

The importance, for regulation, of uncertainty from sampling

In many regulated sectors where analysis is required (for example, soil, water, air, food, and animal feed), decisions are based on the composition of a sample. It has long been known (although seldom acknowledged) that samples are never *strictly* representative—they differ from the target¹ and from each other, giving rise to uncertainty from sampling. Hitherto this uncertainty term has been ignored, a simplistic strategy with the potential to produce flawed decisions. Now new guidance has been developed by Eurachem [1]. The Guide shows how the uncertainty arising from sampling can be effectively addressed. This Technical Brief draws attention to the implications of sampling uncertainty for policy making, and demonstrates how the Eurachem Guide is relevant to the reliability of regulatory decisions.

What is uncertainty from sampling?

When a regulatory decision is made on a batch of material it is usually necessary to know its composition, often in terms of a few key components (e.g., aflatoxin in nuts, or cadmium in soil). For this purpose a sample is taken to represent the batch. Traditional practice has regarded samples taken by a standard method as representative, effectively contributing zero uncertainty to the measurement result. However, it is easy to demonstrate that repeat samples vary in composition, and often to an

sampling uncertainty for

the regulators?

The uncertainty arising from sampling is sometimes much larger than the known contribution from the chemical analysis but has hitherto been unrecognised or not accounted for. Using the smaller estimate of uncertainty, based only on the chemical analysis, control authorities could be mistaken in assuming that a batch of a commodity is compliant with a legislative specification for (say) a contaminant. If the real value of uncertainty is much larger, then it is possible that the true concentration of the contaminant in the batch is greater than the legislative specification (Figure 1). This could lead to litigation and loss of reputation for those involved if the batch were found subsequently to be non-compliant. The legislators need to decide whether to incorporate sampling uncertainty into regulation and, if so, how to specify the decision rules on compliance.

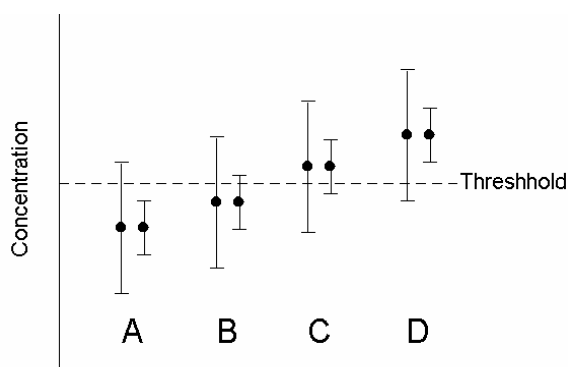


Figure 1. Schematic representation of how the uncertainty intervals (error bars) surrounding measurement results (€) affect the classification of batches of material against a regulatory threshold. A naive estimate of uncertainty, based only on

chemical analysis (shorter error bars) would result in the acceptance of Batch A as having a concentration of a contaminant below the threshold for rejection. The true uncertainty, including the contribution from sampling (longer error bars) shows that there is a chance that the concentration of the contaminant exceeds the threshold: the batch should be considered for rejection or at least investigated further. The classification of Batches B and C is not affected by the different approaches to uncertainty estimation. For Batch D, we see that the naive estimate of uncertainty would result in the conclusion that the batch was definitely contaminated. However, the new estimate (including a contribution from sampling) shows that the concentration of the contaminant in the batch could be below the threshold. In a sector where the over-riding consideration is “beyond reasonable doubt”, the inclusion of the sampling uncertainty would result in Batch D being considered compliant with the legislative specification.

What are the *benefits* of recognising and quantifying sampling uncertainty?

The benefits to the regulator of quantifying this uncertainty are that decisions on compliance will be