Chapter 2
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 regulatory activities, correct decisions concerning the fate of commercial lots can only be made if the mycotoxin concentration in the lot can be estimated with a high degree of accuracy and precision. The mycotoxin concentration of a lot is usually estimated by measuring the mycotoxin concentration in a small representative sample taken from the lot, called the laboratory sample[1] (Fig. 2.1).

Then, based on the measured laboratory sample concentration, a decision is made about the quality of the lot. For example, in a regulatory environment, decisions will be made to classify the lot as acceptable or unacceptable based upon a comparison of the measured sample concentration to a legal limit (the term "sample" by itself in this manual refers to a laboratory sample). 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 regulatory decisions about the fate of bulk lots. In this manual, sampling plans will be defined, sources of uncertainty associated with a mycotoxin sampling plan will be identified, risks associated with misclassifying lots will be discussed, and methods that reduce misclassification of lots will be described.

A mycotoxin-sampling plan is defined by a mycotoxin test procedure and a defined accept/reject limit. A mycotoxin-test procedure is a multi-stage process (Fig. 2.2) and generally consists of three steps: sampling, sample preparation, and analysis (quantification).

[1]Laboratory sample: smallest size sample comminuted in a grinder (Food and Agriculture Organization 2001b).

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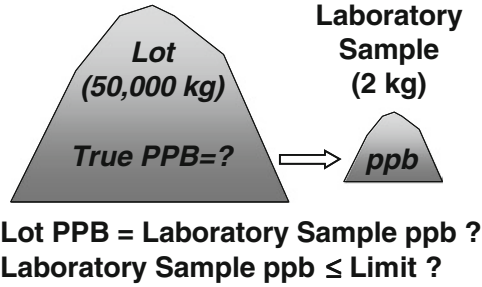

Fig. 2.1 Lot mycotoxin concentration is assumed to equal the measured mycotoxin concentration in a representative laboratory sample

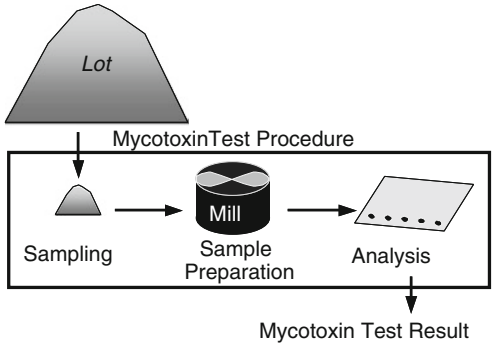

Fig. 2.2 A mycotoxin-test procedure usually consists of a sampling, sample preparation and analytical steps

The sampling step addresses issues such as when, how, how many. It 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, sample preparation includes the processing of the laboratory sample (i.e. grinding in a mill to reduce particle size) and the selection of a test portion, which is removed for subsequent analysis. Finally, in the analytical step, the mycotoxin is solvent extracted from the test portion and quantified using validated analytical procedures.

The measured mycotoxin concentration in the test portion 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 or regulatory limit. It is, therefore, important that the sampling procedure defines a laboratory sample that is as representative as possible of the bulk lot. Comparing the measured concentration in a test portion taken from a laboratory sample to an accept/reject limit is often called acceptance sampling because the actual measured concentration is not as important as whether that concentration, and thus the lot concentration, is above or below a legal limit. In activities other than regulatory acceptance sampling, for example in quality assurance or research, a precise and accurate estimate of the true lot mycotoxin concentration may be required.

According to Codex STAN209-1999, Rev. 1-2001 on "Maximum level and sampling plan for total Aflatoxins in peanuts intended for further processing" (Food and Agriculture Organization 2001b) and the Commission regulation (EC) 401/2006, on "Methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuff" (Commision regulation (EC) 401/2006) each lot of materials which is to be examined must be sampled separately. Large lots should be subdivided into sublots[2] to be sampled separately. The subdivision can be done following the provisions laid down in Table 2.1.

Table 2.1 Subdivision of large lots into sublots for sampling

Lot Weight Tonne (T)	Weight or Number of Sublots	Number of Incremental Samples	Aggregate Sample Weight (kg)	Laboratory Sample Weight (kg)	Weight of Incremental Samples (g)
Peanuts (CODEX Standard)					
≥500	100 tonnes	100	20	20	
>100 and <500	5 sublots	100	20	20	
>25 and ≤100	25 tonnes	100	20	20	200
>15 and ≤25		100	20	20	
<15		10–100	≤20	20	
Groundnuts, pistachios, brazil nuts and other nuts (EC Regulation)					
≥500	100 tonnes	100	30	3 × 10 kg[a]	
>125 and <500	5 sublots	100	30	3 × 10 kg	
≥15 and ≤125	25 tonnes	100	30	3 × 10 kg	300
<15		10–100	≤30	3 × 10 kg	

[a]The division into three laboratory samples is not necessary in case of groundnuts and nuts subjected to further sorting or other physical treatment and of the availability of equipment which is able to homogenise a 30 kg sample.

[2]Sublot: designated part of a large lot in order to apply the sampling method on that designated part. Each sublot must be physically separate and identifiable.

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