AS 4659.2:2015

Guide to determining the equivalence of food microbiology test methods

Part 2: Quantitative tests

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.
This Standard was published on 3 February 2015.

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

This Standard was issued in draft form for comment as DR AS 4659.2:2014.

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®

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Part 2: Quantitative tests

First published as AS/NZS 4659.2:1999.
Second edition redesignated and published as AS 4659.2:2015.

Published by SAI Global Limited under licence from Standards Australia Limited, GPO Box 476, Sydney, NSW 2001, Australia

ISBN 978 1 74342 961 7

PREFACE

This Standard was prepared by the Standards Australia Committee FT-035, Food Microbiology, to supersede AS/NZS 4659.2:1999.

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 quantitative tests will yield a result equivalent to an Australian Standard method;

(c) to update 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 validated 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.

Quantitative methods—for each of the media, reagents or equipment specified in the alternate method five different samples per matrix type will be tested by the reference method and the alternate method. The results are 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 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 an Australian Standard method.

STANDARDS AUSTRALIA

Australian Standard

Guide to determining the equivalence of food microbiology test methods

Part 2: Quantitative tests

1 SCOPE

This Standard sets out a protocol that may be used to determine whether an alternate enumeration method will yield an equivalent result to an Australian Standard food microbiology method (AS 5013 series).

NOTES:

1 An example of such methods is the standard plate count or enumeration of coagulase positive staphylococci.

2 This Standard is not intended to replace the requirement for full validation for methods that have not previously been validated, for example, 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 methods initial validation.

2 REFERENCED DOCUMENTS

The following documents are referred to in this Standard.

AS		
5013	Food microbiology (series)	
5013.12.1	Method 12.1:	Microbiology of food and animal feeding stuffs—Horizontal method for the enumeration of coagulase-positive staphylococci (*Staphylococcus aureus* and other species)—Technique using Baird-Parker agar medium

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 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 sample.

3.3 Matrix

The food sample in which the target organism is to be detected.

3.4 Presumptive

The result given by the alternate method at the point where a decision may be made as to whether or not the matrix may contain the target organism. The method continues to confirm whether the presumptive result is in fact a positive result.

3.5 Reference culture

The culture designated in the appropriate Australian Standard method.