

# codex alimentarius commission



FOOD AND AGRICULTURE  
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Agenda Item 7

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**JOINT FAO/WHO FOOD STANDARDS PROGRAMME**  
**CODEX COMMITTEE ON METHODS OF ANALYSIS AND SAMPLING**  
**Twenty-fifth Session**  
**Budapest, Hungary, 8 – 12 March 2004**

**REVIEW OF THE ANALYTICAL TERMINOLOGY FOR CODEX USE IN THE PROCEDURAL  
MANUAL**

**Government Comments (Japan, New Zealand)**

**JAPAN**

**General comments**

We strongly believe that there should be only one set of definitions in Codex. If there is a need to have multiple definitions for one term, uses of each definition should be clearly described.

**Specific comments**

1. Trueness

We have recognized that the definition of trueness in the Procedural Manual and that in the Harmonized IUPAC Guidelines for single-laboratory Validation of Methods of Analysis adopted at the 26th Session of the Commission by reference do not agree: the former refers to “a series of test results” while the latter refers to single result. This situation necessitates some harmonization.

We prefer the definition contained in the Procedural Manual as it is in agreement with that contained in ISO 5725-1. Therefore, we propose that the definition of trueness in the Procedural Manual should be maintained without amending it to be consistent with the definition in the IUPAC Guidelines as for Codex purposes a footnote was added to the Guidelines which says, “The definitions apply only for the purpose of the Guidelines and are not generally applicable for Codex purposes.”

2. Selectivity vs. Specificity

Currently there is only a definition of “specificity” in the Procedural Manual. While we welcome the inclusion of a new definition of selectivity, we believe these two definitions should be distinct from each other.

**NEW ZEALAND**

**General comment**

It is important that there is consistency in terminology used in Codex documents and that this is revised to keep it consistent with definitions of terminology used in analysis and defined by other international organisations such as IUPAC and ISO. It might be that this could be more readily managed by reference to the definitions maintained by one of these other organisations rather than maintaining an independent set of definitions within Codex. For instance ISO3534 "Statistics - Vocabulary and Symbols" may contain useful alternative definitions for some of these terms.

The notes included with the Codex definitions are however additions to the definitions and may well justify Codex having its own independent set of definitions.

In general we feel that the definitions lean towards those having more statistical expertise and may therefore not meet the needs of the intended audience, which we take to be mainly laboratory people.

### Specific comments

1. We feel it would be useful to define "Test Method" (or more simply "Method"), especially as it is assumed or might simplify later definitions.
2. **Accuracy.** We find this section quite confused, especially the use of the same definition for the concept and the statistic and the notes.

Firstly, since the definitions are essentially the same, we recommend having a single definition for "Accuracy" which we regard more as conceptual.

**Accuracy:** The closeness of agreement between a reported result and the accepted reference value.

The first note, although unwieldy, can stand as it is, as it discusses the general notion of departures of test results from the true or designated values.

The second note is incorrect. Accuracy as a concept and as a statistic applies to both single results as well as averages and other statistics (as estimators of the true values of other parameters). We suggest that this note be deleted.

3. The definition of **bias** does not explain the term, especially with the use of the word 'expectation'. While this may be theoretically correct it provides no assistance to the intended audience. In practice bias is a measure of accuracy obtained as the difference between the average of test results and an accepted reference value.
4. Further, being an estimator of a statistic (the true bias) itself, this difference calculated will itself be subject to inaccuracy.

As such, it seems that bias (and therefore accuracy in the statistical sense) is not sensibly defined in terms of single test results, since this estimate will be contaminated to the greatest degree by measurement error.

5. As it stands **trueness** would appear to be a subset of accuracy and need not be defined separately, unless some other meaning is intended.
6. The second paragraph of the note on **Repeatability [Reproducibility] limit** ends with the equation  $r[R]=2.8sr[sR]$ .  $sr$  and  $sR$  need to be defined.
7. **Inter-laboratory Study.** It is not clear what is meant by "document" (last word in the definition). Does it mean "single, overall estimates of laboratory or test method performance such as repeatability and reproducibility"?

In the notes, first sentence, we suggest that 'precision' is better than confidence. The last sentence, "The IUPAC-1987 protocol (Pure and Applied Chem., **66**, 1903-1911 (1994)) requires a minimum of eight laboratories for method-performance studies," belongs in the notes for the following definition, the definition for a Method-performance study.

We note that the estimates of reproducibility produced from eight laboratories are not very precise, indeed this criterion appears to have been set from a non-statistical viewpoint.

8. The definition of **Sensitivity** includes the statement "i.e. the slope  $s_i$  of the analytical calibration curve." It is not clear why the subscript "i" is added to the slope as there is only one calibration curve for an analyte.
9. We suggest there should be one definition for **Detection limit** and **Determination limit**. It is true that both definitions are in use but there is no need for Codex to accept both options as it is confusing. We consider the second definition in both cases is the more useful definition. Alternatively if both definitions are retained, it would be helpful to give some comment as to which definition is more suitable in specific circumstances.