



Criteria for Approval Export Wine Test Methods

Operational Guideline: Version 3

Prelims

Version 3

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Disclaimer

IMPORTANT DISCLAIMER

Every effort has been made to ensure the information in this report is accurate.

NZFSA does not accept any responsibility or liability whatsoever for any error of fact, omission, interpretation or opinion that may be present, however it may have occurred.

Website

A copy of this document can be found at: <http://www.nzfsa.govt.nz/wine/index.htm>

Explanatory

This statement is for guidance

1. What is the purpose of this Guideline?

This is an NZFSA guideline. It is designed to assist staff of recognised laboratories, and NZFSA to have a common understanding of:

- a. the criteria for NZFSA approval of export wine test methods; and
- b. the process for assessment of export test methods and NZFSA approval.

2. What is included in this Guideline

This guideline may be applied to export test methods used for analysis of wine as per the Wine Act 2003 and associated NZFSA specifications.

The guideline outlines the following:

- a. Criteria for assessing export wine test methods.
- b. The assessment process for approval of export wine test methods.
- c. Forms and other documents required when applying for NZFSA approval of export wine test methods.

Statements contained within a boarder, other than tables, are provided for guidance only.

For example:

3. What are the desired outcomes?

It is expected that after reading this guideline, affected people will understand what is involved in gaining NZFSA approval of export test methods for analysis of wine.

4. References

- a. Wine Act 2003
- b. OIV Compendium of International Methods of Analysis.

5. Glossary of Term

Accreditation Body means an internationally recognised, independent, not for profit organisation which is authorised to accredit organisations to certain ISO standards.

Bias is the average difference between the test results and the accepted reference value.

Export Eligibility Requirement means a regulation or Director-General notice that sets out the requirements that must be met for wine to be eligible for export from New Zealand under Section 38 of the Wine Act 2003.

Fit for purpose in relation to test methods, means that the test method is:

- a. unmodified and being used within its scope.
- b. being used for the specific purpose for which it has been approved by NZFSA.

Limit of detection is the concentration of analyte that leads to the conclusion, with a given probability of error, that the sample concentration exceeds the concentration in a blank.

Official Assurance means a statement made under Section 42 of the Wine Act 2003 to a foreign government, or an agent of a foreign government, attesting that any one or more of the following applies in respect of wine:

- a. any specified process has been completed under that Act with respect to the wine concerned;
- b. the wine concerned meets the standards and specifications set under subpart 2 of Part 2 of the Wine Act 2003, and any relevant New Zealand food standards for that wine;
- c. any overseas market access requirements of any foreign government that are recognised by New Zealand, and that are stated in the assurance, have been met by the system under which the wine was made;
- d. the situation in New Zealand, in relation to any matter concerning wine, is stated in the assurance.

OIV means the Organisation Internationale de la Vigne et du Vin (International Organisation of Vine and Wine) whose compendium of methods of analysis provides a reference point for European Community Members.

Precision is an assessment of the closeness of agreement between independent test results on the same sample obtained under specified conditions.

Range is the area defined by the maximum and minimum concentration of analyte within which the method demonstrates a satisfactory relationship with the reference method or samples of known concentration.

Reproducibility (R) is the precision of a method where test results are obtained using the same method on identical samples in different laboratories with different operators using different equipment. In situations where only one laboratory uses the test method, intermediate precision can be provided. Intermediate precision is a measure of method precision given changes in one or more of time, calibration, equipment, and operator in a single laboratory. Intermediate precision lies between the two extreme measures of precision, repeatability and reproducibility.

Sensitivity rate (the true-positive detection rate) is the probability that the method will classify a test sample as positive, given that the sample is a “known” positive.

Specificity rate (the true-negative detection rate) is the probability that the method will classify a test sample as negative, given that the sample is a “known” negative.

6. Background

NZFSA has issued a notice requiring laboratories to be recognised by NZFSA to provide analytical services to the New Zealand Wine Industry. The notice also requires recognised laboratories to use NZFSA-approved test methods.

[Wine \(Recognised Laboratory\) Notice 2007](#)

[Wine \(Recognised Laboratories\) Amendment Notice 2007](#)

7. Operational Guidance

7.1 Purpose of NZFSA export test method approval

NZFSA needs to have confidence in any test results produced to support official assurances made by the New Zealand government on NZFSA certificates.

Where the importing country’s legislation prescribes the test methods for analysis NZFSA must be confident that the appropriate method is used.

Analysis of wine may also occur to check compliance with the Australia New Zealand Food Standards Code, should this be required.

Approval of export test methods, based on agreed criteria, is one tool that NZFSA can use to ensure that any results produced by a laboratory are robust and credible. The approval of export wine test methods by NZFSA will become particularly important if there is a recall or complaint about a batch of wine.

If a laboratory acting as a NZFSA-recognised agency for the analysis of wine is contracted to test wine for a winemaker, then that winemaker can have confidence in any test results generated from a NZFSA-approved test.

The approval process also ensures that export test methods used for analysis by NZFSA recognised laboratories are either published by credible international sources or are characterised to demonstrate fitness for purpose.

7.2 Criteria for approval of export wine test methods

7.2.1 Approval of export wine test methods

NZFSA approval is required for any export test method used for testing conformance with:

- a. the Wine Act 2003;
- b. NZFSA standards and specifications;
- c. Or, official assurances provided by NZFSA.

NZFSA will only accept results from a recognised laboratory using an export method approved for the specific purpose when assessing whether a wine complies with the above.

The laboratory manager is responsible for demonstrating that the test method is fit for purpose.

7.3 Export test method approval

7.3.1 Generally export test approved methods

Export test methods from the following sources are usually approved by NZFSA, provided they are used within their scope and are unmodified and where relevant meet any legislative requirements of the importing country.

- a. international standards, e.g. ISO, Codex; or

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- b. methods published in reputable international texts, e.g. Standard methods published by AOAC Official Methods of Analysis, “Pearson’s Chemical Analysis of Foods”; or
 - c. national or regional standards or legislation, e.g. New Zealand Standards, Australian Standards, British Standards, Euronorm Standards, EU legislation.

These methods are subjected to the assessment criteria outlined in Section 8.4 and approval is based on the recommendation of the accreditation body.

7.3.2 Other export test methods

Export test methods from the following sources may be approved by NZFSA. These methods are characterised (refer Section 7.3.3 below) and subjected to the assessment criteria outlined in Section 8.3:

- a. refereed scientific journals;
- b. in-house test methods;
- c. other sources; e.g. test methods involving new technology. These methods normally come from instrument manufacturer’s instructions and technical publications.
- d. generally export test approved methods (refer section 7.3.1 above) used outside their scope and/or modified; and
- e. NZFSA-approved export test methods used outside their scope and/or modified.

7.3.3 Characterisation of export test methods

The applicant nominates and uses a suitable standard or code to characterise the export test method. The nominated standard or code specifies the principles and process being used and is demonstrated to be appropriate for the purpose.

The standard or code may be obtained from:

- a. international standards and guidelines;
- b. national and regional standards;
- c. reputable scientific publications or organisations; or
- d. an NZFSA-approved code of practice.

In the absence of a suitable standard or code, then the export test method is characterised using acceptable scientific principles and practices.

Method characterisation can involve considerable time and resources and is a specialist area. It is recommended that advice be obtained from an expert before commencing.

The characteristics listed below must be determined for each export test method. In some situations, e.g. residue analyses, additional characteristics may be required.

e. Method performance characteristics required for continuous methods

Continuous methods produce results that are expressed as numbers.

The following characteristics are required for continuous methods, where applicable (if not applicable, please include a reason why):

- i. bias;
- ii. precision (reproducibility or intermediate precision);
- iii. limit of detection; and
- iv. range.

The export test method must be characterised across the testing range.

Note: For a test method to be approved for EU testing characterisation must demonstrate that the method has accuracy, repeatability and reproducibility of results at least equivalent to the EC reference methods. See Appendix 1 for more information on the EU requirements.

f. Method characteristics required for nominal methods

Nominal methods only report the presence or absence of something.

The following characteristics are required for nominal methods, where applicable (if not applicable, please include a reason why):

- i. specificity rate (this may vary according to the level of analyte present);
- ii. sensitivity rate (this may vary according to the level of analyte present); and
- iii. limit of detection.

The test method must be characterised across the testing range.

8. Process for NZFSA Approval of Export Wine Test Methods

8.1 Application

Where approval is sought for export wine test methods, the party seeking approval:

- a. completes the application form found at:

<http://www.nzfsa.govt.nz/wine/all-documents>

- b. attaches the required information (refer below); and
- c. sends it to NZFSA.(address and contact as specified on the application form)

[Application form WL11 – Wine Export test Method Approval](#)

Information required for generally approved export test methods

For generally approved export test methods (refer section 7.3.1 above), the following information is provided with the completed application form:

- a. a copy of the published test method;
- b. a clear statement as to the proposed scope of application (e.g. wine tested for EU export documentation);
- c. evidence that the test is fit for purpose for the scope;
- d. a copy of the laboratory's test procedure with commentary highlighting any modifications from published procedures;
- e. copies of any relevant validation report publications; and
- f. copies of any method approval/recognition by other competent authorities.

8.2 Information required for other export test methods (characterisation)

For other export test methods (refer section 7.3.2) above, the following information is provided with the completed application form:

- a. a copy of the published test method (where relevant);

- b. a clear statement as to the proposed scope of application i.e. wine tested;
- c. evidence that the test is fit for purpose for the scope;
- d. a copy of the laboratory's test method procedure with commentary highlighting any modifications from published procedures;
- e. report(s) summarising the findings of the work to characterise the test method;
- f. copies of any other method(s) used in the report;
- g. all test results etc;
- h. statistical analysis and calculations; and
- i. any other documentation necessary to support the application.

8.3 Assessment

NZFSA receives applications for export test method approval accompanied by the supporting information listed above. NZFSA assesses the application using the following criteria:

- a. All required information is provided
- b. All references (source material), support the application
- c. For generally approved export test methods (international/national) methods:
 - i. the test method provided is the same as the published method;
 - ii. the test method is adequately documented;
 - iii. the test method is current (not obsolete);
 - iv. the test method is fit for purpose;
 - v. the test method is based on sound scientific principles and procedures; and
 - vi. there are no reports that suggest the test method should not be approved; where reports exist, there is sound scientific data that alleviates the reported concerns.
- d. For "other" export test methods;
 - i. the test method provided is the same as the published method;
 - ii. the test method is adequately documented;

- iii. the test method is current (not obsolete);
- iv. the test method is fit for purpose;
- v. the test method is based on sound scientific principles and procedures;
- vi. there are no reports that suggest the test method should not be approved;
Where reports exist, there is sound scientific data that alleviates the reported concerns; and
- vii. the test method characteristics are determined correctly (this requires checking of the design, the raw data and the calculations of the characteristics).

8.4 Approval

Once assessment is complete and where NZFSA is satisfied that the export test method is suitable, NZFSA approves the export test method including its scope and any appropriate restrictions. NZFSA advises the applicant the outcome of the application. When the export test method is approved, NZFSA adds the export test method to the register (database) of NZFSA-approved export test methods. A list of the NZFSA-approved export test methods, the scope of the approval and any restrictions is available from NZFSA on request.

8.5 Review

NZFSA reviews export test method approvals:

- a. once every five years; or
- b. when there is evidence that the export test method may no longer be fit for purpose; or
- c. when there are changes to regulatory requirements or official assurances.

8.6 Records

Records are kept by the applicant, for as long as is necessary for traceback purposes, of all aspects of the export test method, including its origin, characteristics, assessment and approval, demonstration of fitness for purpose and use.

8.7 For further information

For more information contact NZFSA at:

wine.query@nzfsa.govt.nz

9. Appendix 1 –Requirements for Export to the European Union

9.1 EU Laboratory Analysis

The following laboratory analyses are required for the issue of a New Zealand export certificate for wines exported to the EU.

1. Actual alcoholic strength (% v/v)
2. Total dry extract (g/L)
3. Total sugars (g/L)
4. Total acidity (as Tartaric Acid – g/L)
5. Volatile acidity (as Acetic Acid – g/L)
6. Citric acidity (as Citric Acid – g/L)
7. Total Sulphur Dioxide (mg/L)
8. Total Alcoholic Strength (Actual Alcoholic strength plus $0.0647 \times$ Total Sugars - % v/v)

9.2 Test methods for EU wine analysis

Test methods recommended within the European Community are listed in the OIV Compendium of Methods of Analysis.

http://news.reseau-concept.net/pls/news/p_entree?i_sid=&i_type_edition_id=20473&i_section_id=20486&i_lang=33

9.2.1 Sorbic Acid

Laboratories choosing to use the distillation method for volatile acidity (EC reference method) should assume a bias of 10mg/L to allow for sorbic acid in the measured value of volatile acidity to correct for “true” volatile acidity. This bias or correction is not applied to an analytical method that excludes sorbic acid as part of the measurand for volatile acidity.

9.3 Alternative Analytical Method

NZFSA will accept the use of “Approved Test Methods” and a process has been put in place for a laboratory to have alternative test methods submitted for approval. However, where a dispute arises, the reference methods and usual methods as prescribed in the OIV compendium of international methods of analysis must be used.