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Animal feeding stuffs: Methods of sampling and analysis — Recommendations for the organization and evaluation of collaborative studies for multi-analyte methods of analysis

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National foreword

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European foreword

This document (CEN/TR 17421:2019) has been prepared by Technical Committee CEN/TC 327 “Animal feeding stuffs: Methods of sampling and analysis”, the secretariat of which is held by NEN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by March 2020, and conflicting national standards shall be withdrawn at the latest by March 2020.

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Introduction

One of the important parts of the development of a European standard method of analysis is the collaborative study to validate this method. This study should provide sufficient information whether the method is fit for its intended purpose and on the performance characteristics that can be expected in practice. At the same time the necessary effort for the study organizer and the participating laboratories should be kept at a minimum. This guideline is to provide support to those involved in designing, executing, and evaluating such studies.

General information on how to do this is already described in a number of different documents of which a non-exhaustive list can be found at the end of this document in the Bibliography. CEN/TC 327 recommends that for all collaborative studies executed under the auspices of its working groups the "AOAC guidelines for collaborative study procedures to validate characteristics of a method of analysis" [1] is used as the primary source of information for any issues not dealt with in this document. Other relevant documents have been published by ISO [2], IUPAC [3], and EURACHEM [4].

In addition, this document presents prerequisites related to the acceptance of single-laboratory validation studies, the preparation of the standard operating procedure, and the proper implementation of the analytical method by the participating laboratories to ensure the transferability of the method.

The development of methodologies such as GC-MS, LC-MS, ICP-MS, etc. has made it possible to determine multiple analytes in a single analysis (i.e. same extraction, clean up, and determination procedure). The specificities of such multi-analyte methods need to be taken into account when organizing the collaborative trial in order to minimize the workload required while covering the necessary analyte/matrix/concentrations combinations.

1 Scope

This document provides guidance to study organizers involved in designing, executing and evaluating collaborative studies for multi-analyte methods developed by the various working groups of the CEN/TC 327 "Animal feeding stuffs: Methods of sampling and analysis". The main goal of such studies is to determine the reproducibility standard deviations for the analytes investigated in the selected matrices. They are calculated from the repeatability and the between-laboratory standard deviations determined from the study data. An additional goal may be the determination of the trueness (whenever possible).

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at https://www.iso.org/obp

3.1
material
certain combination of analyte, matrix and concentration

3.2
matrix
components of the test material other than the analyte

[SOURCE: IUPAC Gold book [5]]

Note 1 to entry: The term "matrix" may stand synonymously for "matrix-category".

4 Prerequisites to a collaborative study

4.1 General

Collaborative studies for multi-analyte methods require a lot of effort from the study organizer and the participants. They may require extensive personnel and material resources. Every effort should be made to ensure the success of the study.

4.2 Performance characteristics from single-laboratory validation

The fitness-for-purpose of the method of analysis that is to be standardized needs to be demonstrated by a comprehensive and well-designed single-laboratory validation study. This study is to be executed according to the internationally agreed rules, covering relevant combinations of analytes, matrices and concentrations.

A single-laboratory validation study should provide for each analyte the following performance characteristics: selectivity, working range, analytical sensitivity, precision (repeatability and intermediate precision), and trueness. The estimation of such performance characteristics is described in international documents [4] [6]. Only when the low end of the working range approaches very low