Introduction to Sampling Plan Design and Performance Considerations

Definition of a Sampling Plan

It is important to be able to detect and quantify the mycotoxin concentration in foods and feeds destined for human and animal consumption. In research, quality assurance, and maximum activities, correct decisions concerning the fate of commercial lots can only be made if the mycotoxin concentration in the lot can be made with a high degree of accuracy and precision. The mycotoxin concentration of a bulk lot is usually estimated by measuring the concentration in a small portion of the lot or a sample taken from the lot **(Figure 1)**.

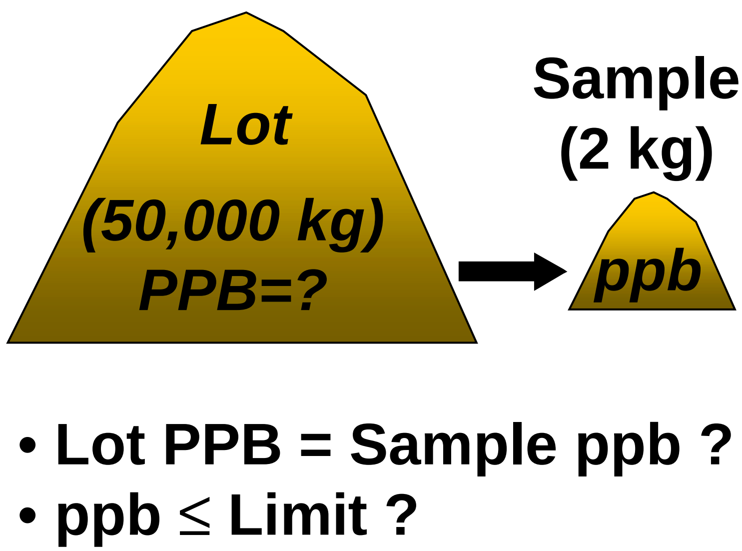

Figure 1. Lot mycotoxin concentration is assumed to equal the measure mycotoxin concentration in a small sample.

The mycotoxin concentration in the bulk lot is assumed to be the same as the measured mycotoxin concentration in the sample. Then based on the measured sample concentration, some decision is made about the edible quality of the bulk lot or the effect of a treatment or a process on reducing the mycotoxin concentration in the lot. For example, decisions will be made to classify the lot as acceptable or unacceptable based upon a comparison of the measured sample concentration to a maximum limit. If the sample concentration does not accurately reflect the lot concentration, then the lot may be misclassified and there may be undesirable economic and/or health consequences. Fortunately, sampling plans can be designed to minimize the misclassification of lots and reduce the undesirable consequences associated with decisions about the fate of bulk lots.

A sampling plan is defined by a mycotoxin test procedure and a defined accept/reject limit. A mycotoxin test procedure is a multi-stage process (**Figure 2**) and generally consists of three steps: sampling, sample preparation, and analysis (quantification).

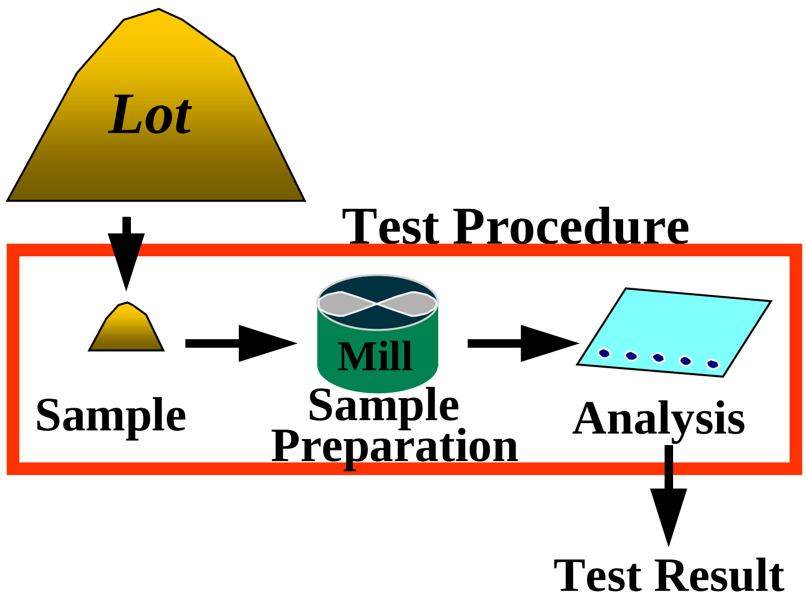

Figure 2. A mycotoxin test procedure usually consists of a sampling, sample preparation and analytical step.

The sampling step specifies how the sample will be selected or taken from the bulk lot, the number of samples, and the size of the sample(s). For granular products, the sample preparation step is also a two-part process where the sample is ground in a mill to reduce particle size and an analytical subsample is removed from the comminuted sample. Finally in the analytical step, the solvent extracted from the comminuted analytical subsample is quantified using approved analytical procedures.

The measured mycotoxin concentration in the sample is used to estimate the true mycotoxin concentration in the bulk lot or compared to a defined accept/reject limit that is usually equal to a maximum limit. Comparing the measured mycotoxin concentration in the sample to an accept/reject limit is often called acceptance sampling because the measured concentration value is not as important as whether the measured mycotoxin concentration (and thus the lot mycotoxin concentration) is above or below a maximum limit. In food processing activities, a precise and accurate estimate of the true lot concentration becomes important.

Designing sampling plans

Because of the variability among sample test results, two types of mistakes are associated with any sampling plan. First, good lots (lots with a true mycotoxin concentration less than or equal to the maximum limit) will test bad and be rejected by the sampling plan. The chances of making this type of mistake is often called the sellers' risk (false positives) since these lots will be rejected at an unnecessary cost to the seller of the product. Secondly, bad lots (lots with a mycotoxin concentration greater than the maximum limit) will test good and be accepted by the sampling program. The chances of making this type of mistake is called the buyers' risk (false negatives) since contaminated lots will be processed into feed or food causing possible health problems and/or economic loss to the buyer of the product. In order to maintain an effective quality control program, the above two risks associated with a sample plan design must be evaluated (**Figure 3**) and minimized to acceptable levels. Based upon these evaluations, the costs and benefits (benefits refers to removal of mycotoxin contaminated lots) associated with a mycotoxin sampling plan need to be evaluated.

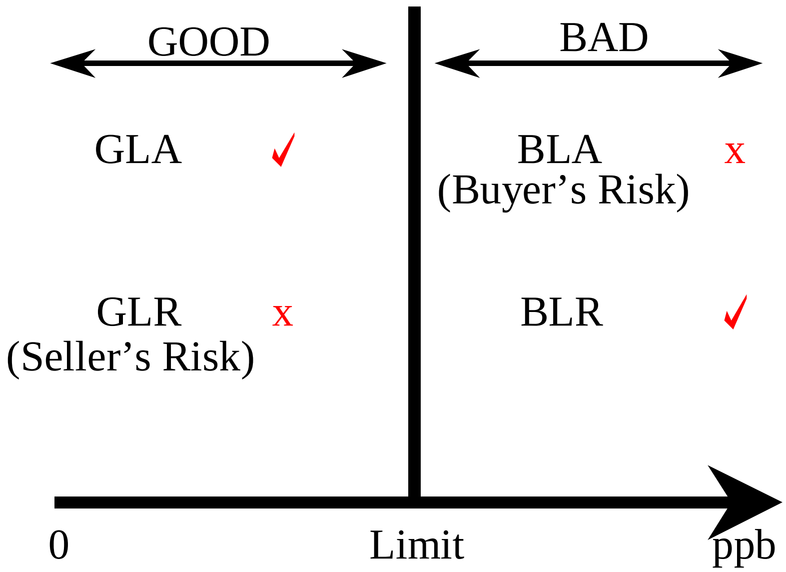

Figure 3. Four possible outcomes when classifying lots as good or bad. Good lots rejected (GLR) and bad lots accepted (BLA) are incorrect decisions. Good lots accepted (GLA) and bad lots rejected (BLR) are correct decisions.

A lot is termed bad when the sample test result C_s is above some predefined accept/reject limit C_a and the lot is termed good when C_s is less than or equal to C_a . While C_a is usually equal to the maximum limit C_L, C_a can be greater than or less than C_L. For a given sample design, lots with a concentration C will be accepted with a certain probability $P(C)=prob(C_s < C_a \mid C)$ by the sampling plan. A plot of P(C) versus the lot concentration C is called an operating characteristic (OC) curve. **Figure 4** depicts the general shape of an OC curve.

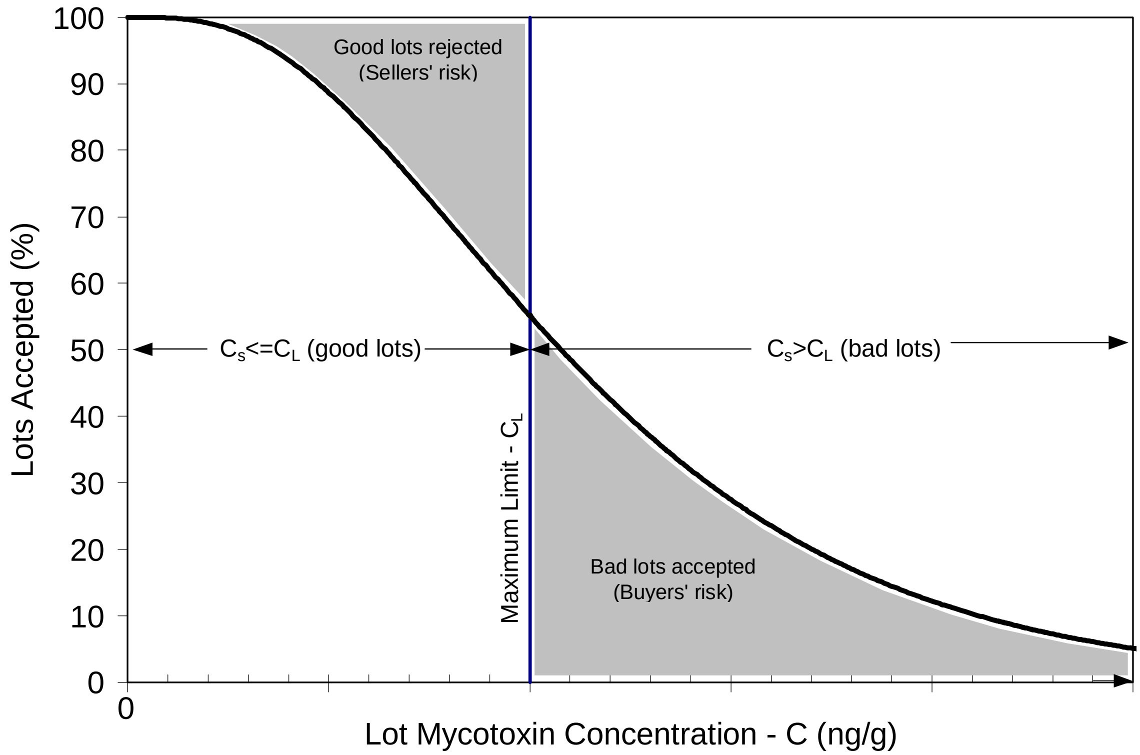

Figure 4. General shape of an operating characteristic (OC) curve. The shape of the OC curve is unique for an mycotoxin test procedure and indicates the magnitude of the buyers' and sellers' risks.

As C approaches 0, P(C) approaches 1 or 100%, and as C becomes large, P(C) approaches zero. Lots with little to no contamination (C =0) are accepted by the sampling plan 100% of the time; lots with very high levels of contamination (C = large) are never accepted (rejected 100% of the time) by the sampling plan; lots with contamination levels near the accept/reject limit are accepted by the sampling plan less than 100% of the time. The shape of the OC curve is uniquely defined for a particular sampling plan design with designated values of sample size, degree of comminution, subsample size, type analytical method, and number of analyses, and the accept/reject limit C_a.

Reducing Misclassification of Treenut Lots

Increasing Sample Size - Reducing the variability or uncertainty associated with the mycotoxin test procedure will reduce the number of lots misclassified and thus reduce both the buyers' risk and the sellers' risk. The uncertainty of the mycotoxin test procedure can be reduced by increasing sample size, grinding the sample into smaller particles, increasing the analytical subsample size, quantifying more aliquots, and using a more precise analytical method such as LC instead of TLC. Because the sampling step accounts for a large portion of the total variability, it is more effective to reduce uncertainty of the mycotoxin test procedure by increasing sample size.

Changing Accept/reject Limit – Changing the accept/reject limit relative to the maximum limit can also be used to reduce either the sellers' risk or the buyers' risk, but not both risks at the same time. When the accept/reject limit is equal to the maximum limit, both the buyer and the seller share in the risks associated with the sampling plan. If the accept/reject limit is reduced to a value below the maximum limit, the OC curve shifts to the left and the area representing the sellers' risk increases and the buyers' risk decreases. If the accept/reject limit is larger than the maximum limit, the OC curve shifts to the right and the area representing the buyers' risk increases and the sellers' risk decreases.

Multiple Samples - Increasing the number of samples of a given size taken from a contaminated lot reduces the risks associated with classifying lots. If the mycotoxin concentration among all sample test results is averaged, the effect is the same as increasing sample size. However, if all sample test results are required to test less than the accept/reject limit, the effect on the OC curve is very different from averaging multiple sample test results. As the number of samples required to test less than or equal to the accept/reject limit increases, the OC curve shifts to the left reducing the buyers' risk but increasing the sellers' risk. The result is similar to reducing the accept/reject limit relative to the maximum limit. This type of sampling plan is often used late in the marketing system on finished product destined for animal or human consumption because the product has a smaller chance of containing a concentration above the maximum limit. The buyer is placing most of the risk on the sell of the product.

Links: Performance of Aflatoxin Sampling Plan Designs for Treenuts

OC Curves for Almonds

OC Curves for Hazelnuts

OC Curves for Pistachio Nuts