



DRAFT TANZANIA STANDARD

Microbiology of the food chain - Method validation - Part 7: Protocol
for the validation of identification methods of microorganisms

TANZANIA BUREAU OF STANDARDS

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statutory national standards body for Tanzania, formally established by the Act.No.3 of 1975, which was amended and repealed by Act.No.2 of 2009.

The Microbiology Technical Committee, under the supervision of the Agriculture and Food Standards Divisional Committee (AFDC), has prepared this Tanzania Standard.

This Tanzania standard is the identical adoption to ISO 16140-7: 2024- Microbiology of the food chain - Method validation - Part 7: Protocol for the validation of identification methods of microorganisms, 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 Tanzania standard.

Some terminologies and certain conventions are not identical with those used in Tanzania standards; attention is drawn 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(s)” appear, referring to this standard they should read “Tanzania Standard(s)”.

1. Scope

This document specifies the general principle and the technical protocol for the validation of identification methods of microorganisms for microbiology in the food chain. As there is no reference method, no method comparison study can be run. Therefore, this document provides a protocol to evaluate the performance characteristics and validate the method workflow using well-defined strains. When required, an additional identification method can be used.

This document is applicable to the validation of identification methods of microorganisms that are used for the analysis of isolated colonies from:

- i. products intended for human consumption;
- ii. products for feeding animals;
- iii. environmental samples in the area of food and feed production and handling; and
- iv. samples from the primary production stage.

Identification methods only validated in accordance with this document cannot be used instead of confirmation described in:

- i. the reference method;
- ii. an alternative method validated in accordance with ISO 16140-2; and
- iii. an alternative method validated in accordance with ISO 16140-6.

In these instances, the identification method is validated in accordance with ISO 16140-6 method that is used as a confirmation method.

This document is applicable to bacteria and fungi. Some clauses can be applicable to other (micro) organisms, which can be determined on a case-by-case basis.