

The Code of Good Manufacturing Practice for the Australian Grape and Wine Industry

**Second Edition** 

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The Australian Wine Research Institute

PO Box 197, Glen Osmond, SA

064 Australia

ACN 007 558 296

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#### Further copies are available on request from:

The Australian Wine Research Institute at the above address

Telephone: (08) 8313 660 Tacsimile:(08) 8313 6601

Email: enquiries@awri.com.a

The Code of Good Manufacturing Practice for the Australian Grape and Wine Industry

Table of contents



Table of	contents	page
1	Introduction	2
2	The concept of Good Manufacturing Practice	3
2.1	The Code of GMP for the Australian grape and wine industry	5
2.2	GMP documentation	5
3	GMP recommendations	6
3.1	General	6
3.1.1	Management	7
3.1.2	Personnel practices	8
3.1.3	Records	10
3.1.4	Finished product	10
3.2	Environmental facilities	12
3.2.1	General	12
3.2.2	External	12
3.2.3	Internal	13
3.2.4	Equipment	15
3.2.5	Environmental risk management	16
3.2.6	Environmental best practice	17
3.2.7	Training	17
3.3	Production	18
3.3.1	Supplier practices	18
3.3.2	Raw materials	19
3.3.3	Equipment	22
3.3.4	Grape growing	22
3.3.5	Grape harvesting	23
3.3.6	Winemaking	24
3.3.7	Laboratory	25
3.3.8	Packaging operations	26
3.3.9	Rework, quarantine and product recall	31
3.4	Storage and distribution	32
4	Glossary	33

# 1 Introduction

This is the second edition of the Code of Good Manufacturing Practice (Code of GMP). It has been prepared by The Australian Wine Research Institute in conjunction with colleagues from the Winemakers Federation of Australia's Wine Industry Technical Advisory Committee and is based on the code developed in New Zealand (Reeves and Fraser 1995).

Its driving purpose is to outline the basic principals that should be followed in the production and packaging of 'wine' and 'wine products" to ensure that safe, sound quality products reach the consumer. 'Safe' includes reference to the environment.

**GMP** refers to a set of guidelines for practices and processes required for the safe manufacture of any product.

Wine<sup>1</sup> means "the product of the complete or partial fermentation of fresh grapes, or a mixture of that product and products derived solely from grapes."

Wine product<sup>2</sup> means "a food containing no less than 700 mL/L of wine as defined in Standard 2.7.4, which has been formulated, processed, modified or mixed with other foods such that it is not wine."

GMP is viewed as the foundation for formal product quality and safety management, but it does not replace food safety and quality management programs.

GMP does not provide an interpretation of legislation and in no way replaces any obligations for compliance. Legal compliance is a minimum operating requirement over which GMP should be overlaid to minimise risk to food safety and environment.

GMP is a statement of generally accepted procedures that should be instituted throughout the Australian wine industry, which, if not instituted, may result in a hazardous product. Indeed, its adoption will facilitate the development and introduction of improved product quality management and food safety programs, such as Hazard Analysis Critical Control Point (HACCP), Safety Quality Food Standard (SQF) 2000 and total quality management (TQM).

The concept of GMP is becoming more recognised and respected. It is, for example, included within the Codex Alimentarius Commission Procedural Manual (the international reference body for food manufacture), recognised within the Australian New Zealand Food Standards Code (which regulates wine and wine product production) and in the European Union and United States' food law.

Increasingly, it is referenced to proscribe the maximum limit of many additives and processing aids used rather than imposing specific quantitative limits. The three general inter-related principles involved in assessing compliance with GMP include:

- a) The quantity of the additive added to food shall be limited to the lowest possible level necessary to accomplish its desired effect.
- b) The quantity of the additive added to food shall also be limited to the level necessary to comply with regulatory requirements.
- The additive is handled in the same way as a food ingredient.

GMP alone, however, is not a HACCP analysis nor a quality assurance (QA) system, and is not a TQM program.

<sup>2</sup> The concept of Good Manufacturing Practice

<sup>&</sup>lt;sup>1</sup> FSANZ Standard 4.5.1

<sup>&</sup>lt;sup>2</sup> FSANZ Standard 2.7.4

GMP cannot, by itself, guarantee the safety of a product at the time of consumption. GMP primarily applies to the processing practices within the business itself and a Code of GMP suggests what is required rather than how they should be achieved. In contrast, HACCP programs represent a 'how to' approach by analysing the hazards and risks, and then formulating the controls for critical hazards. Therefore, the Code of GMP presented here should be regarded as a bare minimum for each company to adopt.

In addition, because a GMP cannot be site-specific, the Code presented here is generalised and requires other documentation that provide details of company policy and practice. Indeed, GMP can be considered as a broad code of conduct for grape growing and winemaking on which other particular procedures (or work instructions) appropriate to a specific site should be based.

Contracts are written where it is stated that raw materials should be produced under conditions of 'good manufacturing practice'. In Australia, there have been successful court cases where one party has sought recompense from another because of problems that arose through goods being produced under conditions that were not commensurate with 'good manufacturing practice'.

This Code of GMP has been developed as a guide to allow individuals in the industry to make their own interpretation of practices they wish to adopt. By observing GMP, it is generally believed that both employers and employees will strive to operate the business in an acceptable, hygienic and safe manner.

GMP is also one of the cornerstones of a full QA system, and is an integral part of a food safety program. However, because many QA systems are not comprehensive, aspects of GMP may be missing in many companies. By having a separate GMP statement, companies can articulate to employees in a general way the type of practices that are acceptable and those that are not.

## 2.1 The Code of GMP for the Australian grape and wine industry

The wine industry is a sector of the food industry and wineries can be considered as food processing premises. Each industry may have its own special needs and considerations in respect to food safety, but there are some universally applicable principles that apply to winemaking as they might apply to other foods. As in other sectors of the food industry, it is useful for the Australian grape and wine industry to express the relevant principles in a Code of GMP.

The following GMP recommendations should be followed by grape growers and winemakers in the production of grapes and wine. It is noted that not all the features listed are a necessary part of a HACCP-based food safety program. The adoption of this Code should improve the safety and hygiene aspects of production, reduce the risks and minimise the number and extent of exposures to hazards, thereby increasing the overall safety of the product for human consumption.

Wine is considered as a food and shall be produced under conditions that ensure that the product is safe for consumption.

#### 2.2 GMP documentation

Each company should document their own procedures in areas relating to the GMP. Such documentation can take any form and might commonly comprise a manual and any relevant instructions. This can be formatted to correspond with the headings used in this Code of GMP.

Wineries with comprehensive QA systems will probably already be complying with many of the elements presented here.

# 3 GMP recommendations

The following Code of GMP is structured as a checklist so that individual companies can add, modify or delete requirements as required.

#### 3.1 General

All acts, regulations, orders or notices relevant to the Australian wine industry shall be complied with at all times with respect to both production methods and presentation of the final product. Some of the relevant acts and regulations include the following:

- Australian New Zealand Food Standards Code which includes, but is not limited to, the Standards 2.7.1, 2.7.4 and 4.5.1.
- National Health and Medical Research Council Australian Drinking Water Guidelines 2011.
- State (Model) Food Act 1980.
- Wine Australia Act 1980 and Regulations.
- Wine Australia's Label Integrity Program.
- Australian Consumer Law 2010.
- Trade Measurement Act 1993.
- State Wine Grapes Industry Act 1991.
- Phylloxera and Grape Industry Act 1995 (SA).
- Environmental Protection Act 1993.
- State environmental protection acts.
- State container deposit legislation acts.
- State occupational health, welfare and safety acts.
- Australian Taxation Office Excise Tariff Act 1921.
- State liquor licensing acts.
- Local council by-laws and development regulations.

#### In addition:

 All Australian wine for export shall be made in compliance with the legal requirements of Australia and the countryof destination: For

- assistance please refer to www.wineaustralia.com.au; and http://www.awri.com.au/industry\_support/regulatory\_assistance/.
- All manufacturing procedures should ensure that the safety of employees and consumers is never compromised.
- Wine for commercial trade should only be made by the licensed company in premises that meet the conditions of the license.
- The company should conduct regular checks for compliance with the conditions of GMP.
- 5. Policies and procedures to minimise production of waste and impact on the environment should be developed and adhered to.
- Any waste materials generated by the winemaker or production
  activities shall be managed so as to ensure minimal impact on the
  environment. Recycling of materials should be practiced where
  possible.

## 3.1.1 Management

- Use internationally-recognised management standards to maintain quality, safety and environmental management, and assist in the achievement of continuous improvement and best management practice. Examples include, but are not limited to, ISO 9000 (quality) and ISO 14000 (environmental) standards. Where possible these standards should be integrated and embedded into practices to simplify and optimise the use of resources.
- Quality management practices should be implemented with consideration of the customers' requirements and they should be appropriate to the scale/size of operation.
- When subcontracting any operations, the subcontractor should be required to follow GMP as a minimum and, preferably, will have an active HACCP program in place.
- There should be a clearly identified management and responsibility structure for making critical decisions. Responsibilities and authorities of all personnel should also be clearly defined.





- Management should have copies of all current relevant legislation regarding the production and sale of wine in Australia, and other countries where exports are being considered or made.
- Personnel responsible for directing grapegrowing and/or winemaking should have the necessary training and/or experience to assure the safety and purity of the finished product.
- 7. Any changes in procedure should be authorised by a pre-designated management representative such as the senior winemaker/winemaker.
- 8. A procedure for approving changes to raw materials, processing conditions and final product specification should be documented and followed at all times. Any specific customer requirements concerning additive usage should be adhered to.
- Where the company does not employ trained laboratorytechnical personnel, critical tests should be performed by an appropriate external agency or consultant.
- All wine, at any stage of production through to shipment (Grapesto-Glass), shall be clearly identifiable and traceable to records (Track & Trace).
- 11. Suppliers, employees and customers should all be engaged to facilitate continuous improvement.

#### 3.1.2 Personnel practices

- 1. All personnel should maintain a good personal hygiene and training should be provided where necessary.
- All personnel should have the necessary training and experience to perform their assigned functions from vineyards through to production, bottling, warehousing and distribution.
- 3. All personnel should wear clean and suitable clothing while working with wine. Suitable closed footwear and the suitable safety and personal protection equipment should be worn in the defined safety areas of the vine-yard, winery, production, bottling and distribution areas. Personnel should not wear loose fitting clothing and jewelry, watches and accessories while working in the production and bottling areas of the winery.

The Code of Good Manufacturing Practice for the Australian Grape and Wine Industry



# 4. Smoking should not be permitted within the wine processing areas and should be discouraged in the workplace. Appropriate signs may be installed. Personnel should eat and smoke only in designated areas.

- 5. Wash basins supplied with a suitable sanitiser, hot water at 55°C and drying facilities should be provided near work areas and in all toilet areas. Personnel should use these to maintain personal cleanliness.
- All personnel should be encouraged to report to management all cases
  of GMP not being followed, and any examples of hazardous conditions
  (in terms of both product and personnel safety).
- All designated occupational health and safety procedures should be followed. The behaviour of personnel should not endanger the health or safety of other employees.
- 8. All personnel are responsible for the cleanliness of their own work area.
- All personnel should be free from any communicable disease or open skin lesions on the exposed skin of the body if the condition is a risk to the safety of the product.
- 10. Medical dressings should be secure on any personnel while they are working with harvested grapes, wine or empty packaging materials.
- 11. All external contractors who come on site need to be inducted into all onsite procedures and policies.

#### 3.1.3 Records

- All records covering the use of raw materials (grapes, chemicals, additives and processing aids) as well as wine and processing conditions during the production process should be kept for at least a minimum of seven years or longer as required by the applicable State and Australian legislation. They should be legible, accurate and easily understood. Records should clearly identify the product and production process to which they relate.
- 2. Records need to be regularly reviewed to ensure currency.
- All records shall have a means of identification so that dates, batches and lot codes can be readily traced in the event of a product recall or regulatory audit.
- Records detailing distribution of a product must be maintained so that the product is readily tracked and traced in the event of a product recall.
- Comprehensive records detailing the disposition of any reworked, recalled or withdrawn products should be kept for a minimum of five years or as required by applicable State and Australian acts and regulations.

#### 3.1.4 Finished product

The Winemakers' Federation of Australia has developed a set of unique guidelines and specifications to provide a basic level understanding of the fundamentals of wine packaging for all wineries and associated co-packing facilities. Please refer to http://wfa.org.au/codes\_of\_conduct.aspx for these wine packaging guidelines.

- Labelling of each container (e.g. bottle) by batch and date coding should be practiced in addition to batch and date code labelling of bins, cartons and pallets.
- All finished batch lots should be confirmed as inspected and tested as appropriate prior to release. Inspection tests should include sensory evaluation, and determination of the concentration of sulfur

- dioxide, alcohol, titratable acidity, pH value and volatile acidity.
- Adequate samples of labelled, finished product should be kept for any possible future reference. Such samples should be clearly labelled and securely stored in a cool and dry location.
- 4. Batch codes should be changed frequently (not less than daily) to facilitate trace-back for product recall. Where the batch lot code involves the date, this should be carefully checked for accuracy and legibility during the production run.
- Product packaging and closures including, but limited to corks, cask valves and screw caps, should be fit for purpose and of sufficient quality to ensure that leakage does not occur during normal storage, handling and distribution.
- All packed product for distribution should be securely packed in cartons or boxes suitable for the protection of the wine during warehousing and distribution. Cartons or boxes should be clearly identified.

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## 3.2 Environmental facilities

#### 3.2.1 General

- The buildings and grounds should be maintained in an orderly, hygienic, and neat and tidy condition with a routine pest inspection and control program.
- 2. All types of waste (e.g. general refuse, winemaking waste and sewage) should be appropriately disposed of according to local requirements and in compliance with current environmental legislation.



#### 3.2.2 External

- 1. The grounds should be kept clean and free from rubbish at all times.
- The external rubbish depot should be kept tidy and orderly. All refuse containers should be kept well covered to prevent access by rodents, birds and other pests, and rubbish removed regularly from the site.
- 3. Where wineries have outside processing areas, tank farms and outdoor fermenters, particular steps should be taken to ensure that such areas are kept free of rubbish, are free draining (surrounding land should not drain onto the winemaking area) and are laid out to allow easy access and cleaning. Fermenters and tanks should be kept as closely closed as practical at all times other than when being worked. Special attention should be paid to ensure the security of such fermenters, tanks and vats.
- 4. There should be no external cracks or gaps in walls and around doors or windows that might allow access for rodents or other pests. All such occurrences should be reported and repaired promptly.

5. A thorough pest control program should be undertaken to keep vermin and other animals from entering buildings and processing areas.

#### 3.2.3 Internal

- Floors in the winery and storage areas should be free draining and free
  from debris build-up, and should be kept in a sound condition. They should
  be constructed of materials that can be readily cleaned and designed to
  facilitate easy cleaning.
- All storage and despatch areas should be regularly inspected for possible cross contamination or damage to raw materials/finished product.
- The winery, and particularly storage areas, should be ventilated to prevent condensation, excessive heat and humidity build- up, and be free of debris build- up. All stored material should be clearly identified.
- 4. The plumbing should be kept in a sound state and all fittings should be of an approved sanitary type.
- The lighting should, at all times, be adequate to meet safe work standards, especially in the processing areas, to ensure safe operation of the equipment and to assist with cleaning. Light fittings should be enclosed wherever possible.
- 6. All equipment should be installed so that easy access is possible for operating, servicing and routine cleaning. All access ways and passages should be kept clear of rubbish, empty packaging, raw materials and finished product at all times. Equipment, including hoses, not in use should be stored in a clean condition in their designated area.
- 7. Any rubbish container within the winery should be secure from rodents and other pests, and should be regularly emptied.
- Pest control baits should be clearly marked and placed so as to
  prevent contamination or accidental spillage. A pest control program
  should be implemented and monitored for its efficacy.



- All personnel eating and changing areas should be maintained, well lit and ventilated, and cleaned regularly. These areas should be isolated from any production and storage area.
- 10. All toilets should be well ventilated, kept clean, and suitably supplied with hand washing sanitiser, hot water at 55°C and drying facilities.
- 11. The bottling area should be specifically designed to prevent ingress of foreign matter and pests. It should be well lit and ventilated to allow proper venting of fumes and steam from bottling washing equipment.
- 12. All light fittings in the bottling and processing areas should be sealed to ensure that glass cannot fall into the processing area at times of breakage.
- 13. There should be adequate equipment washing facilities readily available and in near proximity to the bottling and processing areas.
- 14. There should be sufficient storage and separation for all raw materials and finished product/s so that each item can be clearly identified and not suffer deterioration. They should also be stored securely under lock and key, and kept separate from cleaning chemicals and other materials. Incompatible materials should not be stored together.
- 15. Adequate security and reconciliation procedures should be implemented for any chemical or biological materials at risk of diversion for illicit purposes identified by Science Industry Australia. Please refer to http://www.scienceindustry.com.au/storage/documents/Code.pdf
- 16. A preventative maintenance program should be established to ensure that equipment is routinely inspected and that only food grade materials are used, that any hazardous waste is removed, and that production and processing equipment is left in a clean state fit for use.
- 17. Food containers, including wine bottles, must never be used for the storage of non-food materials, such as lubricating oils and cleaning agents.

## 3.2.4 Equipment

- 1. All equipment should be suitable for its intended purpose.
- Equipment should be of hygienic construction. Contact surfaces should be of food grade materials suitable for use in wineries, and should be resistant to corrosion and inert so as not to impart any taint to wine.
- All equipment should be designed for easy cleaning by being free from cracks and crevices, which are difficult to clean. Welds should be smooth, corners rounded, and all wine-contact surfaces easily accessible and readily cleaned.
- 4. Thorough cleaning and sanitising SOPs should be established, documented and followed to ensure that equipment is clean, and contamination of product with cleaning and sanitiser residues is prevented.
- All equipment which comes into contact with grapes, must, juice or wine should be cleaned and sanitised prior to and promptly after
- Equipment should be installed in such a way as to minimise the possibility of contamination and cross-contamination.
- 7. All lubricants used in places where seepage or leakage to grapes or wine is possible should be approved for use in food processing by the US Food and Drug Administration (FDA) (www.fda.gov), Codex Alimentarius Commission (http://www.codexalimentarius.org/) or another appropriate authority. Care should be used in the lubrication of equipment to avoid contamination of product with lubricants.
- 8. Where a primary and secondaryrefrigerant is used for cooling fermentations, checks should be made to ensure prompt detection of leaks should they occur.
- 9. Glass laboratory equipment, including thermometers, must not be used in the winery.



- 10. Mercury-in-glass thermometers must not to be used in the winery. Digital or mechanical dial thermometers are preferable.
- 11. Fixed pipelines should be clearly labelled or identified to prevent potential cross contamination of a wine. They should be completely free draining so as to prevent any retention of residual pockets of wine or cleaning fluids.
- 12. Filling and corking equipment should be designed to prevent damage to bottles particularly in the neck and bore mouth region.
- Pre-processing checks of all equipment and facility cleanliness should be made.

## 3.2.5 Environmental risk management

In order to meet environmental best practice it is recommended to identify the significant environmental aspects associated with activities, products and services as well as identifying legal obligations and any other requirements or commitments to which the company subscribed. The information of environmental aspects needs to be maintained and kept up to date.

In terms of industry best practice it is procedure to equate an environmental aspect with a **hazard** and an environmental impact with a **risk**. A formal risk assessment should occur before a new or modified plant/process is commissioned in order to identify any risks to people, product or the environment and thereby enable their elimination or reduction.

Key aspects to be covered in environmental risk assessment and ongoing environmental recording, analysis, reporting and reviewing as part of a monitoring program should cover:

- volumes and compositions of waste water;
- impact of operations on water courses;
- soil composition and moisture at irrigation sites;
- groundwater depth and composition at well sites;
- appraisal of vegetation / wood lots;
- solid waste; and
- influent water.

## 3.2.6 Environmental best practice

Best practice with regard to environmental management arising from winery and vineyard operations involves minimising their impact on the environment and acknowledgement of the environmental stewardship role. This can best be achieved through a formal environmental management system which is audited and certified to internationally recognised standards (ISO 14001) or national wine industry led initiatives (EntWine), but not to the exclusion of formally documented and audited in-house standards or third party providers that include the following principles to minimise environmental impacts:

- Complying with relevant environmental laws, authorisations and codes of practice.
- Applying risk management procedures and implementing controls to minimise adverse environmental impacts and pollution.
- Regularly reviewing environmental targets and objectives.
- Continually improving and monitoring environmental performance.
- Providing information and training to employees and contractors on their responsibilities.
- Adopting best practice principles in operating procedures and plant and equipment design where economically practicable.
- Adopting best practice principles for the sustainable design, use and recovery of packaging. For additional information please refer to: http://www.packagingcovenant.org.au/.
- Promoting sound environmental practices to suppliers and customers.

## 3.2.7 Training

The site manager must ensure that all personnel and contractors working on the site are aware of the relevant requirements that may affect the way they carry out their duties. This may mean provision of competence based training to ensure compliance with all relevant legislation, regulations, authorisations, development approval conditions and codes of practice.



#### 3.3 Production

## 3.3.1 Supplier practices

- The principal objective of implementing consistent documentation standards for winemaking additives/processing aids is to define the minimum standard relating to quality and safety documentation thereby facilitating industry wide consistency in data requirements and reducing administrative burden through replication of data requests.
- The expectations for minimum standards for a winery should be maintained regardless as to whether an additive or processing aid is sourced directly from manufacturers and suppliers, or indirectly via brokers, distributors or re-packers.
- 3. Additives/processing aids shall be fit for purpose and comply with food grade requirements as a minimum, including appropriate company inhouse specification or meeting the requirements of the current edition of a recognised monograph source such as the: i) Combined Compendium of Food Additive Specifications, FAO JECFA Monograph (Food and Agriculture Organisation of the United Nations. Rome) or ii) Food Chemicals Codex (United States Pharmacopoeia) or if not in i) or ii) in any of the following: British Pharmacopoeia (TSO, Norwich), United States Pharmacopeia, Pharmaceutical Codex (Council of the Pharmaceutical Society of Great Britain), Martindale; The Complete Drug Reference. The Pharmaceutical Press London; European Pharmacopoeia (Council of Europe, Strasbourg), International Pharmacopoeia (World Health Organization, Geneva), Merck Index, Code of Federal Regulations; Specifications and Standards for Food Additives (Ministry of Health and Welfare Japan) or International Oenological Codex (Organisation International de la Vigne et du Vin) where applicable.
- 4. Additives/processing aids shall comply with the requirements of the Australia New Zealand Food Standards Code 1.3.4 Identity and Purity, 1.4.1 Contaminants and Natural Toxicants and 1.4.2 Maximum Residue Limits. Where applicable, additives/processing aids shall be tested for adulteration, contamination, microbiological contamination, and toxicants.
- 5. Additives/processing aids shall be tested against the relevant

- specification or monographs where an identity/quality standard is claimed.
- A material safety data sheet (MSDS), certificate of analysis (CA) and ingredient specification should be obtained prior to receipt of any additive/processing aid.
- Analytical methods used to test additives/processing aids shall be validated.
- 8. Retention samples of the additive/processing aid should be held by the manufacturer/distributor of the additive/processing aid for five years.
- 9. Re-labelling of containers and repackaging of already manufactured additives/processing aids is considered a step in manufacturing and must retain full traceability of individual batch lots to original manufacture. A declaration as to the appropriateness of the packaging and validated expiry date in this packaging shall be held.

#### 3.3.2 Raw materials

#### 3.3.2.1 Permitted materials

- 1. Only agrochemicals that are registered for use in winegrowing by the Australian Pesticides and Veterinary Medicines Authority (APVMA) shall be applied to grapevines. These must be used in accordance with label directions, taking particular note of export harvest intervals or withholding periods. In the event that there is no maximum residue limit (MRL) within the destination market, the agrochemical should not be used. This information can be sourced from the AWRI website: http://www.awri.com.au/industry\_support/viticulture/agrochemicals/
- Grape chemical application, including timings and rate should be tracked through a spray diary. This document should be inspected prior to grape acceptance.
- Additives and processing aids must be approved for use in the production
  of wine and/or wine product <u>both</u> within the Australia New Zealand Food
  Standards Code <u>and</u> the export market jurisdiction. Please refer to
  www.foodstandards.gov.au and
  http://www.wineaustralia.com/australia/Default.aspx?tabid=262,
  respectively.



- 4. All additives and processing aids used in the production of wine shall be at least food grade.
- Only cleaning chemicals and sanitising agents that are approved for use in food processing by the US Food and Drug Administration, US Alcohol and Tobacco Tax and Trade Bureau or other appropriate authority shall be used.
- All product contact packaging materials (such as closures and bag-in-box) should be approved for the purpose by the US Food and Drug Administration, Alcohol and Tobacco Tax and Trade Bureau or another appropriate authority.

#### 3.3.2.2 Procurement

Faulty materials may potentially be spread across the whole vintage for small winemakers and millions of litres for large winemakers and render the wine unsaleable. A procurement system should be utilised for the purchase of agrochemicals, additives and processing aids, cleaning and sterilant chemicals, and packaging materials, including:

- 1. An Approved Supplier program which has advantages of reliable supply, consistent quality and can permit supplier QA programs.
- 2. In the event of a new source, effort should be devoted to verification of the purity and conformance of the materials.
- Inspection of goods prior to acceptance, including seal and packaging integrity/contamination, product identity and grade, packed date, batch number and shelf-life.
- Non-compliant materials such as damaged packaging and incorrect materials or grade should be rejected, that is, not accepted upon delivery.
- Accepted materials that are subsequently identified as faulty should not be used. They should be quarantined, marked "not for use" and isolated until removal from site can be effected.

#### 3.3.2.3 Storage and handling

1. Wherever possible, goods should be stored within the original container. This enables full traceability and reduces the risk of error, such as replenishing the incorrect container.

- Agrichemicals, additives and processing aids, cleaning and sanitising chemicals and packaging material groups should be stored in separate locations: agrichemicals should not be stored with additives and processing aids or packaging materials.
- 3. Hazardous chemicals shall be clearly identified, be stored with appropriate signage in accordance with the Hazchem warning plate system, under appropriate storage conditions such as ventilation and temperature.



- Occupational Health and Safety (OH&S) requirements, as outlined on the MSDS, shall be met such as eye wash stations, safety showers and personal protective equipment.
- Bunding shall be in place to prevent accidental release of chemicals to the environment.
- 6. Storage areas should be maintained in a clean and tidy state.

#### 3.3.2.4 Water and steam supply

- 1. Opportunities to avoid, reduce, re-use or recycle water should be considered as per environmental hierarchy. Examples could include:
- avoiding the use of water for bottle rinsing by using air knives;
- reducing the volume of water used for tank cleaning through a CIP system;
   or
- recycling rinse water at the bottle rinser.
- 2. Clean water shall be used for all grape contact activities including:
- the application of foliar sprays (agrichemicals) to grapevines prior to harvest;
- clean down of harvest and transport equipment; and
- the incorporation of vineyard additives.
- 3. Potable water shall be used to:
- clean and/or sanitise product contact surfaces such as processing equipment, storage vessels, transfer lines and filling equipment;





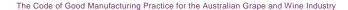
- incorporate additives and processing aids to wine and/or wine product; and
- purge product through processing equipment and transfer lines.
- Potable water may be derived from:
- municipal supply direct to the point of use, that is, mains pressure pipeline;
- municipal supply together with on-site buffer storage;
- clean water treated to potable standard within the facility; and
- it is recommended that back flow protection is installed to prevent product ingress contaminating the water supply and a monitoring program to assure the quality of the water outside of the municipal system.
- 5. Food grade boiler water treatment chemicals shall be used where steam/hot water is used for cleaning and sanitation of product contact equipment.

#### 3.3.3 Equipment

- 1. Processing waste, such as grape skins and lees, should be removed from processing equipment as soon as practicable.
- 2. Standard Operating Procedures (SOPs) should be thoroughly documented for cleaning procedures and should be strictly adhered to at all times, the equipment checked after cleaning and before reuse.

## 3.3.4 Grapegrowing

- 1. Vineyard operations including, but not limited to, the control of pests and diseases should be conducted with minimal impact on the environment, neighbours, operators and/or consumers.
- 2. Grapegrowers should ensure that the agrochemicals applied are registered for use in Australian wine grape production and follow the label instructions.





- 3. Up-to-date records of the chemicals applied and the details of their use should be maintained in a spray diary in accordance with legislative requirements and those of the winery being supplied.
- 4. Grapes grown for export wine should follow the recommendations in the current version of the AWRI publication Agrochemcials registered for use in Australian viticulture or the instructions of the winery or grape purchaser. These restrictions are aimed at meeting the regulatory standards stipulated by the export market. For further information please refer to
  - http://www.awri.com.au/industry\_support/viticulture/agrochemicals/mrls
- 5. Where practical, fertiliser, chemical and irrigation inputs should be applied in response to active monitoring.
- 6. Practices that minimise spray drift from vineyard operations should be employed. All cases of spray drift from or into vineyards should be recorded and reported. In cases of drift onto grape vines, actions should be taken to ensure that the grapes and the wine made are not in contravention of legal requirements.
- 7. Personnel that are responsible for the receipt, storage, handling and use of agrochemicals should have completed appropriate training and comply with relevant legislation.
- 8. All chemicals should be stored in accordance with the Australian Standard AS 2507-1998 Storage and Handling of Agricultural and Veterinary Chemicals.
- 9. Spraying equipment should be routinely calibrated, for example, at least once per season.

## 3.3.5 Grape harvesting

- 1. The containers that hold harvested grapes should be clean, made of food grade materials and should not be capable of contaminating the grapes.
- 2. Where mechanical harvesting is used, the harvester should be operated and maintained such that oil and lubricants are unlikely to contaminate the grapes. Food grade lubricants should be used at all times.
- 3. Grapes should be checked for signs of abnormal or unacceptable contamination prior to crushing.

## 3.3.6 Winemaking

- After cleaning, all equipment should be rinsed with clean potable water. If the equipment is not to be used immediately it should be allowed to drain dry.
- 2. Processing records must be kept so that all batches of product can be readily identified, tracked and traced, and that the amounts of any raw materials used are clearly identified and recorded to comply with all relevant legislation. These records must satisfy the requirements of the Wine Australia's Label Integrity Program and Food Standards Australia New Zealand. A system for checking added quantities of additives and processing aids and final wine concentrations of these, which are limited by legal requirement, must be employed.
- 3. Samples of wine should be inspected and tested as appropriate both before and after any processing operation.
- 4. All hoses should be stored in a manner that allows self draining. They should be sanitised and flushed with potable water before and after use to ensure freedom from any foreign matter.
- Any instance of contamination should be reported to a designated responsible person, such as the winemaker, immediately the contamination occurs or is detected and the wine quarantined or isolated for further action. The contamination should be clearly identified and recorded.
- 6. Any wine spillage should be cleaned up immediately using procedures appropriate to the location of the spillage, such as localised bunding and recovery procedures.
- 7. Any water used in the production of wine, preparation of wine additives, and the washing through of lines and equipment should be of potable standard and meet all legal requirements. Where water is sourced from an 'uncontrolled' source, that is, other than a municipal supply, it should be routinely monitored to ensure compliance with legal requirements.
- 8. Where preservatives such as sulfur dioxide, sorbic acid and sorbates for example, are added prior to bottling, the concentration should be determined and verified to ensure legal compliance.

 The method of disposal of non-compliant wine should be determined by an authorised person, such as the winemaker, in accordance with State and Territory Environmental Protection Authority regulations.

## 3.3.7 Laboratory

- An approved designated person such as the laboratory manager/supervisor, should be responsible for the management, auditing and review of quality systems in the laboratory. Please refer to the Standards Australia website [www.standards.org.au] and/or the NATA website for ISO/IEC 17025:2005 as a guide.
- An approved designated person such as the laboratory
  manager/supervisor should be responsible for the accuracy of the
  information provided to winemakers and production management.
- The laboratory should maintain a manual or electronic version of approved laboratory methods which lists the current approved method or SOPs, and all personnel should have access to MSDS or other relevant documentation for all chemical compounds used.
- 4. Where no suitably equipped laboratory exists on-site, testing should be carried out, at the required time, by a competent approved external analytical facility.
- All analytical methods and equipment should be monitored regularly by defined checking procedures (e.g. quality assurance and calibrated as necessary, duplicates and reference standards) to ensure their continued accuracy and reliability.
- Analyses should be undertaken and completed by an appropriately trained person(s). Training records should be maintained to ensure competency of personnel.
- 7. Traceability of records as necessary, for example, kept in a permanent form (electronic or otherwise) for a minimum of five years.



26

The Code of Good Manufacturing Practice for the Australian Grape and Wine Industry



- Library samples of product should be retained for a minimum of five years or until such time that the product is no longer available.
- Analytical laboratoryglassware and equipment should be stored separately to public tasting areas and associated glassware

## 3.3.8 Packaging operations

- Bottles used for packaging wine should preferably be new. Where recycled bottles are used, they should undergo a validated companyapproved washing process before being filled.
- 2. Equipment, such as bottle washers, fillers, rinsers and corkers, should be checked for correct settings and in-feed and out-feed stars adjusted to ensure that no damage to bottles can occur. Particular attention should be paid to the operation of the filling and corking equipment to ensure that foreign matter, in particular, glass fragments and cork dust, are not generated by faulty adjustment and operation.
- 3. All wine should pass through at least a fine mesh screen in the filler supply line to reduce the risk of insoluble foreign matter passing into the final package
- 4. Filter integrity should be checked, especially in the case of wines containing residual sugar, since microbiological contamination may lead to re-fermentation that could cause an unsafe concentration of carbon dioxide to build up in the bottle.
- Wine should be filtered immediately prior to filling using media of suitable grade so as to ensure that re-fermentation does not occur in the bottle.
- 6. Headspace in cork finished bottled wine should be sufficient to meet legal requirements and also be adequate so that wine expansion due to temperature fluctuations will not cause movement of the corks.

#### 3.3.8.1 Bottling hall procedures

 The necessity for control measures for any potent physical hazard is dependent upon a finding in your hazard analysis that a specific hazard or risk is likely to occur in your finished packaged wine, that is, when such hard or sharp objects such as glass or metal fragments, could pose a health and safety risk. The critical limit is no glass inclusions or metal fragments in the finished product.

- 2. Control M\measures for glass inclusions/glass or metal fragments include the following:
- use of on-line glass detection equipment such as x-ray machines, or alternatively a continued frequency monitoring of packaged product samples post the rinser, filler and also the corker/capper by sample filtration: or
- Challenge Testing, which can be achieved by passing a prepared sample through the x-ray detector or a sample of rinse-water/or packaged wine through membrane filtration and inspecting the residue for any foreign matter contaminants.
- A program of routine challenge testing to confirm removal of any foreign matter, that is, glass or metal inclusions by the packaging equipment should occur either daily or weekly.
- 4. If broken glass or metal fragments are detected the line should be stopped, the foreign matter removed (for identification and source), and the product that has moved through the area since the last inspection is isolated and placed on hold for further inspection; which as a consequence of this inspection may be approved for use, reworked or destroyed.

#### 3.3.8.1.1 Broken glass handling

- A standard operating procedure (SOP) should be implemented for handling of glass wasting during the production packaging process. Glass waste should be clearly identified and kept separate when recycling is practiced.
- Before use, all pallets and cartons of glass bottles should be checked for signs of damage and broken glass. Pallet details should be recorded for packaging operations. Any containers or pallets with broken glass should be isolated/quarantined and thoroughly

inspected. Where broken bottles or contamination of a pallet with broken glass is detected, special care should be taken when removing layer dividers to prevent contamination of lower layers of bottles. It is

preferable that the damaged pallet is returned to the supplier.

- 3. When any glass bottles are broken in the packaging area, a thorough and comprehensive clean-up of the area should be undertaken immediately, as referenced within the SOPs. Initially, cleaning should be accomplished by careful brushing or, if available, a high capacity vacuum cleaner. Only then is washing with water to be undertaken, although not recommended. Methods such as air blast and high pressure water blasting should be avoided, as they tend to cause the further widespread broadcasting of fine glass shards and dust. Bottling can recommence only when the supervisor is satisfied that all broken glass has been completely removed and the process recorded in the daily operations log.
- 4. Where breakage has occurred on the filling line, particular attention must be paid to all adjacent bottles to ensure freedom from glass shard contamination. Where breakage has occurred on the filling machine, particular attention should be paid to the bottles filled from adjacent filler heads [as per the glass breakage SOPs] to ensure that fill height and cleanliness has not been compromised
- Particular attention must be paid to any bottle breakages when filling sparkling wine because of the wider distribution of shards of glass and remains of the shattered bottles. Any nearby open bottles should be removed and decanted.
- 6. It is recommended that routine post-production checks should also occur of all bottled wine to assess the presence any foreign material such as glass or cork dust, for example.

#### 3.3.8.1.2 Bottling

- 1. Where possible, glass bottle storage should be under cover.
- The condition of all glass bottles should be checked prior to use. The integrity of protective packaging and the condition of the bottles should not be damaged or compromised. No visible foreign matter should be tolerated in any bottles.

- Because dimensional differences can cause bottling equipment
  malfunction and bottle chipping, all bottles used for one bottling run
  should be of the same type. When changing bottle size or type, the
  equipment settings must be checked and, if needed, be changed
  before re-start.
- 4. Any open bottles must be shielded between items of bottling equipment by the use of line-covers over the conveyors.
- Where cold rinsing solutions are used they should be made with potable water and with an appropriate biocide. For personnel safety, forced air removal from the rinser is recommended.
- Where bottles are air blast dried following rinsing, the air should be dry, oil free and filtered. Rinser challenge tests should routinely occur by a defined SOP.
- 7. Bottles should be filled using filling equipment and procedures that minimise the ingress of air in order to prevent wine oxidation.
- 8. Where hand filling is used, rinsed bottles should be protected so as to ensure that foreign matter cannot enter the bottle.
- The filling procedure should be organised to minimise delays between cleaning/rinsing/drying operations and filling and sealing to minimise the risk of any possible foreign matter contamination between operations.
- 10. Bottles should be sealed as soon as possible after the filling operation and should not be left standing open. At planned staff breaks, no bottles should be left unfilled or unsealed.
- 11. Prior to the production start-up, the supervisor should check that the filling heads and corking equipment are correctly adjusted to avoid chipping bottle necks. The condition of the necks of bottles filled from each filling head should be inspected for damage and checked regularly during the production run.
- 12. The closure (e.g. cork, synthetic closure and screw cap) hoppers should be fitted with covers to ensure that no external or foreign matter contamination can occur.
- 13. Particular care should be taken when opening bags of closures to ensure that no foreign odours, matter or bag material are present or have dropped into the hopper.

31

- For the bottling of wines, only new unopened bags of sterlised closures should be used.
- Any disgorged and recovered wine should be isolated to a recovery tank.
- 16. Records of all production/packaging runs should be maintained detailing the wine product type, code, quantity and other relevant packaging information. All packaging records should thoroughly be reviewed within 24 hours for QA and compliance to the product specification.
- 17. All finished packaged wine should be removed promptly from the production/packaging area to either a quarantine area or to its designated warehouse location on a positive product release procedure.

## 3.3.8.1.3 Bag-in-box

- Only new, approved food grade bags should be used. The supplier must certify that all bags are of food grade standard and are fit for purpose.
- 2. All wine bags should be pre-evacuated before filling.
- 3. Overfill spillage should be promptly cleaned.

#### 3.3.8.1.4 Bulk shipment

Bulk wine transfer details for bottle-ready wine are included in Appendix 1. Wine Australia also provide guidance and a link to their Bulk Wine Loading Procedure is on

http://www.wineaustralia.com/australia/Default.aspx?tabid=267

Broad objectives for successful bulk wine transfer (within or exported from Australia) include:

 preservation of wine quality through hygiene, sterile filtration and dissolved oxygen management;

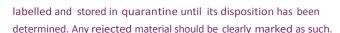
- choice of shipping vessel (tanker, ISO or flexi-tank) can impact the risk of and magnitude of oxygen and taint ingress; and
- chain of custody the use of tamper evident seals to provide assurance that the wine received is in the same condition as that loaded.

## 3.3.8.1.5 Polyethylene terephthalate

- 1. Polyethylene terephthalate (PET) is becoming more widely used in wine and wine products as an alternative to glass due to its light weight, relatively good barrier properties and impact resistance. It can withstand low and high filling pressures, warm, ambient and cold fill processes and is suitable for still and carbonated wines, and is available in semi rigid or rigid configurations from 187 to 2 litres and has a high recyclability rate.
- 2. Some winemaking and bottling line amendments are required to ensure package and product life-cycle integrity, for example:
- Dissolved oxygen (DO) management at product filling (DO should be low).
- Sulfur dioxide<sub>2</sub> management due to the rate of oxygen ingress through some PET formats.
- Line in-feed and out-feed, conveyor and railing amendments to minimise bottle drag and scuffing.
- Capping forces tried and tested to ensure the security of the closure seal and no pack compression damage.
- Technical parameters associated to PET for pre- and post-production should be routinely monitored, including the recognition of defined lifecycle/shelf-life for PET.

## 3.3.9 Rework, quarantine and product recall

- 1. A quarantine system for identifying and separating reject or faulty product should be developed and followed at all times.
- 2. Adequate warehouse space should be provided for the separate storage and isolation of quarantined products.
- 3. All products that do not meet final product specification should be



- Product should be reworked only with prior approval from the authorised person and using the relevant risk assessment methods. Reworking should be viewed as an abnormal procedure requiring special care.
- 5. The reworking (or possibly blending) of any recalled or reject wine should be strictly controlled and documented. The relevant authorised person(s) should determine the details of such reworking.
- An effective product recall program must be developed, documented and followed when required, or alternatively the protocol recommended by Food Standards Australia New Zealand be used.
- 7. Any recalled/withdrawn product should be clearly identified, isolated and stored away from any other finished product, to avoid the likelihood of re-dispatch. Disposition (rework or disposal) of recalled product should be determined by the relevant authorised person as outlined in the food recall program.

## 3.4 Storage and distribution

- All storage areas should be maintained in a clean, dry condition and all goods should be clearly identifiable as to product identity and current status.
- Finished product should be released only after it has been cleared for distribution.
- All customer complaints about the finished product should be recorded and investigated.
- 4. The status of damaged goods in storage areas should be clearly marked.
- Storage areas should be of an adequate size to store the necessary raw materials and the final product segregated without abnormal deterioration or cross contamination.

## 4. Glossary of terms

#### authorised person

The person recognised as having the responsibility for ensuring that each batch of finished wine or wine product has been produced, tested and approved for release in compliance with the specifications of the customer and the mandatory Australian regulations and standards.

## batch (or lot)

A defined quantity of starting material (grapes), wine or wine product processed in a single process or series of processes so that it is expected to be homogeneous. It may sometimes be necessary to divide a batch into a number of sub-batches or tanks, which are later brought together to form a final homogeneous batch.

#### batch number (or lot number)

A distinctive combination of numbers and/or letters which uniquely identifies a wine or wine product, for example, production batch on the labels, its batch records and corresponding certificates of analysis.

#### batch records

All documents associated with the making of a batch of wine or wine product or finished product. They provide a history of each batch of product and of all circumstances pertinent to the quality of the final product.

#### blending

The introduction of all, or part of a batch (of the same/similar product/s), of the required quality into another batch at a defined stage of the winemaking process.

#### bulk product

Any wine or wine product that has completed all processing stages up to, but not including, final packaging.

## calibration

The set of operations that establish, under specified conditions, the relationship between values indicated by an instrument or system for measuring (especially weighing), recording, and controlling, or the values represented by a material measure, and the corresponding known values of a reference standard. Limits for acceptance of the results of measuring should be established\

#### clean area

An area with defined control for chemicals/additives/processing aids constructed and used in such a way as to reduce the introduction, generation and



cross-contamination within the area.

#### clean water

excludes the use of treated wastewater and human effluent

## consignment (or delivery batch lot)

The quantity of a supplied material or substance made by one manufacturer and supplied at one time in response to a particular order. A consignment may comprise one or more packages or containers.

#### contamination

The undesired introduction of impurities of a chemical or microbiological nature, or of foreign matter, into a chemical/additive/processing aid/wine/wine product during pre-production, sampling or packaging, storage or transport.

#### critical operation

An operation in the winemaking process that may cause variation in the quality of the wine or wine product.

#### cross-contamination

Contamination of a wine or wine product, chemical/additive/processing aid, intermediate product or finished product with another starting material or product during processing and production.

#### finished product

A finished product that has undergone all stages of winemaking, including packaging in its final container and labelling, and;

- for each batch of beverage product, there should be an appropriate laboratory determination of satisfactory conformity to its finished product specification prior to release; and
- products failing to meet the established specifications or any other relevant quality criteria should be rejected.

## in-process control

Checks performed during the winemaking process/production in order to monitor and, if necessary, to adjust the process to ensure that the product conforms to its specifications. The control of the environment or equipment may also be regarded as a part of in-process control.

## intermediate product

A partly processed wine or wine product that must undergo further process steps before it becomes a bulk product.

## manufacture

All operations of purchase of materials and products, production, quality control, release, storage and distribution of a wine or wine product, and all related controls.

## manufacturer

A company that carries out operations such as production, packaging, repackaging, labelling and re-labelling of a wine or wine product.

#### master record

A document or set of documents that serve as a basis for the batch documentation - batch process records, together with a description of the procedures carried out to produce the specified quantity of a finished wine or wine product as well as the process instructions.

## packaging

All operations, including the filling and labelling, that a bulk product has to undergo in order to become a finished packaged wine or wine product, and all related records.

## packaging instructions

Formally authorised packaging instructions should exist for each product, pack size and type. These should normally include, or make reference to:

- the name of the product;
- a description of its strength;
- the pack size expressed in terms of the number, weight or volume of the product in the final container:
- a complete list of all the packaging materials required for a standard batch size, including quantities, sizes and types, with the code or reference number relating to the specifications for each packaging material;
- where appropriate, an example or reproduction of the relevant printed packaging materials and specimens, indicating where the batch number and expiry date of the product have been marked;
- special precautions to be observed, including a careful examination of the packaging area and equipment in order to ascertain the line clearance before and after packaging operations;
- a description of the packaging operation, including any significant subsidiary operations, and equipment to be used; and
- details of in-process controls with instructions for sampling and acceptance limits.



## packaging material

Any material, including printed material, employed in the packaging of a product, including any outer packaging used for transportation or shipment. Packaging materials are referred to as primary or secondary according to whether or not they are intended to be in direct contact with the product.

Potable water is water pure enough for humans to drink and use for other domestic purposes such as cooking, washing, bathing and showering

## processing operations

potable water

Before any processing or winery operation is started or carried out, steps should be taken to ensure that the work area and equipment are clean and free from any foreign products/potential contaminants, product residues and cleaning agents for example, that not required for the current operation. For example:

- Any necessary in-process controls and environmental controls should also be carried out.
- Means should be instituted of indicating failures of equipment or of services such as water and gas to equipment.
- Defective equipment should be withdrawn from use until the defect has been rectified.

#### production

All operations involved in the preparation of a product, from receipt of materials (grapes), through the winemaking processing, packaging and repackaging, labelling and re-labelling, to completion of the finished product.

#### qualification

Action of proving that any premises, systems and items of equipment work correctly and actually lead to the expected results. The meaning of the word 'validation' is sometimes extended to incorporate the concept of qualification.

## quality management

Quality management is usually defined as the aspect of a management function that determines and implements the 'quality policy', that is, the overall intention and direction of an organisation regarding quality, as formally expressed and authorised by senior management. The basic elements of quality management are:

 An appropriate infrastructure or 'quality system', encompassing the organisational structure, procedures, processes and resources.  Systematic actions necessary to ensure adequate confidence that a product will satisfy the given requirements for quality.

#### quality assurance

The totality of *quality management* is termed 'quality assurance'. Within an organisation, quality assurance serves as a management tool. In contractual situations, 'quality assurance' also serves to generate confidence in the supplier, co-packer/packer/producer. The concepts of quality assurance, GMP and quality control are interrelated aspects of quality management. They are described here in order to emphasise their relationship and their fundamental importance to the production and control of all wine and wine products

#### quality control

Quality control is the part of GMP concerned with sampling, specifications and testing; and with the organisation, documentation and release procedures which ensure that the necessary and relevant tests are carried out and that all packaging materials, bulk wines and wine products are not released for packaging, nor products released for sale or supply, until their quality has been judged to be satisfactory. Quality control is not confined to laboratory operations but must be involved in all decisions concerning the quality of the product.

#### quarantine

The status of starting the physical isolation of grapes/wine/wine products/chemicals/additives/ processing aids or any packaging materials, intermediates, or bulk or finished products, or by other effective means, while a decision is awaited on their release, rejection or reprocessing.

#### reconciliation/mass balance

A comparison between the theoretical quantity and the actual quantity produced.

## reprocessing

Subjecting all or part of a batch or blend, lot of an in-process product or bulk product of a single batch/lot to a previous step in the winemaking process due to failure to meet predetermined specifications. Reprocessing procedures are foreseen as occasionally necessary and, in such cases, are validated and approved as part of the winemaking or marketing process.

#### reworking

Subjecting an in-process or bulk process intermediate or final product or

package, of a batch to an alternate production process due to a failure to meet predetermined specifications. Reworking is an unexpected occurrence and infrequently occurs.

## self-contained area

Premises or areas which provide complete and total separation of various aspects of an operation (cleaning chemicals to processing chemicals), including equipment, with well established procedures, controls and monitoring. This includes physical barriers, but does not necessarily imply two distinct and separate buildings

## specification

Lists of detailed requirements with which the products or materials used or purchased for the winemaking process have to conform. They serve as a basis for quality evaluation

## Standard Operating Procedure (SOP)

An authorised written procedure giving instructions for performing operations not necessarily specific to a given product or material (winemaking processes – handling, blending, filtering, stabilisation, equipment operation, maintenance and cleaning; validation; cleaning of premises, environmental control; sampling and inspection). Certain SOPs may be used to supplement product-specific master and batch production process documentation.

#### validation

Action of proving, in accordance with the principles of GMP, that any procedure, process, equipment, material, activity or system actually leads to the expected results.