



DRAFT TANZANIA STANDARD

Microbiology of the food chain - Method validation - Part 4: Protocol
for method validation in a single laboratory

TANZANIA BUREAU OF STANDARDS

FOR STAKEHOLDERS' COMMENTS

0 National Foreword

The Tanzania Bureau of Standards is the statutory national standards body for Tanzania, formally established by the Act.No.3 of 1975, which was amended and repealed by Act.No.2 of 2009.

This draft Tanzania standard is being prepared by the Microbiology Technical Committee, under the supervision of the Agriculture and Food Standards Divisional Committee (AFDC).

This draft Tanzania standard is the identical adoption of ISO 16140-4:2020- Microbiology of the food chain - Method validation - Part 4: Protocol for method validation in a single laboratory, published by International Organization for Standardization (ISO).

Terminology and conventions

The text of the International standard is hereby being recommended for approval without deviation for publication as draft Tanzania standard.

Some terminologies and certain conventions are not identical with those used in Tanzania standards; attention is drawn especially to the following: -

- 1) The comma has been used as a decimal marker for metric dimensions. In Tanzania Standards, it is current practice to use "full point" on the baseline as the decimal marker.
- 2) Where the words "International Standard" appear, referring to this draft standard they should read "Tanzania Standard".

1 SCOPE

This document specifies the general principles and the technical protocols for single-laboratory validation of methods for microbiology in the food chain. The protocols in this document only validate the method for the laboratory conducting the study.

This document is applicable to single-laboratory validation of:

- methods used in the analysis (detection or quantification) of microorganisms in:
- products intended for human consumption;
- products intended for animal feeding;
- environmental samples in the area of food and feed production, handling;
- samples from the primary production stage;
- methods for the confirmation or typing of microorganisms. This validation will replace only the confirmation or typing procedure of a specified method (see Annex G). This document is, in particular, applicable to bacteria and fungi. Some clauses can be applicable to other (micro) organisms or their metabolites, to be determined on a case-by-case basis.

Single-laboratory validation is required if an interlaboratory validation in accordance with ISO 16140-2 is not appropriate. Possible applications are:

- validation of an in-house method;
- method evaluation study in the validation process of a reference method in accordance with
- ISO 17468;
- extension of the scope of an ISO 16140-2 validated method, e.g. category extension or test portion size;

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- modifications of existing methods.

Single-laboratory validation is the second step in the standardization of a reference method (see ISO 17468). It is only applicable to methods that are fully specified with regard to all relevant parameters (including tolerances on temperatures and specifications on culture media) and that have already been optimized.

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