



AFDC 8 (1905) DTZS  
ISO 16140-5:2020

## DRAFT TANZANIA STANDARD

---

Microbiology of the food chain - Method validation - Part 5: Protocol  
for factorial interlaboratory validation for non-proprietary methods

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statutory national standards body for Tanzania, formally established by the Act.No.3 of 1975, which was amended and repealed by Act.No.2 of 2009.

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 16140-5:2020- Microbiology of the food chain - Method validation - Part 5: Protocol for factorial interlaboratory validation for non-proprietary methods, 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 (based on orthogonal, factorial studies) for the validation of non-proprietary methods for microbiology of the food chain.

This document is applicable to the validation of methods used for 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.

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.

This document specifies protocols for the validation against a reference method for both quantitative and qualitative methods. This document also provides a protocol for the validation of quantitative methods without a reference method. Qualitative methods cannot be validated without a reference method in accordance with this document.

NOTE: ISO 16140-2 specifies the general principle and the technical protocol for the validation of alternative, mostly proprietary, methods against a reference method.

**AFDC 8 (1905) DTZS**  
**ISO 16140-5:2020**

This document is only applicable to the validation of 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.

Methods that have been validated in accordance with this document can be used by the laboratories of the specified population of laboratories.

FOR STAKEHOLDERS COMMENTS