AS 4659.1:2015

Australian STANDARD

Guide to determining the equivalence of food microbiology test methods

Part 1: Qualitative tests

STANDARDS Australia

This Australian Standard® was prepared by Committee FT-035, Food Microbiology. It was approved on behalf of the Council of Standards Australia on 9 December 2014.
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The following are represented on Committee FT-035:

- ACT Health
- Australian Food and Grocery Council
- Australian Institute of Food Science and Technology
- Australian Society for Microbiology
- CSIRO
- Dairy Industry Association of Australia
- Department of Agriculture (Australian Government)
- Department of Health, Vic.
- Department of Health, WA
- Food Technology Association of Australia
- Meat and Livestock Australia
- National Association of Testing Authorities Australia
- National Measurement Institute
- Queensland Health Forensic and Scientific Services
- University of Melbourne

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Standards Australia wishes to acknowledge the participation of the expert individuals that contributed to the development of this Standard through their representation on the Committee and through the public comment period.

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Australian Standard®

Guide to determining the equivalence of food microbiology test methods

Part 1: Qualitative tests

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PREFACE

This Standard was prepared by the Standards Australia Committee FT-035, Food Microbiology, to supersede AS/NZS 4659.1:1999.

After consultation with stakeholders in both countries, Standards Australia and Standards New Zealand decided to develop this Standard as an Australian Standard rather than an Australian/New Zealand Standard.

The objectives of this revision are—

(a) to provide guidance on determining the equivalence of microbiological test methods;

(b) to explain how to determine whether an alternate method for qualitative tests will yield a result equivalent to an Australian Standard method;

(c) to update the references; and

(d) to incorporate minor technical variations to emphasize the scope and limitations of the Standard.

This Standard is one of a series of guides covering determination of the equivalence of food microbiology test methods. The series now comprises the following:

AS	
4659	Guide to determining the equivalence of food microbiology test methods
4659.1	Part 1: Qualitative tests
4659.2	Part 2: Quantitative tests
4659.3	Part 3: Confirmation tests

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FOREWORD

An alternate method will be considered to be equivalent if it is shown to yield results that are not statistically different to those obtained using the Australian Standard method. A method can only be considered to be equivalent for the matrix in which the tests were performed.

Reference cultures specified in the relevant part of AS 5013 need to be included when performing an alternate method as specified in the relevant part of AS 5013, even after equivalence of the alternate method has been determined according to this Standard.

For the purpose of determining equivalence of the alternate method, five strains of the target organism (including the reference strain) are inoculated into five different samples of the matrix being tested at one level and tested by the reference method and the alternate method. The number of positive and negative results is recorded and statistical analysis performed.

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

It is not intended that this Standard be applied retrospectively to existing laboratory validation studies, nor that it replace the validation of methods performed under the auspices of organizations such as, but not limited to, the Association of Official Analytical Chemists International (AOAC International) and Association Française de Normalisation (AFNOR); or those methods validated according to ISO 16140:2003, *Microbiology of food and animal feeding stuffs – Protocol for the validation of alternative methods*.

This Standard, for the determination of equivalence, is intended for individual laboratories wishing to demonstrate performance of procedures that are alternatives to Australian Standard methods. It allows an equivalence determination to be performed in a single laboratory. The result of following the procedures in this Standard is the production of a report that 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 an Australian Standard method.

STANDARDS AUSTRALIA

Australian Standard

Guide to determining the equivalence of food microbiology test methods

Part 1: Qualitative tests

1 SCOPE

This Standard sets out a protocol that may be used to determine whether an alternate method will yield a result equivalent to an Australian Standard food microbiology method (AS 5013 series), the result for which is reported as 'detected' or 'not detected'.

NOTES:

1 An example of such a test is AS 5013.10, the method for the detection of *Salmonella*.

2 This Standard is not intended to replace the requirement for full validation for methods that have not previously been validated, for example, according to ISO 16140 or under the auspices of AOAC International, AFNOR, etc, or for the determination of equivalence of a standard method used with a matrix outside the scope of the method's initial validation.

2 REFERENCED DOCUMENTS

The following documents are referred to in this Standard:

AS		
5013	Food microbiology (series)	
5013.10	Method 10:	Microbiology of food and animal feeding stuffs—Horizontal method for the detection of *Salmonella* spp. (ISO 6579:2002, MOD)
5013.24.1	Method 24.1:	Microbiology of food and animal feeding stuffs—Horizontal method for the detection and enumeration of *Listeria monocytogenes*—Detection method (ISO 11290-1:1996, MOD)
ISO		
16140	Microbiology of food and animal feeding stuffs—Protocol for the validation of alternative methods	

3 DEFINITIONS

For the purpose of this Standard the definitions below apply:

3.1 Alternate method

The method for which equivalence is to be determined.

3.2 Detected

The method indicates that the target organism is present in a specified quantity of the matrix.

3.3 Equivalent

A determination, according to this Standard, that two methods (the reference and alternate methods) give results that are not statistically different when testing defined types of food samples.