

This is a preview of "ISO 16140-1:2016". [Click here to purchase the full version from the ANSI store.](#)

First edition
2016-06-15

Microbiology of the food chain — Method validation —

Part 1: Vocabulary

*Microbiologie de la chaîne alimentaire — Validation des méthodes —
Partie 1: Vocabulaire*



Reference number
ISO 16140-1:2016(E)

© ISO 2016



COPYRIGHT PROTECTED DOCUMENT

© ISO 2016, Published in Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

This is a preview of "ISO 16140-1:2016". [Click here to purchase the full version from the ANSI store.](#)

Contents

	Page
Foreword	iv
Introduction	v
1 Scope	1
2 Terms and definitions	1
Bibliography	12

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: [Foreword - Supplementary information](#)

The committee responsible for this document is ISO/TC 34, *Food products*, Subcommittee SC 9, *Microbiology*.

This first edition of ISO 16140-1, together with ISO 16140-2, cancels and replaces ISO 16140:2003, which has been technically revised. It also incorporates the Amendment ISO 16140:2003:Amd.1:2011.

ISO 16140 consists of the following parts, under 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*

The following parts are under preparation:

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

This is a preview of "ISO 16140-1:2016". [Click here to purchase the full version from the ANSI store.](#)

Introduction

The use of validated methods is an important requirement for obtaining reliable results with a specific method. It also facilitates the comparability of results obtained with the same method in different laboratories. Validation procedures covered by ISO 16140 (all parts) involve various aspects of validation, such as validation of alternative (proprietary) methods, single laboratory validation, validation of (alternative) methods using a limited number of laboratories, and verification of methods (demonstration of a laboratory to correctly apply a validated method). In addition, there is a close link to ISO 17468 describing the procedure for the validation of the standard methods themselves.