ANNEX II

REFERENCE MATERIAL

The reference material as referred to in Articles 5(3)(j) and 17(3)(j) of Regulation (EC) No 1829/2003 shall be produced in accordance with internationally accepted technical provisions such as ISO Guides 30 to 34 (and more particularly ISO Guide 34, specifying the general requirements for the competence of reference material producers). The reference material shall be preferably certified and, if such is the case, certification shall be done in accordance with ISO Guide 35.

For verification and value assignment, a method that has been properly validated (see ISO/IEC 17025:5.4.5) shall be used. Uncertainties have to be estimated according to GUM (ISO Guide to the Expression of Uncertainty in Measurement: GUM). Major characteristics of these internationally accepted technical provisions are given below.

A. Terminology:

reference material (RM): material or substance, one or more of whose property values are sufficiently homogenous and well-established to be used for calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials;

Certified reference material (CRM): reference material, accompanied by a certificate, one or more of whose property values are certified by a procedure which establishes its traceability to an accurate realisation of the unit in which the property values are expressed, and for which each certified value is accompanied by an uncertainty at a stated level of confidence.

B. GM RM containers:

— GM RM container (bottles, vials, ampoules, etc.) must be tight and contain not less than the stated amount of material,

— samples must have appropriate homogeneity and stability,

— the commutability of the GM RM has to be assured,

— packaging must be appropriate to the purpose,

— labelling must be of good aspect and quality.

C. Homogeneity testing:

between-bottle homogeneity must be examined;

any possible between-bottle heterogeneity must be accounted for in the overall estimated RM uncertainty. This requirement applies even when no statistically significant between-bottle variation is present. In this case, the method variation or the actual calculated between-bottle variation (whichever is larger) must be included in the overall uncertainty;

D. Stability testing:

stability must be positively demonstrated by appropriate statistical extrapolation for the GM RM shelf-life to be within the stated uncertainty; the uncertainty related to this demonstration is normally part of the estimated RM uncertainty;

assigned values are valid only for a limited time and must be subject to a stability monitoring.

E. Batch characterisation:

the methods used for verification and for certification must:

— be applied under metrologically valid conditions,

— have been properly technically validated before use,

— have precision and accuracy compatible with the target uncertainty;

each set of measurements must:

— be traceable to the stated references, and

— be accompanied by an uncertainty statement whenever possible;

participating laboratories must:

— have the required competence for the execution of the task,

— be able to achieve traceability to the required stated references,

— be able to estimate its measurement uncertainty,

— have in place a sufficient and appropriate quality assurance system.

F. Final storage:

— to avoid a posterior degradation, all samples are best stored under conditions designated for the final storage of the GM RM before measurements are started,

— otherwise, they must be transported from door to door keeping them at all times under such storage conditions for which it has been demonstrated that there is no influence on the assigned values.

G. Establishment of a certificate for CRMs:

— a certificate complemented by a certification report has to be established, containing all information relevant to and needed by the user. The certificate and report must be made available when the GM CRM is distributed,

— certified values must be traceable to stated references and be accompanied by an expanded uncertainty statement valid for the entire shelf-life of the GM CRM.

Changes to legislation:
There are outstanding changes not yet made to Commission Regulation (EC) No 641/2004. Any changes that have already been made to the legislation appear in the content and are referenced with annotations.
View outstanding changes

Changes and effects yet to be applied to the whole legislation item and associated provisions

- Signature words omitted by S.I. 2019/705 reg. 45
- Art. 3(1)(a) words omitted by S.I. 2019/705 reg. 44(a)
- Art. 3(1)(d) words omitted by S.I. 2019/705 reg. 44(b)