

# codex alimentarius commission



FOOD AND AGRICULTURE  
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ORGANIZATION



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Agenda Item 4

CX/MAS 06/27/5  
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## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING

Twenty-seventh Session

Budapest, Hungary, 15-19 May 2006

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

The proposed definitions in the Review of the *Analytical Terminology for Codex Use* are distributed for comments. Governments and international organizations wishing to comment are invited to do so in writing, preferably by Email, to the Secretary, Joint FAO/WHO Food Standards Programme, FAO, Viale delle Terme di Caracalla, 00100 Rome, Italy, Fax: +39 (06) 5705 4593, e-mail : [codex@fao.org](mailto:codex@fao.org) with a copy to Dr. Mária Váradi, Central Food Research Institute (KÉKI), H-1022 Budapest, Herman Ottó út 15 (Fax No., +361.212.9853 & 361.355.8928; e-mail, [m.varadi@cfri.hu](mailto:m.varadi@cfri.hu) **before 20 April 2006**.

## BACKGROUND

The 24<sup>th</sup> 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 26<sup>th</sup> Session of the Commission as new work (ALINORM 03/41, para. 138-140 and Appendix VIII). The 25<sup>th</sup> 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). Comments were requested in a circular letter (CL 2003/43-MAS). The Delegation of the United States with the assistance of an electronic working group prepared recommendations and a rationale for appropriate definitions. The Delegation of the United States presented this revised document at the 26<sup>th</sup> session of CCMAS. It was pointed out that a number of definitions were under revision by international organizations and that it would be premature to revise them at this stage in the Committee (ALINORM 05/28/03, para. 43-51). Ultimately, CCMAS agreed that the Delegation of the United States, with the assistance of an electronic working group open to all interested members and observers, would revise the document on the basis of the comments received and the discussion at the present session. It was agreed that the document should clearly identify:

- a) The definitions that could be harmonized and amended for inclusion in the Procedural Manual;
- b) The definitions that were under revision by the international organizations concerned and should not be considered until such revision had been completed; and
- c) The definitions required in addition to those in the Procedural Manual, especially for the purposes of Codex texts addressing methodology issues

## **RECOMMENDATIONS**

Proposed analytical terminology for use in the Procedural Manual was researched and divided into the three categories based on the status of the VIM and ISO-3534-2 and the need for additional terms. Definitions are presented in Appendices I: Definitions that can be harmonized and amended for inclusion in the Procedural Manual, II: Definitions that are required in addition to those in the Procedural Manual and III: Definitions that were under revision which should not be considered until revision is completed. It is recommended that the definitions in Appendices I and II be discussed at the 27<sup>th</sup> 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 consensus on what should be the internationally harmonized definitions or determine that this task is not achievable. If sufficient consensus is found within CCMAS, then the new list of definitions in Appendices I and II, as revised during this or future meetings should be proposed to the Codex Commission as amendments to the Codex Procedural Manual. Definitions in Appendix III may be discussed at the 27<sup>th</sup> session of CCMAS or a later meeting when the VIM and ISO 3534-2 are in their final distribution stage.

**APPLICABILITY**

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

**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.

**Notes:**

1.  $LD = 3 * S_a / b$  where LD is the limit of detection,  $S_a$  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 LD needs to be experimentally determined unless the targeted concentrations are well above the LD and the LD, therefore, becomes irrelevant.

**REFERENCES:**

1. *Nordic Committee on Food Analysis, NMKL Procedure No. 4, 2005*
2. *Codex Alimentarius Commission, Procedural Manual, 15th edition, 2006,*
3. *Polymerase chain reaction technology as an analytical tool in agricultural biotechnology, JAOAC, 88(1):128-135, 2005*

**LIMIT OF QUANTITATION**

The limit of quantification (LQ) (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.

**Notes:**

1.  $LQ = 10 * S_a / b$  where LQ is the limit of quantification,  $S_a$  is the standard deviation of x blank results ( $x > 20$ ) and b is the slope of the calibration curve/regression line. Because  $LQ > LD$ , 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 LQ needs to be experimentally determined unless the targeted concentrations are well above the LQ and the LQ, therefore, becomes irrelevant.

**REFERENCES:**

1. *Codex Alimentarius Commission, Procedural Manual, 15th edition, 2006*
2. *Nordic Committee on Food Analysis, NMKL Procedure No. 4, 2005*
3. *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 quantity 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 defined confidence level (generally taken to be equal to 1%).

**REFERENCE:**

### **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**

1. The materials used in such a study of analytical quantities are usually representative of materials to be analysed 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.
2. 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.
3. The main distinguishing feature of this type of study is the necessity to follow the same written protocol and test method exactly.
4. 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*

### **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 actually measured.

#### **Notes:**

1. 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  $c_{ref}$ .
2.  $c_{ref}$  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:**

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

### **REPEATABILITY [REPRODUCIBILITY]**

{ISO 3534-1}

Precision under repeatability [reproducibility] conditions.

#### **REFERENCES:**

1. *ISO 3534-1 Statistics, vocabulary and symbols-Part 1:Probability and general statistical terms, ISO, 1993*
2. *ISO Standard 78-2: Chemistry – Layouts for Standards – Part 2: Methods of Chemical Analysis, 1999)*
3. *Codex Alimentarius Commission, Procedural Manual, 15th edition, 2006*
4. *AOAC International methods committee guidelines for validation of qualitative and quantitative food microbiological official methods of analysis, 2002.*

## **REPEATABILITY [REPRODUCIBILITY] LIMIT**

{ISO 3534-1}

The value less than or equal to which the absolute difference between two test results obtained under repeatability [reproducibility] conditions may be expected to be with a probability of 95%.

Notes:

1. The symbol used is  $r$  [R]. {ISO 3534-1}
2. When examining two single test results obtained under repeatability [reproducibility] conditions, the comparison should be made with the repeatability [reproducibility] limit,  $r$  [R] =  $2.8s_r$  [R]. {ISO 5725-6, 4.1.4}

REFERENCES:

1. *ISO 3534-1 Statistics, vocabulary and symbols-Part 1:Probability and general statistical terms, ISO, 1993*
2. *ISO 5725-6 "Accuracy (trueness and precision) of a measurement methods and results—Part 6: Use in practice of accuracy values", ISO, 1994*
3. *ISO Standard 78-2: Chemistry – Layouts for Standards – Part 2: Methods of Chemical Analysis (Second Edition, 1999)*
4. *Codex Alimentarius Commission, Procedural Manual, 15th edition, 2006*

## **REPEATABILITY [REPRODUCIBILITY] RELATIVE STANDARD DEVIATION**

Relative standard deviation ( $RSD_{r[R]}$ ) calculated from results generated under repeatability [reproducibility] conditions is  $(s_{r[R]} / \bar{x}) \times 100$ , where  $\bar{x}$  is the mean.

REFERENCE:

1. *Codex Alimentarius Commission, Procedural Manual, 15th edition, 2006*
2. *AOAC International methods committee guidelines for validation of qualitative and quantitative food microbiological official methods of analysis, 2002.*

## **ROBUSTNESS**

A measure of the capacity of an analytical procedure to remain unaffected by small but deliberate variations in method parameters providing 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*

**EMPIRICAL METHOD OF ANALYSIS**

A method which determines a value that can be arrived at only in terms of the method *per se* and serves by definition as the only method for establishing the measurand. (Sometimes called "defining method of analysis.")

**REFERENCE:**

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

**ERROR**

Result of a measurement minus the true value of the measurand. {VIM}

**REFERENCES:**

1. *VIM, International vocabulary for basic and general terms in metrology, 2nd Edition, 1993, ISO, Geneva*
2. *Harmonised guidelines for internal quality control in analytical chemistry laboratories, 1995*

**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,  $PRSD_R = 2C^{-0.15}$ ;

$$\begin{aligned} \text{HorRat}(R) &= RSD_R/PRSD_R, \\ \text{HorRat}(r) &= RSD_r/PRSD_R, \end{aligned}$$

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.*

**QUALITY ASSURANCE**

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

**REFERENCES:**

1. *Quality assurance and quality management - vocabulary, ISO 840, 1994*
2. *Harmonised guidelines for internal quality control in analytical chemistry laboratories, 1995*
3. *International harmonised protocol for the proficiency testing of (chemical) analytical laboratories, 1993*

**RATIONAL METHOD OF ANALYSIS**

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

**REFERENCE:**

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

**RELATIVE UNCERTAINTY**

Uncertainty derived from a relative standard deviation.

**REFERENCE:**

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

### **SURROGATE**

Pure compound or element added to the test material, the chemical and physical behaviour of which is known [or assumed] to be representative of the native analyte.

### **REFERENCE:**

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

### **TRACEABILITY**

Property of the result of a measurement or the value of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons all having stated uncertainties.

### **REFERENCES:**

1. *International vocabulary for basic and general terms in metrology, 2nd Edition, ISO, Geneva, 1993*
2. *Harmonised guidelines for internal quality control in analytical chemistry laboratories, 1995*

### **VALIDATED RANGE**

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

### **REFERENCE**

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

### **APPENDIX III. DEFINITIONS THAT WERE UNDER REVISION WHICH SHOULD NOT BE CONSIDERED UNTIL REVISION IS COMPLETED**

#### **ACCURACY**

{ISO 3534-2}

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

#### **Notes:**

1. In practice the accepted reference value is substituted for the true value
2. 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.
3. Accuracy refers to combination of trueness and precision.

#### **REFERENCE:**

*ISO Draft Standard 3534-2: Vocabulary and Symbols Part 2: Applied Statistics, ISO, Geneva, 2004*

#### **BIAS**

{ISO 3534-2}

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

#### **Notes:**

1. 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. {ISO 3534-1}
2. 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”
3. In practice the accepted reference value is substituted for the true value
4. Expectation is the expected value of a random variable, e.g. assigned value or long term average {ISO 5725-1}

#### **REFERENCE:**

*ISO Draft Standard 3534-2: Vocabulary and Symbols Part 2: Applied Statistics, ISO, Geneva, 2004*

#### **CERTIFIED REFERENCE MATERIAL**

Reference material, accompanied by an authenticated certificate, having for each specified quantity a value, measurement uncertainty and stated metrological traceability chain. {VIM}

#### **Notes:**

1. A certificate should refer to a protocol describing the certification process
2. 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.

3. The quantity values assigned to a certified reference material are some times 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.
4. A certified reference material lies within the definition of a measurement standard
5. Some reference materials and certified reference materials have quantities which, because they cannot be correlated with an established chemical structure or for other reasons, cannot be measured according to measurement procedures giving measurement results that are metrologically traceable to measurement units of the International system of units or other system of units.

#### REFERENCE:

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

#### **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

#### REFERENCES:

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

#### **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:

1. Measurement uncertainty quantitatively characterizes the knowledge about the measurand, based on the information used. {VIM}
2. 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}
3. 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}
4. 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}
5. 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}

6. 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*

**PRECISION**

{ISO 3534-2}

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

**Notes:**

1. Precision depends only on the distribution of random errors and does not relate to the true value or to the specified value.
2. 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.
3. Quantitative measures of precision depend critically on the stipulated conditions. Repeatability and reproducibility conditions are particular sets of extreme conditions.

**REFERENCES:**

*ISO Draft Standard 3534-2: Vocabulary and Symbols Part 2: Applied Statistics, ISO, Geneva, 2004*

**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:**

1. The term reference material designates a family of materials without necessarily implying a hierarchy according to the magnitude of measurement uncertainty.
2. 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.
3. 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*

**REPEATABILITY CONDITIONS**

{ISO 3534-2}

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 observer  
the measuring or test equipment used under the same conditions  
the same location  
repetition over a short period of time

**REFERENCE:**

*ISO Draft Standard 3534-2: Vocabulary and Symbols Part 2: Applied Statistics, ISO, Geneva, 2004*

**REPRODUCIBILITY CONDITIONS**

{ISO 3534-2}

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 Draft Standard 3534-2: Vocabulary and Symbols Part 2: Applied Statistics, ISO, Geneva, 2004*

**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: {VIM}

1. 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
2. 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 ‘result’ comprise the estimated value only. The measurement uncertainty associated with this ‘result’ is then stated separately.
3. If the measurement uncertainty is considered to be negligible for some purpose, the information may be reduced to a single quantity value.

**REFERENCES:**

1. *IUPAC, Nomenclature for the presentation of results of chemical analysis, 1994.*
2. *VIM, International vocabulary for basic and general terms in metrology, Draft Standards 3rd Edition, 2004, ISO, Geneva*

**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}

**REFERENCES:**

*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:

1. The sensitivity can depend on the value of the quantity being measured
2. 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*

**TRUE VALUE**

{ISO 3534-2}

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 Draft Standard 3534-2: Vocabulary and Symbols Part 2: Applied Statistics, ISO, Geneva, 2004*

**TRUENESS**

{ISO 3534-2}

The closeness of agreement between the expectation of a test result or a measurement results and a true value

**Notes:**

1. The measure of trueness is usually expressed in terms of bias.
2. Trueness has been referred to as “accuracy of the mean”. This usage is not recommended.
3. In practice the accepted reference value is substituted for the true value.
4. Expectation is the expected value of a random variable, e.g. assigned value or long term average {ISO 5725-1}

**REFERENCES:**

*ISO Draft Standard 3534-2: Vocabulary and Symbols Part 2: Applied Statistics, ISO, Geneva, 2004*

**IV. REFERENCES**

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4. International vocabulary for basic and general terms in metrology, ISO, Geneva, 2nd Edition, 1993.
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