reviewing the food safety literature, we found that sampling plans are sometimes designed without taking into consideration the test efficiency. At most only the test sensitivity is considered. Economically designed microbiological sampling plan are rare in practice. This is in part due to the difficulty in estimating the producer's cost of releasing a contaminated batch.

The results of this study indicate that the specificity of the test is relevant in the risk assessment even when it is close to one and it should be considered when developing microbiological criteria. The relevance of this factor is exponentially proportional to the sample size. This might have a substantial impact on plans e.g. $n = 60$, $c = 0$ for *Salmonella* in powdered infant formula (CAC, 2008). Higher protection for the consumers is generally associated with larger sample sizes. Often the microbiological tests are capable of analyzing higher analytical amounts. Both factors n and w should be balanced when a higher stringency is desired. This obviously needs validation that for example the sp remains stable independently of w.

Moreover, in the validation of procedures for pathogenic microorganisms, methods with high specificity are generally preferable when $n > 1$. Despite the difficulties to estimate some of the

relevant costs, optimization based on costs as discussed here might help food producers and safety authorities to select nearly optimum inspection plans.

When the inspection is done by producers and historical data is available, an informative prior for p is recommended. Conversely, a noninformative prior should be selected when the inspection is done from the consumer's perspective and the batches come from different sources. One should keep in mind that some 'noninformative priors' can be very informative in zero inflated problems.

A common assumption in the imperfect classifiers theory is that se and sp are independent of the prevalence in the population under study. However, this hypothesis has been refuted in several studies, which have shown variations in se and sp. See for instance Brenner et al. (1997); Leeflang et al. (2013). This is presumably more complex in food safety due to the nature of the material under study and the analytical methods. To the best of our knowledge this issue has not been properly addressed before in microbiological risk assessment.

The resampling dilemma

The dilemma of having false positive and negative samples might lead us to seek for potential solutions. One of the first things come to mind is to resample those batches where the pathogen was detected. See the discussion about resampling in ICMSF (2002); Lund (1986). It can be argued that by sampling and testing again the negative impact of imperfect specificity can be reduced. A common preference is to opt for larger sample size. Let us consider that we decide to resample a batch using $n = 10$ samples, under the same conditions (same analytical amount, sampling, test, laboratory, etc). If the batch is truly contaminated with low probability of contamination say $p = 0.01$ and let $se = 0.997$ and $sp = 0.987$, the probability of detecting contamination in the batch with 10 samples is only 0.12. If we resample this batch after a positive result is obtained, the conditional probability of detection is just 0.014. This clearly shows that resampling (under the conditions previously described) could yield the release of a contaminated batch. The argument that reinspecting will certainly discern between good and poor quality might be fallacious. Clearly other strategies such as more accurate analytical test can be explored as well.

Further research might investigate the correlation between the contamination with *Cronobacter* spp. and the level of *Enterobacteriaceae* in the batch. This last one is a hygienic characteristic commonly monitored in diary products, which is presumably related to *Cronobacter* spp.

Appendix 5.A Glossary of symbols and definitions

se	sensitivity: probability of obtaining a positive result given that the sample is contaminated
sp	specificity: probability of obtaining a negative result given that the sample is noncontaminated
p	probability of contamination
p_e	apparent probability of contamination
P_a	probability of acceptance
n	sample size
c	acceptance number
d	observed number of nonconforming samples
n_I	number of increments when using composite samples
w	analytical unit amount (g or mL)
β	consumer's risk
a	first shape parameter of the beta distribution for p
b	second shape parameter of the beta distribution for p
a_{se}	first shape parameter of the beta distribution for se
b_{se}	second shape parameter of the beta distribution for se
a_{sp}	first shape parameter of the beta distribution for sp
b_{sp}	second shape parameter of the beta distribution for sp
C	analytical testing cost
C_c	costs associated with a poor quality batch due to false negatives
C_p	costs incurred by the producer due to false positives
λ	concentration of the contamination

Appendix 5.B Reported values of sensitivity and specificity.

Microorganism	Classif.	Detection method	Food category	Source	*se*(%)	*sp*(%)
Cronobacter spp.	Culture	ISO 22964 (2006)	PIF*	Iversen et al. (2008)	100	94.2
Cronobacter spp.	Culture	CSB	PIF	Iversen et al. (2008)	100	93.9
Cronobacter spp.	Culture	ISO 22964 (2006)	PIF	Zhu et al. (2012)	76**	81**
Cronobacter spp.	PCR	Impedance	PIF	Zhu et al. (2012)	85	100
Cronobacter spp.	PCR	Esak2/Esak3	PIF	Cawthorn et al. (2008)	87	94
Cronobacter spp.	PCR	Esakf/Esakr	PIF	Cawthorn et al. (2008)	100	90
Cronobacter spp.	Culture	CES	PIF	Cawthorn et al. (2008)	100	98
Cronobacter spp.	Culture	DFI	PIF	Cawthorn et al. (2008)	100	98
Salmonella spp.	PCR	TaqMan	Meat/Raw Milk	Malorny et al. (2004)***	100	100
Salmonella spp.	EIA	Assurance EI ®	Poultry	Eijkelkamp et al. (2009)	98	96
Salmonella spp.	ELISA	ELISA VIDAS®	Poultry	Eijkelkamp et al. (2009)	93	96
Listeria	Culture	ISO 11290 (1997)	Cheese/Meat/Egg	Scotter et al. (2001)	85.6	97.4
Listeria	Culture	selective plating	Cheese	Niederhauser et al. (1993)	67	100
Listeria	PCR (B)	-	Cheese	Niederhauser et al. (1993)	75	100
Listeria	PCR	BAX®	Env. samples	Hoffman and Wiedmann (2001)	94.7	97.4
Listeria	PCR	BAX®	Raw fish	Hoffman and Wiedmann (2001)	84.8	100

Note:*Powdered Infant Formula(PIF), **Zhu et al. (2012) linked the low *se* values to the presence of competitive micro flora that did not allow the growth of *Cronobacter* spp. during the pre-enrichment stage. ***Malorny et al. (2004) used small sample sizes (between 20 to 46).

Appendix 5.C Models in JAGS for the numerical integration

5.C.1 R codes to obtain the P_a using numerical integration

```
model {
  pe <-p * se + (1 - p) * (1 - sp)
  p ~ dbeta(a,b)
  se ~ dbeta(a.se, b.se)
  sp ~ dbeta(a.sp, b.sp)
  Pa = (1 - pe) ^ n
 }
```

5.C.2 R codes to obtain the P_a using numerical integration using n_i composite samples

```
model {
  pe <-pc * se + (1 - pc) * (1 - sp)
  pc <-1 - (1 - p) ^ ni
   p ~ dbeta(a,b)
  se ~ dbeta(a.se, b.se)
  sp ~ dbeta(a.sp, b.sp)
  Pa = (1 - pe) ^ n
 }
```

5.C.3 R codes to obtain the P_a, p and p_e in the accepted batches using MCMC

```
model {
  x ~ dbin(p,n)
  p ~ dbeta(a,b)
  se ~ dbeta(a.se, b.se)
  sp ~ dbeta(a.sp, b.sp)
  pe <-p * se + (1 - p) * (1 - sp)
  Pa = (1 - pe) ^ n
 }
```

5.C.4 R codes to obtain the P_a using numerical integration based on μ and σ

```
model {
  pe <-p * se + (1 - p) * (1 - sp)
  p = 1 - exp(-lambda)
  lambda ~ dlnorm(mu , 1 / (sigma ^ 2) )
  se ~ dbeta(a.se, b.se)
```

```
  sp ~ dbeta(a.sp, b.sp)
  Pa <-1 - pe
}
```

5.C.5 R codes to obtain the P_a using numerical integration based on the zero inflated Poisson-lognormal distribution with μ and σ

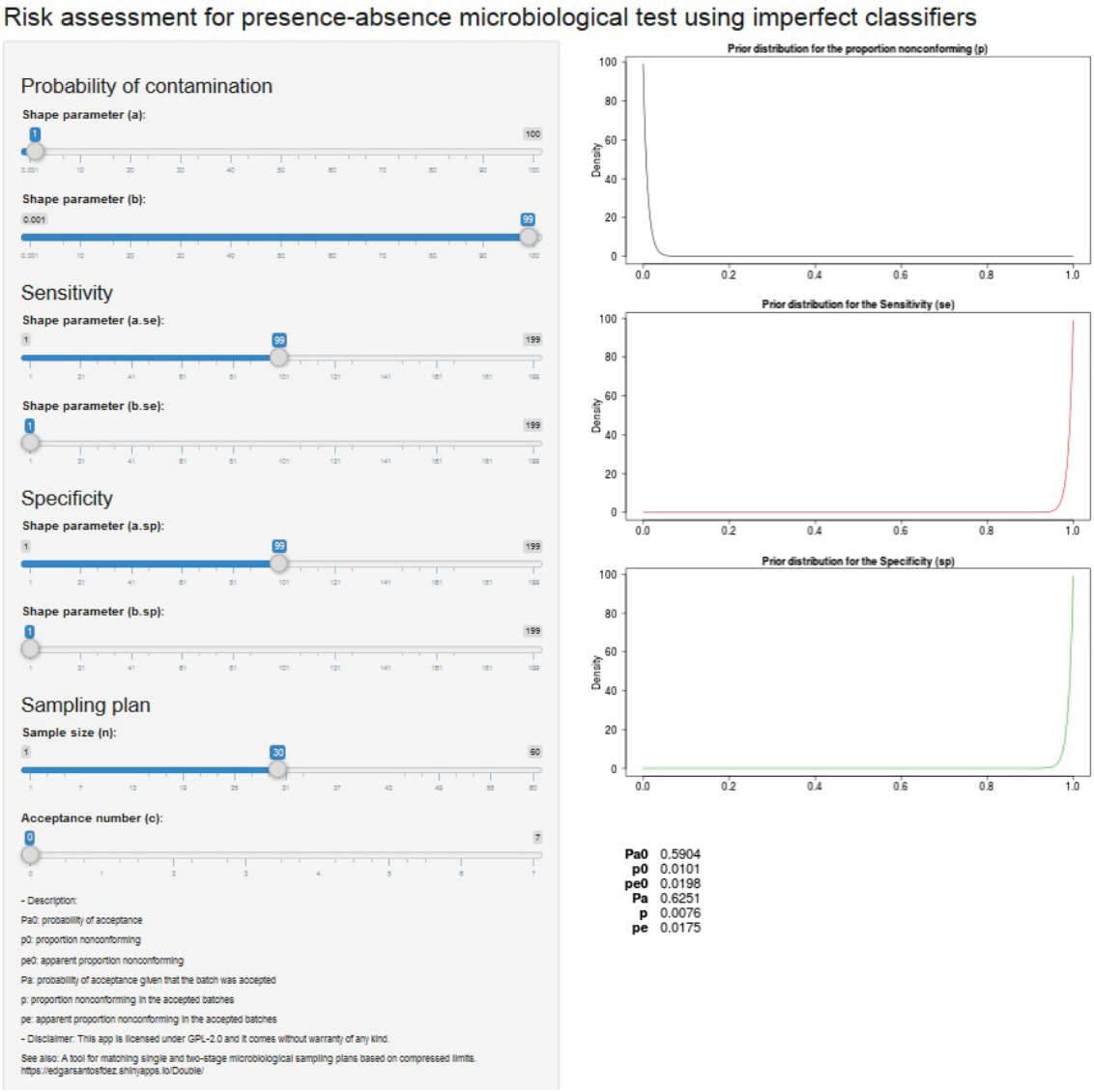
```
model {
  pa <-p * se + (1 - p) * (1 - sp)
 p = 1 - exp(-lambda)
 lambda = h * x
 x ~  dlnorm(mu, 1 / (sigma ^ 2) )
 h ~ dbern(PI)
 se ~ dbeta(a.se, b.se)
 sp ~ dbeta(a.sp, b.sp)
 Pa = (1 - pa) ^ n
}
```

5.C.6 R codes used for the MCMC simulation (Scenario 1)

```
model {
for ( i in 1:Ntotal ) {
  y[i] ~ dbern(pe[i])
  pe[i] <-p[i] * se + (1 - p[i]) * (1 - sp) # apparent prevalence
  p[i] = 1 - exp(-30 * lambda[i])           # prev using 30 comp samples
  lambda[i] = h[i] * x[i]                   # the zero inflated lambda
  h[i] ~ dbern(theta)                       # prop of non zeroes in the rate
  x[i] ~ dlnorm(mu[i], 1 / (0.8 ^ 2))       # rate is lognormally distributed
  mu[i] ~ dnorm(-4, 1 / (0.8 ^ 2))}         # mu changes from batch to batch
se ~ dbeta(99, 1)
sp ~ dbeta(99, 1)
lambda0 <-lambda[1]
lambda1 <-lambda[234]
theta ~ dbeta(2,20)}
```

Appendix 5.D Shiny app to estimate the risk for presence-absence tests

This interactive shiny tool allows the computation of the batch probability of acceptance given various beta prior distributions for the proportion nonconforming and the test sensitivity and specificity. It uses MCMC simulations and considers that no positives results has been found in a sample of size n. This interactive tool is available at:
https://edgarsantosfdez.shinyapps.io/PreAbs.


Risk assessment for presence-absence microbiological test using imperfect classifiers
Probability of contamination
Shape parameter (a):
Shape parameter (b):
Sensitivity
Shape parameter (a.se):
Shape parameter (b.se):
Specificity
Shape parameter (a.sp):
Shape parameter (b.sp):
Sampling plan
Sample size (n):
Acceptance number (c):
- Description:
Pa0: probability of acceptance
p0: proportion nonconforming
pe0: apparent proportion nonconforming
Pa: probability of acceptance given that the batch was accepted
p: proportion nonconforming in the accepted batches
pe: apparent proportion nonconforming in the accepted batches
- Disclaimer: This app is licensed under GPL-2.0 and it comes without warranty of any kind.
See also: A tool for matching single and two-stage microbiological sampling plans based on compressed limits.
https://edgarsantos.shinyapps.io/Double/
Prior distribution for the proportion nonconforming (p)
Prior distribution for the Sensitivity (se)
Prior distribution for the Specificity (sp)
Density
Pa0 0.5904
p0 0.0101
pe0 0.0198
Pa 0.6251
p 0.0076
pe 0.0175

Chapter 6

A New Variables Acceptance Sampling Plan for Food Safety

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http://www.sciencedirect.com/science/article/pii/S0956713514001765

6.1 Abstract

The variables sampling plans for microbial safety are based on the log transformation of the observed counts. We propose a new variables plan for lognormal data using the angular transformation. In a comparison with the classic approach, this new method shows more stringency and allows the use of a smaller sample size to obtain the same level of consumer protection. This transformation is robust when the underlying distribution departs from the lognormal distribution as well as in the presence of contamination. A description of the new plan and the software codes are provided.

Keywords

food safety; acceptance sampling; lognormal distribution; robust plan; *sinh-arcsinh* transformation

6.2 Introduction

Sampling inspection plans are used to assess the "fitness for use" of batches of products providing protection to the consumers. Sampling inspection cannot be avoided due to the high cost

[1] Cited in Jarvis, B. (2016). *Statistical Aspects of the Microbiological Examination of Foods*. Academic Press. Elsevier/Academic Press

associated with laboratory testing and the destructive nature of the microbiological tests makes 100% inspection impossible. A single sample of size n is usually inspected or tested for the specified microbiological criteria for conformance. The conformance criteria are often regulated for potentially dangerous pathogens e.g. Regulation (EC) No 2073/2005, (European Commission, 2005). In addition to variables plans, attribute plans are also used for food safety inspection. In a two-class attribute plans , items are classified as conforming or not while the variables plans deal with parameters such as the mean concentration. The International Commission on Microbiological Specification for Foods in ICMSF (2002) as well as the Codex Alimentarius Commission (CAC) in CAC (2004) recommend both attribute and variables plans for food quality assessment. The performance of simple attributes plans in the food safety context is widely studied, see for instance, Hildebrandt et al. (1995), Legan et al. (2001), Dahms (2004), Wilrich and Weiss (2009). However, the variables plans are preferred because the whole information from the sample is taken into account in the decision making process so that the same level of protection can be obtained with small sample sizes. Nonetheless, the application of variables plans requires the knowledge of the underlying probability distribution of the characteristic of interest. When the distribution of microorganism departs from the assumed model, the proportion of the population that does not satisfy the microbiological limit (or the fraction nonconforming) will be erroneously estimated.

The lognormal model arises as a result of a multiplicative process, particularly in the proliferation of microbes in the form of clusters or agglomeration. The lognormal distribution is also the *maximum entropy* distribution when the mean and standard deviation are fixed. The maximum entropy property captures the most variation on the positive real line and hence the lognormal model becomes the conservative model for common cause or baseline situation. Safety plans for variables as recommended by ICMSF (2002) and CAC (2004) rely on the lognormality. This distribution has been found suitable empirically to describe frequencies of pathogens in food (Jongenburger et al., 2012b; Kilsby and Baird-Parker, 1983). The probability density function of the lognormal distribution is given in Table 6.5 of the Appendix. Since microbial enumeration is commonly expressed on a logarithmic scale (base 10), the traditional theory of acceptance sampling for variables based on the normal distribution can be applied.

The common cause or baseline variation pertains to the scenario in which only the usual sources of variation are acting in the food production chain, e.g. the level of microorganism is in the acceptable range. By contrast, special causes of variation are the result of a poor food handling and its identification is vital to avoid foodborne diseases. Often only few units of each lot are tested because of the budget constraints on laboratory analysis. A small sample size may fail to detect high levels of fraction nonconforming compromising protection to the consumer. The paper presents a new decision criterion with a better performance than the classic approach as well as robust to distributional uncertainties. The proposed variables plan provides the same level of protection to the producer with fewer units of the batch to be tested, but with a stringent level of protection to the consumer.

6.3 Material and methods

6.3.1 The Operating Characteristic (OC) curve

The performance of a sampling plan is revealed by its Operating Characteristic (OC) curve, which is a plot of the probability of acceptance against the process level or the fraction nonconforming (p). This curve shows how well a sampling inspection plan discriminates between good and bad quality. If two OC curves are matched to give the same level protection to the producer, we would then prefer the OC curve which is steeper or more stringent. The ideal OC curve has probability of acceptance equal to one until the critical fraction nonconforming after which it drops to zero. See e.g. Montgomery (2005). OC curves are often assessed at given two points (AQL, α) and (LQL, β) where AQL and LQL are the acceptance and limiting quality limits (levels), and α and β the producer's and consumer's risk respectively. The AQL is the maximum fraction nonconforming that is considered acceptable as a process level for the consumer, while the LQL is the proportion nonconforming that is expected to be accepted with a low probability for an isolated batch. CAC (2004) recommends for characteristics associated with sanitary risks to employ low acceptable levels such as 0.1%. On the other hand, the limiting levels are often fixed lower than the traditional 10% for food safety.

6.3.2 Variables plans for food safety

Suppose that a characteristic of interest (X) such as the cell count follows a lognormal distribution. The log-concentration (Y) is then normally distributed with mean μ and standard deviation σ. At a given microbiological limit (m), the decision criterion results in: $\bar{Y} + kS_y < m_y$ where k is the acceptability constant for the operation of the variables plan where $\bar{Y} = \sum Y_i/n$ is the sample mean, $S_y = \sqrt{\sum (Y_i - \bar{Y})^2/(n-1)}$ is the sample standard deviation and $m_y = \log(m)$ is the transformed Upper Specification/Safety Limit. This plan will be referred as classical approach from now on. The following test statistic is obtained by rearranging the last equation.

$$Z_1 = \frac{m_y - \bar{Y}}{S_y} \tag{6.1}$$

The regulatory (specification) limit m is often fixed using base-line or "common-cause" samples which are free from known food safety issues. The test statistic Z_1 expresses the distance between the specification limit and the sample mean $\bar{Y}$ in sample standard deviation units. When this distance is below a critical value k, the resulting proportion nonconforming (p) is greater than expected. In other words, the lot is accepted whenever $Z_1 \geqslant k$, otherwise the lot is rejected. When the true standard deviation of the process is unknown, the acceptance criterion is then obtained using the noncentral t-distribution using the consumer's point (LQL, β), ICMSF (2002). Another alternative is when producers use Good Manufacturing Practice (GMP) limits which are set well below the regulatory limit. In this case, the critical distance can be obtained from Kilsby et al. (1979).

6.3.3 New plans based on the *sinh-arcsinh* transformation

Suppose that instead of applying logarithm to the cell count the *sinh-arcsinh* transformation (Jones and Pewsey, 2009) is used. Hyperbolic functional transformations are commonly applied to improve the degree of normality of a quality characteristic.

$$H = \sinh\left[\delta \sinh^{-1}(x) - \varepsilon\right] \tag{6.2}$$

where $\sinh = (e^x - e^{-x})/2$ and $\sinh^{-1} = \log\left(x + \sqrt{x^2+1}\right)$ are the hyperbolic sine and its inverse. The hyperbolic functions are the counterpart in the hyperbola of the classic trigonometric functions. This transformation allows to control the skewness and kurtosis with the parameters δ and ε. The skewness and kurtosis are measures of the asymmetry and the peakedness of the distribution respectively. We used a particular combination of parameters, $\delta = 0.1$ and $\varepsilon = 0$. Let $V = H(x)$ and $m_v = H(m)$, then an analogous test statistic to Eq. 6.1 for the new approach can be defined.

$$Z_2 = \frac{m_v - \bar{V}}{S_v} \tag{6.3}$$

This plan will be referred as the new method from now on.

6.3.4 Simulation algorithm

The critical values for Z_1 and Z_2 as well as the probability of acceptance values are obtained by Monte Carlo simulation since the analytical solution is intractable for the new approach. The computation and simulations were carried out using R open source software (R Core Team, 2013) using the following algorithm:

- Step 0. Set the point (AQL,α) on the OC curve to protect the producer. This point represents the aim of the producer that batches with fraction nonconforming AQL should be accepted with probability $1-\alpha$. Let the microbiological common cause situation be described by the lognormal distribution with log-scale parameter, $\mu = 0$ and shape, $\sigma = 1$ taking advantage of the invariance property of the standard normal distribution.
- Step 1. Generate a random sample of data from the lognormal distribution for a given sample size.
- Step 2. Compute the Z statistic and replicate this random sample generation process (such as 100,000 simulations) to obtain the vector $\mathbf{A}$.
- Step 3. Obtain the critical distance by dividing the frequency distribution of $\mathbf{A}$ in a proportion of size α, i.e. as the α-quantile; $k_i = q_\alpha(\mathbf{A})$.
- Step 4. The presence of special causes, leading to food safety concerns, is modelled by a shift in μ, say from μ_0 to $\mu_0 + \triangle$, where $0 < \triangle \leq 2$.

- Step 5. P_a values can be computed numerically as the proportion of samples for which the test statistic is over the critical values given above. The bigger the shift in μ, the lower $P_a = \mathrm{P}\{A_i(\mu_0 + \triangle) \geq k_i\}$ would be.

The code for the steps 0–3 is presented in the Appendix section. Notice the difference with the ICMSF (2002) variables plans in which the acceptance criterion is obtained from the consumer's perspective and the producer's risks are not controlled.

6.4 Results

Critical values for an $AQL = 0.1\%$, different sample sizes and producer's risk probabilities (α) are shown in Table 6.1. The k-values for the Z_1 statistic given in Table 6.1 are the same as can be found in the variables sampling plan literature. See the Appendix section for critical distances for other set of AQL values.

Table 6.1 Calculated estimates of the critical distance factor (k) for two values of producer's risk, an $AQL = 0.001$ and $\sigma = 1$.

	$\alpha = 0.01$		$\alpha = 0.05$	
n	k_1	k_2	k_1	k_2
2	0.97	1.03	1.41	1.63
3	1.22	1.34	1.63	1.90
4	1.39	1.54	1.77	2.08
5	1.51	1.71	1.87	2.22
10	1.85	2.16	2.15	2.61
15	2.02	2.41	2.29	2.82
20	2.14	2.57	2.38	2.95
30	2.28	2.79	2.49	3.13
40	2.37	2.93	2.56	3.23
50	2.43	3.02	2.61	3.31
60	2.48	3.10	2.64	3.37

An evaluation of the performance of the new method in comparison to the traditional approach is shown in Figure 6.1. A reasonable sample size of size $(n = 10)$ and two producer's risk levels ($\alpha = 0.01, 0.05$) were considered. Following the approach of Wilrich and Weiss (2009), this figure shows two X-axes: one for the proportion nonconforming (p) and the other for the associated process level in log10 (CFU$/g$). It can be seen from these figures that the new approach reduces at a consumer's risk of 10% the rejectable fraction nonconforming in about 3% while maintaining the producer's risk at 1%. Alternatively the new approach will reduce the number of test to be done. For instance, the same or more protection is obtained with nine and eight units at $\alpha = 0.01$ and 0.05 respectively in comparison with that of obtained with 10 units using by the classic approach. Figures 6.5 and 6.6 in the Appendix section show OC curves for various sample sizes recommended in ICMSF (2002) and other popular combinations of AQL and α.

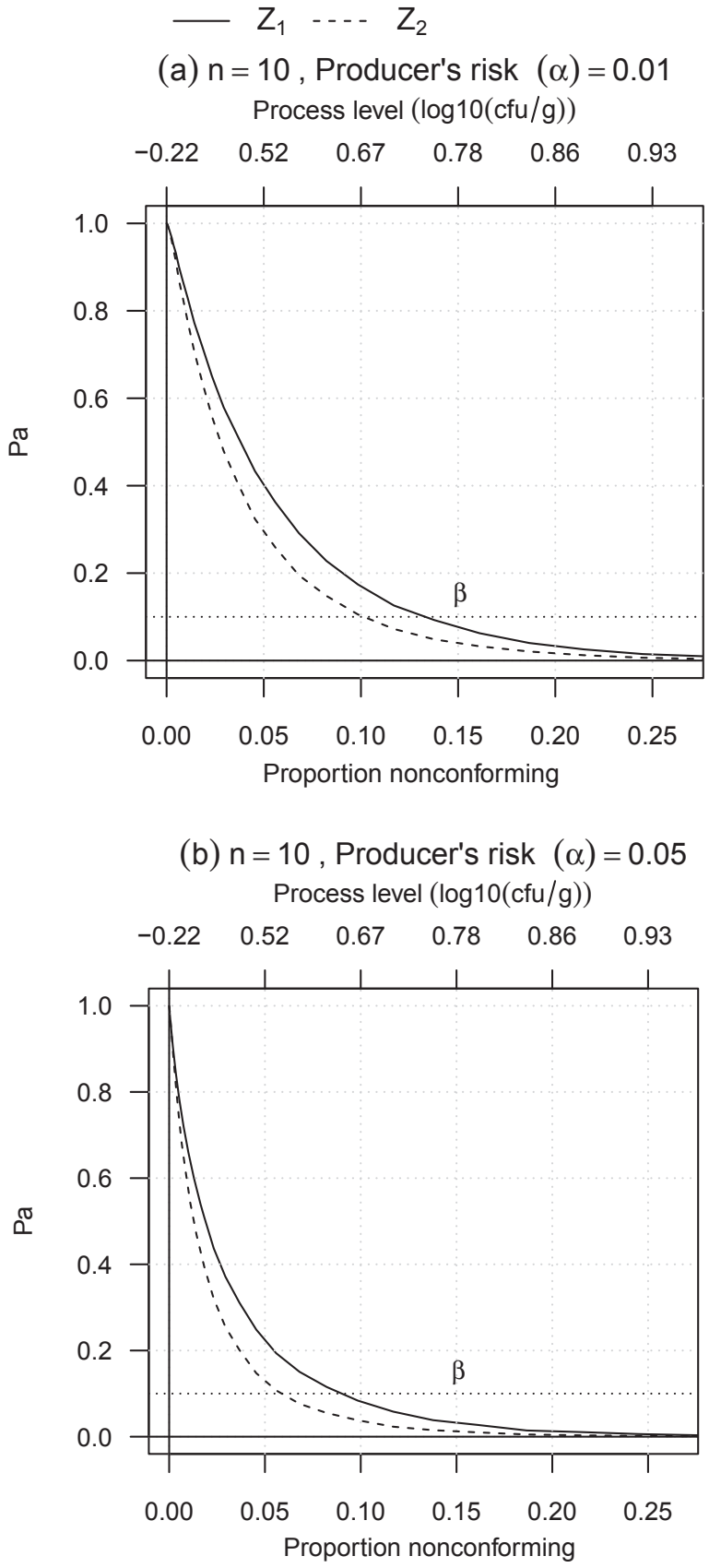


Fig. 6.1 Comparison of Operating Characteristic (OC) curves for $n = 10$, $AQL = 0.1\%$ and different values of producer's risk. The OC curves of the *log* and *sinh-arcsinh* transformations are shown in solid and dashed lines respectively. The new approach offers better consumer protection by lowering the consumer's risk at poor quality levels.

6.5 The misclassification error

For a given m, the Type I or false positive misclassification error (say, e_1) is always involved, see Lavin (1946) and Govindaraju (2007). This error is very small for regulatory limits, but necessary for the GMP warning limits which are fixed well below the regulatory limits. The false negative or Type II misclassification error is not relevant for fixing the m because it arises only in the presence of special causes having food safety implications. The observed proportion nonconforming $\left(p^{'}\right)$ is in fact equivalent to $e_1\,(1-p)$. For lognormal quality characteristics, Albin (1990) introduced a variables plan in which the OC curve is constructed for a given ratio of the means of unacceptable and acceptable quality limits. This procedure also takes into account the probability of false positive misclassification error. After allowing for the possibility of a baseline sample showing a false positive result, the probability of acceptance cannot be 1 for $p = 0$. Consequently, the true probability of acceptance starts at $1 - e_1$ when $p = 0$; see Govindaraju (2007) for a discussion on this issue. Zero microbial count in samples tested may be due to the measurement error. Non-detection is not the same as absence when in fact could be associated with factors such as the instruments, the measurer or the material preparation. For this reason, in tests like Aerobic Plate Count (APC) the event of no colonies found is reported as less than 25 CFU. Consider an e_1 value of 1%, the apparent proportion nonconforming result in: 0.99% for an apparent $AQL = 0.1\%$. This affects the performance of the OC curve considerably as can be seen in Figure 6.2.

6.6 Example

The new approach for lot disposition is illustrated in this section. Table 6.2 gives the aerobic colony count data obtained in poultry from ICMSF (2002).

Table 6.2 Result of five samples in aerobic colony count in poultry from ICMSF (2002). The second and third row express the count using log_{10} and *sinh-arcsinh* transformations respectively.

APC	40000	69000	81000	200000	350000
$log_{10}\,(APC)$	4.602	4.839	4.908	5.301	5.544
$H\,(APC)$	1.385	1.480	1.509	1.679	1.791

For a given microbiological limit equal to 10^7CFU the test statistics are: $Z_1 = 5.187$ and $Z_2 = 6.270$. If, for example, a k value related to $\alpha = 5\%$ and $AQL = 0.1\%$ is used, the following critical values are obtained: $k_1 = 1.87$ and $k_2 = 2.22$. At this high regulatory limit the batch is accepted by both methods. Now, consider a lower m value, say 6×10^5 CFU; the resulting statistics result in: $Z_1 = 1.955$ and $Z_2 = 2.053$. Thus the batch is rejected at this level by the new approach, while the traditional method sentences it as acceptable. As the proposed method tends to have OC curves dropping more steeply, this method provides better consumer protection against an increase in p or μ. This practical example illustrates how the difference in the OC curves can lead to different outcomes.

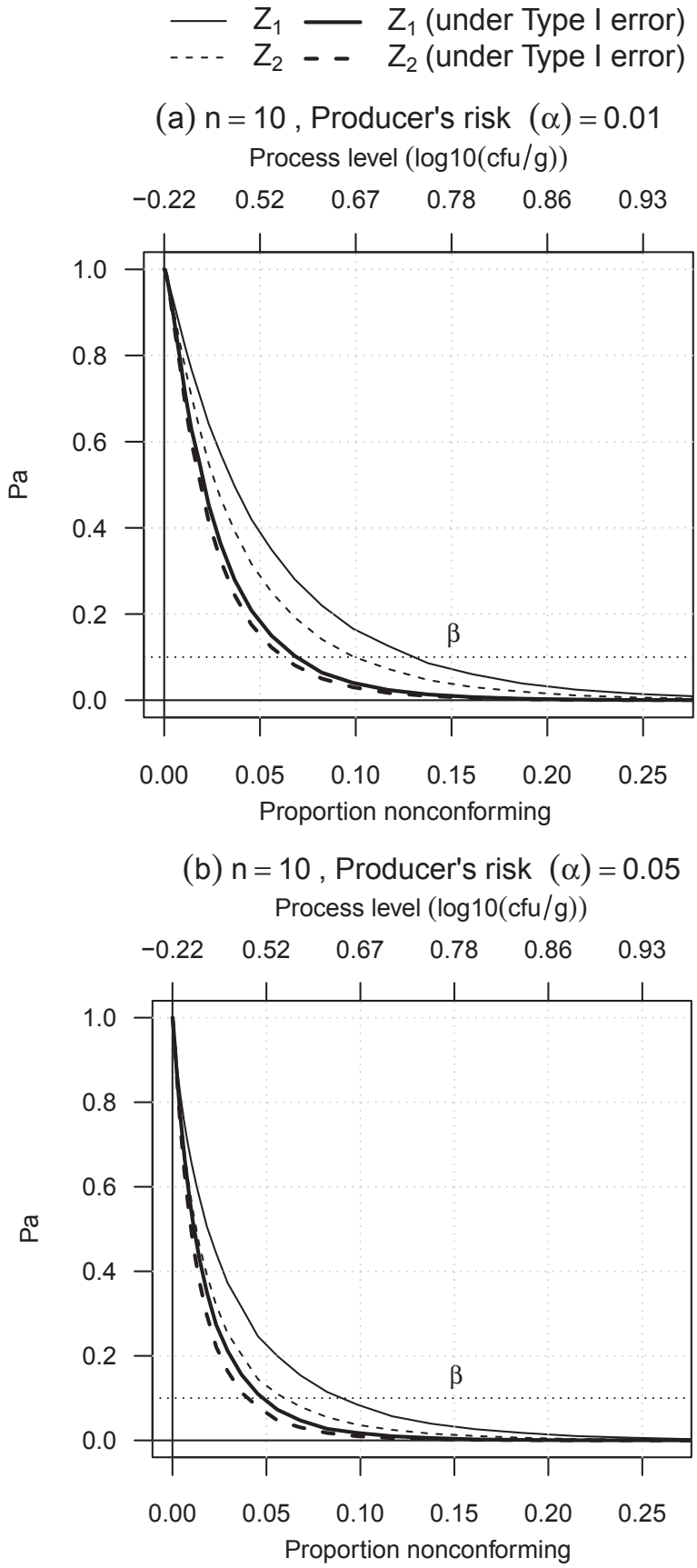


Fig. 6.2 Comparison of Operating Characteristic (OC) curves at a false positive misclassification error of 1% for $n = 10$, $AQL = 0.1\%$ and different values of producer's risk. The OC curves of the *log* and *sinh-arcsinh* transformations are shown in heavy solid and dashed lines respectively.

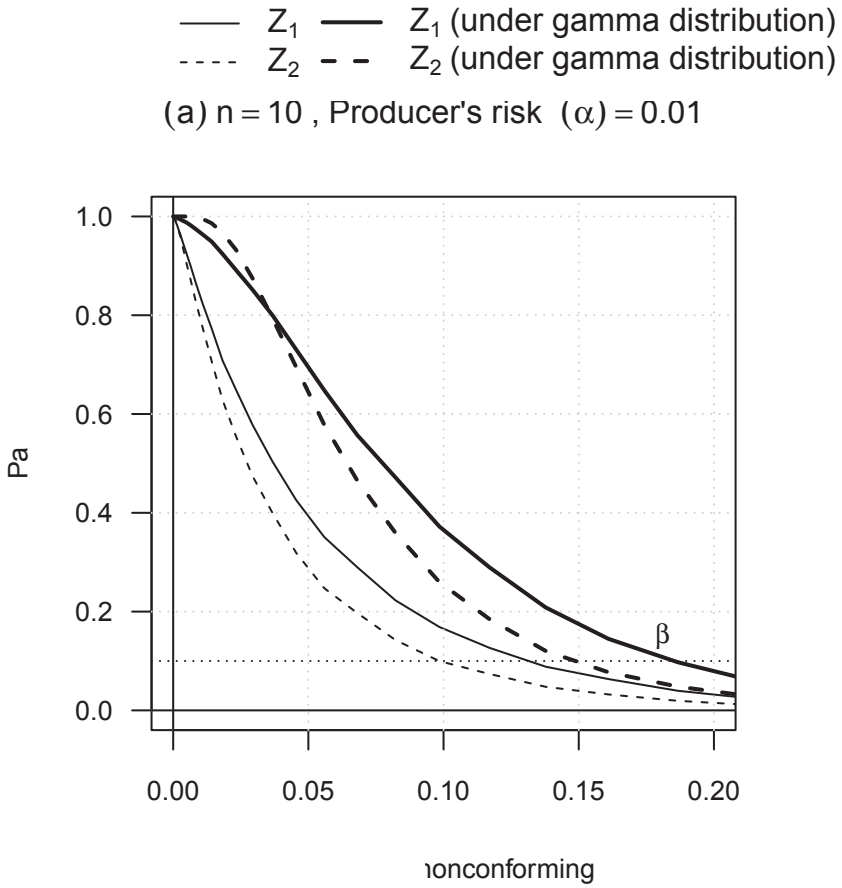
6.7 Assessment of robustness

It is well known that the performance of classical variables plans is sensitive to departures from the assumed model used to describe the cell count, which causes the fraction nonconforming to be incorrectly estimated. In practice, we would prefer a robust sampling plan whose OC curve remain stable when the underlying distribution changes and in presence of extreme values. For instance, the number of pathogens in a baseline study may fit a lognormal model as well as a few other related distributions such as gamma. Even though the lognormal distribution is justifiable as a standard distribution for microbial characteristics, it is important to ensure that the plan based on the lognormal assumption also works satisfactorily when the unknown true model is gamma. If the OC curve of the plan is forced closer to the vertical axis the protection to the consumer is improved.

The performance of new and classical procedures is evaluated in three common scenarios: assuming lognormality when the true distribution is gamma , Weibull and contaminated lognormal. All these three alternatives also produce right-skewed data. Let us first consider the gamma, $G(c,b)$ and Weibull, $W(\kappa,\lambda)$ alternatives. The initial parameters of the gamma and Weibull distributions for the common cause situation can be fixed giving equal values for the mode, density and overall goodness of fit in relation to $LN(0,1)$. For the gamma distribution, the following combination of parameters guarantees a match in terms of mode and density: $b = 0.75$ and $c = 1.5$. See Figure 6.7 in Appendix. The shape parameter was fixed at this level and a shift in the scale parameter, equivalent to the modification in the μ parameter of the lognormal, was introduced to model the special cause situation. This guarantees that for each point the gamma and the lognormal will have the same mode. The proportion nonconforming was used to construct the OC curve since the parameters in the lognormal and gamma distributions are not equivalent. The results obtained are shown in Figure 6.3. When the true distribution is gamma, the resulting plan is less stringent for both methods but the OC curve for the new method is rather robust.

Finally, the Weibull distribution is used as the true model, for comparison with the lognormal OC curve. The starting shape and scale parameters associated with the same mode are $\kappa = 1.3$ and $\lambda = 1.14$. This combination of parameters also produces a similar shape as can be seen in Figure 6.7. Fixing the shape and increasing the corresponding scale parameter over 1.14 gives very similar results as those obtained with the gamma distribution.

The basic idea behind a contaminated or mixture distribution is that the majority of data comes from a specific distribution $f(x)$, but includes a certain level of contamination with observations from a different distribution $g(x)$, often the same statistical model but with a greater mean/variance. If the contamination level is given by p, then the resulting probability density function is given by: $h(x) = (1-p)f(x) + pg(x)$. See, for instance Fowlkes (1979). This technique is often employed to evaluate the robustness of a statistical test procedure. Suppose that previous experience shows that a microbial count is right skewed justifying the lognormal assumption. Therefore, a sample will be judged by this hypothesis using the critical distance k



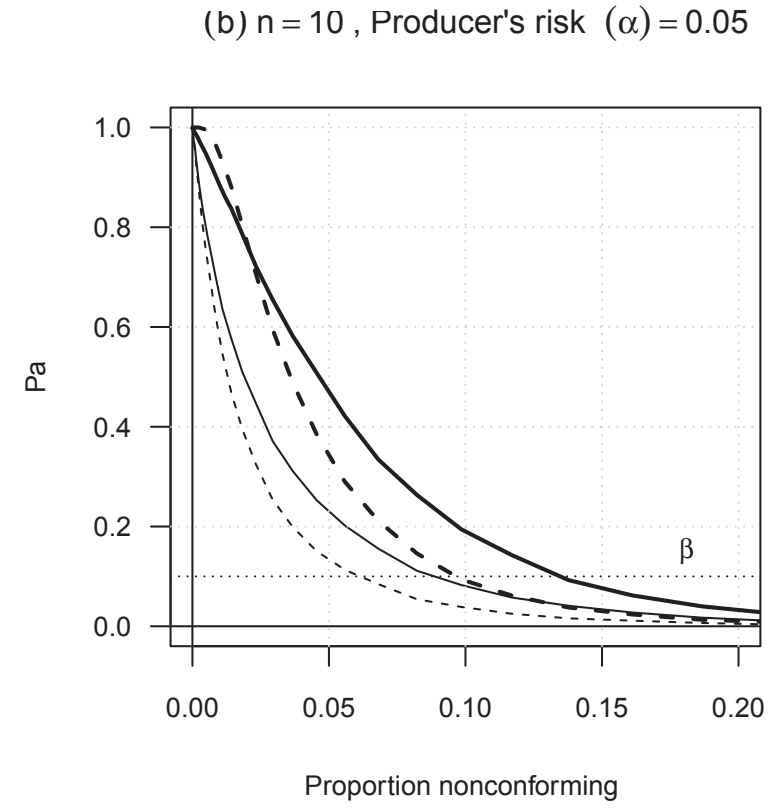


Fig. 6.3 Effect in the OC curves when the true distribution is gamma (displayed in thicker line width). The difference in the LQL at a β risk for the Z_2 statistic is much smaller than that of Z_1.

corresponding to the given sample size, the producer's risk and the *AQL*. Let the mixed model be composed of two lognormal distributions with $\mu = 0$ and standard deviations one and two respectively, and let the degree of contamination be 20%. This leads to a mixed distribution that is more right-skewed than assumed. The performance of the classic and the new approach is shown in Figure 6.4. Notice that both approaches tend to reject at lower *LQL* but the classical alternative seems to be more affected. The method based on the *sinh-arcsinh* transformation is found to be more robust for both α levels. This means that the new approach better preserves its integrity when the true distribution is contaminated.

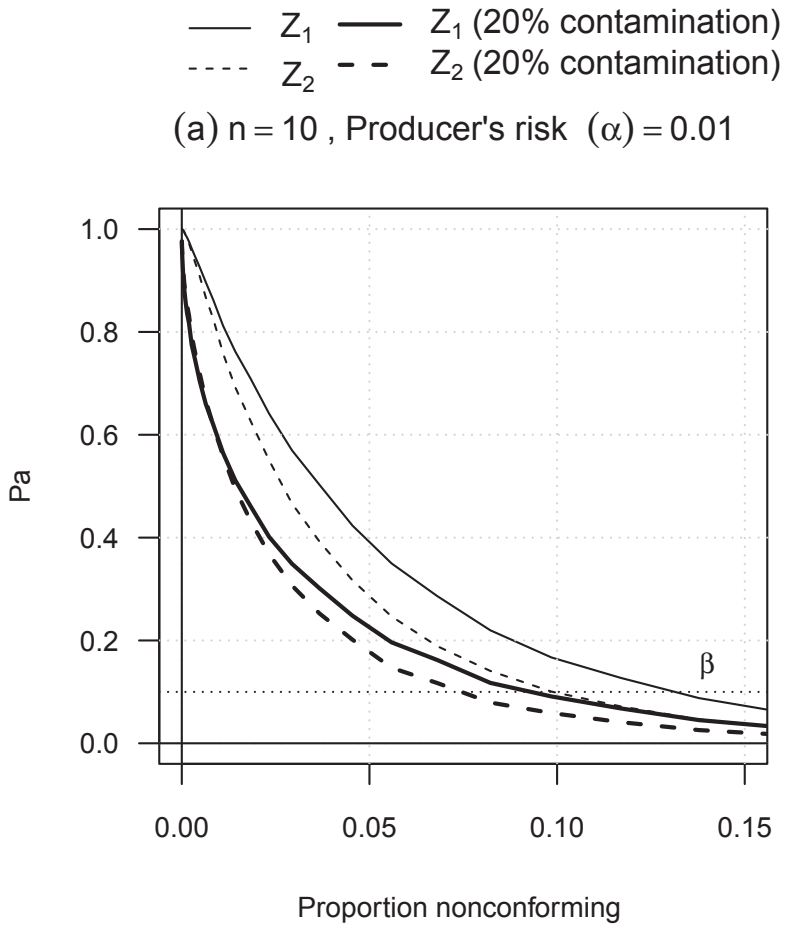
6.8 Discussion

As noted in Jongenburger et al. (2012b) and by others, the lognormal distribution is widely used to describe the number of pathogens in a sample, despite the fact that it is a continuous distribution. This density is criticized because of the fact that it does not allow zero counts, whereas discrete distributions such as the negative binomial allow a positive probability for zero counts. The absence of microorganisms in the sample has a zero probability of occurrence according to the lognormal density and this can be a drawback when the model is characterized by an over-dispersion of pathogens. Nevertheless, this issue could be addressed by adequate material preparation, using composite sampling (which allows a better homogenization) or using the three-parameter lognormal distribution. In recent years, other distributions have been proposed as an alternative to lognormal. For instance, Gonzales-Barron et al. (2010a) suggested the use of heterogeneous Poisson distributions. More recently Gonzales-Barron and Butler (2011b) and Mussida et al. (2013a) recommended compound distributions such as Poisson-gamma and Poisson-lognormal. These distributions were found suitable to characterize the colony count in powdered food products by Jongenburger et al. (2012c). However, we need to recognize that there is always an inherent distributional uncertainty with small samples. It is, therefore, important to use a standard distribution but achieve robustness in lot disposition.

OC curves usually start at proportion nonconforming (p) equal to zero. Unavoidable Type I misclassification error (false positives) results in a non-zero apparent proportion nonconforming $\left(p^{'}\right)$. This leads to $p^{'} = e_1\,(1-p)$, a fact not well recognized in the food safety literature. The proposed procedure incorporates this measurement error for lot disposition and controls the risks as suggested in Albin (1990) and others. Moreover, a higher degree of consumer protection can be achieved when compared to the traditional method with the same sample size because the proposed method achieves a steeper OC curve while maintaining the same producer's risk.

6.9 Conclusions

The performance of variables sampling plans using log-transformed data was compared with that obtained using the *sinh-arcsinh* transformation, for right skewed distributions used for modelling microbiological counts. This transformation was found to lower the consumer's risk in all the



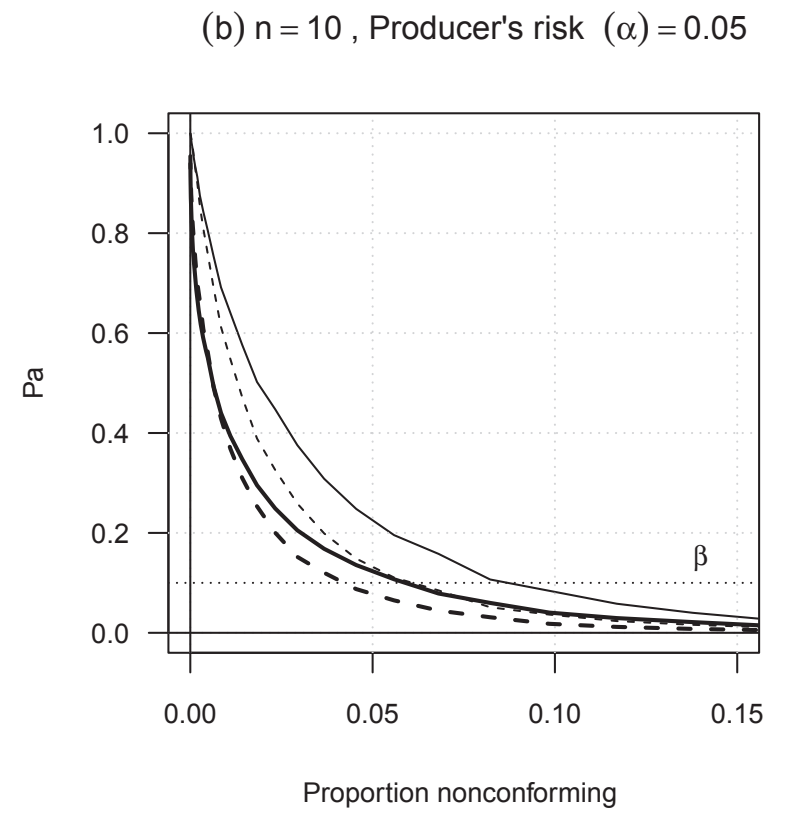


Fig. 6.4 Effect in the OC curves when the true distribution is contaminated lognormal (displayed in thicker line width). The Z_2 statistic shows a much smaller reduction in LQL than Z_1.

scenarios explored. Another important advantage is the greater robustness of the proposed method. A real life example was given to show how the proposal can offer better consumer protection than the traditional method.

Appendix 6.A Effect of the parameters in the sampling performance

The use of the *sinh-arcsinh* transformation is beneficial even for small sample sizes under certain conditions, say $n = 2$, 3 or 5. Figures 6.5 and 6.6 compare the OC curves of both methods for different combinations of α, AQL and n. For higher sample sizes, the OC curves drop more vertically and the reduction in consumer's risks for the new method is evident. It can also be noted that small AQL values also achieve similar reduction in consumer's risks.

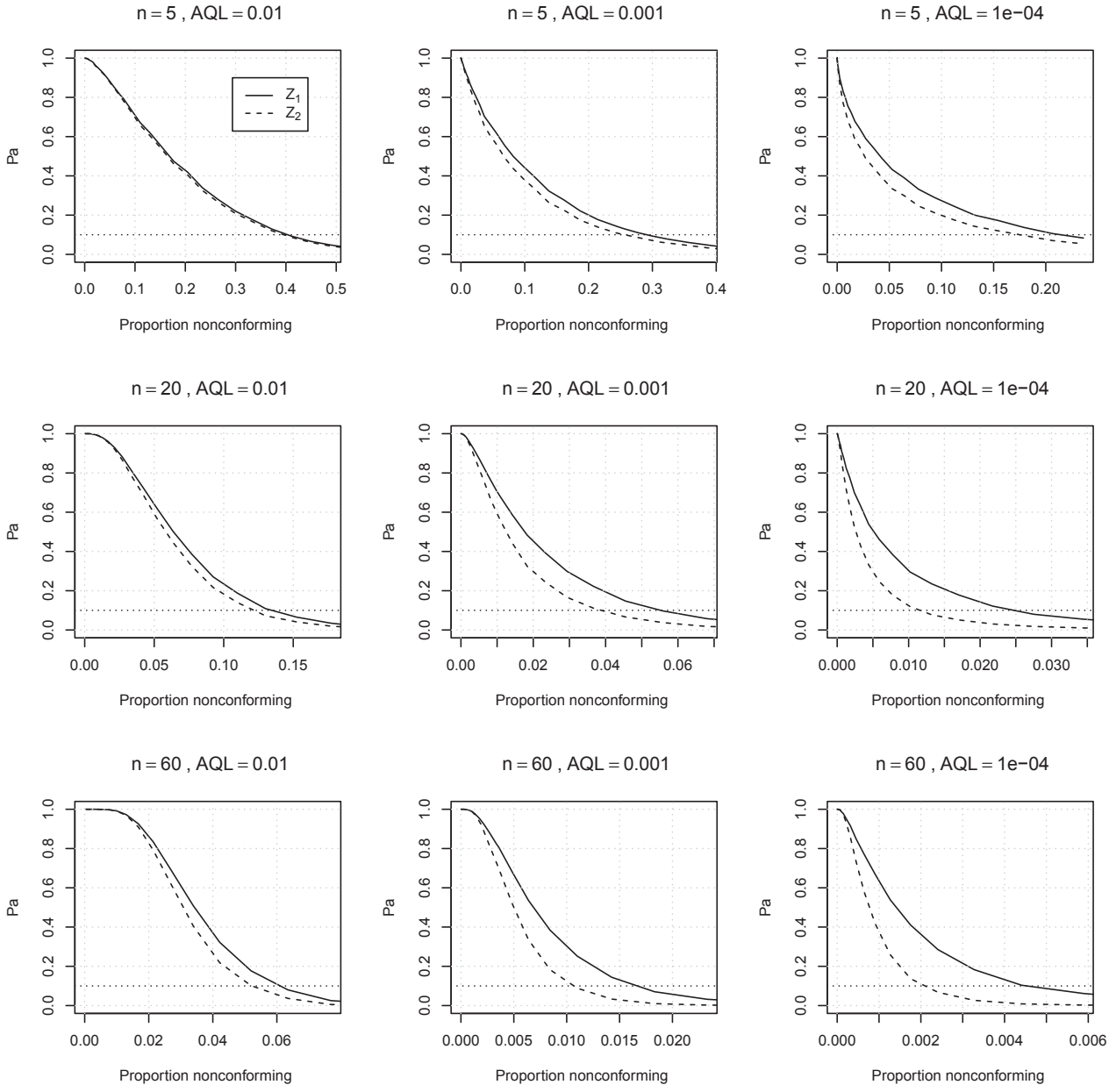


Fig. 6.5 Comparison of OC curves at a producer's risk (α) of 0.01 for different combinations of sample size and *AQL*. The common cause situation is assumed to be the lognormal distribution with $\mu = 0$ and $\sigma = 1$, both in log scale.

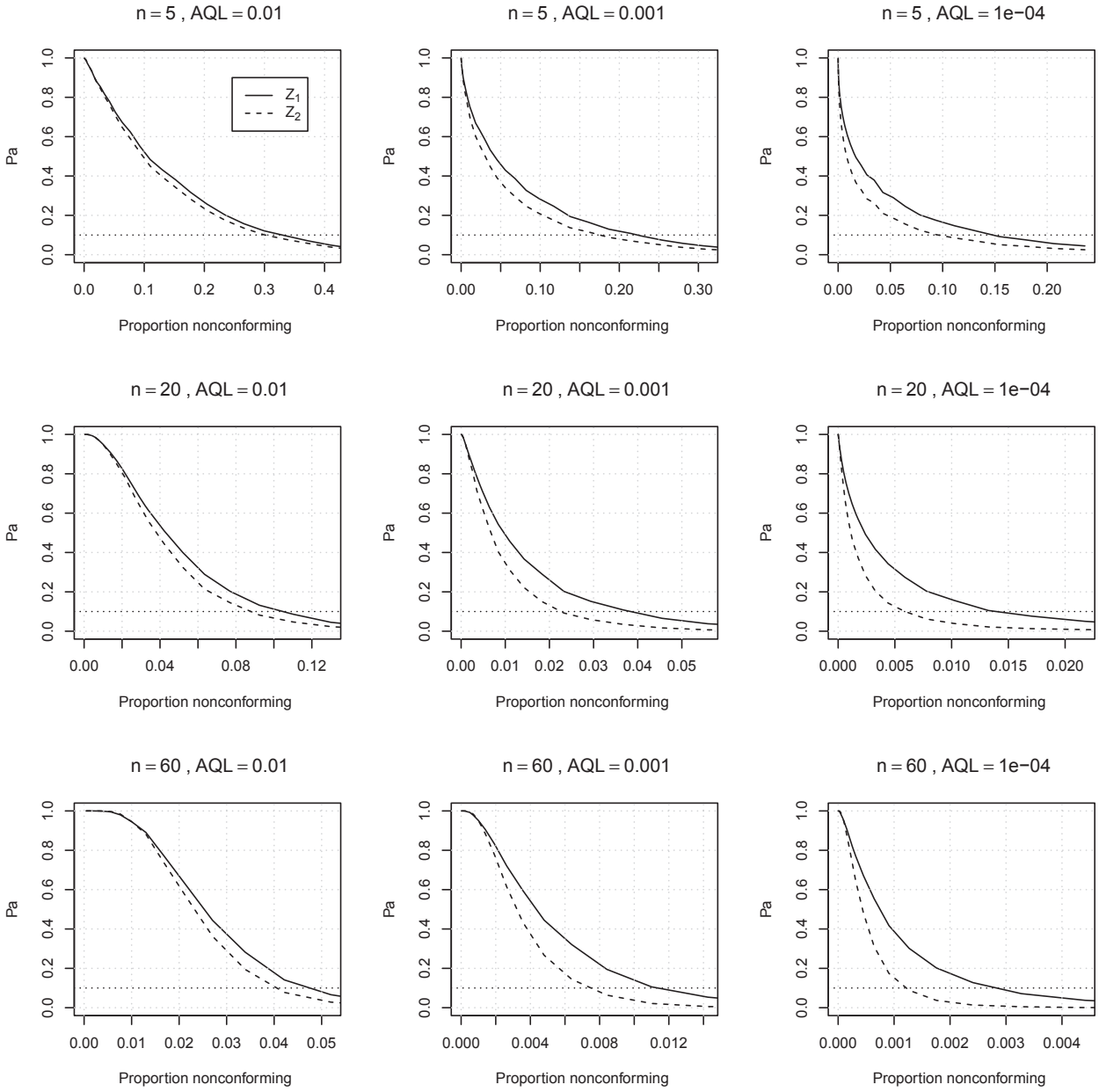


Fig. 6.6 Comparison of OC curves at a producer's risk (α) of 0.05 for different combinations of sample size and *AQL*. The common cause situation was modelled in the lognormal distribution using $\mu = 0$ and $\sigma = 1$, both in log scale.

Appendix 6.B Tabulated critical distances

Table 6.3 and 6.4 show the estimated acceptability constants k_1 and k_2 for a larger range of AQL and sample sizes used in practice (included in the ICMSF (2002) plans).

Table 6.3 Monte Carlo estimates of the critical distance factor (k) for three values of producer's risk and $AQL = 0.01$.

	$\alpha = 0.01$		$\alpha = 0.02$		$\alpha = 0.05$	
n	k_1	k_2	k_1	k_2	k_1	k_2
2	0.56	0.54	0.71	0.71	0.95	1.02
3	0.78	0.78	0.91	0.94	1.13	1.22
4	0.92	0.95	1.04	1.10	1.25	1.37
5	1.03	1.08	1.14	1.22	1.33	1.48
10	1.31	1.44	1.41	1.57	1.56	1.79
15	1.46	1.63	1.54	1.75	1.68	1.95
20	1.55	1.76	1.63	1.87	1.75	2.05
30	1.67	1.93	1.73	2.02	1.84	2.18
40	1.74	2.03	1.80	2.12	1.90	2.27
50	1.79	2.11	1.85	2.19	1.94	2.33
60	1.83	2.17	1.89	2.25	1.97	2.38

Table 6.4 Calculated estimates of the critical distance factor (k) for three values of producer's risk and $AQL = 0.0001$.

	$\alpha = 0.01$		$\alpha = 0.02$		$\alpha = 0.05$	
n	k_1	k_2	k_1	k_2	k_1	k_2
2	1.26	1.41	1.43	1.66	1.76	2.13
3	1.56	1.78	1.72	2.02	2.02	2.46
4	1.75	2.03	1.90	2.27	2.18	2.68
5	1.89	2.22	2.04	2.44	2.30	2.85
10	2.28	2.77	2.41	2.97	2.63	3.31
15	2.48	3.06	2.60	3.25	2.79	3.56
20	2.61	3.26	2.72	3.43	2.89	3.71
30	2.77	3.51	2.87	3.67	3.02	3.92
40	2.88	3.68	2.96	3.82	3.10	4.05
50	2.95	3.80	3.03	3.93	3.16	4.14
60	3.01	3.89	3.08	4.01	3.20	4.21

Appendix 6.C Software code

The R code shown below computes the acceptability constants k_1 and k_2 for a given combination of α, AQL and n.

```
stats <-function(n = n, mu = mu, s = s, m = m){
 sample <-rlnorm(n = n, meanlog = mu, sdlog = s)
 # Z1 using log transformation
 Z1 <- (log(m) - mean(log(sample))) / sd(log(sample))
 # Z2 using sinh.arcs transformation
```

```
 sinh.arcs <-function(x, epsilon = 0, delta = 0.1) {sinh(delta *
 asinh(x) - epsilon)}
 Z2 <-(sinh.arcs (m) - mean(sinh.arcs(sample))) / sd(sinh.arcs(sample))
 cbind(Z1, Z2)}
# Computation of the acceptance constant (k)
n <-20 # Sample size
mu <-0 # Mean of the lognormal distribution in log scale
s <-1 # Standard deviation of the lognormal distribution in log scale
alpha <-0.01 # Producer's risk
AQL <-0.001 # Acceptable Quality Limit
 trials <-1e5 # Number of simulations
m <-qlnorm(AQL, lower.tail = 0, sdlog = s) # Microbiological limit (m)
A <-mapply(FUN = stats, n = rep(n, trials ), mu = mu, s = s, m = m)
k <-apply(A, 1, f <-function(x) quantile(x, probs = alpha))
```

Appendix 6.D Step-by-step guide

The sampling design for the new approach can be developed by using the following guide:

- Define the producer's risk (α) and the number of samples to be drawn (n).
- For a given regulatory limit (m), compute the associated AQL as the right tail area in the lognormal distribution. If m is not established, define an AQL and obtain m as the quantile of the lognormal distribution.
- Compute the statistic Z_2.
- For a given n, AQL and α, obtain k from Table 6.1, 6.3 or 6.4. For other combinations, obtain k using the R snippet.
- Apply the decision criterion. If $Z_2 \geq k$ accept the lot; otherwise reject.

Distribution Matching

Figure 6.7 shows the three distributions matched through their mode and density. The lognormal distribution is more skewed that the gamma and Weibull models.

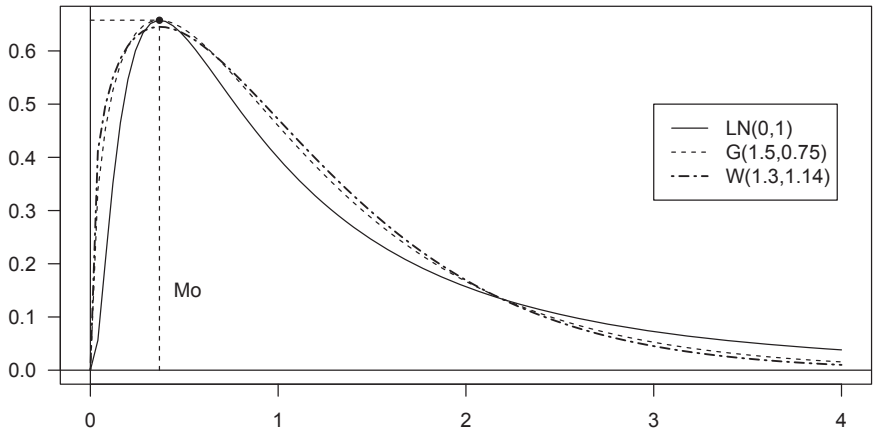


Fig. 6.7 Lognormal probability density function with $\mu = 0$ and $\sigma = 1$ in solid line matched with the gamma $(c = 1.5, b = 0.75)$ and Weibull $(\kappa = 1.3, \lambda = 1.14)$ distributions through the mode and the density. The gamma and Weibull distribution are in dashed and dotdashed line.

Appendix 6.E Symbols and definitions.

Table 6.5 Glossary of symbols and definitions.

$LN(\mu,\sigma)$	lognormal distribution with
$f(x/\sigma,\mu)=\frac{1}{x\sigma\sqrt{2\pi}}\exp\left(-\frac{(\ln(x)-\mu)^2}{2\sigma^2}\right)$	probability density function
μ	logscale
σ	shape parameter
$Z_1=\frac{m_y-\bar{Y}}{S_y}$	test statistic for the normal distribution
$Z_2=\frac{m_v-\bar{V}}{S_v}$	statistic of the *sinh-arcsinh* transformation
$H=\sinh\left[\delta\sinh^{-1}(x)-\varepsilon\right]$	*sinh-arcsinh* transformation
m	microbiological limit
$\bar{Y}=\sum Y_i/n$	sample mean
$S_y=\sqrt{\sum(Y_i-\bar{Y})^2/(n-1)}$	sample standard deviation
e_1	Type I measurement error
n	number of samples
q	quantile function
k	critical distance
AQL	Acceptable Quality Limit
LQL	Limiting Quality Level
α	producer's risk
β	consumer's risk

Appendix 6.F Justification of chosen constant for sinh-arcsinh transformation.

Let us assume other possible values for δ and ε, namely $\delta=0.1,0.5,1$ and 2; and $\varepsilon=0,0.25,0.50,0.75$ and 1. Consider $n=10$, $AQL=0.001$ and $\alpha=0.01$. The efficiency of the new sampling plan can be given in terms of limiting quality reduction compared to a reference the traditional plan based on the log transformation.

$$\Delta LQ=(1-LQL_2/LQL_1)\times 100 \tag{6.4}$$

where LQL_2 and LQL_1 are the Limiting Quality Levels obtained using the *sinh-arcsinh* and employing the regular log transformation respectively. The larger the LQL reduction, the better the discriminatory power of the new approach. Figure 6.8 shows a level plot of the LQL reduction (in %) as a function of δ and ε. While ε has a minor effect in the OC curve, the parameter δ has a significant impact. Smaller δ values will yield smaller LQL values. The suggested method achieves up to 30% of LQL reduction when compared to the traditional sampling plan for the fixed sample size.

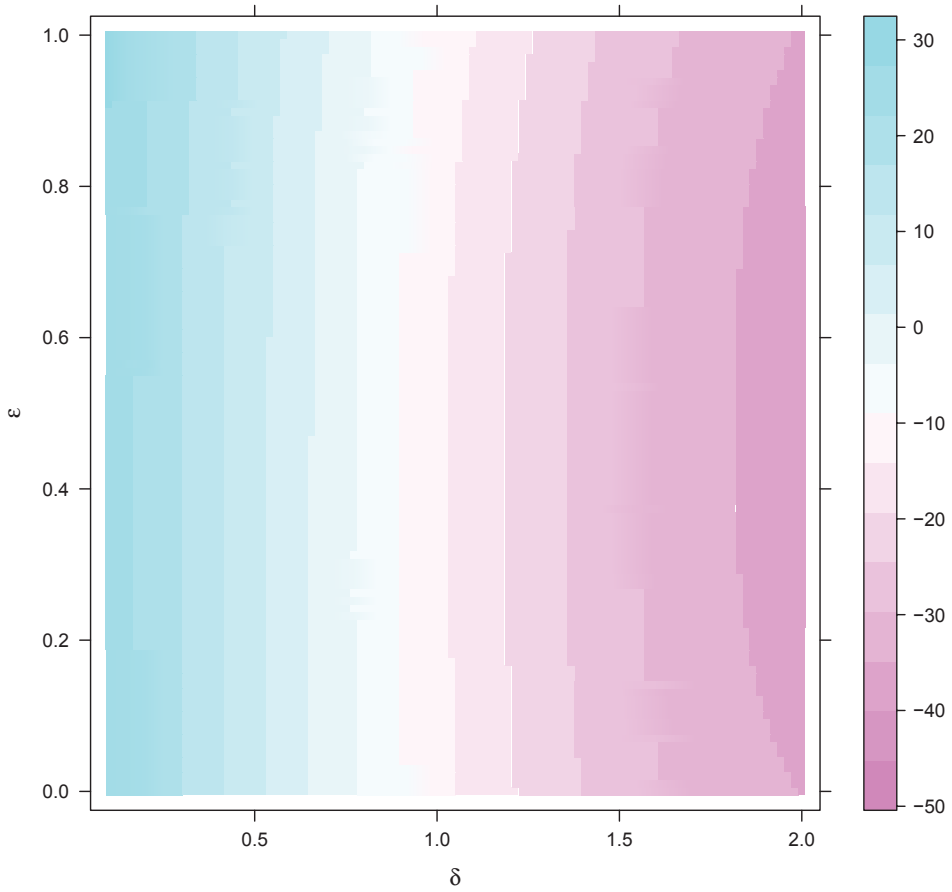


Fig. 6.8 *LQL* reduction level plot based on δ and ε. The blue zone is where the plan based on *sinh-arcsinh* reduces the *LQL*.

Chapter 7

Variables Sampling Plans using Composite Samples for Food Quality Assurance

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7.1 Abstract

Testing composite samples is a useful strategy to achieve sampling economy. Several studies have shown the effectiveness of this technique under the assumption of perfect mixing of primary samples. This paper investigates the effect of imperfect composite sample preparation on the performance of two and three-class variables sampling inspection plans, and identifies scenarios in which testing composite samples is not advantageous. The design of sampling plans using composite samples is discussed and an implementation guide based on two points of the OC curve for perfect and imperfect mixing is provided.

Keywords

Food safety; Composite samples; Imperfect mixing; Sampling plan

7.2 Introduction

Acceptance sampling methodology is used for disposition of lots of commodities as suitable to be consumed. Lots are assessed as acceptable or otherwise based on a sample of n test results or measurements. Sampling inspection plans therefore provide assurance to the consumers on the quality and safety of accepted lots. Attribute inspection plans are used when an item or a test sample is classified as conforming or not. Variables inspection plans are used when measurements

are made on a continuous scale. Variables plans are convenient since they require smaller sample sizes when compared to the attribute plan alternatives. Smaller sample sizes generally mean lower inspection costs. When attribute plans are employed for food safety, each tested sample is commonly classified as conforming when the microbial count is under a regulatory limit e.g. less than 1 CFU 100 kg^{-1} of *salmonella* in dried milk. The International Commission on Microbiological Specifications for Foods, in ICMSF (2002) and the Codex Alimentarius Commission (CAC) in CAC (2004) provide guidelines on using sampling inspection plans for food quality/safety assurance. Both protocols recommend inspection plans by attribute and for variables.

Sampling inspection plans for food safety commonly assume the concentration of microorganisms to be lognormally distributed. Numerous studies reflect that this statistical model is satisfactory to describe the frequencies of pathogens, see for instance Kilsby and Baird-Parker (1983). The lognormal model is the maximum entropy distribution when the mean and the variance are fixed and therefore it is the most conservative statistical model used to describe the variation due to common or chance causes. The advantage of using the lognormal model is that, by expressing the cell counts on a logarithmic scale, the variables inspection plans for the normal distribution can be applied. This methodology is used in the sampling plans discussed by Kilsby et al. (1979) and Smelt and Quadt (1990).

The performance of a sampling plan is assessed using its Operating Characteristic (OC) curve. The OC curve gives the probability of acceptance (P_a) for various batch quality levels; see Fig. 7.1. The batch quality is commonly expressed in proportion nonconforming (fraction of the population that does not comply to the microbiological limit). The fraction nonconforming product can be estimated using the sample mean and the standard deviation. The consumer's point of interest on the OC curve is typified using the Limiting Quality Level (LQL) and the consumer's risk (β). The producer's point of interest on the OC curve is typified using the Acceptance Quality Limit (AQL) and the producer's risk (α). The AQL is the maximum proportion nonconforming that is considered acceptable for the consumer, while the LQL is the proportion nonconforming, that is expected to be rejected with a high probability.

A single sampling plan is designed by either: (1) two points in the OC curve (AQL, α and LQL, β) or (2) the sample size (n) plus a restriction. The restriction may be: one point in the OC curve, the acceptance constant (attribute plans) or the critical distance (variables plans). The standard practice in quality control is to use the first approach, while the second method is popular in food quality assurance. For food safety, the focus is on the LQL rather than the AQL because the primary objective of inspection is to provide consumer protection. However, the consumer's point of interest on the OC curve alone does not uniquely define a sampling plan. Therefore, the AQL point is additionally used to match the OC curves and for design purposes.

Variables plans for the proportion nonconforming based on two points of the OC curve were originally introduced by Wallis (1947). For the unknown standard deviation case, approximate solutions were proposed by Lieberman and Resnikoff (1955) and Owen (1967). Kilsby et al. (1979) extended the variables inspection plan to include the good manufacturing practice (GMP)

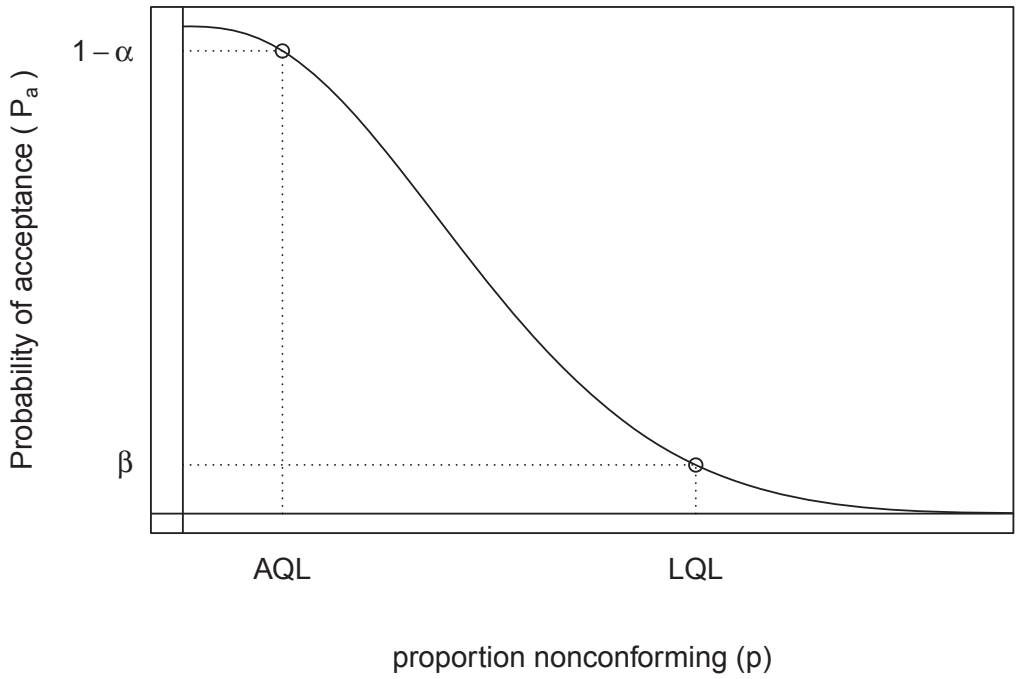

Fig. 7.1 Illustration of the Operating Characteristic (OC) curve.

limits. This design is based on the point on the OC curve representing the consumer's interest along with a limited range of sample sizes to obtain the critical distances under the noncentral *t* distribution. This design approach was adopted by ICMSF (2002), and Smelt and Quadt (1990) then extended it for cases in which the standard deviation is calculated using historical data. In two-class variables plans, the batch quality is assessed in terms of the fraction of the product nonconforming (or alternatively conforming) to the specification or regulatory limit(s). In three-class variables plans, the batch quality is assessed in terms of fraction of the product nonconforming to the regulatory limits as well as the fraction of the product failing to meet the tighter GMP-type limits. In other words, the three-class plans consider the possibility of marginal batch quality in addition to poor and good quality.

Despite the fact that many authors studied variables sampling plans for food microbiology, the additional risk due to the mixing of primary samples have not been incorporated in the sampling plan design. In this paper we assess the sampling economy when the test material preparation involves composite samples. However, this research excludes the case in which only a single composite sample is tested but focusses on testing several composite samples.

The paper is organized in the following way. It begins in Section 7.3 by examining the use of composite samples for food quality assurance. In section 7.4 we discuss the theoretical aspects of imperfect mixing. The performance of sampling plans based on composites and based on individual units are compared in Section 7.5, while in Section 7.6 we provide the design of a variables plan for composite samples. In section 7.7 we analyze the performance of three-class variables plans. The Appendix includes the symbols and important definitions and the implementation guide. All simulations and graphs were carried out with **R** software (R Core

Team, 2015). Dirichlet and multivariate hypergeometric random numbers were generated using the **R**-packages **gtools** (Warnes et al., 2013) and **BiasedUrn** (Fog, 2013), respectively.

7.3 Food safety and composite samples

The use of composite samples becomes a very attractive alternative when the cost of collecting large number of primary samples is low in relation to the analytical testing costs. A composite sample can be defined as "the physical mix of individual sample units or a batch of unblended individual sample units that are tested as a group"(Patil, 2006). Compositing is a physical averaging process. A highly representative composite sample is useful to estimate the population mean levels. In recent years, there is a growing interest in composite sampling for food safety, (Jarvis, 2007; Ross et al., 2011). However, the use of composite samples remains controversial. As stated in ICMSF (2002), an "increase in the stringency of examination, without correspondingly increasing laboratory effort" can be obtained by compositing. On the other hand, CAC (2004) recommends composite sampling only for economic reasons "given the loss of information on sample-to-sample variation due to the combination of primary samples". Jongenburger (2012b) also favours the use of the individual units instead of composite units due to the dilution effect independently of the higher workload.

In food microbiology, composite testing is used with the aim of lowering the analytical cost and reducing the variability in the test result, (Jarvis, 2007; Ross et al., 2011). A composite sample Y_j $(j = 1,2,\cdots,n_c)$ is formed by mixing/blending X_i $(i = 1,2,\cdots,n_I)$ individual or primary units. This process of compositing is often assumed to be perfect for all Y_j , e.g. Van Belle et al. (2001), El-Baz and Nayak (2004), Jonkman et al. (2009), etc. In other words, it is assumed that

$$Y_j = \bar{X}_j = \sum_{i=1}^{n_I} X_{ij}/n_I \tag{7.1}$$

implying that each primary sample contributes equally or perfectly to every final composite. The variance of the composite measurement is then given by $\sigma_y^2 = \sigma_x^2/n_I$. Fig. 7.2 shows the process in which n_c composite samples are formed each one by mixing n_I individual samples. Laboratory tests are done using the composite samples (Y_j's). Testing a single composite multiple times is carried out in some situations but this alternative is not considered in this paper. This is because multiple testing of a single composite only captures the measurement error related variability and not the variability in the lot or production process. When $n_I = 1$ means that the primary sample units are tested individually without preparing composites.

In studies involving parameter estimation e.g. El-Baz and Nayak (2004), the number of primary samples mixed together to form a composite is commonly fixed in the range of two to 10 (i.e. n_I = 2 to 10). Higher values of n_I are not considered due to the risk of dilution. Presence-absence type of attribute testing normally requires higher n_I values such as 30, see e.g. (Jarvis, 2007). This because presence-absence tests involve incubation. If the composite sample contains one or more cells, the test is likely to yield a positive result. The approach discussed

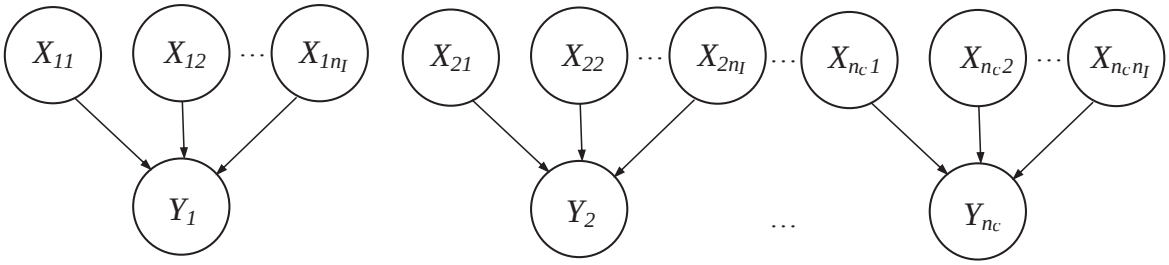

Fig. 7.2 Formation of n_c composite samples each one by mixing n_I primary samples.

in this paper cannot be applied to pathogens that requires enrichment during the test material preparation e.g. *salmonella*.

A special case of compositing is the use of automatic samplers in industrial processes associated with bulk materials in which the final composite is a result of combining of hundreds and sometimes thousands of primary samples of very small quantity. This approach allows good representation of the temporal distribution of microorganisms during the production, but can also dilute large bacterial spikes when the sampled quantity is very small. This case is not considered in this research.

The use of composite samples is recommended in the literature for estimating the mean of right-skewed populations such as lognormal and gamma. Van Belle et al. (2001) and El-Baz and Nayak (2004) showed that the effectiveness of this type of sampling depends on the number of composite samples and the population variance. However, these studies do not consider the effect of unequal contributions of primary samples in the mixing process.

7.4 Imperfect mixing

If the composite preparation technique is imperfect or alternatively if the physical averaging of primary samples is less satisfactory, the final composite becomes less representative. Physical characteristics involved may also render mixing less than perfect. The process of mixing/blending represents an important source of variability which cannot be ignored in the sampling plan design. This fact is recognized in environmental studies, see for instance Patil et al. (2010) and Edland and Van Belle (1994). Similarly, Corry et al. (2007) identified the homogenization process as an important source of sampling error.

Heterogeneity is also tackled using the Gy's Theory of Sampling (ToS) (Gy, 1979) which covers several components of errors associated with the heterogeneity of materials such as fundamental error and grouping/segregation error. The effect of an imperfect mixing/blending is not fully established in the food safety literature. The effectiveness of composites is addressed in presence-absence type of testing (Jarvis, 2007), but not for variables sampling plans used for lot disposition. In the presence of heterogeneity, the composite measurement is nothing but a weighted average (Brown and Fisher, 1972; Elder et al., 1980; Rohde, 1976). If the proportions of the contributions made by the primary samples are well controlled, the weights become fixed and it can be described by a discrete uninform probability distribution. Imperfect

mixing leads to unequal contributions of primary samples towards the composite sample and hence the weights of such contributions become random and can be described by a non-uniform probability distribution (Patil et al., 2010). In other words, when the composite is subsampled, the contribution of each individual unit is different in terms of volume or mass. This means that the weights will be proportional to the corresponding contribution. Since each contribution is unknown, the weights are then randomly distributed.

That is, we treat the jth composite sample measurement as

$$Y_j = w_1 X_1 + w_2 X_2 + \cdots + w_{n_I} X_{n_I} = \sum_{i=1}^{n_I} w_i X_i \tag{7.2}$$

where w_i are the stochastic weights subject to $\sum_{i=1}^{n_I} w_i = 1$. A matrix algebraic treatment to describe the composite samples and weights can be found in Lancaster and Keller-McNulty (1998).

The quality of the mixing of the primary samples during the test material preparation is specific for every category of food. Since liquids can be easily homogenized, they are often mixed by manual shaking. However, manual mixing often cannot break the clumps in solid materials and therefore mechanical mixing is required. Mechanical mixing is commonly carried out using mixers or stomachers. Some of the sample preparation methods recommended by Greenfield and Southgate (2003) result in imperfect composite. For instance, the mixing of solids such as grains, flours and dried milk is carried out in solid state by hand, using spatula and subsampling after quartering. In solids, the use of diluent significantly improves the degree of homogenization.

Since the structure of the composite is unknown due to lack of population data, theoretical models are used in the literature to study various scenarios of sampling variabilities, mixing strategies and their effect on composite samples. We now consider three non-uniform probability distributions to describe the weights. Two of them have been used previously, the Dirichlet distribution (D) in Rohde (1976) and the multivariate hypergeometric distribution (MH) (Brown and Fisher, 1972; Elder et al., 1980). Each distribution is used to represent different mixing scenarios. We are not matching the parameters of these distributions so that a wider range of situations can be covered.

The Dirichlet density function is given by:

$$f(w_1, \cdots, w_{n_I}; a_1, \cdots, a_{n_I}) = \frac{\Gamma\left(\sum_{i=0}^{n_I} a_i\right)}{\prod_{i=0}^{1} \Gamma(a_i)} \prod_{i=1}^{n_I} w_i^{a_i - 1} \tag{7.3}$$

where $\mathbf{a} = (a_1, a_2, \cdots, a_{n_I})$ is the vector of concentration parameters and as usual $\sum w_i = 1$. The concentration parameters determine the contribution of the individual samples. The concentration parameters are specific to the bulk material and the mixing/blending technique employed. No empirical information is usually available because their determination requires the full knowledge of the population variability. Hence we carried out a *what-if* analysis to assess the impact of a change in the concentration parameters on the sampling plan. We considered three scenarios of

imperfect mixing with $a = 0.1$ (poor mixing), 1 (moderate mixing) and 5 (good mixing). Here $a = 0.1$ means $a_i = 0.1$ for all i, $(i = 1, 2, \cdots, n_I)$. The first two concentration parameters were also used in Nauta (2005). For large a_i values, the weights tend to be nearly constant. For a mechanistic justification of the Dirichlet model, see e.g. Patil et al. (2010); Rohde (1976).

The multivariate hypergeometric distribution is also used for modelling bulk materials composed of discrete units and solid materials such as grains and coal. This distribution is defined as an *urn model*. Suppose that the physical elements of each primary sample are associated with balls of a certain colour. If $m_1, m_2, \cdots, m_{n_I}$ balls of different colours are placed in an urn and a sample of n balls is drawn without replacement, then the probability of obtaining an specific number of balls of each colour $(x_1, x_2, \cdots, x_{n_I})$ in the sample is given by

$$P(X_1 = x_1, X_2 = x_2, ..., X_{n_I} = x_{n_I}) = \frac{\binom{m_1}{x_1}\binom{m_2}{x_2}\cdots\binom{m_{n_I}}{x_{n_I}}}{\binom{m}{n}} \tag{7.4}$$

where $\binom{m_i}{x_i}$ is the binomial coefficient and the weights are computed as $w_i = x_i / \sum_{j=1}^{n_I} x_j$. When each individual unit has the same probability to contribute to the final composite the "odds" are equal and the central hypergeometric distribution is relevant. However, for unequal odds, some of the units contribute to the composite more heavily than others. This case leads to the non-central hypergeometric distributions which can be modelled by using the Wallenius' noncentral hypergeometric distribution or with the Fisher's noncentral hypergeometric distribution (Fog, 2008).

Three different scenarios of composite formation are considered. The first one assumes that the contribution of each individual primary sample is unbiased (central hypergeometric distribution) while the last two scenarios assume that some of the primary samples contribute more than others to the composite sample (noncentral hypergeometric distribution). In the second scenario, it is assumed that half of the primary samples are 10 times more likely to contribute to the composite sample, while in the third scenario only one of the primary samples is 10 times more likely to be represented in the composite sample.

7.5 Variables plan for composite samples

Let the characteristic X of interest representing the number of microorganisms be lognormally distributed and subjected to an upper microbiological limit (m). This microbiological (regulatory) limit is usually set after fitting an in-control or baseline distribution. The *AQL* is then proportion of the product with microbial count in excess of m for the common cause or baseline state. Let $V = \log(X)$ and $m_v = \log(m)$. The lot acceptance criterion is of the form $\bar{v} + kS_v \leqslant m_v$, where $\bar{v} = \sum_{i=1}^{n} v_i / n$, k is the critical distance or acceptability constant and S_v is the sample standard deviation of V. Alternatively, the test statistic

$$Z_m = (m_v - \bar{v}) / S_v \tag{7.5}$$

expresses the allowable distance in standard deviation units between the mean and the specification. When the value of Z_m is lower than k, the fraction of nonconforming product in the lot is higher than the AQL and hence the lot is rejected. Under the assumption of normal distribution for V, the acceptability constant k and the required sample size n can be obtained using formulae, see Duncan (1986) or Montgomery (2007). The traditional plan design assumes the use of primary samples.

It is established in the literature that the sum of independent lognormal random variables can be approximated by a single lognormal distribution (Johnson et al., 1994, pp. 217). Therefore, the enumeration of cells in the composite samples (Y_j) is also assumed to be lognormal. The analytical test size of Y_j is equal to the analytical size in the individual units X_{ij} for the purpose of this research. Let $U = \log(Y)$ be the log-count of microorganisms obtained from the composite samples. The acceptance criterion for the composite samples is then $\bar{u} + kS_u \leqslant m_v$, where $\bar{u} = \sum_{i=1}^{n} u_i/n$, k is the critical distance and S_u is the sample standard deviation of U.

Derivation of an analytical expression for the OC function of the variables plan based on the composite samples is too complex and hence we need to resort to Monte-Carlo simulation to obtain OC curves. The simulation algorithm for the sampling based on primary units is described below. The common cause situation is modelled with the lognormal with $\mu = 0$ and $\sigma = 1$ both in log scale. The Z_m test statistic is obtained from a vector X generated from the lognormal distribution. For the purpose of the simulations, the AQL value is used to compute m since there is a one-to-one relationship between proportion nonconforming and the distribution quantile. The critical distance k is obtained as the α-quantile of Z_m replicated (at least 50,000 times). Batches under the common cause situation will be accepted with probability $1 - \alpha$. The special causes of variation mean a non-random change in the process and they are due to factors such as temperature misuse, environmental factors and poor handling. Special causes are modelled by increasing the μ until $\mu + 2$ at intervals of 0.05. The probability of acceptance is given for the proportion of Z_m values greater than or equal to the critical distance.

The simulation algorithm for composite samples is slightly different. The Z_m test statistic is obtained from a vector $\mathbf{Y}$ resulting from the average (perfect mixing) or weighted average (imperfect mixing) of the individual sample units (X_{ij}). The weights for imperfect mixing are modelled using the three distributions discussed in last section. The OC curves are forced to match at the producers' point $(AQL, 1 - \alpha)$ and then examined whether the consumer's risk at other rejectable levels is as small as possible.

To compare the sampling plan performance, let us start with the sampling plan using individual units. Let $AQL = 0.01$, $\alpha = 0.01$ and consider a reasonable sample size $n_c = 20$. In this case the analytical tests are done using the individual units. The resulting OC curve is shown in Fig. 7.3 in thin solid line. Consider than that the 20 tests are carried out over composite samples each one formed by $n_I = 4$ and 8 individual units. Therefore each alternative require $4 \times 20 = 80$ and $8 \times 20 = 160$ primary samples respectively. The OC curves when the mixing of the individual units is considered as perfect are given in heavy solid line. The thin and the heavy solid lines give the worst and best case scenarios respectively in terms of consumer's risk but

they remain the same in Fig. 7.3–7.5. Suppose that the mixing process is less satisfactory and can be described using the Dirichlet distribution. Consider the concentration parameters introduced in the last section to describe three different mixing scenarios. The resulting OC curves are given in dotted ($a = 0.1$), dashed ($a = 1$) and dotdashed ($a = 5$).

From Fig. 7.3, we note that the use of composite samples achieves a significant reduction in the LQL at the same β risk (say $\beta = 0.10$). The benefit of using composite samples is due to the natural averaging process as result of the physical mix. However, the composite sample formed with four primary samples ($n_I = 4$) achieves only a little reduction in the consumer's risks when the concentration parameter is small ($a = 0.1$). The effect of dilution is not compensated by the improvement in the performance of detecting large fraction nonconforming product levels. As one would expect, the more evenly the primary samples contribute towards the composite sample, the steeper the OC curve becomes. In case of uneven contributions, the OC curve becomes less steeper thereby increasing the consumer's risks. In other words, the discriminatory power of the sampling plan (capacity to discriminate between good and poor quality) depends on the standard deviation of the weights in addition to the number of primary samples used for composite sample formation.

Now consider the case in which the composite sample formation is modelled by employing the multivariate hypergeometric distribution. The OC curves obtained using Monte-Carlo simulation for these scenarios are presented in Fig. 7.4.

Consider the case in which the contributions are derived from the negative binomial distribution , $NB(d,b)$. The resulting OC curves are shown in Fig. 7.5. We particularly note that compositing does not reduce the consumer's risk when $d = 1$ and $n_I = 4$ when compared to testing n_c primary samples.

When mixing is imperfect, the stochastic nature of mixing can be studied only using theoretical models. By employing various probability models, we can examine how the consumer's risks are affected and how much efficiency is lost or gained by the use of composite samples. Figures 7.3 to 7.5 show that testing n_c composite samples is a better strategy than testing n_c primary samples, and the consumer's risks are not affected adversely because of compositing. The performance of the sampling based on composites requires good mixing for controlling the risks. We also note that perfectly mixed samples achieve the lowest consumer's risks in general for a given n_c and n_I. In the next section, we use just the Dirichlet distribution for generating weights since it allows modelling a variety of mixing scenarios with a single parameter.

7.6 Design of the variables sampling plan based on composite samples.

In this section we examine the number of samples to be tested in order to control the producer's and consumer's risks at desired levels for selected combinations of AQL and LQL values for $n_I = 1,4$ and 8. Tables 7.1 and 7.2 in the Appendix show the number of samples to be tested

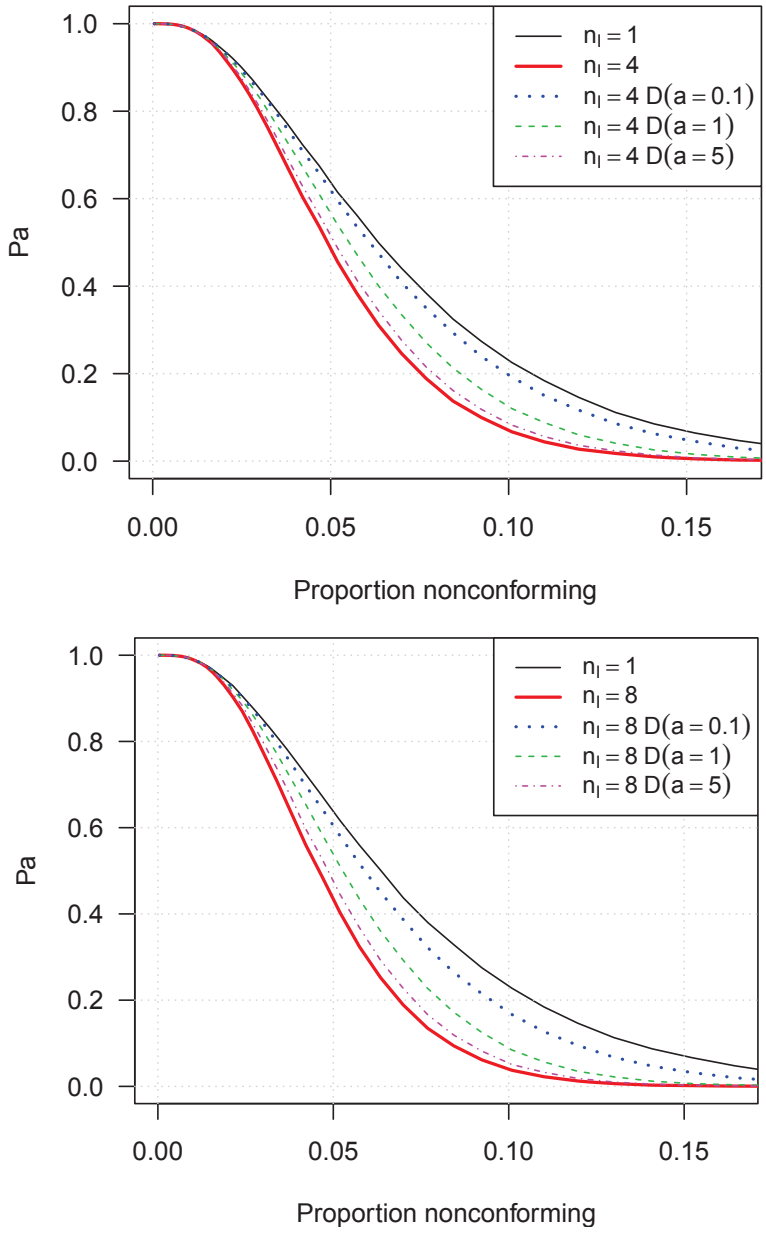

Fig. 7.3 Comparison of the OC curves for $n_c = 20$, $\alpha = 0.01$, $AQL = 0.01$ with $n_I = 1$, 4 and 8. The thin solid line gives the OC curve when the units are tested individually ($n_I = 1$) and the heavy solid line shows the case in which the composite samples are formed under perfect mixing. The other OC curves are associated with imperfect composites described using a Dirichlet distribution with $a = 0.1$ (dotted), $a = 1$ (dashed), and $a = 10$ (dotdash). P_a is the probability of acceptance.

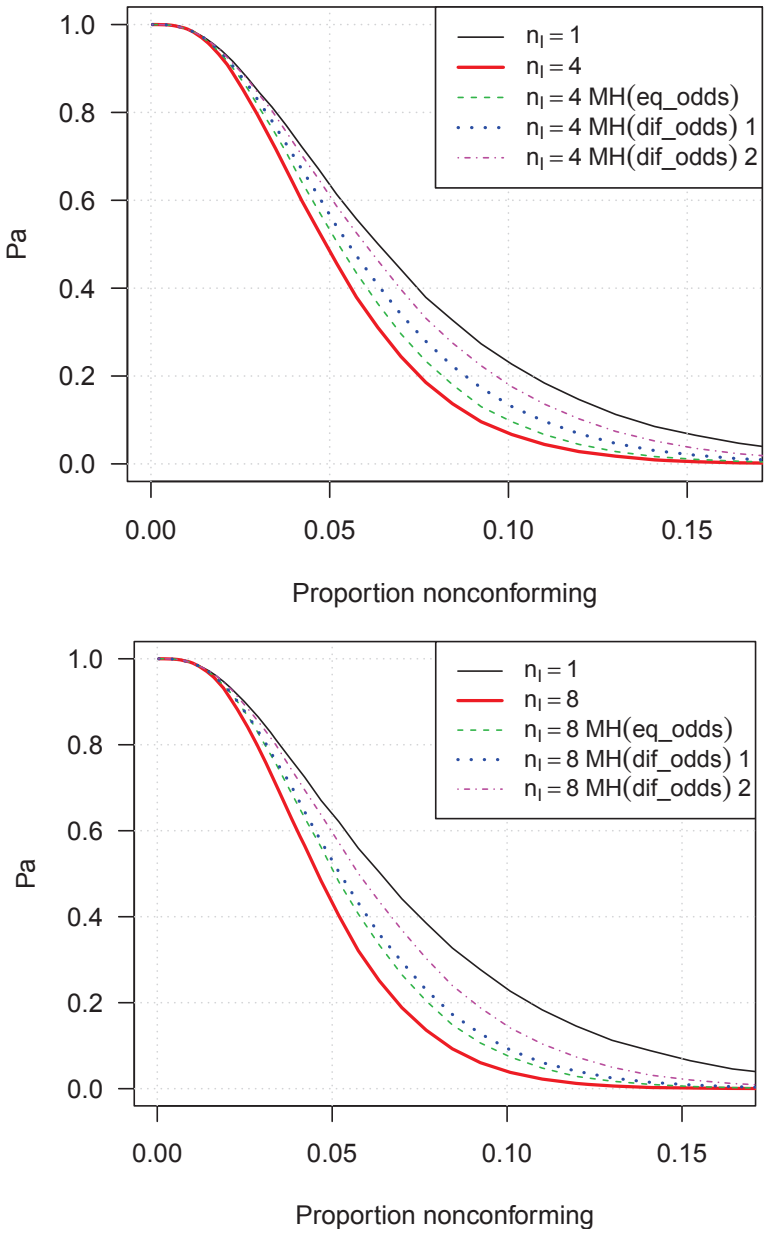

Fig. 7.4 Comparison of the OC curves for $n_c = 20$, $\alpha = 0.01$, $AQL = 0.01$ with $n_I = 1$, 4 and 8. The thin solid line gives the OC curve when the units are tested individually ($n_I = 1$) and the heavy solid line shows the case in which the composite samples are formed under perfect mixing. The other OC curves refer to imperfect mixing with weights described using multivariate central (dashed) and noncentral hypergeometric distribution (dotted and dotdashed).

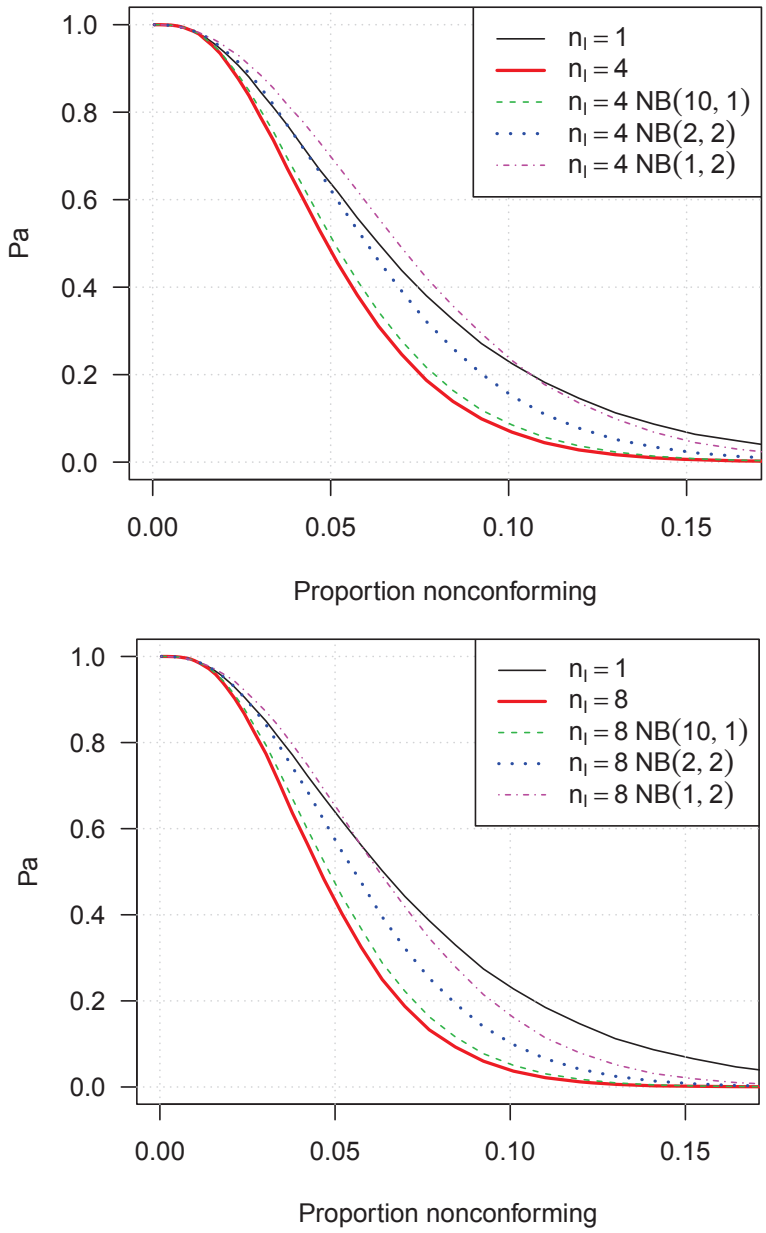

Fig. 7.5 Comparison of the OC curves for $n_c = 20$, $\alpha = 0.01$, $AQL = 0.01$ with $n_I = 1$, 4 and 8. The thin solid line gives the OC curve when the units are tested individually ($n_I = 1$) and the heavy solid line shows the case in which the composite samples are formed under perfect mixing. The other OC curves are associated with imperfect mixing described by negative binomial distribution with shape (d) and scale (b).

for various scenarios (testing using individual units and testing composite samples with perfect and different imperfect mixing conditions). The associated acceptability constants k are given in brackets. The number of samples to be tested n when the units are tested individually follow from the traditional variables plans discussed in textbooks such as Duncan (1986). The reduction in the number of samples that are tested is between 30% to 50% for the variables plans based on composite samples when mixing is assumed to be perfect. However poor mixing does not reduce the sample sizes n_c greatly.

It is well known in the acceptance sampling literature that the closer the quality levels (*AQL* and *LQL*) are, higher the required sample size will be. For example, the sample size requirement for $AQL = 0.01$, $\alpha = 0.01$, $LQL = 0.10$ and $\beta = 0.10$ is less than the sample size required for $AQL = 0.05$, $\alpha = 0.01$, $LQL = 0.10$ and $\beta = 0.10$. For safety characteristics, the *AQL* and *LQL* values cannot be high. But care should be taken to set them apart so that a higher rate of rejection of poor lots can be achieved using small sample sizes. A step-by-step guide for determining the sample size and the acceptability constant is presented in the Appendix.

Table 7.1 Estimates of the required sample size and the critical distance for the lognormal distribution using individual units and composite samples with $n_I = 4$. The contribution for an imperfect mixing is modelled using the Dirichlet distribution.

AQL	*LQL*	α	β	$n_{c1(k)}$	$n_{c2(k)}$	$n_{c3(k)}$	$n_{c4(k)}$	$n_{c5(k)}$
0.001	0.10	0.01	0.10	$13_{(1.965)}$	$9_{(2.864)}$	$12_{(2.092)}$	$10_{(2.521)}$	$9_{(2.751)}$
0.001	0.10	0.05	0.10	$10_{(2.155)}$	$7_{(3.223)}$	$9_{(2.298)}$	$8_{(2.858)}$	$7_{(3.096)}$
0.001	0.15	0.01	0.10	$9_{(1.811)}$	$6_{(2.575)}$	$9_{(1.950)}$	$7_{(2.318)}$	$7_{(2.584)}$
0.001	0.15	0.05	0.10	$7_{(2.013)}$	$5_{(3.022)}$	$7_{(2.199)}$	$6_{(2.714)}$	$5_{(2.903)}$
0.01	0.10	0.01	0.10	$30_{(1.666)}$	$18_{(2.330)}$	$27_{(1.760)}$	$22_{(2.124)}$	$20_{(2.301)}$
0.01	0.10	0.05	0.10	$21_{(1.761)}$	$13_{(2.532)}$	$19_{(1.876)}$	$16_{(2.287)}$	$14_{(2.478)}$
0.01	0.15	0.01	0.10	$18_{(1.515)}$	$10_{(2.052)}$	$16_{(1.593)}$	$13_{(1.894)}$	$11_{(2.028)}$
0.01	0.15	0.05	0.10	$13_{(1.639)}$	$8_{(2.330)}$	$12_{(1.745)}$	$9_{(2.067)}$	$8_{(2.241)}$

Note: $c1$ denotes testing of individual sample units ($n_I = 1$) and $c2$ denotes testing using composite samples under perfect mixing conditions ($n_I = 4$). $c3$, $c4$ and $c5$ correspond to the imperfect mixing ($n_I = 4$) modelled by the Dirichlet distribution with $a = 0.1, 1$ and 5 respectively.

Other statistical models such as the negative binomial (NB) can also be used to describe the weights. However, this case has not been addressed in the literature before. Let $X_1, X_2, ..., X_{n_I}$ be i.i.d. random variables from the NB distribution with density given by:

$$f(x) = \binom{k+x-1}{k} (1-p)^x p^k \tag{7.6}$$

where k and x are the number of successes and failures respectively. As before, define $w_i = x_i / \sum_{j=1}^{n_I} x_j$. The NB model arises as a mixed Poisson-gamma distribution where the Poisson parameter (λ) is distributed as gamma with shape parameter (d) and scale parameter $b = (1-p)/p$. Three possible scenarios of weights (from good to poor mixing) being generated by $NB(d = 10, b = 1)$, $NB(d = 2, b = 2)$ and $NB(d = 1, b = 2)$ were examined.

7.7 Three-class variables plan

The three-class variables plans (Newcombe and Allen, 1988) are an extension of the three-class attribute plans originally introduced by Bray et al. (1973a). In three-class plans for attributes test results are classified as acceptable, marginally acceptable and unacceptable. The ICMSF (2002) considers three-class attributes plans in Cases 1–9. In the three-class variables plans, the lot is sentenced as acceptable if the observed proportion nonconforming and proportion of marginal items are lower than some predefined limits. The advantage of the three-class plan for variables is that it requires a smaller sample size when compared with the three-class plans for attributes (Newcombe and Allen, 1988). Wilrich and Weiss (2009) proposed the three-class sampling by variables for safety characteristics and studied the performance when the density departs form the lognormal model.

Three-class plan for variables involves two microbiological limits $m < M$ (see Fig. 7.6), two critical distances $k_2 < k_1$ and two acceptable quality limits $AQL_1 < AQL_2$. Let p_1 and p_2 be the

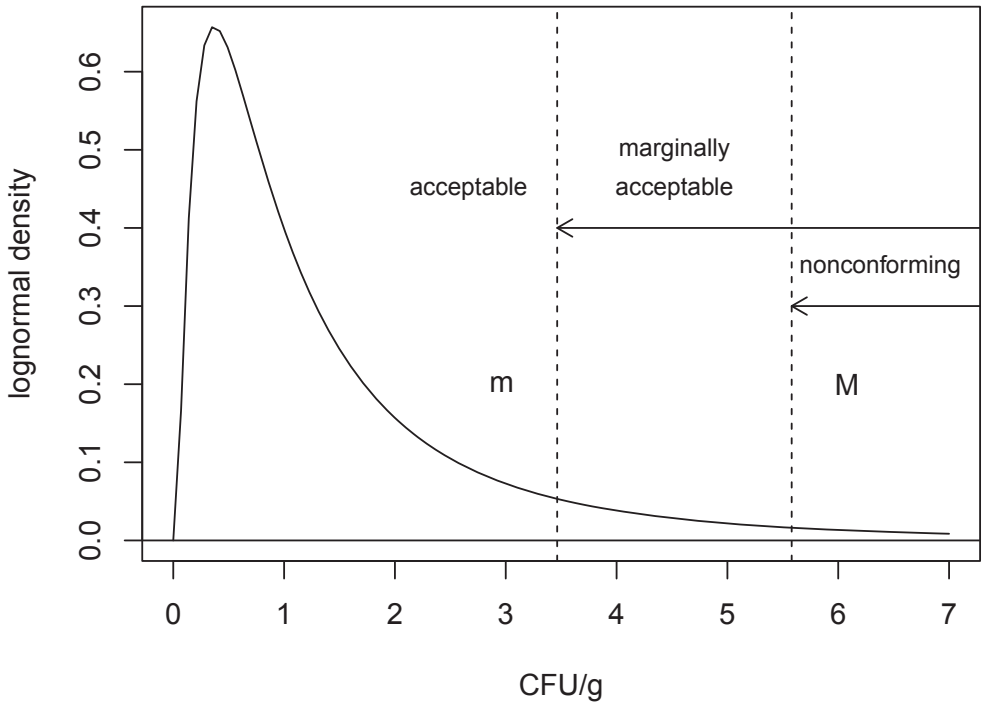

Fig. 7.6 Illustration of the three-class plan using a lognormal distribution with two microbiological limits.

proportion of items exceeding M and m respectively, i.e. the proportion of nonconforming and marginally acceptable items in the lot respectively. The probability of acceptance is given by the joint probability function $Pr\left(\bar{v} + k_1 S_v \leqslant M_v \cap \bar{v} + k_2 S_v \leqslant m_v\right)$. The sampling performance is revealed by the OC surface which is the plot of the proportion nonconforming and marginally

acceptable versus the probability of acceptance of the lot. In a three-class situation after taking *logs* of the cell count, the joint probability distribution of $\bar{v}+k_1S_v$ and $\bar{v}+k_2S_v$ follows a bivariate normal distribution $V \sim \mathcal{N}(\mu, \Sigma)$.

In this section we again use the same Monte-Carlo simulations to estimate the critical distances and compute the probability of acceptance. The algorithm to obtain the OC surface is similar to the algorithm that was introduced in Section 7.5. The main differences are:

- The limits M and m are obtained from AQL_1 and AQL_2 respectively.
- The critical distances k_1 and k_2 are computed as the α-quantile of the Z_M and Z_m statistics replicated at least 50,000 times. The Z_M statistic is similar to Z_m (Eq.7.5), but replacing m_v by $M_v = \log(M)$.
- The probability of acceptance results from the proportion of cases in which both $Z_M \geqslant k_1$ and $Z_m \geqslant k_2$.

Consider the following example. Let the frequencies of pathogens be lognormally distributed, let $n_I = 1$ (individual units), $n_c = 10$, $AQL_1 = 0.001$, $AQL_2 = 0.01$ and $\alpha = 0.01$. The OC contour and surface plot is shown in Fig. 7.7.

To investigate the effectiveness of the use of composite samples with a perfect mixing process, we fixed $n_I = 4$. The resulting OC contour is shown in Fig. 7.8.

For $p_1 = 0.05$ and $p_2 = 0.10$, the consumer's risk is found to be 0.20 for the tests using individual units while the compositing reduces the consumer's risk to about 0.09. Similar reduction was found at other combinations of p_1 and p_2. Let the imperfect mixing of individual units be described using a Dirichlet distribution with $a = 0.1, 1$ and 5. Fig. 7.9, 7.10 and 7.11 show the OC contour plots under these conditions. The use of composite samples does not improve the performance of the plan significantly in comparison with the testing of units individually when $a = 0.1$ (Fig. 7.9). However, when the mixing quality improves (modelled with $a = 1$ and 5), the absolute consumer's risk is reduced by about 5 and 10% respectively. Similar reductions were again found at other combinations of p_1 and p_2.

7.8 Conclusions

In this article we have studied the effect of using composite samples on two and three-class plans for variables when the mixing process is perfect and imperfect. Testing composite samples is a very effective way to reduce the workload when the mixing is perfect; however in some cases the potential saving may not justify the risk of dilution, particularly if the mixing is poor. The decision to opt for composite or individual samples depends on the effectiveness of the physical mixing and the levels of consumer's risks.

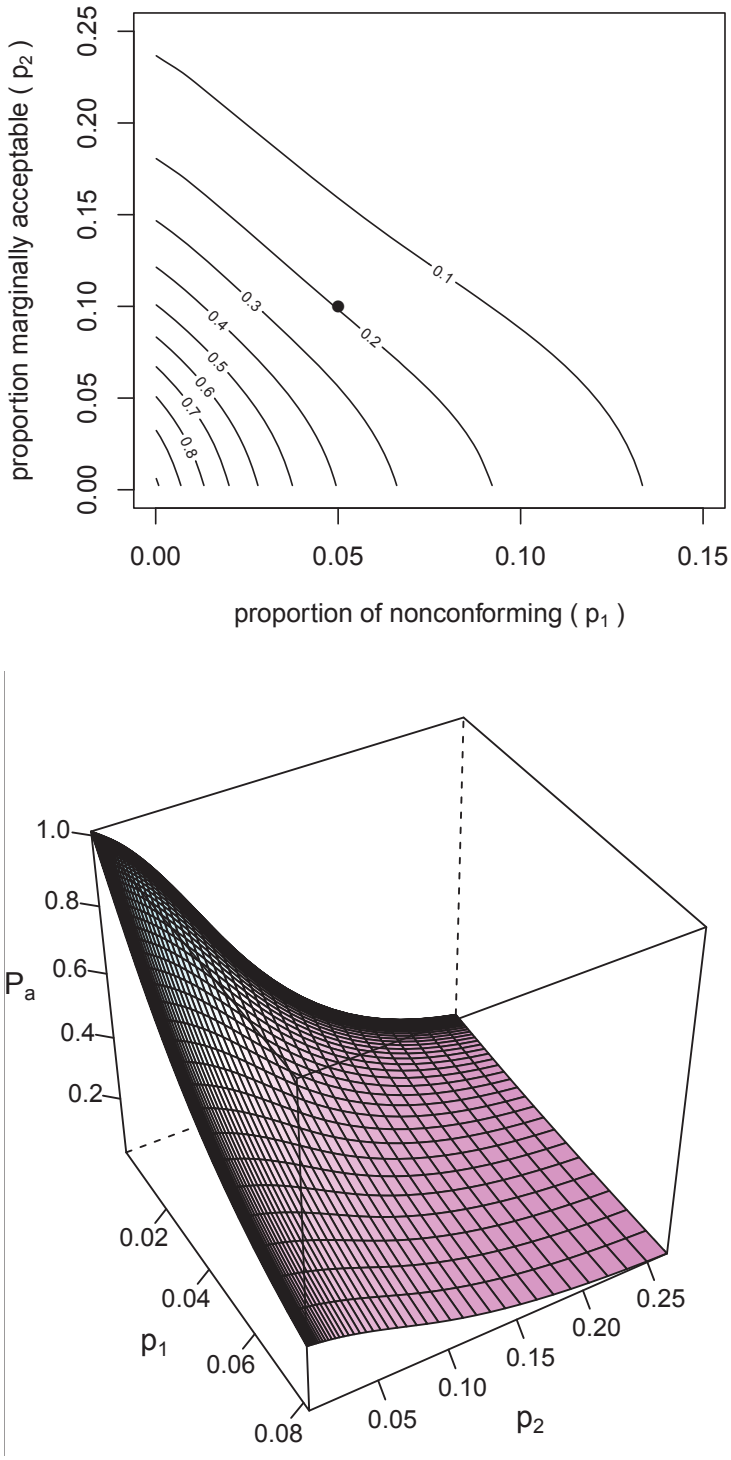

Fig. 7.7 (a) OC contour plot and (b) OC surface of the three-class variables plans using $n_c = 10$ primary samples, $AQL_1 = 0.001$, $AQL_2 = 0.01$ and $\alpha = 0.01$.

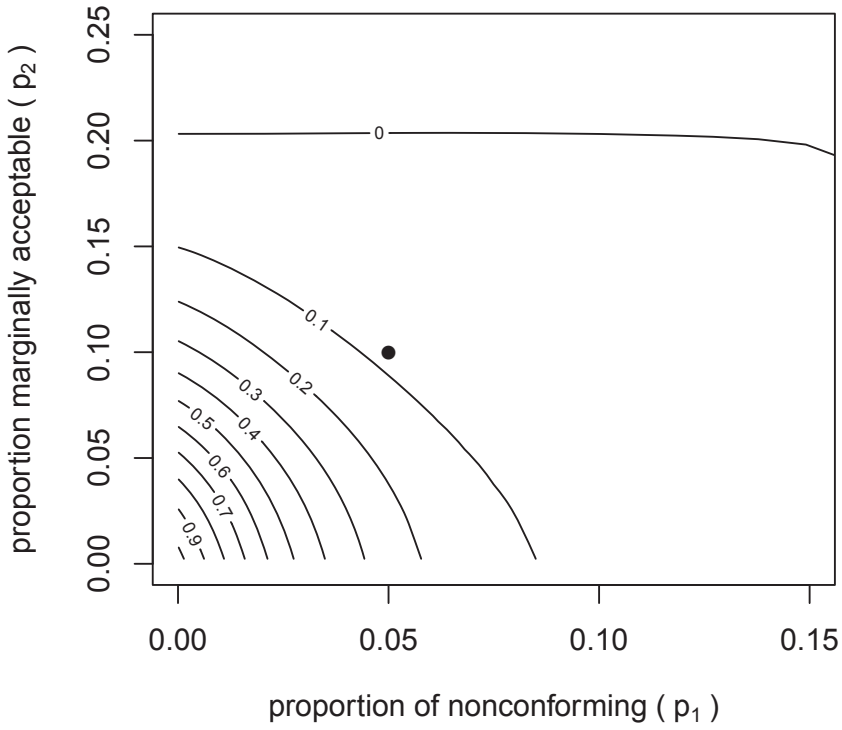

Fig. 7.8 OC contour plot of the three-class variables plans using composite samples assuming a perfect mixing with $n_I = 4$, $n_c = 10$, $AQL_1 = 0.001$, $AQL_2 = 0.01$ and $\alpha = 0.01$.

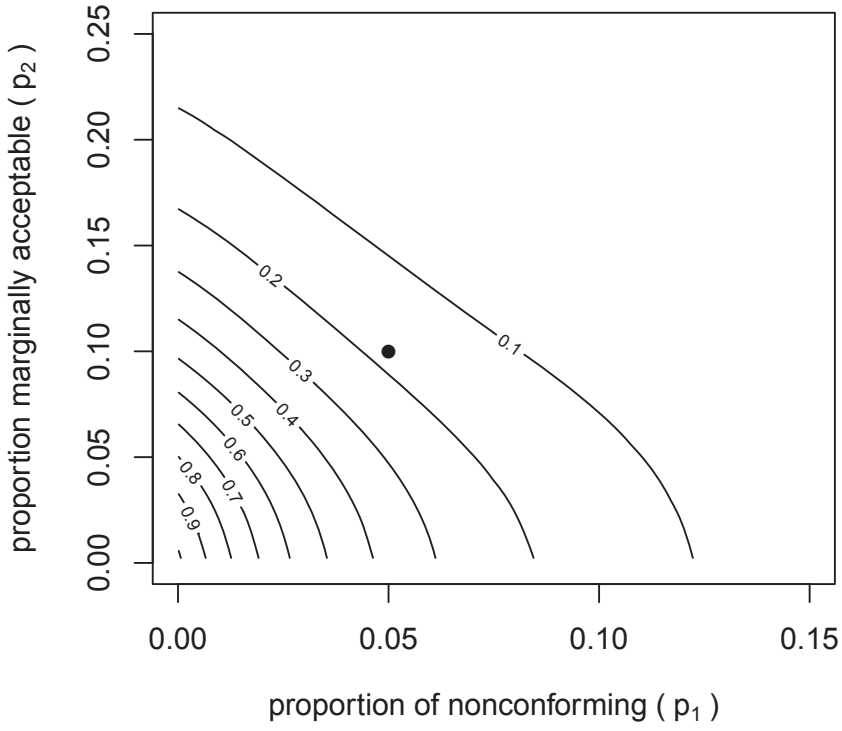

Fig. 7.9 OC contour plot of the three-class variables plans using composite samples assuming the mixing as imperfect with $a = 0.1$, $n_I = 4$, $n_c = 10$, $AQL_1 = 0.001$, $AQL_2 = 0.01$ and $\alpha = 0.01$.

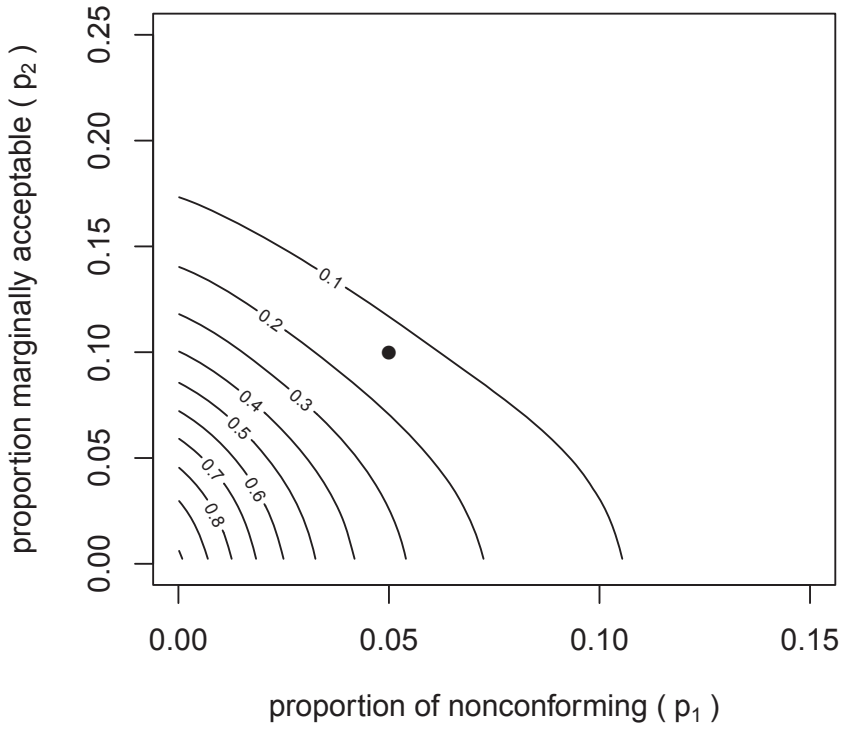

Fig. 7.10 OC contour plot of the three-class variables plans using composite samples assuming the mixing as imperfect with $a = 1$, $n_I = 4$, $n_c = 10$, $AQL_1 = 0.001$, $AQL_2 = 0.01$ and $\alpha = 0.01$.

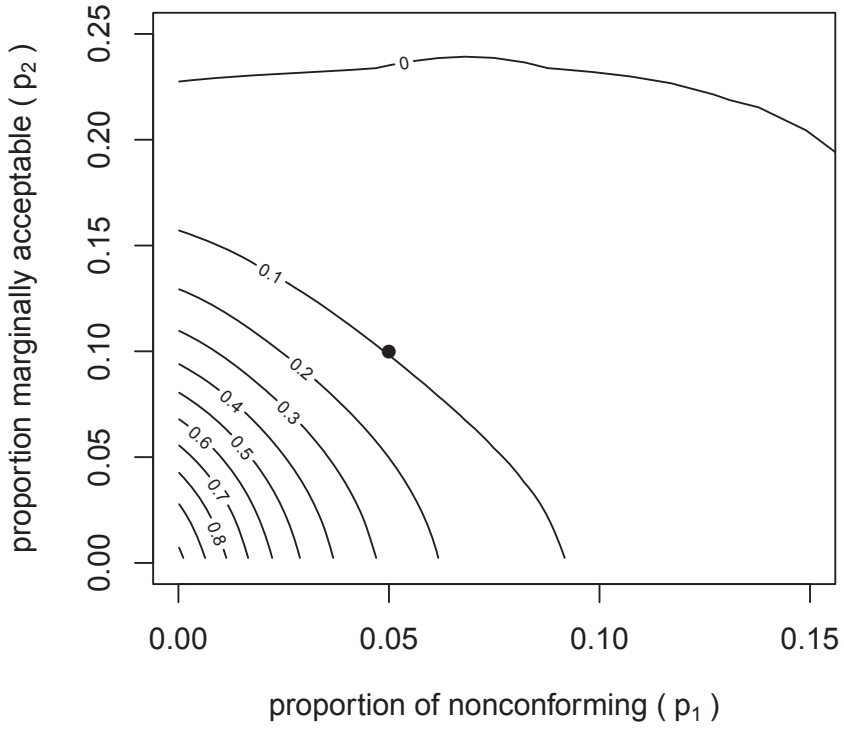

Fig. 7.11 OC contour plot of the three-class variables plans using composite samples assuming the mixing as imperfect with $a = 5$, $n_I = 4$, $n_c = 10$, $AQL_1 = 0.001$, $AQL_2 = 0.01$ and $\alpha = 0.01$.

Appendix 7.A Glossary of symbols and definitions

$D(a)$	Dirichlet distribution
$f(w_1,\cdots,w_{n_I};a_1,\cdots,a_{n_I}) = \frac{\Gamma\left(\sum_{i=0}^{n_I} a_i\right)}{\prod_{i=0}^{1}\Gamma(a_i)} \prod_{i=1}^{n_I} w_i^{a_i-1}$	probability density function
a	concentration parameter
MH	multivariate hypergeometric distribution
$P(X_1 = x_1, X_2 = x_2, ..., X_{n_I} = x_{n_I}) = \frac{\binom{m_1}{x_1}\binom{m_2}{x_2}\cdots\binom{m_{n_I}}{x_{n_I}}}{\binom{m}{n}}$	probability density function
$NB(x,p)$	negative binomial distribution
$f(x) = \binom{k+x-1}{k}(1-p)^x p^k$	probability mass function
$G(d,b)$	gamma distribution
$f(x/d,b) = \frac{1}{\Gamma(d)b^d} x^{d-1}\exp\left(-\frac{x}{b}\right)$	probability density function
d	shape parameter
b	scale parameter
$LN(\mu,\sigma)$	lognormal distribution
$f(x/\sigma,\mu) = \frac{1}{x\sigma\sqrt{2\pi}}\exp\left(-\frac{(\ln(x)-\mu)^2}{2\sigma^2}\right)$	probability density function
μ	logscale
σ	shape parameter
m	upper specification limit or regulatory limit
M	second upper specification limit
$\bar{X} = \sum X_i/n$	sample mean
$S = \sqrt{\sum (X_i - \bar{X})^2/(n-1)}$	sample standard deviation
α	producer's risk
β	consumer's risk
AQL	Acceptance Quality Limit
LQL	Limiting Quality Level
k	acceptability constant (critical distance)
n_I	no. of primary samples (individual units)
n_c	no. of composite samples (each consists of n_I)
p_1	proportion of product exceeding M
p_2	proportion of product exceeding m

Appendix 7.B Sampling plan design

Table 7.2 Estimates of the required sample size and the critical distance for the lognormal distribution using individual units and composite samples with $n_I = 8$. The contribution for an imperfect mixing is modelled using the Dirichlet distribution.

AQL	LQL	α	β	$n_{c1(k)}$	$n_{c2(k)}$	$n_{c3(k)}$	$n_{c4(k)}$	$n_{c5(k)}$
0.001	0.10	0.01	0.10	$13_{(1.965)}$	$8_{(3.698)}$	$12_{(2.282)}$	$10_{(3.134)}$	$8_{(3.461)}$
0.001	0.10	0.05	0.10	$10_{(2.155)}$	$6_{(4.143)}$	$9_{(2.534)}$	$7_{(3.484)}$	$7_{(4.043)}$
0.001	0.15	0.01	0.10	$9_{(1.811)}$	$5_{(3.235)}$	$8_{(2.064)}$	$7_{(2.836)}$	$6_{(3.209)}$
0.001	0.15	0.05	0.10	$7_{(2.013)}$	$4_{(3.801)}$	$6_{(2.332)}$	$5_{(3.268)}$	$5_{(3.796)}$
0.01	0.10	0.01	0.10	$30_{(1.666)}$	$15_{(2.969)}$	$26_{(1.914)}$	$20_{(2.555)}$	$17_{(2.851)}$
0.01	0.10	0.05	0.10	$21_{(1.761)}$	$11_{(3.242)}$	$18_{(2.033)}$	$14_{(2.763)}$	$12_{(3.107)}$
0.01	0.15	0.01	0.10	$18_{(1.515)}$	$9_{(2.650)}$	$15_{(1.715)}$	$11_{(2.232)}$	$9_{(2.468)}$
0.01	0.15	0.05	0.10	$13_{(1.639)}$	$7_{(2.997)}$	$11_{(1.872)}$	$8_{(2.509)}$	$7_{(2.826)}$

Note: $c1$ denotes testing of individual sample units ($n_I = 1$) and $c2$ denotes testing using composite samples under perfect mixing conditions ($n_I = 8$). $c3$, $c4$ and $c5$ correspond to the imperfect mixing ($n_I = 8$) modelled by the Dirichlet distribution with $a = 0.1, 1$ and 5 respectively.

Appendix 7.C Sampling plan guide

The procedure for the two-class composite sampling design for variables design of the two-class variables plan based on composite samples is described in the following guide:

1. Fix the consumer's (LQL, β) and producer's (AQL, α) points.
2. From previous experience or according to the mixing process and type of commodity set the expected concentration parameter (a) in the Dirichlet distribution.
3. Define the number of individual units ($n_I = 4$ or 8). For other n_I values, the sampling plan parameters can be obtained approximately by interpolation.
4. Obtain from Table 7.1 or 7.2 the number of composites to be formed (n_c) and the critical distance (k).
5. Compute the statistic Z_m.
6. Accept the lot if $Z_m \geq k$; otherwise reject it.

Chapter 8

General conclusions and future perspectives.

This thesis was driven by the needs in the food industry for more efficient sampling plans for batch inspection. Several sampling plans with application to food microbiological inspection have been introduced. Issues such as the use of composite samples, compressed limits and analytical unit amounts have been discussed. The techniques developed in this research allow producers, food safety authorities and regulatory agencies to (1) reduce the risk for the consumers (2) utilize smaller sample sizes (3) attain smaller costs and (4) employ easy-to-use free software. The design of several inspection plans has been discussed and step-by-step guidance has been given. Both frequentist and Bayesian approaches have been used. Moreover, the computational codes have been published and several apps have been developed. Some of the chapters contain data analysis mostly for parameters estimation needed for assessing risks.

More specifically, Chapter 2 studied the risk as a function of the analytical unit amount for isolated and streams of lots. The effects of heterogeneity are also examined in attributes and variables plans. Chapter 3 aimed at the application and extension of the compressed limit theory to food safety problems. This chapter introduced a novel three-class compressed limit plan and discussed the zero acceptance number sampling plans, both with potential use in the food industry. A double sampling plan by attributes intended for bacterial counts was introduced in Chapter 4. This plan that is based on the compressed limit theory is the first double plan (to the best of our knowledge) that matches the zero acceptance number plan. Measurement error is one of the main issues in microbial testing. The effects of imperfect testing are studied in Chapter 5. Bayesian inference was used to estimate prevalence jointly with the test's sensitivity and specificity. The design of more suitable sampling plans in terms of risk and cost is addressed. A novel variables sampling plan for lognormally distributed variables was introduced in Chapter 6. The properties, benefits and demerits of this plan are discussed. Finally, Chapter 7 was dedicated to studying the use of composite samples in plans by variables. The sampling design is given for different composite scenarios. It showed the benefits of compositing rather than testing primary units under certain conditions.

8.1 Future plan of work

Assurance of safety primarily warrants compliance to multiple food safety regulations and consumers specific characteristics. Some bacteria pertain to common families and often association or correlation can be established. Some microorganism indicators have been linked to high chances of pathogen contamination. Future studies should explore: (1) these connections and associations, (2) statistical models to better characterize the risk, (3) the design of more efficient sampling plans including multivariate alternatives.

Testing for pathogens usually comprises a pre-enrichment stage, which allows the recovery or resuscitation of the cells. For instance, ISO 22964 (2006) is the standard for the detection of *Enterobacter* sakazakii. Decimal dilutions are usually prepared using test portions or analytical amounts of 10g or 300g for the pre-enrichment stage. Theoretically increasing the analytical amounts in this stage will yield a higher probability of detecting the target cell if the pathogen is present in the batch. However, the trade-off is that a higher volume might need higher incubation time to allow the cell multiply over the limit of detection. See the comments in this regards given by Ross et al. (2011). This and other issues need further theoretical work and validation.

Much of the risk assessment relies on the correctness of the statistical model. In pathogen detection, the tests are generally presence/absence, where the positives results are reported as 'detected'. In the absence of numerical results, it becomes difficult to find suitable statistical models and appropriate parameters for fitting the frequencies of cells. Moreover, the actual testing regime does not allow a proper spatial characterization of the occurrence of contamination. There is a need for studies revealing the spatial contamination in nonconforming and recalled batches. More effort should be put into making microbiological datasets publicly available. The sampling inspection plans discussed in this research may have to be tailored differently in future work for other food industries and processes.

Summing up, the uncountable sources of variation found from sample collection to laboratory testing and emerging issues in food safety make microbiological acceptance sampling a fertile territory for future research and development.

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Appendix A

Contributions to publications

DRC 16

MASSEY UNIVERSITY
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STATEMENT OF CONTRIBUTION TO DOCTORAL THESIS CONTAINING PUBLICATIONS

(To appear at the end of each thesis chapter/section/appendix submitted as an article/paper or collected as an appendix at the end of the thesis)

We, the candidate and the candidate's Principal Supervisor, certify that all co-authors have consented to their work being included in the thesis and they have accepted the candidate's contribution as indicated below in the *Statement of Originality*.

Name of Candidate: Edgar Santos-Fernández

Name/Title of Principal Supervisor: Dr. K. Govindaraju

Name of Published Research Output and full reference:

Santos-Fernández, E., Govindaraju, K., and Jones, G. (2016). Quantity-based microbiological sampling plans and quality after inspection. Food Control,63:83–92

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