



DRAFT TANZANIA STANDARD

Microbiology of the food chain - Method validation - Part 6: Protocol for the validation of alternative (proprietary) methods for microbiological confirmation and typing procedures

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the statutory national standards body for Tanzania, formally established by the Act.No.3 of 1975, which was amended and repealed by Act.No.2 of 2009.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 16140-6:2019- Microbiology of the food chain - Method validation - Part 6: Protocol for the validation of alternative (proprietary) methods for microbiological confirmation and typing procedures, 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 principle and the technical protocol for the validation of alternative confirmation methods for microbiology in the food chain. This document compares the result of the alternative confirmation method against the confirmation procedure of a reference method or, if needed, a reference confirmation method (e.g. whole genome sequencing).

This document is applicable to the validation of alternative confirmation methods used for the analysis (detection or quantification) of isolated 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.

Validated alternative confirmation methods can be used to replace (partly or completely) the confirmation procedure described in:

- the reference method;
- an alternative method validated in accordance with ISO 16140-2 only if one of the isolation agars specified in the validation study of the alternative confirmation method is used.

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This document is also applicable to the validation of alternative typing methods, where the reference method can be, for example, a serological method (e.g. serotyping of *Salmonella*) or a molecular method (e.g. typing of Shiga toxin-producing *E. coli*).

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

Validation studies in accordance with this document are primarily intended to be performed by organizations or expert laboratories involved in method validation, but can also be used by a single laboratory, especially when performing in-house validation under certain conditions (see ISO 16140-4).

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