Transition period for the implementation of ISO 16140-3

1 Introduction

During the transition period, this document is intended to be used for the implementation of ISO 16140-3, *Microbiology of the food chain – Method validation – Part 3: Protocol for the verification of reference methods and validated alternative methods in a single laboratory*.

It provides information on the verification of methods that is permitted during the transition period (until 2027-12-31) as agreed by ISO/TC 34, *Food products*, SC 9, *Microbiology*, and CEN/TC 463, *Microbiology of the food chain*. This transition period is provided because some reference methods are not yet (fully) validated and will give standardization organizations (including ISO and CEN committees) time to validate their reference methods.

This document and ISO 16140-3 are intended to be used by:

— user laboratories (accredited and non-accredited);

— (technical) assessors involved in the evaluation of verification data generated for reference methods and validated alternative methods;

— accreditation bodies.

It can also be useful for regulatory authorities, risk managers and customers.

2 General principles for the transition period

The general principle for verification is that the method to be verified (either alternative or reference) has been validated. However, some reference methods (including ISO or CEN standards) are not yet (fully) validated.

The transition arrangement is as follows:

— until 2027-12-31, user laboratories may perform method verification of non-validated reference methods and in accordance with ISO 16140-3:2021, Annex F;

— from 2028-01-01, only validated reference methods are applicable for method verification (see ISO 16140-3:2021, Clauses 5 or 6). This means that when reference methods (including ISO or CEN standards) are introduced in a laboratory and they have not been validated (no performance characteristics are included), they shall be validated before a verification can be performed in accordance with ISO 16140-3.

For the implementation of ISO 16140-3, a differentiation is made between methods in these situations:

— methods already accredited under the scope of laboratory application (see Clause 3 shown below);

— methods or (food) categories new to the laboratory (see Clause 4 on the next page);

— methods that have been revised after they have been accredited under the scope of laboratory application (see Clause 5 on the next page).

NOTE The word “accredited” is used above as accredited laboratories have to verify or validate their methods before implementation and obtaining accreditation (see ISO/IEC 17025:2017, *General requirements for the competence of testing and calibration laboratories*).

3 Methods already accredited under the scope of laboratory application

Validated (reference or alternative) methods accredited under the scope of laboratory application, for which a verification had already been conducted before the publication of ISO 16140-3, do not need to be re-verified in accordance with the principles of ISO 16140-3 upon publication of this International Standard. However, they may be required to be re-verified, using ISO 16140-3, when changes are made to the method (see Clause 5).

NOTE During the transition period, this is also applicable to non-validated reference methods.

4 Methods or (food) categories new to the scope of laboratory application

Any validated method that is introduced into the laboratory, after the publication of ISO 16140-3, shall be verified in accordance with ISO 16140-3 before implementation.

New (food) categories of already accredited methods that are extensions to the existing scope of laboratory application shall also be verified before initiating routine testing. Those new (food) categories shall have been included in the validation study, meaning they belong to the scope of validation.

NOTE During the transition period, this is also applicable to non-validated reference methods.

5 Methods that have been revised after they have been accredited under the scope of laboratory application

Specific requirements apply depending on whether they are validated reference methods (see a), non-validated reference methods (see b), or validated alternative methods (see c).

a) Validated reference methods: when ISO or CEN standards are revised, an evaluation is made of the impact of the technical revision on the performance characteristics. This is stated in the Introduction of the applicable International Standard. Several cases can be distinguished:

- a minor (technical) change does not require re-verification;
- a major (technical) change that, after re-validation, has no (or minor) impact on the performance characteristics, does not require re-verification;
- a major (technical) change that, after re-validation, has a major impact on the performance characteristics requires re-verification.

b) Non-validated reference methods: revised non-validated reference methods (including ISO or CEN standards) can only be used for verification during the transition period (see Clause 2). From 2028-01-01, only validated reference methods can be used for verification.

c) Validated alternative methods: changes to a validated alternative method that require re-validation or additional validation of the method, may also require re-verification of the method in accordance with ISO 16140-3.

NOTE It is the responsibility of the validation/certification bodies to decide on the extent of the re-validation once an alternative method is revised and if re-verification is needed.

Possible changes that require re-validation of the method and therefore also may require re-verification of the method include:

- a major (technical) change in the reference method(s) used to perform method validation;
- a major (technical) change or revision of ISO 16140-2:2016 (the protocol used for alternative method validation) or ISO 16140-6:2019 (the protocol used for alternative confirmation method validation);
- a change to the scope of the method (extensions or exclusions). The verification will be limited to the (food) categories that are included in the change of the scope of validation.
- technical changes to parameters or application (reagents, primers, incubation temperatures/times, etc.) of the alternative method that have been shown to affect the alternative method performance.