

Australian/New Zealand Standard™

**Guide to determining the equivalence of
food microbiology test methods**

Part 1: Qualitative tests



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AS/NZS 4659.1:1999

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Australia New Zealand Food Authority
 Australian Chamber of Commerce and Industry
 Australian Food and Grocery Council
 Australian Government Analytical Laboratories
 Australian Industry Group
 Australian Institute of Food Science and Technology
 Australian Poultry Industries Association
 Commonwealth Scientific and Industrial Research Organization
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 Food Science Australia
 Food Technology Association of Victoria
 National Association of Testing Authorities Australia
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Dairy Industry Quality Centre

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PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee FT/4, Food Microbiology.

The objective of this Standard is to provide guidance on determining the equivalence of microbiological test methods. This Part covers how to determine whether an alternate method for qualitative tests will yield a result equivalent to an Australian Standard or to a Joint Australian/New Zealand Standard method.

It is not intended that this Standard be applied retrospectively to existing laboratory validation studies, nor that it replace the validation of methods such as performed under the auspices of the Association of Official Analytical Chemists, International or the Micro Val project of the European Union, which usually aim to validate a method which is applicable to a number of foods and applicable under a variety of laboratory conditions.

This guide to validation is intended for individual laboratories wishing to validate procedures that are alternatives to Standard methods. It allows the validation to be performed in a single laboratory. The result of following the procedures in this Guide is the production of a report which will in some specific situations allow a laboratory and its clients to determine or agree on whether an alternative method is suitable as a substitute for a Standard method. The results may then be applied to other laboratories.

This Standard is one of a series of Guides covering determination of the equivalence of food microbiology test methods. The other three Parts cover quantitative tests, confirmation tests and antibiotic tests.

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FOREWORD

An alternate method will be considered to be validated if it is shown to yield results that are equivalent to those of the Australian or Australian/New Zealand Standard method. A method can only be considered to be validated for the matrix in which the tests were performed. A validation study applies to the method and the matrix employed, not to the laboratory or staff where the validation was performed. This means that a method validated for a particular matrix can be adopted by other laboratories on the basis of the validation report.

The alternate method may prove to be superior to the reference method for a number of reasons, even though it may not be validated according to the criteria in this Guide. In this case, as with any validation study, it is the right of any laboratory and its client to choose a method based on all the available information.

Reference cultures need to be used when performing an alternate method, as specified in the relevant part of AS 1766 or AS/NZS 1766, even after validation of the alternate method according to this Guide.

Five strains of the target organism are inoculated into five different samples of the matrix at one level and tested by the reference method and the alternate method. The number of positive and negative results are recorded and statistical analysis performed. An equivalent number of uninoculated controls are also tested.

NOTE: The purpose of using five samples is an attempt to encompass the variation that may be found within the matrix.