codex alimentarius commission

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**Agenda Item 4** **CX/MAS 07/28/5**

**JOINT FAO/WHO FOOD STANDARDS PROGRAMME**

**CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING**
**Twenty-eighth Session**
**Budapest, Hungary, 5-9 March 2007**

# REVIEW OF THE *Analytical Terminology for Codex* Use IN THE PROCEDURAL MANUAL

## BACKGROUND

The 24th Session of the Codex Committee on Methods of Analysis and Sampling (CCMAS) agreed to initiate the revision of the Definitions contained in the Codex Procedural Manual (Analytical Terminology for Codex Use) (ALINORM 03/23, para. 95). This was approved by the 26th Session of the Commission as new work (ALINORM 03/41, para. 138-140 and Appendix VIII). The 25th session, CCMAS initiated a review of the analytical terminology for use in the Procedural Manual and proposed several amendments to the Analytical Terminology that were subsequently adopted by the Commission and incorporated into the Procedural Manual (ALINORM 04/27/23, para 66-76). The Delegation of the United States presented a document containing revised definitions at the 26th session of CCMAS, but because a number of definitions were under revision by international organizations, the Committee determined that it was premature to revise them (ALINORM 05/28/03, para. 43-51). At the 27th session of CCMAS in response to a request to identify which definitions could be harmonized and amended for inclusion in the Procedural Manual and which new definitions addressing methodological issues would be identified the Delegation of the United States with the help of an electronic working group presented revised definitions that 1) could be harmonized and included in the Procedural Manual; 2) that were required in addition to those of the Procedural Manual and 3) that were under revision by international organizations and should not be considered until revision was completed. A proposal from the 18th Interagency Meeting taking the analytical definitions out of the Procedural Manual and developing a separate Guideline for governments, thus facilitating updates of the definitions was subsequently introduced and discussed. The Committee agreed with this proposal and planned to seek the approval of the Commission to continue this work with the following amendment: transferring the Analytical Terminology section in the Procedural Manual to a separate Proposed Draft Guideline on Analytical Terminology, that would be developed as a Codex document through the Step Procedure. The Guideline is an ongoing work that will be developed. When adopted, it will replace the current section on Analytical Terminology in the Procedural Manual. The Committee agreed to finalise at least part of the definitions for adoption by the 31st Session of the Commission in 2008 and that, following the approval of the Commission the electronic working group led by the United States in cooperation with all interested delegations would propose a first draft of the Guideline for comments at Step 3 and consideration by the 28th Session of the Committee.

**RECOMENDATIONS**

A proposed analytical terminology guideline for Codex Alimentarius is presented. ISO has published statistical definitions (ISO 3534-2) and many of the definitions under revision are now harmonizable. The VIM remains in draft form but may be finalized in the coming year. It is recommended that the definitions be discussed at the 28th session of CCMAS. It is again recommended that CCMAS not propose these changes for the Codex Procedural Manual until the Inter-Agency Meeting (IAM) members come to a final consensus on the proposed guideline. If sufficient consensus is found within CCMAS, then the following Draft Guidelines should be submitted to the Codex Commission as a work item at Step 3.

# APPENDIX I

## INTRODUCTION

The Codex Committee on Methods of Analysis and Sampling has agreed on Analytical Terminology for Codex use. A number of these terms were previously included in the Codex Procedural Manual. These terms, together with the terms which are included in specific International Protocols/Guidelines already adopted by Codex by reference are given below.

These Guidelines are published as a Codex Guideline (GL xx-20xx).

## SPECIFIC ANALYTICAL TERMS

The following analytical terms are used in the Procedural Manual and are defined below:

Accuracy
Applicability (and practicability)
Bias
Certified reference material
Empirical method of analysis
Error
HorRat
Interlaboratory study
Laboratory performance (Proficiency) study
Limit of detection
Limit of quantification
Linearity
Material-certification study
Measurement uncertainty
Method-performance study
Precision
Quality assurance
Rational method of analysis
Recovery/recovery factors
Reference material
Relative uncertainty
Repeatability
Reproducibility
Repeatability conditions
Repeatability (Reproducibility) limit
Repeatability (Reproducibility) standard deviation
Repeatability (Reproducibility relative standard deviation
Reproducibility conditions
Result
Robustness (ruggedness)
Selectivity
Sensitivity

Surrogate
Traceability
True value
Trueness
Validated range

The following terms are no longer to be used and so are not defined:

limit of determination
specificity

## DEFINITIONS OF SPECIFIC ANALYTICAL TERMS

***Accuracy:*** The closeness of agreement between a test result or measurement result and the true value.

Notes:

In practice the accepted reference value is substituted for the true value.

The term "accuracy", when applied to a set of test results or measurement results, involves a combination of random components and a common systematic error or bias component.

Accuracy refers to combination of trueness and precision.

Reference:

*ISO Standard 3534-2: Vocabulary and Symbols Part 2: Applied Statistics, ISO, Geneva, 2006*

***Applicability:*** The analytes, matrices, and concentrations for which a method of analysis may be used satisfactorily to determine compliance with a Codex standard.

Note:

In addition to a statement of the range of capability of satisfactory performance for each factor, the statement of applicability (scope) may also include warnings as to known interference by other analytes, or inapplicability to certain matrices and situations.

Reference:

Codex Alimentarius Commission, Procedural Manual, 15th edition, 2006

***Bias:*** The difference between the expectation of the test result or measurement result and the true value.

Notes:

Bias is the total systematic error as contrasted to random error. There may be one or more systematic error components contributing to bias. A larger systematic difference from the accepted reference value is reflected by a larger bias value.

The bias of a measuring instrument is normally estimated by averaging the error of indication over the appropriate number of repeated measurements. The error indication is the: "indication of a measuring instrument minus a true value of the corresponding input quantity".

In practice the accepted reference value is substituted for the true value.

Expectation is the general mean of observed values {ISO 5725-1}

Reference:

ISO Standard 3534-2: Vocabulary and Symbols Part 2: Applied Statistics, ISO, Geneva, 2006

***Certified reference material (CRM):*** Reference material, accompanied by an authenticated certificate, having for each specified quantity a value, measurement uncertainty and stated metrological traceability chain. {VIM}

Notes:

A certificate should refer to a protocol describing the certification process.

Certified reference materials are generally prepared in batches. For a given batch, quantity values and measurement uncertainties are obtained by measurements on samples representative of the batch.

The quantity values assigned to a CRM are sometimes conveniently and reliably obtained when the material is incorporated into a specially fabricated device. The quantity value is sometimes the output of the device. Such devices may also be considered CRMs.

Some certified reference materials have quantity values that are not metrologically traceable to an International system of units.

Reference:

*VIM, International vocabulary for basic and general terms in metrology, Draft Standards 3rd Edition, 2004, ISO, Geneva*

***Empirical method of analysis:*** A method in which the quantity estimated is simply the result found on following the stated procedure.

Note:

This differs from measurements intended to assess method-independent quantities such as the concentration of a particular analyte in a sample, in that the method bias is conventionally zero and matrix variation (i.e. within the defined class) is irrelevant

Reference:

Harmonised guidelines for single-laboratory validation of methods of analysis, 2002.

***Error***: Difference of quantity value obtained by measurement and true value of the measurand. {VIM}

Note:

It is often necessary to distinguish “error of measurement” from relative error of measurement.

Reference:

*VIM, International vocabulary for basic and general terms in metrology, Draft Standards 3rd Edition, 2004, ISO, Geneva*

***HorRat:*** The relative interlaboratory standard deviation normalized with respect to concentration that is indicative of method performance for a large majority of methods in chemistry. It is the ratio of the interlaboratory relative standard deviation found to that calculated from the Horwitz equation,

$PRSD_R = 2C^{-0.15}$:

$HorRat(R) = RSD_R/PRSD_R$ ,

$HorRat(r) = RSD_r/PRSD_R$ ,

where C is concentration expressed as a mass fraction (both numerator and denominator expressed in the same units). Acceptable values lie between 0.5 and 2. (To check proper calculation of $PRSD_R$, a C of $10^{-6}$ should give a $PRSD_R$ of 16%.)

If applied to within-laboratory studies, the acceptable range of HorRat(r) is 0.3-1.3.

Reference:

*A simple method for evaluating data from an interlaboratory study, J AOAC, 81(6):1257-1265, 1998*

**Interlaboratory Study:** A study in which several laboratories measure a quantity in one or more "identical" portions of homogeneous, stable materials under documented conditions, the results of which are compiled into a single document.

Notes:

The larger the number of participating laboratories, the greater the confidence that can be placed in the resulting estimates of the statistical parameters. The IUPAC-1987 protocol (Pure & Appl. Chem., 66, 1903-1911(1994)) requires a minimum of eight laboratories for method-performance studies.

Reference:

Codex Alimentarius Commission, Procedural Manual, 15th edition, 2006

***Laboratory-Performance (Proficiency) Study:*** An interlaboratory study that consists of one or more measurements by a group of laboratories on one or more homogeneous, stable, test samples by the method selected or used by each laboratory. The reported results are compared with those from other laboratories or with the known or assigned reference value, usually with the objective of improving laboratory performance.

Notes:

Laboratory-performance studies can be used to support laboratory accreditation or audit performance. If a study is conducted by an organization with some type of management control over the participating laboratories— organizational, accreditation, regulatory, or contractual—the method may be specified or the selection may be limited to a list of approved or equivalent methods. In such situations, a single test sample is insufficient to judge performance. A laboratory-performance study may be used to select a method of analysis that will be used in a method-performance study. If all laboratories, or a sufficiently large subgroup, of laboratories, use the same method, the study may also be interpreted as a method-performance study, provided that the test samples cover the range of concentration of the analyte.

Laboratories of a single organization with independent facilities, instruments, and calibration materials, are treated as different laboratories.

Reference:

Codex Alimentarius Commission, Procedural Manual, 15th edition, 2006

**Limit of Detection:** The amount of an analyte corresponding to the lowest measurement signal which with a defined confidence may be interpreted as indicating that the analyte is present in the test sample, but without allowing quantitation.

The detection limit is conventionally defined as field blank + 3σ, where is the standard deviation of the field blank value signal (IUPAC definition).

However, an alternative definition which overcomes most of the objections to the above approach (i.e. the high variability at the limit of measurement can never be overcome) is to base it on the rounded value of the reproducibility relative standard deviation when it goes out of control (where

$3\sigma_R$ = 100%; $\sigma_R$ = 33%, rounded to 50% because of the high variability). Such a value is directly related to the analyte and to the measurement system and is not based on the local measurement system.

Notes:

1. LOD = $3*\sigma_a/b$ where LOD is the limit of detection, $\sigma_a$ is the standard deviation of x blank results and b is the slope of the calibration curve/regression line.

2. For quantitative tests using the polymerase chain reaction (PCR), the distribution of blank values is typically truncated and thus not normally distributed (non-Gaussian) around zero. Thus, the LOD needs to be experimentally determined unless the targeted concentrations are well above the LOD and the LOD, therefore, becomes irrelevant.

References:

Nordic Committee on Food Analysis, NMKL Procedure No. 4, 2005

Codex Alimentarius Commission, Procedural Manual, 15th edition, 2006

Polymerase chain reaction technology as an analytical tool in agricultural biotechnology, J.AOAC, 88(1):128-135, 2005

**Limit of Quantification:** The limit of quantification (LOQ) (also called limit of determination) of an analytical procedure is the lowest amount of analyte in a laboratory sample which can be quantitatively determined with a defined confidence.

As for detection limit except that 6 or 10 are required rather than 3.

However, an alternative definition that corresponds to that proposed for the detection limit is to use $\sigma R$ = 25%. This value does not differ much from that assigned to the detection limit because the upper limit of the detection limit merges indistinguishably into the lower limit of the determination limit.

Notes:

1. LOQ = $10*\sigma_a/b$ where LOQ is the limit of quantification, $\sigma_a$ is the standard deviation of x blank results (x > 20) and b is the slope of the calibration curve/regression line. Because LOQ>LOD, fewer laboratories are required to establish a value at the same level of confidence.

2. For quantitative tests using the polymerase chain reaction (PCR), the distribution of blank values is typically truncated and thus not normally distributed (non-Gaussian) around zero. Thus, the LOQ needs to be experimentally determined unless the targeted concentrations are well above the LOQ and the LOQ, therefore, becomes irrelevant.

References:

Codex Alimentarius Commission, Procedural Manual, 15th edition, 2006

Nordic Committee on Food Analysis, NMKL Procedure No. 4, 2005

Polymerase chain reaction technology as an analytical tool in agricultural biotechnology, J. AOAC, 88(1):128-135, 2005

**Linearity:** The ability of a method of analysis, within a certain range, to provide an instrumental response or results proportional to the quality of analyte to be determined in the laboratory sample. This proportionality is expressed by an a priori defined mathematical expression. The linearity limits are the experimental limits of concentrations between which a linear calibration model can be applied with a known confidence level (generally taken to be equal to 1%).

Reference:

Codex Alimentarius Commission, Procedural Manual, 15th edition, 2006

***Material-Certification Study:*** An interlaboratory study that assigns a reference value ("true value") to a quantity (concentration or property) in the test material, usually with a stated uncertainty.

Note:

A material-certification study often utilises selected reference laboratories to analyse a candidate reference material by a method(s) judged most likely to provide the least-biased estimates of concentration (or of a characteristic property) and the smallest associated uncertainty.

Reference:

Codex Alimentarius Commission, Procedural Manual, 15th edition, 2006

**Measurement uncertainty:** Parameter that characterizes the dispersion of the quantity values that are being attributed to the measurand, based on the information used. {VIM}

Notes:

Measurement uncertainty quantitatively characterizes the knowledge about the measurand, based on the information used. {VIM}

Measurement uncertainty characterizes the dispersion of a set or distribution of quantity values for the measurand, obtained by available information. The dispersion is due to definitional uncertainty of the measurand and random and systematic effects in the measurement. {VIM}

The parameter may be, for example, a standard deviation called standard measurement uncertainty (or a given multiple of it), or the half-width of interval having a stated coverage probability. {VIM}

Measurement uncertainty comprises, in general many components. Some of these components may be evaluated by Type A evaluation of measurement uncertainty from the statistical distribution of the quantity values from a series of measurements and can be characterized by experimental standard deviations. The other components which may be evaluated by Type B evaluation of measurement uncertainty can also be characterized by standard deviations, evaluated from assumed probability distributions based on experience or other information. {VIM}

It is understood that the result of a measurement result is the best estimate of the value of the measurand, and that all the components of measurement uncertainty, including those arising from systematic effects, such as components associated with corrections and assigned values of measurement standards, contribute to the dispersion. {VIM}

Depending upon its intended use, an expanded measurement uncertainty of a measurement result may be given with a stated coverage factor, giving a coverage interval intended to contain the value of the measurand with high probability, or encompass a stated large fraction of the dispersed quantity values that are being attributed to the measurand. {VIM}

Reference:

*1. VIM, International vocabulary for basic and general terms in metrology, Draft Standards 3rd Edition, 2004, ISO, Geneva*

***Method-Performance Study:*** An interlaboratory study in which all laboratories follow the same written protocol and use the same test method to measure a quantity in sets of identical test samples. The reported results are used to estimate the performance characteristics of the method. Usually these characteristics are within-laboratory and among-laboratories precision, and when necessary and possible, other pertinent characteristics such as systematic error, recovery, internal quality control parameters, sensitivity, limit of quantitation, and applicability.

Notes

The materials used in such a study of analytical quantities are usually representative of materials to be analyzed in actual practice with respect to matrices, amount of test component (concentration), and interfering components and effects. Usually the analyst is not aware of the actual composition of the test samples but is aware of the matrix.

The number of laboratories, number of test samples, number of determinations, and other details of the study are specified in the study protocol. Part of the study protocol is the procedure which provides the written directions for performing the analysis.

The main distinguishing feature of this type of study is the necessity to follow the same written protocol and test method exactly.

Several methods may be compared using the same test materials. If all laboratories use the same set of directions for each method and if the statistical analysis is conducted separately for each method, the study is a set of method-performance studies. Such a study may also be designated as a method-comparison study.

Reference:

*Codex Alimentarius Commission, Procedural Manual, 15th edition, 2006*

***Precision:*** The closeness of agreement between independent test/measurement results obtained under stipulated conditions.

Notes:

Precision depends only on the distribution of random errors and does not relate to the true value or to the specified value.

The measure of precision is usually expressed in terms of imprecision and computed as a standard deviation of the test results. Less precision is reflected by a larger standard deviation.

Quantitative measures of precision depend critically on the stipulated conditions. Repeatability and reproducibility conditions are particular sets of extreme conditions.

Reference:

*ISO Standard 3534-2: Vocabulary and Symbols Part 2: Applied Statistics, ISO, Geneva, 2006*

***Quality assurance:*** All those planned and systematic actions necessary to provide adequate confidence that a product or service will satisfy given requirements for quality.

Reference:

*Harmonized guidelines for internal quality control in analytical chemistry laboratories, 1995*

***Rational method of analysis*:** A method that determines an identifiable chemical(s) or analytes(s) for which there may be several equivalent methods of analysis available.

Reference:

*Harmonized guidelines for the use of recovery information in analytical measurement, 1998*

***Recovery:*** Proportion of the amount of analyte, present in, added to or present in and added to the analytical portion of the test material, which is extracted and presented for measurement.

Notes:

Recovery is assessed by the ratio $R = c_{obs} / C_{ref}$ of the observed concentration or amount $^{c}obs$ obtained by the application of an analytical procedure to a material containing analyte at a reference level $c_{ref}$ .

$c_{ref}$ will be: (a) a reference material certified value, (b) measured by an alternative definitive

method, (c) defined by a spike addition or (d) marginal recovery.

Reference:

*Harmonized guidelines for the use of recovery information in analytical measurement, 1998*

*Use of the terms "recovery" and "apparent recovery" in analytical procedures, 2002*

***Reference material:*** Material, sufficiently homogenous and stable with respect to one or more specified quantities, used for calibration of a measuring system, or for assessment of a measurement procedure, or for assigning values and measurement uncertainties to quantities of the same kind for other materials. {VIM}

Notes:

The term reference material designates a family of materials without necessarily implying a hierarchy according to the magnitude of measurement uncertainty.

Reference material comprises both precision control material, which need not have an assigned quantity value and measurement standard functioning as trueness control material or calibrator.

The term reference material is also used for materials realizing nominal properties such as color.

Reference:

*VIM, International vocabulary for basic and general terms in metrology, Draft Standards 3rd Edition, 2004, ISO, Geneva*

***Relative uncertainty:*** Uncertainty derived from a relative standard deviation.

Reference:

*Harmonized guidelines for single-laboratory validation of methods of analysis, 2002*

***Repeatability [Reproducibility]:*** Precision under repeatability [reproducibility] conditions.

Reference:

*ISO 3534-1 Statistics, vocabulary and symbols-Part 1: Probability and general statistical terms, ISO, 1993*

*ISO Standard 78-2: Chemistry – Layouts for Standards – Part 2: Methods of Chemical Analysis, 1999)*

*Codex Alimentarius Commission, Procedural Manual, 15th edition, 2006*

*AOAC International methods committee guidelines for validation of qualitative and quantitative food microbiological official methods of analysis, 2002.*

***Repeatability conditions:*** Observation conditions where independent test/measurement results are obtained with the same method on identical test/measurement items in the same test or measuring facility by the same operator using the same equipment within short intervals of time.

Note:

Repeatability conditions include: the same measurement procedure or test procedure; the same operator; the same measuring or test equipment used under the same conditions; the same location and repetition over a short period of time.

Reference:

*ISO Standard 3534-2: Vocabulary and Symbols Part 2: Applied Statistics, ISO, Geneva, 2006*

***Reproducibility conditions*:** Observation conditions where independent test/measurement results are obtained with the same method on identical test/measurement items in different test or measurement facilities with different operators using different equipment.

Reference:

*ISO Standard 3534-2: Vocabulary and Symbols Part 2: Applied Statistics, ISO, Geneva, 2006*

***Repeatability [Reproducibility] limit:*** The value less than or equal to which the absolute difference between final values, each of them representing a series of test results or measurement results obtained under repeatability [reproducibility] conditions may be expected to be with a probability of 95%.

Notes:

The symbol used is r [R]. {ISO 3534-2}

When examining two single test results obtained under repeatability [reproducibility] conditions, the comparison should be made with the repeatability [reproducibility] limit, r [R] = 2.8σr[R]. {ISO 5725-6, 4.1.4}

When groups of measurements are used as the basis for the calculation of the repeatability [reproducibility] limits (now called the critical difference), more complicated formulae are required that are given in ISO 5725-6: 1994, 4.2.1 and 4.2.2.

Reference:

*ISO Standard 3534-2: Vocabulary and Symbols Part 2: Applied Statistics, ISO, Geneva, 2006*

*ISO 5 725-6 "Accuracy (trueness and precision) of a measurement methods and results—Part 6: Use in practice of accuracy value", ISO, 1994*

*Codex Alimentarius Commission, Procedural Manual, 15th edition, 2006*

***Repeatability [reproducibility] standard deviation*:** Standard deviation of test results or measurement results obtained under repeatability [reproducibility] conditions.

Notes:

It is a measure of the dispersion of the distribution of the test or measurement results under repeatability [reproducibility] conditions.

Reference:

*ISO Standard 3534-2: Vocabulary and Symbols Part 2: Applied Statistics, ISO, Geneva, 2006*

***Repeatability [reproducibility] relative standard deviation:*** $RSD_{r[R]}$ is computed by dividing the repeatability [reproducibility] standard deviation by the mean.

Note:

Relative standard deviation (RSD) is a useful measure of precision in quantitative studies.

This is done so that one can compare variability of sets with different means. RSD values are independent of the amount of analyte over a reasonable range and facilitate comparison of variabilities at different concentrations.

The result of a collaborative test may be summarized by giving the RSD for repeatability (RSDr) and RSD for reproducibility (RSDR).

*AOAC International methods committee guidelines for validation of qualitative and quantitative food microbiological official methods of analysis, 2002.*

***Result:*** The final value reported for a measured or computed quantity, after performing a measuring procedure including all sub-procedures and evaluations. {IUPAC, 1994}

Notes:

The information consists of a set of quantity values reasonably being attributed to the measurand, usually summarized as a single quantity and a measurement uncertainty. The single quantity value is an estimate, often an average or the median of the set. {VIM}

If the measurand is considered to be sufficiently well described by a single quantity value (see GUM, 1993, 1,2), it is common practice to have the term 'measurement result' comprise the estimated value only. The measurement uncertainty associated with this 'measurement result' is then stated separately. {VIM}

If the measurement uncertainty is considered to be negligible for some purpose, the information may be reduced to a single quantity value. {VIM}

Reference:

*IUPAC, Nomenclature for the presentation of results of chemical analysis, 1994.*

*VIM, International vocabulary for basic and general terms in metrology, Draft Standards 3rd Edition, 2004, ISO, Geneva*

***Robustness (ruggedness*)**: A measure of the capacity of an analytical procedure to remain unaffected by small but deliberate variations in method parameters and provides an indication of its reliability during normal usage

Reference:

*ICH Topic Q2 Validation of Analytical Methods, the European Agency for the Evaluation of Medicinal Products: ICH Topic Q 2 A - Definitions and Terminology (CPMP/ICH/381/95), 1995*

***Selectivity:*** Capability of a measuring system, using a specified measurement procedure to provide measurement results for two or more quantities of the same kind involving different components in a system undergoing measurement, without interference from each other or from the quantities of the system. {VIM}

Reference:

*VIM, International vocabulary for basic and general terms in metrology, Draft Standards 3rd Edition, 2004, ISO, Geneva*

***Sensitivity:*** Quotient of the change in the indication of a measuring system and the corresponding change in the value of the quantity being measured. {VIM}

Notes:

The sensitivity can depend on the value of the quantity being measured.

The change considered in the value of the quantity being measured must be large compared with the resolution of the measurement system.

Reference:

*VIM, International vocabulary for basic and general terms in metrology, Draft Standards 3rd Edition, 2004, ISO, Geneva*

***Surrogate:*** Pure compound or element added to the test material, the chemical and physical behavior of which is taken to be representative of the native analyte.

Reference:

*Harmonized guidelines for the use of recovery information in analytical measurement, 1998*

***Traceability:*** Property of a measurement result relating the result to a stated reference or the value of a standard whereby it can be related to stated references through an unbroken chain of comparisons, each contributing to the stated measurement uncertainty.

Notes:

A stated reference can be a definition of a measurement unit, through its practical realization, or a measurement procedure, or a national or international measurement standard.

A prerequisite to traceability is a previously established calibration hierarchy.

For measurements with more than one input quantity to the measurement function, each of the input quantities should itself be traceable.

Reference:

*VIM, International vocabulary for basic and general terms in metrology, Draft Standards 3rd Edition, 2004, ISO, Geneva*

*Harmonized guidelines for internal quality control in analytical chemistry laboratories, 1995*

***Trueness:*** The closeness of agreement between the expectation of a test result or a measurement result and a true value

Notes:

The measure of trueness is usually expressed in terms of bias.

Trueness has been referred to as “accuracy of the mean”. This usage is not recommended.

In practice the accepted reference value is substituted for the true value.

Expectation is the expected value of a random variable, e.g. assigned value or long term average {ISO 5725-1}

Reference:

*ISO Standard 3534-2: Vocabulary and Symbols Part 2: Applied Statistics, ISO, Geneva, 2006*

*ISO Standard 5725-1: Accuracy (trueness and precision) of measurement methods and results, Part 1: General principles and definitions, ISO, Geneva, 1994.*

**True value:** The value which characterizes a quantity or quantitative characteristic perfectly defined in the conditions which exist when the quantity or quantitative characteristic is considered.

Note:

The true value of a quantity or quantitative characteristic is a theoretical concept and, in general, cannot be known exactly

Reference:

*ISO Standard 3534-2: Vocabulary and Symbols Part 2: Applied Statistics, ISO, Geneva, 2006*

**Validated range:** That part of the concentration range of an analytical method which has been subjected to validation.

Reference

*Harmonized guidelines for single-laboratory validation of methods of analysis, 2002*

**REFERENCES**

1. Terms and definitions used in connections with reference materials, ISO Guide 30:1992
2. GUM, Guide to the expression of uncertainty in measurement, ISO, Geneva, 1993.
3. The international harmonised protocol for the proficiency testing of (chemical)

analytical laboratories, Pure Appl. Chem., 65, 2123-2144, 1993.-

4. International vocabulary for basic and general terms in metrology, ISO, Geneva, 2nd Edition, 1993.
5. Statistics, vocabulary and symbols - Part 1: Probability and general statistical terms, ISO 3534 -1: 1993.
6. VIM, International vocabulary for basic and general terms in metrology, 2nd Edition, ISO, Geneva, 1993.
7. ISO Standard 5725-1: Accuracy (trueness and precision) of measurement methods and results, Part 1: General principles and definitions, ISO, Geneva, 1994.
8. IUPAC, Nomenclature for the presentation of results of chemical analysis, Pure and Applied Chemistry, 66(3):595-608, 1994.
9. Quality management and quality assurance-vocabulary ISO 8402, second edition, 1994.
10. The harmonised guidelines for internal quality control in analytical chemistry laboratories, Pure Appl. Chem., 67:649–666, 1995.
11. ICH Topic Q2 Validation of Analytical Methods, The European Agency for the Evaluation of Medicinal Products: ICH Topic Q 2 A - Definitions and Terminology (CPMP/ICH/38 1/95), 1995
12. Protocol for the design, conduct and interpretation of method-performance studies, Pure Appl. Chem. 67(2):331-343, 1995.
13. Harmonized guidelines for the use of recovery information in analytical measurement, IUPAC/ISO/AOAC International/Eurachem technical report, 1998.
14. A simple method for evaluating data from an interlaboratory study, J AOAC, 81(6): 1257-1265, 1998.
15. ISO Standard 78-2: Chemistry – layouts for standards – Part 2: Methods of chemical analysis, ISO, second edition, 1999.
16. Selectivity in Analytical Chemistry, Pure Appl. Chem., 73(8):1381-1386, 2001.
17. AOAC International Methods committee guidelines for validation of qualitative and quantitative food microbiological methods of analysis, J AOAC, 85(5): 1187-1200, 2002
18. Harmonised guidelines for single-laboratory validation of methods of analysis, Pure Appl. Chem., 74(5):835-855, 2002.
19. Use of the terms “recovery “ and “apparent recovery” in analytical procedures, Pure Appl. Chem., 74(11): 2201-2205, 2002
20. Codex Alimentarius Commission, Procedural Manual, 13th edition, Food and Agriculture Organization of the United Nations, World Health Organization, 2003.
21. Codex Alimentarius Commission, Food and Agriculture Organization of the United Nations, World Health Organization, Alinorm 04/27/23, Report of the twenty-fifth session of the Codex committee on methods analysis and sampling, 2004
22. VIM, International vocabulary for basic and general terms in metrology, Draft Standards, 3rd Edition, ISO, Geneva, 2004
23. Validation of chemical analytical methods, NMKL Procedure No. 4, Nordic Committee on Food Analysis, p 20, 2005
24. Polymerase chain reaction technology as an analytical tool in agricultural biotechnology, J AOAC, 88(1):128-135, 2005.
25. ISO Standard 3534-1: Vocabulary and Symbols Part 1: Applied Statistics, ISO, Geneva, 2006.
26. ISO Standard 3534-2: Vocabulary and Symbols Part 2: Applied Statistics, ISO, Geneva, 2006.