

Proficiency tests for contaminants in food and herbal medicine in the Asia Pacific region

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Proficiency-test (PT) programs organized by Asia Pacific Laboratory Accreditation Cooperation have been recognized as supporting mutual recognition arrangement amongst member laboratories for more than 15 years. Responding to the needs of laboratories in the region, several recent programs have had specific focus on food and herbal medicine testing. This article describes the overall performance of participating laboratories and the operation of three related PTs for trace elements, organochlorine pesticides and veterinary drugs. We also discuss the effectiveness of the PT programs and the assessment trends in PTs.

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1. Introduction

Asia Pacific Laboratory Accreditation Cooperation (APLAC) is a cooperation of accreditation bodies in the Asia Pacific region that accredits laboratories, inspection bodies and reference-material producers [1]. It is one of five specialist regional bodies under the framework of Asia Pacific Economic Cooperation (APEC) and also one of the three recognized regional cooperation bodies [together with European Accreditation (EA) and Inter-American Accreditation Cooperation (IAAC)] of International Laboratory Accreditation Cooperation (ILAC) [2]. ILAC itself is the world's principal international organization for the development of laboratory-accreditation practices and procedures, the promotion of laboratory accreditation as a trade-facilitation tool and the recognition of competent test facilities around the globe. One of APLAC's primary roles is to organize proficiency tests (PTs) in the region so as to strengthen technical

competence for member laboratories and to support development of mutual recognition arrangement (MRA). To achieve and to maintain such an important role, the APLAC PT Committee was founded in early 1994. The responsibilities of the PT Committee are to oversee all work in relation to the conduct of PT programs and measurement audits via the arrangement of workshops, seminars and training programs. Since their first meeting convened in October 1994, regular meetings have been held in conjunction with APLAC General Assemblies.

To initiate APLAC PT programs, accreditation bodies are required to submit proposals to the PT Committee for review and approval. The proposed program should comply with management and technical criteria stipulated in APLAC's and relevant international standards for PT. It should contain the objective and adequate scientific data to support the design and the operation of the program. Priority will be given to those that have not been organized by other scheme providers but have potential demands from users.

Upon receiving a proposal from an accreditation body, the PT Committee's Chairman will circulate the document to members for comment and endorsement. The organizing accreditation body will then revise the protocol, if necessary, to address the comments and the feedback received. The cost for material preparation, transport of samples and relevant analytical work involved in the program is borne by the organizing accreditation

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body, though partial funding is normally provided. Since APLAC's programs are organized by different accreditation bodies, the majority are on ad hoc basis.

Since its first PT program held in May 1994, APLAC has organized about 100 programs on calibration and measurement. More than 70 of the completed programs were in the chemical-measurement field, covering different test parameters over a wide variety of matrices (e.g., children's products, commodities, construction materials, environmental samples, food, herbal materials and pharmaceuticals). The programs share the ultimate target of establishing mutual agreement on the equivalence of the operation of member laboratories in the region and hence facilitating the removal of technical trade barriers related to testing activities. The programs also provide an invaluable tool for the comparability of testing and the consolidation of laboratory accreditation under ISO/IEC 17025 [3].

Several food problems in the region (e.g., Sudan dyes in duck eggs [4], malachite green (MG) in fish [5] and melamine in milk products [6]) have had a severe impact on food-safety and public-health issues. However, the rapid growth of herbal-medicine trade [7], especially in the Asia Pacific region, has resulted in the enactment of contemporary regulations for import and export of medicinal commodities (e.g., control of herbs arising from the contamination of residual pesticides and toxic elements [8–11] during cultivation). As a consequence, quantitative measurement of contaminants in food and herbal materials has become routine monitoring work in regulatory authorities and testing laboratories. In view of the current trend, APLAC has been organizing a number of PT programs on contaminants in food and herbs in order to reveal the competence of participating laboratories involved in testing.

This article presents the general operation procedures, the associated quality requirements and performance assessment of APLAC PT programs. As illustrative case studies, we report on three recently completed PTs on contaminants in food and herbal-medicine samples. These include residual organochlorine pesticides in ginseng root, heavy metals in a herbal plant and MG in eel muscle. Finally, we discuss the use of assigned values and deviation from target performance in assessment in PT programs.

2. Infrastructure of APLAC PT programs

The PT programs provide analytical forums for the comparability of calibration and measurement, and build up participants' ability to take appropriate corrective actions where technical deficiencies are found. They also provide a flow of know-how between their accreditation bodies and establish a mechanism for achieving high levels of technical performance. The

APLAC PT Committee regularly evaluates the effectiveness of programs so that they fully meet the objectives of supporting removal of technical barriers to trade and underpinning testing and measurement activities.

All chemical-testing programs are conducted in accordance with the requirements in APLAC PT002 [12], ISO Guide 43-1 [13] or ILAC Guide 13 [14]. (Note: ISO Guide 43 is being replaced by the new ISO/IEC 17043 [15] standard in 2010). As shown in Table 1, a number of programs encompassing a wide range of test parameters in various food and herbal matrices were organized by different accreditation bodies over the past few years. The duration of the programs (from invitation to issuance of final report) varied from four months to over a year, depending on the analysis time given and the complexity involved in the coordinators preparing materials. The number of participating laboratories in the programs showed that the involvement was consistently high.

2.1. General operation procedures

The organizing accreditation body invites national accreditation bodies within APLAC and the invitation usually extends to the two regional accreditation bodies (EA and IAAC) as well as ILAC's unaffiliated accreditation bodies. Invited accreditation bodies receive an information protocol that details the sample nature and analytes to be tested, the maximum number of participating laboratories, and statistical methods of assessing participants' performance. For participants' reference, it also contains a confirmed schedule (timeline for homogeneity test, stability test, sample dispatch, result-submission deadline, and issuance of interim and final reports). In addition, methods for the determination of assigned values and performance-standard deviation should be clearly defined before the program commences.

Accreditation bodies are requested to pass the information to their interested accredited laboratories and to notify the organizer of the particulars of their nominees. After receiving analytical results from participants, the organizing accreditation body prepares and issues an interim report. Participants should check the correctness of their submitted data in the interim so as to avoid erroneous statistical analysis in the final report. A draft report (e.g., containing the assessment results and technical commentary on the sources of error, method effects, and overall performance) is then submitted to the PT Committee for review.

The organizing accreditation body should respond with sound explanations on the comments and questions raised by the PT Committee and, if necessary, incorporate them into the revised report. Upon PT Committee approval, a final report is distributed to all parties concerned and posted on the APLAC website [1] for

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