



**International  
Standard**

**ISO 16140-4**

**Microbiology of the food chain —  
Method validation —**

Part 4:  
**Protocol for method validation in a  
single laboratory**

**AMENDMENT 1: Validation of a larger  
test portion size for qualitative methods**

*Microbiologie de la chaîne alimentaire — Validation des  
méthodes —*

*Partie 4: Protocole pour la validation de méthodes dans un seul  
laboratoire*

*AMENDEMENT 1: Validation d'une taille de prise d'essai plus  
grande pour des méthodes qualitatives*

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**AMENDMENT 1  
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This document was prepared by Technical Committee ISO/TC 34, *Food products*, Subcommittee SC 9, *Microbiology*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 463, *Microbiology of the food chain*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

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# Microbiology of the food chain — Method validation —

## Part 4:

## Protocol for method validation in a single laboratory

### AMENDMENT 1: Validation of a larger test portion size for qualitative methods

#### Clause 3

Add the following terminological entry:

#### 3.13

##### **larger test portion size**

measured (volume or mass) representative sample taken from the laboratory sample or test sample for use in the preparation of the initial suspension that is larger than the test portion that has been described in the original method and/or validation document

#### 4.1

Add the following text after the second paragraph:

The protocol used to validate a larger test portion size for qualitative methods in a single laboratory shall be as given in Annex H.

[ISO 16140-4:2020/Amd 1:2024](https://standards.iso.org/iso/16140/-4/ed-1/en/amd/1/)

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#### 5.1.1.4, note

Replace the text with the following:

NOTE An Excel®-based program<sup>1</sup> is available for performing the RLOD calculations from <https://standards.iso.org/iso/16140/-4/ed-1/en/amd/1/>.

#### 5.1.2.4, Note 2

Replace the text with the following:

NOTE 2 An Excel®-based program<sup>2</sup> is available for performing the LOD<sub>50</sub> calculations from <https://standards.iso.org/iso/16140/-4/ed-1/en/amd/1/>.

#### 6.1.2.3, Note 2

Replace the text with the following:

NOTE 2 An Excel®-based program<sup>4</sup> is available for performing the LOD<sub>50</sub> calculations from <https://standards.iso.org/iso/16140/-4/ed-1/en/amd/1/>.

*Annex H*

Add the following annex after Annex G, before the Bibliography.

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