

New Zealand Food Safety

Haumaru Kai Aotearoa

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Wine Notice

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Laboratories Recognised for Testing of Wine for Export

16 October 2014

TITLE

Wine Notice: Laboratories Recognised for Testing of Wine for Export

COMMENCEMENT

This Wine Notice comes into force on 17 October 2014.

REVOCATION

This Wine Notice revokes the following Notices:

- Wine (Laboratories Recognised for Export Testing) Notice 2011, and
- Notice of Direction Recognised Laboratories: Inter-Laboratory Comparison Programmes July 2011.

ISSUING AUTHORITY

This Wine Notice is issued under section 120 of the Wine Act 2003.

Dated at Wellington this 16 day of October 2014

Peter Thomson
Director, Plants, Food & Environment
Ministry for Primary Industries
(acting under delegated authority of the Director General)

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Contact for further information
Ministry for Primary Industries (MPI)
Regulation and Assurance Branch
Plants, Food and Environment Directorate
PO Box 2526,
Wellington 6140
Email: wine.query@mpi.govt.nz

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Introduction

This introduction is not part of the Wine Notice, but is intended to indicate its general effect.

Purpose

- (1) This Notice specifies requirements for laboratories responsible for chemical testing and analysis of wine for export to markets requiring an official assurance for wine imports.

Background

- (1) This Notice is issued under the Wine Act 2003.
- (2) Some of the objectives of the Wine Act 2003 are to ensure compliance with wine standards and to safeguard official assurances issued to enable entry into overseas markets.
- (3) Recognised laboratories assist in meeting these objectives through the testing of wine for export.

Who should read this Wine Notice?

- (1) Any laboratory recognised or wishing to become recognised as an agency responsible for the chemical testing and analysis of wine for export under Section 71 of the Act.

Why is this important?

- (1) Operating other than in accordance with this Notice may lead to either the suspension of recognition under section 82J of the Act, or the withdrawal of recognition under section 82N of the Act.

Contacts

- (1) For questions or further information relating to this notice, please email wine.query@mpi.govt.nz.

Other information

- (1) The Wine Notice: Notice for Wine Recognised Agencies and Persons issued on 24 June 2014 does not apply to laboratories recognised for testing of wine for export.

Part 1: Requirements

1.1 Application

- (1) This Notice applies to any laboratory recognised or wishing to become recognised as an agency responsible for the chemical testing and analysis of wine for export under Section 71 of the Act.

1.2 Definitions

- (1) In this Notice, unless the context otherwise requires, defined terms are as set out in Schedule 1.
- (2) Any term or expression that is defined in the Act or regulations made under the Act, and used (but not defined) in this Notice, has the same meaning as in that Act or those regulations.

1.3 General requirements in relation to laboratories responsible for testing of export wine samples

- (1) Recognised laboratories must:
 - a) be agencies recognised under section 71 of the Act in respect of such functions and activities; and
 - b) ensure that only test methods meeting the requirements set out in clause 2.1(1)d) are used for testing of export wine samples.

1.4 Incorporation by reference

- (1) The following documents are incorporated by reference, under section 121 of the Act, and form part of this Notice:
 - a) NZS ISO/IEC 17025:2005, General Requirements for the Competence of Testing and Calibration Laboratories" (the "Standard").
 - b) European Commission (EC) Reference Methods published by the European Commission in accordance with Article 15 (2) of Commission Regulation (EC) no. 606/2009 of 10 July 2009, as published in the Official Journal of the European Union C 43/01, 19.2.2010 and available online at <http://eur-lex.europa.eu/JOIndex.do?ihmlang=en>.
- (2) Amendments to these documents are also incorporated into, and form part of this Notice, from the date specified in the document for the amendment to take effect from.

Part 2: Recognition of Laboratories and Requirements Applying to Recognised Laboratories

2.1 Requirements for recognised laboratories

- (1) A recognised laboratory must:
- a) be accredited in relation to relevant methods used for the analysis of export wine samples by an accreditation body to the standards for testing laboratories set out in ISO 17025; and
 - b) meet the requirements of ISO 17025 and clause 2.1(1)d) when managing and overseeing the functions and activities for which it is recognised, and must notify the Director-General within one working day of any instances where these requirements are not met; and
 - c) be assessed by an accreditation body at least annually from the date of recognition to confirm that it continues to meet the requirements of ISO 17025 and clause 2.1(1)b), and a copy of the relevant parts of this assessment must be forwarded to the Director-General as soon as practicable after being received by the recognised laboratory; and
 - d) only use EC reference methods, or alternative methods which meet the following criteria to test export wine samples:
 - i) $2.8 \times$ (standard deviation of intermediate precision) is less than the reproducibility limit of the EC reference methods as given in Schedule 2, for all wine types and analyte concentrations being tested; and
 - ii) fitness for purpose has been shown by four samples from two consecutive rounds of the inter-laboratory comparison programme set out in clause 2.2(1)a) being analysed as set out in clause 2.2(1)b), and having results within $\pm 2 Z_{EC}$; and
 - e) participate in an ILCP as outlined in clause 2.2.

2.2 Requirements for participation in an Inter-laboratory Comparison Programme

- (1) Every recognised laboratory must:
- a) Participate in all rounds of the IWAG ILCP (see www.interwinery.com.au) for the following analytes: actual alcohol, glucose & fructose, citric acid, total acidity, volatile acidity, total sulphur dioxide and specific gravity.
 - b) Perform an analysis of the ILCP results for all analytes except specific gravity, against EC reference method reproducibility limits (as provided in Schedule 2) that:
 - i) Uses the mean result for a specific sample and analyte as provided by the IWAG ILCP as the estimate of the true value.
 - ii) Calculates the Z_{EC} score for each analyte and sample using the following formula:

$$Z_{EC} = \frac{\text{analytical result obtained by laboratory} - \text{estimate of the true value from ILCP}}{(\text{EC reference method reproducibility limit} / 2.8)}$$

- c) Graphs the Z_{EC} score for each analyte and method on a control chart which must:
 - Display Z_{EC} on the y axis.
 - Have the y axes set so that all Z_{EC} scores appear on the control chart.
 - Show the Z_{EC} scores for the previous 24 months (month and year being on the x axis).
 - Show the control limits of $+2$ and $-2 Z_{EC}$ for all analytes.
- d) Report specific gravity results:

- i) Against the Z score provided by the IWAG ILCP.
- ii) In a control chart as in 2.2(1)c) above, using IWAG ILCP Z scores instead of Z_{EC} scores.
- e) Identify any ILCP results which have an absolute Z_{EC} (Z for specific gravity) of greater than 2 (variant ILCP results).
- f) Report the results and analysis to the Director-General by electronic or other means within five working days of the laboratory's ILCP results being made available or less frequently as notified by the Director-General in writing. For each sample and analyte tested the report must include:
 - i) The laboratory result.
 - ii) The estimate of true value from the ILCP.
 - iii) The Z_{EC} score as calculated in sub clause (b) above.
 - iv) The Z score for specific gravity as in sub clause (d) above.
 - v) A control chart indicating all Z_{EC} scores (Z scores for specific gravity) for the preceding 24 months as in subclauses (c) and (d)ii) above.
 - vi) An indication of variant ILCP results.
- g) Follow up variant ILCP results in a timely manner and report the details of the follow up to the Director-General. This follow up must include where appropriate or where requested by the Director-General:
 - i) Retesting of ILCP samples.
 - ii) Investigation of the cause of the variant ILCP result.
 - iii) The impact on tests reported to clients.
 - iv) Review and modification of laboratory procedures.
 - v) Consideration of the future accuracy of results and appropriateness of continued testing using the method resulting in variant ILCP results.

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Part 3: Chemical Testing, Analysis and Reporting Requirements for Export Wine Samples

3.1 Receipt of export wine samples for testing

- (1) Testing must only be carried out on samples that are suitable for testing. To be suitable for testing:
 - a) The following details of the physical sample must match those for the corresponding sample in the MPI sample and testing database:
 - i) the company name; and
 - ii) vintage and variety; and
 - iii) lot/batch codes on the sample label; and
 - iv) the colour/style of the sample.
 - b) The wine must be clear (that is, filtered). Unless it is indicated as a bulk 'unfinished' sample.

3.2 Reporting of test results

- (1) A recognised laboratory must ensure test results for suitable samples, as defined in clause 3.1(1), are submitted to the Director-General or the authorised wine export certification provider within five working days of receiving the sample.
- (2) The test results referred to in sub clause (1) must be submitted electronically into the MPI sample and testing database.
- (3) A recognised laboratory must ensure the use of the following calculations and adjustments when test results are reported for export wine samples:
 - a) total sugar must be calculated as fructose (g/L) + glucose (g/L); and
 - b) total alcoholic strength must be calculated as actual alcoholic strength (%v/v) + 0.06x (total sugar (g/L)).

Part 4: Administrative Requirements

4.1 Systems and Processes

- (1) A recognised laboratory must establish, document and maintain systems and processes to ensure that:
 - a) all applicable legislation, the laboratory's conditions of recognition, and any relevant conditions given by the Director-General under section 57 of the Act are implemented and complied with by the recognised laboratory; and
 - b) all persons under the management and control of the recognised laboratory in respect of those functions and activities (and including but not limited to any contractors and subcontractors), comply with the legislation, conditions and directions referred to in sub clause (a).

4.2 Authorisation of personnel

- (1) Those responsible for the management of a recognised laboratory must nominate and authorise specific personnel to:
 - a) Perform or direct effective and timely actions when non-compliance by the laboratory with the Act or the provisions of this Notice is identified.
 - b) Notify the Director-General regarding non-compliance of the kind referred to in sub clause (a).
 - c) Disseminate the relevant legal and technical requirements of or made under the Act including (but not limited to) this Notice, to all persons engaged in the management and carrying out of chemical testing and analysis of wine for export on behalf of the laboratory.

4.3 Recordkeeping and management

- (1) Every recognised laboratory must create records relating to those functions and activities, including records of the methods used, and the precision achieved.
- (2) Records may be kept in electronic or other form, but in any case must be clear and accurate, and kept in a readily accessible and retrievable format.
- (3) Records retained under sub clause (1) must be:
 - a) available for immediate inspection by a wine officer, the Director-General or any other person authorised to act on the Director-General's behalf; or
 - b) if not immediately available for inspection, retrievable within 48 hours or such longer period as is notified to the laboratory by the inspecting wine officer, Director-General, or other person authorised to act on the Director-General's behalf; and
 - c) be retained for a period of at least seven years.

4.4 General reporting to the Director-General

- (1) All recognised laboratories must submit a written annual report to the Director-General in August of each year in which those functions are performed, that includes:
 - a) A list of test methods used for export wine testing and analysis over the previous 12 months with reference to related EC reference methods (if applicable).
 - b) Current estimates of intermediate precision and repeatability for each test method, wine type and analyte concentration range being tested.

- c) A summary of any issues arising from the recognised laboratory's participation in the ILCP during the previous 12 months, and any corrective actions undertaken.

4.5 Change in management of recognised laboratory

- (1) Where there is a change in directorship, management, or control of a recognised laboratory, the laboratory must notify the Director-General in writing within 30 days of the change.

4.6 Ceasing to provide wine export testing and analysis services

- (1) Without limiting anything in section 82Q of the Act, a recognised laboratory must give the Director-General not less than six months notice should it decide to cease managing the provision of all or any such functions or activities.

4.7 Sub-contracting

- (1) Unless expressly permitted to do so in its conditions of recognition, a recognised laboratory must not sub-contract any of the export wine testing and analysis functions or activities under its recognition to a third party without the prior written approval of the Director-General.

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Schedule 1 – Definitions

In this Notice, unless the context otherwise requires:

- (1) **Accreditation Body** means an internationally recognised, independent organisation which is authorised to accredit organisations to certain ISO standards.
- (2) **Accuracy** means the closeness of the agreement between the result of a measurement and the true value of the measurand.
- (3) **Act** means the Wine Act 2003.
- (4) **Authorised Wine Export Certification Provider** means a person or body contracted to, or otherwise authorised by, the Director-General to carry out administrative functions relating to wine export certification on behalf of the Director-General including (but not limited to) the administration of the wine export certification database.
- (5) **EC Reference Methods** means:
 - a) methods published by the European Commission in accordance with Article 15 (2) of Commission Regulation (EC) No 606/2009 of 10 July 2009 (and as published in the Official Journal of the European Union C 43/1, 19.2.2010 and available online at <http://eur-lex.europa.eu/JOIndex.do?ihmlang=en>, incorporated by reference into this Notice under clause 1.4; and
 - b) includes any amendments, additions, deletions, revocations or updates to those methods notified by amending instrument in accordance with section 121(4) of the Act.
- (6) **Export Wine Samples** means samples of wine submitted for an assessment of export eligibility where the official assurance requires the reporting of results from chemical testing and analysis.
- (7) **Inter-laboratory Comparison Programme (ILCP)** means a programme where common samples are periodically supplied to participating laboratories by an independent organisation, samples are analysed by participating laboratories, and results are then collated and compared by the independent organisation.
- (8) **Intermediate Precision** means a measure of method precision given changes in one or more of time, calibration, reference standards, equipment, and operator in a single laboratory. Intermediate precision lies between repeatability and reproducibility and may be referred to as within laboratory reproducibility.
- (9) **ISO17025:**
 - a) refers to the standard NZS ISO/IEC 17025:2005 which is the current edition of the Australian/New Zealand Standard on “General Requirements for the Competence of Testing and Calibration Laboratories”, incorporated by reference into this notice under clause 1.4; and
 - b) includes the latest edition of that standard, together with any additions, amendments, and deletions made to or from that standard notified by amending instrument in accordance with section 121(4) of the Act.
- (10) **IWAG ILCP** means the Australian Interwinery Analysis Group ILCP (as specified at www.interwinery.com.au)
- (11) **OMAR** means an Overseas Market Access Requirement for wine exports from New Zealand, notified or made available by the Director-General under section 41 of the Act. These are available online at: <http://www.foodsafety.govt.nz/industry/sectors/wine/exporting/grape/market-access.htm>.
- (12) **Precision** is an assessment of the closeness of agreement between independent test results on the same sample under specified conditions. Precision must be stated as the standard deviation from a series of measurements made under conditions of repeatability, intermediate precision and/or reproducibility.

- (13) **Recognised Laboratory** means a laboratory recognised as an agency under the Act as responsible for all or any of the functions and activities referred to in clause 1.1 (1) of this Notice.
- (14) **Repeatability** means the precision of a test method where test results are obtained using the same method on identical samples in the same laboratory with the same operator and equipment within short intervals of time.
- (15) **Reproducibility** means 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.
- (16) **Reproducibility Limit** means the value less than or equal to which the absolute difference between two test results obtained under reproducibility conditions may be expected to be with a probability of 95%. The formula used for the reproducibility limit in the EC reference methods is $2.8 \times$ reproducibility standard deviation.
- (17) **Variant ILCP Result** means Z_{EC} results with an absolute value of greater than 2.
- (18) **Wine Export Certification** means the issuance of wine export certification under section 38 of the Act and includes the issuance of official assurances by the Director-General under section 41 of the Act.
- (19) **Z_{EC} score** means a statistic used for assessing performance of a laboratory in an inter-laboratory comparison programme against the precision published in the relevant EC reference method. It is calculated as:

$$\underline{Z_{EC}} = (\text{analytical result obtained by laboratory} - \text{estimate of the true value from ILCP})$$

$$(\text{EC reference method reproducibility limit} / 2.8)$$

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Schedule 2 – Reproducibility Limits for EC Reference Methods

Reproducibility limits to be used in the calculation of Z_{EC} are given in the following table:

Analyte	Product and Analyte Concentration	Reproducibility Limit (2.8x Reproducibility standard deviation)
Alcohol	All wine concentrations	0.229%vol.
Glucose and Fructose	All wine concentrations	$0.24 + 0.076 \times (\text{concentration of glucose (g/L)} + \text{concentration of fructose (g/L)}) \text{ g/L}$ <ul style="list-style-type: none"> Note 1: This differs from that in the method OIV-MA-AS311-02 as both glucose and fructose are being quantified. Note 2: The concentration of glucose and the concentration of fructose used in the calculation of the reproducibility limit should be the ILCP mean.
Total Acidity	<ul style="list-style-type: none"> White and rosé wines Red wines 	0.3g tartaric acid/L 0.4g tartaric acid/L
Volatile Acidity	All wine and concentrations	0.08g acetic acid/L
Citric Acid	<ul style="list-style-type: none"> Citric acid less than 400mg/L Citric acid greater than 400mg/L 	39mg/L 65mg/L
Sulphur Dioxide	<ul style="list-style-type: none"> Sulphur dioxide less than 50mg/L Sulphur dioxide greater than 50mg/L 	9mg/L 15mg/L