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English Version

Animal feeding stuffs - Methods of sampling and analysis - Performance criteria for single laboratory validated and ring-trial validated methods of analysis for the determination of mycotoxins

Aliments des animaux - Méthodes d'échantillonnage et d'analyse - Critères de performance des méthodes d'analyse des mycotoxines validées dans un seul laboratoire ou suite à un essai interlaboratoires

Futtermittel - Probenahme und Untersuchungsverfahren - Leistungskriterien für laborintern validierte und im Ringversuch validierte Analysemethoden zur Bestimmung von Mykotoxinen

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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European foreword

This document (CEN/TS 17455:2020) 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.

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Introduction

The European Committee for Standardization (CEN) selects and elaborates methods of analysis for organic contaminants that are to become European Standards. These standards can be used for those contaminants that are subject to regulation. When used for this purpose, the main functions of a standard are to enable feed manufacturers to determine with reasonable certainty whether a consignment may be put on the market and to enable regulatory authorities to determine equitably whether feedstuffs on the market comply with legal or recommended limits.

CEN/TC 327/working group (WG) 5 decided to establish a criteria guide in order to allow benchmarking of methods of analysis for their fitness for purpose [1]. The performance criteria laid down therein are based on published data, collected from official reports on inter-laboratory studies [2] to [12].

Where performance characteristics are absent or limited in availability, the criteria were estimated based on the experiences and opinions of the experts of the CEN working group. The selection criteria could need updating in future revisions of this document, if newer or more accurate data on method performance characteristics become available. This document lists relevant performance parameters and gives information on their definition. It further describes how they can be practically obtained; it indicates guidance values demonstrating fitness for purpose. As a result, these guidance values serve as a benchmark for experienced analytical laboratories.

This document may contain useful information for CEN members, the European Commission, the EFTA secretariat, other governmental agencies or outside bodies. The criteria in this CEN report are used as guidance in the CEN/TC 327/WG 5. In general, method performance criteria are generated for collaborative trials or for single laboratory validation (SLV) studies. The first case describes how a method performs when used by several laboratories, giving greater confidence that the method is applicable and can be implemented with the obtained method performance. The second case only demonstrates how a method performs in a particular laboratory. As a result, SLV should be conducted with care to avoid misinterpretation. This is important as reproducibility (between laboratory variance) can only be derived from collaborative trials. Furthermore, performance parameters such as limit of detection (LOD) and limit of quantification (LOQ) are laboratory specific as the quantitative measurement capability strongly depends on the instrumental conditions used by each laboratory.

This document relates to current EU legislation concerning performance requirements of analytical methods for mycotoxins in food and feed chain, such as Regulation (EC) No 2017/625 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules [13] as well as Regulation (EC) No 401/2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs [14]. The latter is specific for food, however as recent legislation on some mycotoxins does not specify the intended final use, either food or feed, rather the raw commodity (Commission Recommendation 2013/165/EU on the presence of T-2 and HT-2 toxin in cereals and cereal products) performance requirements for analytical methods are in the future anticipated to be equivalent independent of the commodities' destination purpose.

Further this criteria approach document also relates to pre-existing documents such as the ISO 5725-series, CR 13505 [15] and CEN/TR 16059 [16].

1 Scope

This document specifies performance criteria for the selection of single-laboratory validated or collaborative study validated methods of analysis of mycotoxins in feed. The terms and definition of the relevant parameters for method validation are included. The performance requirements and characteristics are provided. This document could serve as a guide:

— to assess the quality of new European Standard methods under validation;

— to review the quality of previous collaborative trials;

— to confirm the extension of the scope of an already published European Standard applied to other analyte concentrations or matrices; or

— to evaluate the fitness-for-purpose of single-validated methods.

The performance criteria can apply to methods dedicated to the determination of mycotoxins.

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/ui

3.1
accuracy
closeness of agreement between a test result and the accepted reference value

Note 1 to entry: The term accuracy, when applied to a set of test results, involves a combination of random components and a common systematic error or bias component.

Note 2 to entry: It is assessed by determining trueness and precision.

[SOURCE: ISO 5725-1:1994, 3.6, see [17], modified; 2002/657/EEC, see [18], modified]

3.2
applicability
scope of the analytical method; description of the analytes, matrices, and concentration ranges (mass fractions) for which a method of analysis can be used satisfactorily to determine compliance with a given standard (i.e. CEN, ISO, CODEX)

Note 1 to entry: In addition to a statement of the range of capability of satisfactory performance for each factor, the statement of applicability (scope) also includes warnings as to known interference by other analytes, or inapplicability to certain matrices and situations.