



AFDC 8 (1902) DTZS  
ISO 16140-2:2016

## **DRAFT TANZANIA STANDARD**

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Microbiology of the food chain - Method validation - Part 2: Protocol for the validation of alternative (proprietary) methods against a reference method

**TANZANIA BUREAU OF STANDARDS**

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## **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the statutory national standards body for Tanzania, formally established by the Act.No.3 of 1975, which was amended and repealed by Act.No.2 of 2009.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 16140-2:2016- Microbiology of the food chain - Method validation - Part 2: Protocol for the validation of alternative (proprietary) methods against a reference method, 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 part of ISO 16140 specifies the general principle and the technical protocol for the validation of alternative, mostly proprietary, methods for microbiology in the food chain. Validation studies according to this part of ISO 16140 are intended to be performed by organizations involved in method validation.

This part of ISO 16140 is applicable to the validation of methods 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, and
- samples from the primary production stage.

This part of ISO 16140 is in particular applicable to bacteria and fungi. Some clauses of this part of ISO 16140 could be applicable to other (micro) organisms or their metabolites on a case-by-case-basis.

In the future, guidance for other organisms (e.g. viruses and parasites) will be included in either this part or a separate part of ISO 16140.