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CORRESPONDENCE

Sampling in the context of conformity assessment

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Dear Editor,

EU official control laboratories (likewise in other regulatory schemes) are mandated to test products and services in order to assess their compliance towards specified requirements. Such laboratory activities must be accredited to ISO/IEC 17025 [1]. Their fitness for purpose is demonstrated by a set of performance characteristics fulfilling predefined requirements. The measurement procedure used must be properly validated [1].

Several international organisations (ISO, CEN, AOAC Int., IUPAC and EURACHEM) provide guidance on how to validate measurement procedures. These studies are, most commonly, carried out using sufficiently homogeneous materials, such as certified reference materials (when available), reference materials or in-house materials (e.g. spiked blank matrices), containing the relevant content of the analyte to be investigated. However, real laboratory samples are generally far less homogeneous than these surrogate materials. Further testing must be done, and measurement uncertainty reassessed, before including these (routine) laboratory samples into the (analytical) scope of a given measurement method.

When testing samples for compliance assessment, sampling must be recognised [1] as part of the overall measurement procedure. This not only to include the effects of analyte heterogeneity in primary and laboratory samples, but also to include all sources of uncertainty throughout the whole measurement process.

Regarding sampling, the following issues should be considered:

- Sampling plans and sampling procedures shall be designed to "ensure the validity of subsequent testing or calibration results" [1].
- A primary sample is taken for subsequent testing as it is seldom feasible (even realistic) to test the complete sampling target, such as the full lot/batch of a food commodity.
- The much-used term "representative sample" is not appropriate for use in the modern context of data quality and decision-making. It reflects only the sampler's intention, not the qualities of the resultant sample. A preferred term is "appropriate sample", to which a numeric uncertainty component estimate can be attached. (*Note: use of the term "uncertainty from sampling" apparently deviates from the earlier idea of uncertainty as the property of the result of a measurement, and is therefore better expressed as "measurement uncertainty component due to sampling"*).
- "Appropriate sampling" is sampling that is fit for its intended purpose, rather than fully representative [2, 3]. Representative sampling has been defined so that a "random sample selected in such a way that the observed values have the same distributions in the sample as in the population" [4]. In contrast, appropriate sampling enables reported measurement results that have their associated uncertainty that make them fit-for-purpose. In that way, appropriate samples are sufficiently representative to achieve their stated purpose.
- An "appropriate sample" ensures that when the uncertainty from sampling is combined with the uncertainty component arising from testing, it fits its intended purpose. Appropriate sampling recognises that the sampling process contributes to the measurement uncertainty (MU), whereas representative sampling is often used to imply that the MU only arises from the analytical process.
- The composition of a primary sample taken from a heterogeneous "sampling target" differs from the mean composition of the whole target. An "appropriate sample" should be unbiased in the sense that the mean composi-

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tion of *n* successive samples should approach the mean composition of the target as *n* increases. This condition can be achieved only in terms of a fixed sampling protocol, of which the implementation can be randomised in space or time. Strictly speaking, only random samples can be unbiased and can have a meaningful uncertainty attached.

- Successive samples, collected from a heterogeneous "target" according to a randomised protocol (that is, unbiased samples), differ in composition among themselves. The variance of the measured values is an unbiased estimate of the square of the standard uncertainty but excludes systematic effects, such as sampling bias. The between-sampler bias can be included in the uncertainty estimate by using measurement made on the target by multiple samplers [5]. However, none of these estimates are true values of the measurement uncertainty, but the confidence interval within which the true value lies can be calculated [6].
- In statements of conformity (of a given target/lot/batch) to a specification or standard, the decision rule employed must refer to the sampling target, not to an individual laboratory sample taken from it and received in the testing laboratory.

Therefore, the concept of "appropriate sample" is of paramount importance. Ignoring the uncertainty contribution from sampling will often jeopardise the conformity assessment supported by decision rules based on a reliable estimate of the total uncertainty associated with a measured value [7–9].

Having regard to the above, the following statement should be included in validation reports as an awareness message to laboratory managers, regulators and accreditation bodies:

> "In compliance assessment, decision rules must be based on complete measurement uncertainty estimates, including the sampling component".

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Declarations

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