Guidelines for Single Laboratory Validation (SLV) of Chemical Methods for Metals in Food

Introduction

The application of analytical methods within a regulatory analysis or accredited laboratory framework imposes certain requirements on both the analyst and laboratory. Under ISO-17025, accredited laboratories are expected to demonstrate both "fitness for purpose" of the methods for which they are accredited and competency of their assigned analysts in performance of the methods[1]. The Codex Alimentarius Commission has issued a general guideline for analytical laboratories involved in the import and export testing of foods which contains four principles[2]:

- Such laboratories should demonstrate internal quality control procedures which meet the requirements of the Harmonised Guidelines for Internal Quality Control in Analytical Chemistry[3];
- Such laboratories should be regular participants in appropriate proficiency testing schemes which have been designed and conducted as per the requirements of the International Harmonized Protocol for Proficiency Testing of (Chemical) Analytical Laboratories[4];
- Such laboratories should become accredited for tests routinely performed according to ISO/IEC-17025:1999 General requirements for the competence of calibration and testing laboratories (now ISO/IEC-17025[1]); and
- Such laboratories should use methods which have been validated according to the principles laid down by the Codex Alimentarius Commission whenever such methods are available.

General requirements for validation of analytical methods according to principles laid down by the Codex Alimentarius Commission are provided in the Codex Manual of Procedures, including provision for "single laboratory" validation of analytical methods[5]. However, there remains considerable misunderstanding among analysts as to precisely what is meant and what is required to demonstrate "method validation". Additional guidance for possible future inclusion in the Manual of Procedures is currently under discussion in the Codex Committee on Methods

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