SLOVENSKI STANDARD
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Mikrobiologija v prehranski verigi - Validacija metode - 6. del: Protokol za validacijo alternativnih (lastniških) metod za postopke mikrobiološke potrditve in tipizacije (ISO/DIS 16140-6:2017)

Microbiology of the food chain - Method validation - Part 6: Protocol for the validation of alternative (proprietary) methods for microbiological confirmation and typing procedures (ISO/DIS 16140-6:2017)

Mikrobiologie von Lebensmitteln und Futtermitteln - Verfahrensvalidierung - Teil 6: Arbeitsvorschrift für die Validierung mikrobiologischer Nachweisverfahren (ISO/DIS 16140-6)

Microbiologie de la chaîne alimentaire - Validation des méthodes - Partie 6: Protocole pour la validation des méthodes alternatives (propriétaires) pour confirmation et identification microbiologique (ISO/DIS 16140-6:2017)

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Microbiology of the food chain — Method validation —

Part 6:
Protocol for the validation of alternative (proprietary) methods for microbiological confirmation and typing procedures

Microbiologie de la chaîne alimentaire — Validation des méthodes —

Partie 6: Protocole pour la validation des méthodes alternatives (propriétaires) pour confirmation et identification microbiologique

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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This document was prepared by Technical Committee ISO/TC 34, *Food products,* Subcommittee SC 9, *Microbiology* (Working Group WG 3, *Method validation).*

A list of all parts of the ISO 16140 series can be found on the ISO website.

Introduction

The ISO 16140 series has been elaborated in response to the need for various ways to validate or verify test methods. It is the successor of ISO 16140:2003, *Microbiology of food and animal feeding stuffs — Protocol for the validation of alternative methods.* ISO 16140 series consists of several parts with the general title, *Microbiology of the food chain — Method validation:*

— *Part 1: Vocabulary*

— *Part 2: Protocol for the validation of alternative (proprietary) methods against a reference method*

— *Part 3: Protocol for the verification of reference and validated alternative methods implemented in a single laboratory*

— *Part 4: Protocol for single-laboratory (in-house) method validation*

— *Part 5: Protocol for factorial interlaboratory validation for non-proprietary methods*

— *Part 6: Protocol for the validation of alternative (proprietary) methods for microbiological confirmation and typing procedures*

ISO 17468, *Microbiology of the food chain — Technical requirements and guidance on establishment or revision of a standardized reference method*[7], is a closely linked International Standard. This International Standard, which establishes technical rules for the development and validation of standardized methods, is intended for the development of standardized methods by ISO/TC 34, *Food products*, Subcommittee SC 9, *Microbiology* and CEN/TC 275/WG 6, *Microbiology of the food chain.*

In general two stages are needed before a method can be used in a laboratory:

— The first stage is the validation of the method. This is either conducted in several laboratories (parts 2 and 5 of ISO 16140) or in one laboratory (part 4 of ISO 16140).

— The second stage is method verification, where a laboratory demonstrates that it can satisfactorily perform a validated method. This is described in part 3 of ISO 16140 (method verification). In part 3, a separation is made between verification of (food) items that are included in the validation study and (food) items that are not tested in the validation study but belong within the scope of validation.

NOTE 1 Standardized reference methods (with and without published validation data) only require verification before implementation in the laboratory.

NOTE 2 In this part of ISO 16140, the word 'item' is sometimes combined with 'food' to improve the readability of this document. However, the word 'food' is interchangeable with 'feed' and the other areas of the food chain as mentioned in the Scope of ISO 16140-6.

Part 4 of ISO 16140 addresses validation within a single laboratory. The results are therefore only valid in the laboratory which conducted the study. In this case, verification (part 3 of ISO 16140) is not required.

Part 5 of ISO 16140 describes protocols for situations where a more rapid validation is required or when the method to be validated is highly specialised, and, the number of participating laboratories required by ISO 16140-2 cannot be reached.

The flow chart in Figure 1 gives an overview of the links between the different parts mentioned above. It also guides the users in selecting the right part of the ISO 16140 series, taking into account the purpose of the study and the remarks given above. For this, it is important to distinguish between 'reference method' and 'standardized reference method'. A reference method is an internationally recognized and widely accepted method (term 2.59 of ISO 16140-1:2016) and a standardized reference method is a reference method described in a standard (term 3.5 of ISO 17468:2016). In the ISO 16140 series, reference method includes standardized reference method. The flow diagram acknowledges that published validation data may not be available for some standardized reference methods.

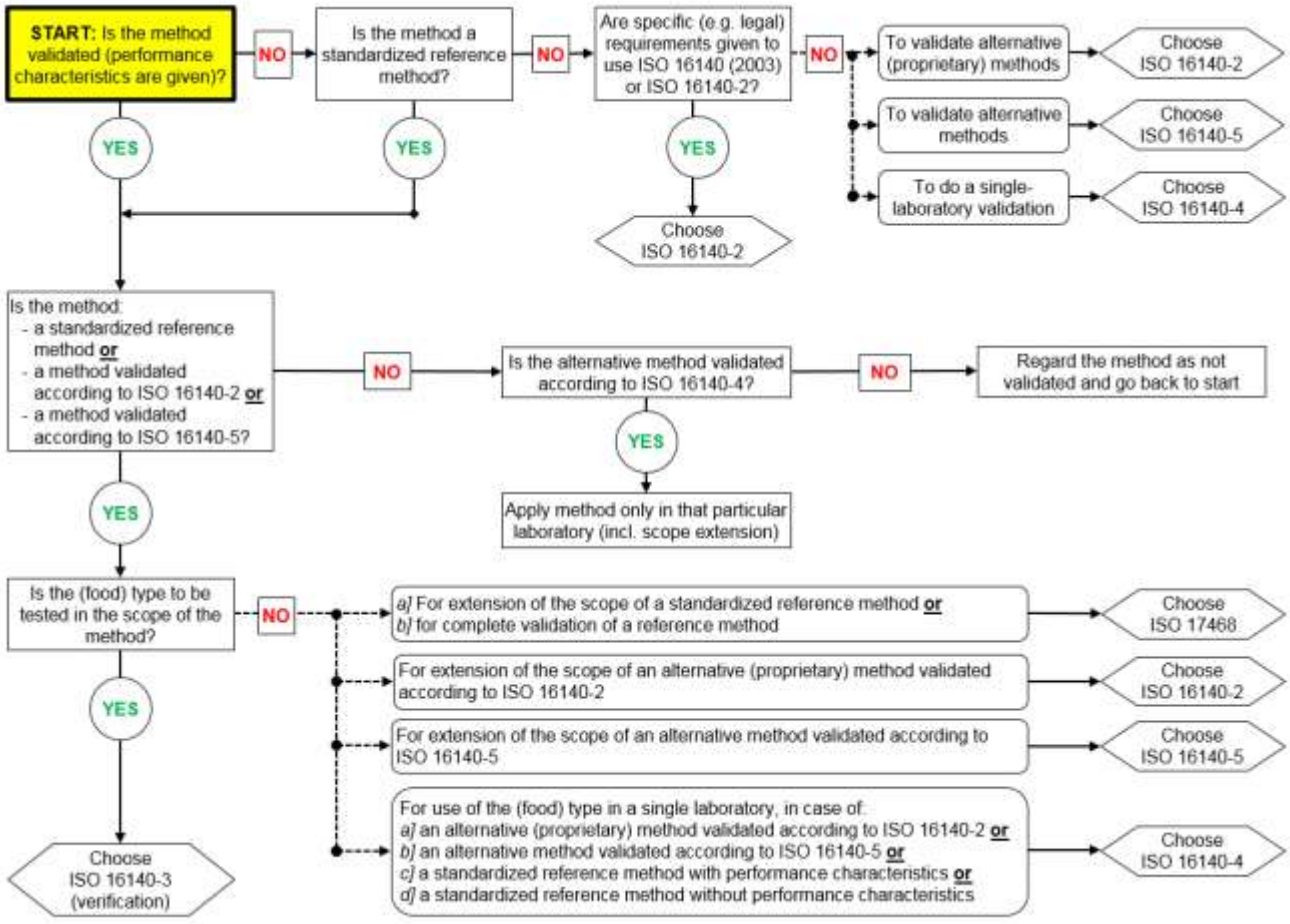

Figure 1 — Flow chart for application of the different parts of the ISO 16140-series

Part 6 of ISO 16140, is somewhat different from the other parts in the ISO 16140 series in that it relates to a very specific situation where only the confirmation procedure of a method is validated. The confirmation procedure advances a suspected (presumptive) result to a confirmed positive result. The typing of pure strains (e.g. serotyping of *Salmonella*) is included in part 6 of ISO 16140.

The procedure described in this part of ISO 16140 is intended for the 'full' validation of alternative (proprietary) methods for microbiological confirmation and typing, further referred to as 'alternative confirmation methods'. The procedure for verification of alternative confirmation methods in a single laboratory will be described in part 3 of ISO 16140.

During the validation study, the performance of the alternative confirmation method will be compared to the performance of the reference confirmation procedure.

