Food Control 50 (2015) 530–538

Contents lists available at ScienceDirect

Food Control

journal homepage: www.elsevier.com/locate/foodcont

Variables sampling plans using composite samples for food quality assurance

Edgar Santos-Fernández*, K. Govindaraju, Geoff Jones

Institute of Fundamental Sciences, Massey University, Private Bag 11222, Palmerston North, 4442, New Zealand

ARTICLE INFO

Article history:
Received 6 May 2014
Received in revised form
18 September 2014
Accepted 24 September 2014
Available online 8 October 2014

Keywords:
Food safety
Composite samples
Imperfect mixing
Sampling plan

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.

1. 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/GL 50 (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, Aspinall, and Baird-Parker (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. 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.

* Corresponding author.
E-mail addresses: e.santosfernandez@massey.ac.nz, edgar.santosfdez@gmail.com (E. Santos-Fernández), k.govindaraju@massey.ac.nz (K. Govindaraju), g.jones@massey.ac.nz (G. Jones).

http://dx.doi.org/10.1016/j.foodcont.2014.09.041
0956-7135/

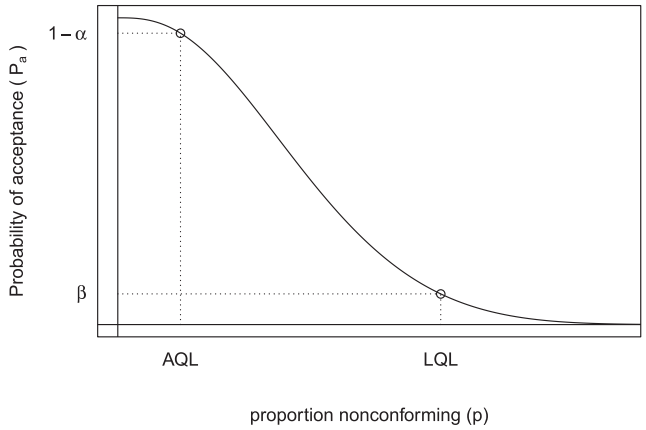

Fig. 1. Illustration of the Operating Characteristic (OC) curve.

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) 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 2 by examining the use of composite samples for food quality assurance. In Section 3 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 4, while in Section 5 we provide the design of a variables plan for composite samples. In Section 6 we analyse 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, 2014). Dirichlet and multivariate hypergeometric random numbers were generated using the `R`-packages `gtools` (Warnes, Bolker, & Lumley, 2013) and `BiasedUrn` (Fog, 2013), respectively.

2. 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, Fratamico, Jaykus, & Zwietering, 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/GL 50 (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 (2012) 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, Griffith, and Edland (2001), El-Baz and Nayak (2004), Jonkman, Gerard, and Swallow (2009), etc. In other words, it is assumed that.

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

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. 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. $n_I = 2$–10). Higher values of n_I are not considered due to the risk of dilution. Presence–absence type of attribute testing normally

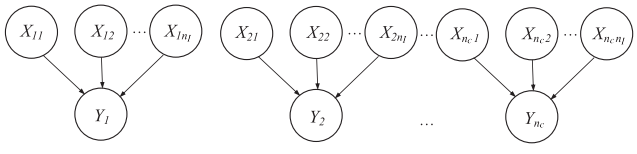

Fig. 2. Formation of n_c composite samples each one by mixing n_I primary samples.