APLAC

Asia Pacific Laboratory Accreditation Cooperation

APLAC GUIDELINES FOR FOOD TESTING LABORATORIES

PURPOSE

This document provides guidance to APLAC members and their accredited laboratories on the operation of food testing laboratories and their accreditation to ISO/IEC 17025. It uses the same section headings and numbering system as ISO/IEC 17025.

AUTHORSHIP

This publication has been written by the APLAC Technical Committee.

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INTRODUCTION

The requirements specified in ISO/IEC 17025, *General requirements for the competence of testing and calibration laboratories*, are stated in general terms and, while they are applicable to all test and calibration laboratories, explanations might be needed. Such explanations on applications to food testing laboratories are referred to in this document as "applications". Applications do not include additional general requirements not included in ISO/IEC 17025. Applications can be thought of as an elaboration of the generally stated criteria (requirements) for specified fields of test, test technologies, products, materials or specific tests. (ISO/IEC 17025, Appendix B).

This document is intended to provide context and guidance for laboratories using ISO/IEC 17025 for food testing, especially in support of international food trade activities. This document does not re-state all the provisions of ISO/IEC 17025 and laboratories are reminded of the need to comply with all of the relevant criteria detailed in ISO/IEC 17025.

This document may also be used by accreditation bodies as a general guideline to provide appropriate criteria for the assessment and accreditation of laboratories providing food testing services.

Laboratories are also reminded of the need to comply with relevant statutory or legislative requirements.

1. SCOPE

1.1 The *Codex Alimentarius* (Codex) has become the key reference for consumers, food processors, national food control agencies and the international food trade. Furthermore *the Agreement on the Application of Sanitary and Phytosanitary Measures* (SPS) and the *Agreement on Technical Barriers to Trade* (TBT) both encourage the international harmonisation of food standards and also cite Codex standards, guidelines and recommendations as the preferred international measures for facilitating international trade in food. (See http://www.codexalimentarius.net/). It should, however, be recognised that the Codex is intended only as a guide, and governments themselves decide what use to make of the Codex documents.

1.2 APEC (Asia Pacific Economic Cooperation) has developed a Mutual Recognition Arrangement (MRA) on Conformity Assessment of Foods and Food Products calling for consistency with SPS and TBT requirements, as well as with Codex. The APEC and Codex documents state support for laboratory accreditation activities to ISO/IEC Guide 25 (now ISO/IEC 17025) from a body that operates in accordance to ISO/IEC Guide 58 (now ISO/IEC 17011) and thus accreditation bodies that are signatories to the APLAC Mutual Recognition Arrangement (MRA) and ILAC Arrangement have demonstrated that they and the organisations that they accredit meet those Standards.

1.3 This document is intended as a guidance document for food testing laboratories in the context of the APEC Food and Food Products MRA, in harmony with the wider interests of the Codex Alimentarius recommendations.

1.4 Food analysis is inter-disciplinary in nature. The growth in our knowledge of food sciences and analytical techniques has facilitated accurate reporting of food composition. Food testing is required to evaluate food products for their nutritive and

safety values in terms of microbiology, mycotoxins, pesticide and other chemical residues, toxic metals, additives and packaging materials, in addition to their proximate, biochemical, biophysical and engineering analysis.

1.5 The scope of activity of food testing laboratories is applicable mainly in the following areas:

Food Chemistry;
Food Microbiology;
Food Rheology and other Physical Testing;
Food Toxicology;
Functional Testing;
Molecular Biology (including testing for genetically modified organisms);
Sensory Testing.

Specific guidance for accreditation in each area is not addressed in this document. There are several documents listed in the bibliography that apply to food testing laboratories, including:

A1 for chemical laboratories;
A4 for microbiological laboratories;
A10 for sensory testing.

2. REFERENCES

2.1 APLAC MR 001 – *Procedures for Establishing and Maintaining the APLAC Mutual Recognition Arrangement Amongst Accreditation Bodies*

2.2 ISO/IEC 17000:2004, *Conformity Assessment – Vocabulary and general principles*

2.3 ISO/IEC 17011:2004, *Conformity Assessment – General requirements for accreditation bodies accrediting conformity assessment bodies*

2.4 ISO/IEC 17025:2005, *General requirements for the competence of testing and calibration laboratories*

2.5 ISO/TS 21748:2004, *Guidance for the use of repeatability, reproducibility and trueness estimates in measurement uncertainty estimation*

2.6 ILAC P10:2002, *ILAC Policy on Traceability of Measurement Results*

3. TERMS AND DEFINITIONS

For the purposes of this document, the relevant terms and definitions given in ISO/IEC 17000 apply.

Terms defined and used in the guidelines from the AOAC/FAO/IAEA/IUPAC expert consultation group are also useful (see Bibliography, reference A7).

3.1 Food testing laboratory: A laboratory that carries out tests on foods at any stage in the process chain (raw commodity to processed product), food packaging materials or associated samples of environmental significance.

4. MANAGEMENT REQUIREMENTS

The numbering of the clauses below follows the numbering of ISO/IEC 17025. Where clause numbers from that Standard are omitted no further clarification is required for food testing laboratories. Further guidelines for specific disciplines may apply and can be found in separate publications.

4.3 Document control

4.3.2.2 b) Laboratories should monitor Codex as a source of internationally accepted standard methods for food testing, and should also monitor the requirements of their national and other regulatory authorities to ensure the documents and methods they are using continue to be suitable and are in compliance with applicable requirements, especially for tests done for regulatory purposes.

4.4 Review of requests, tenders and contracts

4.4.1 c) For laboratories that are providing services to internal customers and that are doing tests that will ultimately support regulatory requirements, any specifications by the regulatory authority should also be taken into account when selecting the appropriate test method and subcontractor. Testing in support of export certification should take into account the regulatory and contractual requirements of the importing economy or organisation.

4.9 Control of nonconforming testing and/or calibration work
4.11 Corrective action
5.10.9 Amendments to test reports

The requirements in these sections of the Standard are important, especially when dealing with food safety issues. Laboratories should seek regulatory guidance if necessary and ensure that the needs of the customers are met. Rapid notification of nonconforming results to customers and, if necessary, to regulators may be necessary to prevent or reduce public health incidents.

5. TECHNICAL REQUIREMENTS

5.2 Personnel

When undertaking contract review and selecting methods, personnel need to understand the nature of the foods they are testing, and the reasons for the testing.

5.3 Accommodation and environmental conditions

5.3.1 The Codex guidelines for the design of a food testing laboratory are applicable. Other regulations and Standards may need to be consulted.

5.3.4 When entry into laboratory areas is restricted, as appropriate, it is important the staff is made aware of the intended use of the areas and the restrictions imposed when working within such areas.

5.3.5 It is important for laboratories to have a pest control program or schedule as called for under the internationally recognised Hazard Analysis and Critical Control Point (HACCP) system.

5.4 Test and calibration methods and method validation

The international community is actively discussing the subject of test method validation and uncertainty on all fronts, and laboratories should monitor these discussions to remain abreast of the most recent developments, and their impact on accreditation requirements. Reports from Codex on the subject, including some reference documents, are available on the Codex website. International discipline-specific documents are also being developed and published. Websites such as those of CITAC, EURACHEM and AOAC should also be monitored for updates (see Bibliography section).

ILAC and regional bodies such as APLAC and EA also provide guidance documents for the laboratory community. These in turn may be adopted by accreditation bodies that disseminate the information to their member laboratories, often on their websites. Laboratories would benefit from making themselves aware of websites, especially those of their recognised accreditation body.

5.4.2 Where regulatory authorities prescribe methods to be used for testing under their regulations, laboratories should ensure that the requisite method is used. The Codex Alimentarius Harmonization of Food Standards, is recommended as an acceptable reference for sources of test methods when they are not specified by regulation or by the customer.

5.4.5 It is recommended that standard methods be used as far as possible to ensure comparability of results. When laboratory-developed methods need to be used, matrix interference should be considered. It is recommended that laboratory-developed test methods be validated either by using a matched matrix reference material or, if it is not available, a sample spiked with the analytes of interest. Laboratories are referred to references B1 and B2 of the Bibliography for method validation by inter-laboratory comparison, and to reference A14 of the Bibliography for guidance on single-laboratory validation of methods.

Laboratories should consider the international references in the Bibliography below that contain practical examples. These were identified at the time of publication of this document but they are not all inclusive and other references could be applicable. For microbiological testing, there are currently CEN and ISO documents on method validation in the final draft phase; the AOAC Research Institute plans to publish these once they are finalised and they will, therefore, have international status.

5.4.6 ISO/IEC 17025 requires laboratories to have and to apply procedures for the estimation of uncertainty of measurement, particularly in those cases where the limits of compliance of a parameter are critical, and for validation of non-standard test methods. For estimation of measurement uncertainty, reference should be made to ISO/TS 21748, *Guidance for the use of repeatability, reproducibility and trueness estimates in measurement uncertainty estimation*. Often for food testing, overall intermediate precision or inter-laboratory precision will include most, if not all, major sources of uncertainty. However, the other factors should be investigated when estimating measurement uncertainty.

5.4.6.2 Every measurement has an uncertainty associated with it, resulting from various stages of sampling, analysis, and other factors.

Typically, the major contributors to uncertainty are:

a) sampling and sub-sampling; lack of sample homogeneity;
b) extraction; digestion; sample preparation;
c) inherent instability of reference standards and reference materials;
d) calibration of equipment and instruments;
e) variation of environmental and supply conditions;
f) operator variation;
g) non-repeatability of results

5.6 Measurement traceability

ILAC has developed a policy on measurement traceability of test results, set out in ILAC P10:2002 *ILAC Policy on Traceability of Measurement Results*. This document applies to laboratories accredited by signatories to the APLAC Mutual Recognition Arrangement (MRA). In addition, accreditation bodies have their own specific policies on this topic.

5.6.2.2 Most food testing methods are empirical (the result depends on the defined method) and therefore traceability is to the consensus result for that method and matrix. Even minor deviations from the detail of a standard method should be validated for all practices to which the method is to be applied and for all matrices, to confirm that the results are the same as those obtained from defined standard methods.

5.6.3.2 Pure substance reference materials should be used whenever possible to demonstrate traceability of instrument calibration. There is also a need to document and characterise reference materials which, in some disciplines, are currently synthesised or available from limited sources such as pharmaceutical companies and research and development laboratories.

5.7 Sampling

5.7.1 Laboratories may need to provide those submitting samples with information regarding sample collection and handling in the field, and may also need to provide special sample containers. Published standards for sampling plans are available from regulatory authorities and Codex. Preserving sample integrity and preventing contamination are important issues, especially when dealing with a perishable product or with the possibility of cross contamination. Where a laboratory is to report on ("certify") the results for a food shipment, valid statistical sampling is required and a component for sampling variation should be included in the measurement uncertainty estimate.

5.8 Handling of test and calibration items

5.8.1 It is critical that food testing laboratories preserve sample integrity and avoid contamination and deterioration of the samples. Food is frequently perishable and should be stored in a manner to prevent deterioration, such as refrigerated for short term storage and frozen for long term storage. Some parameters deteriorate, and

analysis for those should be done upon receipt. Chain of custody requirements may be applicable to certain regulatory samples.

5.9 Assuring the quality of test and calibration results

Laboratories should have quality control procedures of appropriate rigour in place for the test and its intended use. For example, the approach may differ if a substance is banned by law or if there is a regulatory limit for the substance. The laboratory should implement a quality control plan. Typically, this plan should include the use of blanks, control samples, spike recoveries and/or duplicates, where applicable.

5.9 b) In addition to the guidelines specified in ISO/IEC 17025, laboratories accredited by a body that is a signatory to the APLAC MRA are required to participate in a minimum number of proficiency testing (PT) activities. These will be clearly defined by the body providing the accreditation and, in some cases, by the regulator. This is also recommended by Codex (see Annex B1).

ISO/IEC Guide 43-2, *Proficiency testing by interlaboratory comparisons - Part 2: Selection and use of proficiency testing schemes by laboratory accreditation bodies*, contains information of interest to laboratories in the reporting and design of PT schemes, the use of results, and corrective action and feedback by laboratories.

Proficiency testing records should include:

- full details of the analyses or examinations undertaken, the results and conclusions drawn;
- an indication that performance in the program has been reviewed;
- details of the investigations and corrective action undertaken, where necessary.

5.10 Reporting the results

Laboratories are encouraged to make a reference to their accreditation status on test reports. Where an accreditation body is a signatory to the APLAC MRA, its accredited laboratories and inspection bodies may, in words approved by the accreditation body, make claim to this recognition on their reports and certificates. The same applies for laboratories only that are accredited by an accreditation body that is a signatory to the ILAC Arrangement.

ANNEX A: BIBLIOGRAPHY

A1. EURACHEM Guide, *Guide to Quality in Analytical Chemistry – An Aid to Accreditation*, Edition 2002. This is available as a free download from http://www.eurachem.ul.pt/

A2. EURACHEM/CITAC Guide CG4, *Quantifying Uncertainty In Analytical Measurement* (Second Edition), EURACHEM Secretariat, BAM, Berlin, 2000. This is available as a free download from http://www.eurachem.ul.pt/

A3. EURACHEM Guide, *The Fitness For Purpose of Analytical Methods, A guide to method validation and related topics, 1998*. Also available as a free download from http://www.eurachem.ul.pt/

A4. EA 4/10 *Accreditation for Microbiological Laboratories*, Edition July 2002, rev 02. The publication has been prepared by the food working group of the EA Laboratory Committee in collaboration with Eurachem. This is also available as a free download from http://www.eurachem.ul.pt/

A5. *Harmonized Guidelines for Internal Quality Control in Analytical Chemistry Laboratories*, IUPAC, Pure & Applied Chemistry, 67 (1995), 649-666

A6. Frederick M Garfield, *Quality Assurance Principles for Analytical Testing Laboratories*, 1992, AOAC International.
Updated version: Frederick M Garfield, Eugene Klestra and Jerry Hirsch. *Quality Assurance Principles for Analytical Laboratories*, 2000, AOAC International. Refer to the AOAC website: http://www.aoac.org/

A7. A. Fajgelj and A. Ambrus (ed), *Principles and Practices of Method Validation*, The Royal Society of Chemistry, 2000, ISBN:0-85404-783-2. Includes "Guidelines for single-laboratory validation of analytical methods for trace-level concentrations of organic chemicals"; these guidelines were elaborated by the AOAC/FAO/IAEA/IUPAC expert consultation group.

A8. AOAC INTERNATIONAL *Guidelines for Laboratories Performing Microbiological and Chemical Analysis of Food and Pharmaceuticals* - An Aid to Interpretation of ISO/IEC 1702:2005 (Revised September 2006), ISBN:935584-76-5. http://www.aoac.org

A9. EA-4/09, *Accreditation for sensory testing laboratories*, 2003. Many other documents are also available on the EA (European co-operation for Accreditation) web site, especially the E4 series that relate to ISO/IEC 17025: http://www.european-accreditation.org/

A10. APLAC PT 003 *Proficiency Testing Directory*. Available in the documents section of the APLAC website: http://www.aplac.org

A11. The EPTIS Database lists hundreds of PT schemes (PTS) operated in Europe and the US. It may assist in finding suitable PTS. EPTIS is a non-commercial joint publication by 20 international organisations and is open for further international participation. It is hosted by the German Federal Institute for Materials Research and Testing (BAM) and supported by EA, Eurachem, Eurolab, IAAC, IRMM and ILAC. http://www.eptis.bam.de/

A12. The Codex Alimentarius, http://www.codexalimentarius.net/

A13. M. Thompson, S. L. R. Ellison, and R. Wood. *Harmonised Guidelines for single-laboratory validation of methods of analysis*, IUPAC Technical Report, (v), Pure & Applied Chemistry, 74(5), (2002), 835-855.

ANNEX B: Codex Alimentarius References

The Codex Alimentarius Commission was created in 1963 by FAO and WHO to develop food standards, guidelines and related texts such as codes of practice under the Joint FAO/WHO Food Standards Program. The main purposes of the Codex Program are the protection of the health of consumers, ensuring fair trade practices in the food trade, and promotion of the coordination of all food standards work undertaken by international governmental and non-governmental organisations. The Codex website, http://www.codexalimentarius.net/, offers documents in English, French, Spanish, Chinese and Arabic. The Codex Alimentarius Volume 13 contains *Methods of Analysis and Sampling*

B1: Codex SECTION 8.6 CAC/GL 27-1997, *Guidelines For The Assessment Of The Competence Of Testing Laboratories Involved In The Import And Export Control Of Food*, provides a framework for the implementation of quality assurance measures to ensure the competence of testing laboratories involved in the import and export control of foods.

The guidelines are intended to assist countries in the application of requirements for trade in foodstuffs in order to protect the consumers and to facilitate fair trade. Codex recommends the adoption of ISO/IEC Guide 25 (now ISO/IEC 17025) by laboratories involved in the import and export control of foods. It also recommends participation in appropriate proficiency testing schemes for food analysis that conform to the requirements laid down in *The International Harmonized Protocol for the Proficiency Testing of (Chemical) Analytical Laboratories*, Pure & Applied Chemistry, 65 (1993), 2132-2144; the use of methods of analysis that have been validated according to the principles laid down by the Codex Alimentarius Commission; and the use of internal quality control procedures, such as those described in the *Harmonized Guidelines for Internal Quality Control in Analytical Chemistry Laboratories*, Pure & Applied Chemistry, 67, (1995) 649-666.

Codex also states that bodies assessing the laboratories should comply with ISO/IEC Guide 58: (replaced by ISO/IEC 17011 in 2004).

Note: *The Codex Guidelines for the Assessment of the Competence of Testing Laboratories Involved in the Import and Export Control of Food* were adopted by the Codex Alimentarius at its 22nd Session in 1997. The document has been sent to all member nations and associate members of FAO and WHO as an advisory text, and it is up to individual governments to decide what use they wish to make of the Guidelines.

The Codex also addresses topics covering harmonisation of food standards, and recognises that, while it can be difficult for some economies to accept the Codex standards in a statutory sense, an increasing number of economies are aligning their national food standards, or parts of them (especially those relating to safety), with those of the Codex Alimentarius.

Alinorm reports are available in the “meeting and events section” of the Codex website under “Reports”. Subjects such as proposed draft guidelines for measurement uncertainty have been discussed and recommendations formulated: see ALINORM 03/23, APPENDIX V.

B2: Codex SECTION 8.6 CAC/GL 28-1997, *Food Control Laboratory Management: Recommendations,* note the following Protocols and Guidelines for quality assurance of food control laboratories.

International Harmonized Protocol for the Proficiency Testing of (Chemical) Analytical Laboratories, Pure & Applied Chemistry, 65 (1993), 2132-2144, J.AOCO International, 76 (1993), 926-940

Protocol for Design, Conduct and Interpretation of Method Performance Studies, Pure & Applied Chemistry, 67 (1995), 331-343

Harmonized Guidelines for Internal Quality Control in Analytical Chemistry Laboratories, Pure & Applied Chemistry, 67 (1993), 649-666