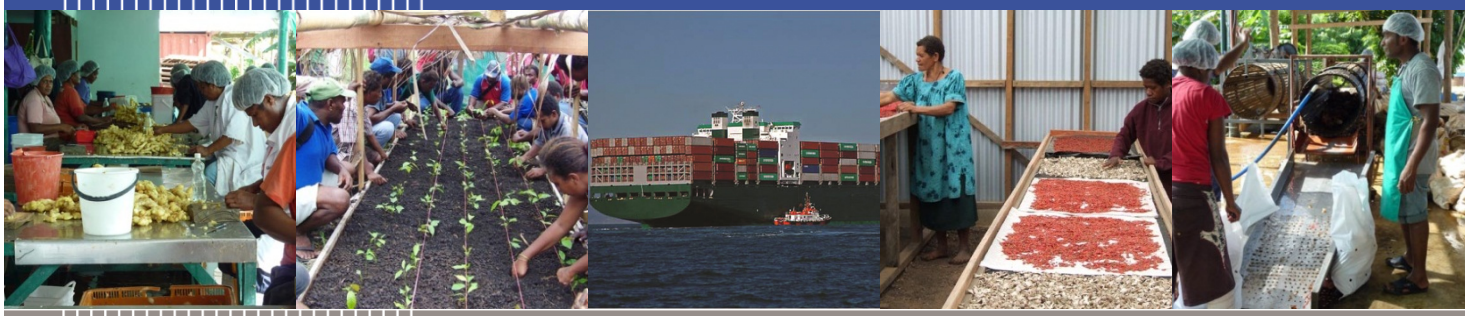

Pacific Horticultural and Agricultural Market Access Program (PHAMA)

Technical Report 32: Establishing Improved Diagnostic Services in Vanuatu: Scoping Study (VAN03)

15 NOVEMBER 2012

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Date: **15 November 2012**
Reference: 42444103
Status: FINAL

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Table of Contents

Tables

Appendices

Abbreviations

Abbreviation	Description
APHA	American Public Health Association
AQ	AsureQuality NZ Ltd
AUS	Australia
COA	Certificate of Analysis
DLQS	Department of Livestock & Quarantine (Vanuatu)
DOE	Department for the Environment (Vanuatu)
DOF	Department of Fisheries (Vanuatu)
DOG	Department of Geology (Vanuatu)
EU	European Union
FDA	Food and Drug Administration (USA)
FFA	Free Fatty Acids
FTDC-AU	Food Technology & Development Centre – Analytical Unit (Vanuatu)
GC-MS	Gas Chromatography Mass Spectroscopy
GC-MS/MS	Gas Chromatography Tandem Mass Spectroscopy
IANZ	International Accreditation NZ
ICP-MS	Inductively Couple Plasma Mass Spectroscopy
IEC	Ministry of Health (Vanuatu)
ILCP	Inter Laboratory Comparison Program
ISO	International Organisation for Standardisation
KTP	Key Technical Person
LC-MS/MS	Liquid Chromatography Tandem Mass Spectroscopy
MOH	Ministry of Health (Vanuatu)
NAR	NATA Accreditation Requirements
NATA	National Association of Testing Authorities (Australia)
NZ	New Zealand
OMAR	Overseas Market Access Requirement
PC2	Physical Containment Level 2
PHAMA	Pacific Horticultural & Agricultural Market Access Program
PPE	Personal Protective Equipment
QMS	Quality Management System
SOP	Standard Operating Practice
UNELCO	Union Electrique du Vanuatu Ltd
USP	University of the South Pacific
VU	Vanuatu
WHO	World Health Organisation

Executive Summary

An Australian government initiative, operating under the AusAID program, is seeking to increase exports of high value primary products from Pacific Island countries. The Pacific Horticultural and Agricultural Market Access Program (PHAMA) is designed to address constraints to market access for primary production products by providing practical and targeted assistance under a multi-component, multiple phase project. To achieve the objectives, AusAID will work collaboratively with regulatory and industry bodies to gain and maintain access to key markets for selected products.

Vanuatu has been identified as having a range of value-added food industries and a range of products have been identified as of prime interest including kava, vanilla, spices, copra and copra meal, cocoa and meat. A range of diagnostic services (skills, equipment and procedures) are required to ensure such products meet quality and/or safety standards (e.g. water quality testing) and to show compliance of the product itself with the standards.

The islands of Efate (Port Vila) and Santo (Luganville) both support a range of the industries of prime interest, and have various diagnostic service providers offering varying degrees of capability. AsureQuality have been appointed by PHAMA to undertake a scoping study to report on the current status of the testing facilities available and to provide recommendations concerning the establishment of diagnostic services for testing in the food and related industries in Vanuatu.

If export markets for food, and related products for human consumption, are to be expanded, laboratories providing testing facilities must attain the ISO/IEC 17025:2005 standard. The adoption of additional requirements, as set out in AS/NZ standards for laboratory construction and safe operation must also be adopted, as these are accepted as international best practice, and much of their content, particularly around facility standard and safety, would be expected as minimum to attain ISO/IEC 17025:2005. This is to satisfy clause 5.3.1 of ISO/IEC 17025:2005 which seeks to ensure the laboratory facility and environmental conditions do not compromise the quality of results obtained at the testing laboratory.

None of the existing laboratories visited are currently at the ISO/IEC 17025:2005 standard, for multiple reasons, including the standard of facilities available, the standard of suitable quality procedures being used and the suitability of current laboratory equipment available.

Of the five existing government owned laboratory facilities and three privately owned laboratories visited, all would require extensive refurbishment and investment in new, or maintenance of existing instruments and apparatus, to achieve the required internationally required standard for export testing.

The facility of the privately owned COFLEY laboratory, situated on the UNELCO power supply premises, was much closer to the standard of facility necessary to achieve ISO/IEC 17025:2005 accreditation status, but would still require improvements to the facility and systems.

Staff with relevant qualifications are available at the government laboratories visited and at the COFLEY laboratory. However, further training particularly around the development and operation of a Laboratory Quality Management System (QMS), would be required.

Our recommendation, based on the findings of a two week study in Vanuatu, visiting laboratory facilities, industry representatives and operators, is that a local facility should be developed to allow microbiological and simple chemistry (moisture, pH etc.) testing in Port Vila, and that this facility should be accredited and operate to the ISO/IEC 17025:2005 standard. More complex chemistry

testing, involving the use of high end testing instrumentation (Gas Chromatography and Liquid Chromatography) should be outsourced to an ISO/IEC 17025:2005 accredited international laboratory provider outside of Vanuatu.

Details and recommendations on how this can be achieved are provided within this report.

1 Background

AsureQuality is a world class provider of food safety and bio-security services to the food and primary production sectors worldwide. Our Laboratory Services group which has a team of over 400 people based in Australasia, provides diagnostic services to customers in over 40 countries around the globe.

AsureQuality has been contracted by PHAMA to undertake a scoping study as part of their program to address constraints to market access for agricultural and value added products in Vanuatu.

The objectives of the study are:

(i) to identify the capability and capacity of current in-country food safety/standards diagnostic service providers;
(ii) determine which testing can be conducted effectively in-country and which should be conducted off-shore to ensure cost effective and timely delivery of results;
(iii) provide a report outlining a proposed and costed model for diagnostic service delivery.

The scoping took into consideration the availability of suitable testing facilities, staff, training facilities, the timelines for testing requirements, the availability of consumables and where these should be sourced from, the logistics of sample movement, the cost of building facilities where none are present or appropriate and options for outsourcing testing work to international laboratory providers.

In order to generate the best possible understanding of the nature and volume of the testing required for market access the scoping study also involved meetings with commercial representatives for key current export, or potential export industries including, but not restricted to, kava, cassava, coffee, beef, honey, coconut oil, copra meal and tamino oil.

AsureQuality's Laboratory Services Business Manager, Alan Stanley, and specialist microbiologist, Michaela Taylor, spent two weeks in Vanuatu to carry out the scoping study between 27 February and 9 March 2012 inclusive, accompanied by PHAMA representative Timothy Tumukon. Meetings were scheduled with various stakeholders and laboratories to conduct investigation and assessment.

Dr Alan Stanley is a Business Manager for five AsureQuality laboratories involved in organic chemical residue, seed, plant pathology and entomology testing in both New Zealand and Australia. Alan has worked for AsureQuality for seven years. Prior to that he worked in the pharmaceutical industry in the UK and USA, studied chemistry in the UK and USA, and has been involved in laboratory research work and testing, or laboratory management, for over 21 years.

Michaela Taylor is an Account Manager with AsureQuality working closely with our food customers throughout New Zealand and overseas. Prior to this, Michaela was the Team Leader for AsureQuality's Wellington microbiology laboratory responsible for day to day operations and maintaining quality systems. Michaela has over 12 years' experience working in food microbiology laboratories throughout New Zealand.

Table 1-1 Visits and meetings undertaken by AsureQuality staff and PHAMA representatives between 27 February and 9 March 20012 inclusive

Date	Stakeholder	Location
27 February 2012	PHAMA	Port Vila
27 February 2012	FTDC-AU	Port Vila
27 February 2012	Azure Water	Port Vila
27 February 2012	Department of Livestock and Quarantine	Port Vila
28 February 2012	Vanuatu Direct Limited	Port Vila
28 February 2012	Tanna Coffee	Port Vila
28 February 2012	Ministry of Health – Environmental Health	Port Vila
29 February 2012	Forney Enterprises	Port Vila
29 February 2012	Ministry of Lands (Geology) Laboratory	Port Vila
29 February 2012	UNELCO	Port Vila
29 February 2012	Vincent Lebot	Port Vila
1 March 2012	Department of Fisheries	Port Vila
1 March 2012	South Seas Commodities	Port Vila
1 March 2012	The Kava Store	Port Vila
2 March 2012	Joseph Jacobe	Port Vila
2 March 2012	Lapita Cafe	Port Vila
5 March 2012	Gilbert Gibson	Port Vila
5 March 2012	Thomas Bayer	Port Vila
6 March 2012	Agricultural Research and Technical Centre	Santo
6 March 2012	Venui Vanilla Co Ltd	Santo
7 March 2012	COPSL	Santo
8 March 2012	Dr Peter Hoyle	Santo
8 March 2012	Santo Meat Packers	Santo
9 March 2012	Localex Limited	Santo
9 March 2012	Asenate Pikioune	Santo

2 Report on Laboratory Facilities Visited

2.1 Introduction

For laboratory testing carried out on produce consumed within Vanuatu, the prevailing internal legislation at the time may dictate to what standard and to what level of international recognised accreditation the laboratory testing facilities should adopt and follow, if any.

With produce destined for export the situation is different, and should a product fall under an Overseas Market Access Requirement (OMAR) for an importing country, then the importing country will require that laboratories testing the product and issuing a Certificate of Analysis (COA) are operating to internationally recognised accreditation standards. Failure to comply may not necessarily prevent export initially, but it places a risk on the security of market access for a particular market and product if border violations are detected by the importing country. If multiple violations were to occur, this may result in blanket restrictions for all produce or, at the very least, even tighter restrictions being imposed for future exports. Although random sampling and testing cannot guarantee issues not to arise, by following internationally recognised testing protocols and the Codex Alimentarius Commission, sampling plans, issues and risks are minimised. Additionally properly tested and certificated produce may be able to be exported and sold at premium rates into certain markets.

For laboratory testing of this nature the major relevant standard is ISO/IEC 17025:2005 General Requirements for the Competence of Testing and Calibration Laboratories. This standard is available for purchase from the ISO website.

http://www.iso.org/iso/Catalogue_detail?csnumber=39883

The abstract of the standard states:

“ISO/IEC 17025:2005 specifies the general requirements for the competence to carry out tests and/or calibrations, including sampling. It covers testing and calibration performed using standard methods, non-standard methods, and laboratory-developed methods.

It is applicable to all organisations performing tests and/or calibrations. These include, for example, first-, second- and third-party laboratories, and laboratories where testing and/or calibration forms part of inspection and product certification.

ISO/IEC 17025:2005 is applicable to all laboratories regardless of the number of personnel or the extent of the scope of testing and/or calibration activities. When a laboratory does not undertake one or more of the activities covered by ISO/IEC 17025:2005, such as sampling and the design/development of new methods, the requirements of those clauses do not apply.

ISO/IEC 17025:2005 is for use by laboratories in developing their management system for quality, administrative and technical operations. Laboratory customers, regulatory authorities and accreditation bodies may also use it in confirming or recognising the competence of laboratories. ISO/IEC 17025:2005 is not intended to be used as the basis for certification of laboratories.

Compliance with regulatory and safety requirements on the operation of laboratories is not covered by ISO/IEC 17025:2005.”

This is the general standard and criteria required for internationally recognised laboratory testing and must be read in conjunction with other standards, specifically for the proposed testing of food as

discussed within this report, these would be AS LAB C 1- Biological testing and AS LAB C 2- Chemical Testing.

Other standards may be applicable in some circumstances depending on the product being exported and to which country or intended market the product is targeted.

2.2 Existing Laboratory Facilities in Port Vila, Vanuatu

During the laboratory visits AsureQuality staff, Alan Stanley and Michaela Taylor were accompanied by Timothy Tumukon, representing PHAMA. Whilst on the laboratory sites we were accompanied by authorised staff from the companies, government departments or agencies that operated or owned the laboratory facilities.

The general agenda of each meeting, following formal introductions, was normally a period of questions and answers led by the AsureQuality team; this was followed by a tour of the laboratory facility. During the tour photographs of the facility were taken to assist with the preparation of this report. Copies of test methods, certificates of analysis and other useful information were also obtained, when available, from some facilities. Data from these copies has been used to assist in the preparation of this report. No photographs were taken or copies of documents were removed from the laboratory facilities without seeking and receiving permission from the authorised staff supervising the tour of the facility.

A list of general questions asked at the laboratories can be found in Appendix B. Not all questions were necessarily asked at each facility, depending on our findings and how the visit progressed.

Table 2-1 Laboratories visited in Port Vila and Luganville, Vanuatu, between 27 February and 8 March 2012

Date	Laboratory Facility	Authorised Laboratory Representative	AsureQuality Staff	PHAMA Staff
27 February 2012	FTDC-AU	Ruth Amos, Laboratory Manager	Alan Stanley Michaela Taylor	Timothy Tumukon
27 February 2012	DOQ Entomology Laboratory	Sylvario Bule Baegeorge Swua	Alan Stanley Michaela Taylor	Timothy Tumukon
29 February 2012	MOH Laboratory	Nellie Ham John Masiga	Alan Stanley Michaela Taylor	Timothy Tumukon
29 February 2012	DOG Laboratory	Errie Sami	Alan Stanley Michaela Taylor	Timothy Tumukon
29 February 2012	Cofely Vanuatu Labortory	Frederic Petit, Director General George Matariki, Laboratory technician	Alan Stanley Michaela Taylor	Timothy Tumukon
06 March 2012	VARTC, IRHO Plantation Laboratory, Santo	Marie Melteras, Centre Director	Alan Stanley Michaela Taylor	Timothy Tumukon
07 March 2012	Copra Processing Plant Laboratory, Santo	Samuel Tiwok, Laboratory Technician	Alan Stanley Michaela Taylor	Timothy Tumukon
08 March 2012	Santo Meat Packers Laboratory	Toru Mochizuki	Alan Stanley Michaela Taylor	Timothy Tumukon

During laboratory visits AsureQuality staff used the NATA ISO17025:2005 Laboratory Assessment Worksheet (L12.5.2)/Issue 9/May 2009; this assessment worksheet has been designed by NATA to assist laboratory staff in their preparation for an assessment to the ISO/IEC 17025:2005 standard. A copy of a blank NATA assessment work sheet can be found in the supplementary material provided.

Throughout this report references made concerning accreditation requirements will be to clauses within NATA Accreditation Requirements (NAR), these corresponding to the relevant clauses within the overarching ISO/IEC 17025:2005 standard.

2.3 General Observations

None of the laboratories visited had a Quality Management System (QMS) in operation, or had any laboratory management policies in place. A number of facilities explained that management policies were under development. There was no evidence in any laboratory that inter-laboratory comparison trials are currently participated in (i.e. participation within the last year). In one laboratory (DOG) copies of ILCP documentation for an AsureQuality water chemistry proficiency testing scheme, for potable water analysis, were viewed. Dated March 2009, there was no evidence that the laboratory had actually participated in the scheme. However, upon investigation, we were able to ascertain participation by contacting Global Proficiency in New Zealand (Global Proficiency are a subsidiary company of AsureQuality).

Checking Global Proficiency databases we found water chemistry samples had been sent to two Vanuatu laboratories in 2007–2011. Water Chemistry proficiency rounds are coordinated by the University of the South Pacific (Fiji), and despatched to several laboratories located through the South Pacific as requested. Details are as follows for Vanuatu:

- Dept of Geology, Mines & Water Resources Lab, Port Vila, Vanuatu. Contact: Erickson Sammy, Water Resource Manager. Participated in Water Chemistry (Potable Water) in March each year from 2007 through to 2011 (registration not received for 2012).
- Public Health Department Lab, Port Vila, Vanuatu. Contact: Nellie Muru Wouloseje. Participated in Water Chemistry (Potable Water) in March 2007 and March 2008.

2.4 Observations of the Standard of Facility for Each Laboratory Visited

Section 5.3 of the NAR refers to the accommodation and environmental conditions of a testing laboratory. Section 5.3.1 requires that the laboratory facility and environmental conditions do not compromise the quality of results obtained from testing carried out within the laboratory. Section 5.3.2 discusses monitoring and requires that the laboratory monitors, controls and records environmental conditions, and that tests and/or calibrations are stopped when results will be jeopardised by the environmental conditions. Section 5.3.4 discusses access to the laboratory, which must be controlled, and section 5.3.5 seeks to ensure good housekeeping measures are in place within the laboratory.

The ISO/IEC 17025:2005 standard does not refer to specific building requirements; however the above criteria need to be addressed by the quality of the laboratory building and the general environment within the laboratory (i.e. temperature, humidity).

Internationally accepted standards for laboratory construction and safety are detailed in the AS/NZS 2243.3.2012 Safety in Laboratories Part 3: Microbiology Safety and Containment; this standard refers to general building construction for laboratories.

For example, the floors of the laboratory shall be smooth, easy to clean, impermeable to liquids and resistant to commonly used reagents and disinfectants. Water back flow prevention is required, Bench tops shall be able to withstand heat generated by general laboratory procedures, e.g. flaming loops and heating of media. This is only for PC1 containment, the standard becomes stricter depending on what organisms the laboratory work with e.g. *E.Coli*, *Listeria* etc. Specific requirements will be discussed in greater detail in subsequent sections of this report.

There are a number of safety standards that refer to construction and requirements. The main one referred to AS/NZS 2982.1.

AS/NZS 2982:2010 refers to laboratory design and construction and sets out requirements relating to the design and construction of buildings that house laboratories. It applies both to new laboratories and to where existing buildings are converted to laboratory use. Special sections are included for hazardous substances, biological substances and radiological entities.

Other relevant standards include but are not restricted to:

- AS/NZS 2243.1:2005 Safety in laboratories – Planning and operational aspects;
- AS/NZS 2243.5:2004 Safety in laboratories – Non-ionising radiations – Electromagnetic, sound and ultrasound;
- AS/NZS 2243.10:2004 Safety in laboratories – Storage of chemicals;
- AS 2243.7-1991 Safety in laboratories – Electrical aspects;
- AS/NZS 2243.8:2006 Safety in laboratories – Fume cupboards;
- AS/NZS 2243.2:2006 Safety in laboratories – Chemical aspects.

2.5 Report on Individual Laboratory Facilities Visited

2.5.1 Food Technology and Development Centre-Analytical Unit (FTDC-AU)

The facility was a ground floor complex in a building occupied by other businesses and comprises a staff room/meeting room (approx. 10 x 10m), the main laboratory room (approx. 10 x 10 m) and a store room (approx. 6 x 10 m), the store room was derelict and not sealed to the elements with free access *via* a large hole in the wall.

Surfaces in the main laboratory room were not sealed and of porous material or cracked ceramic tiles, cupboards doors and frame were all wooden and in a general state of disrepair. There was no security system controlling access to the facility, other than main doors being locked. Ceilings were broken, floors were vinyl tiling that were broken and lifting, and some cupboard doors fell off when opened.

For this facility to be suitable for assessment to the ISO/IEC 17025:2005 standard and for laboratory testing to take place, extensive refurbishment would be required to bring the facility building to an acceptable standard. This would include, but not necessarily be limited to, the removal of all current fixtures and fittings and then complete replacement of flooring, wall and ceiling materials, the new materials complying with acceptable international standards as set out in the aforementioned AS/NZ standards. New benching materials and sink units would be required and appropriate air conditioning for internal climate control would be necessary in order to maintain constant temperature and humidity

levels. Consideration should also be given to the security of the facility such that unauthorised persons could not enter the facility unnoticed. If pathogenic materials e.g. *Salmonella*, or *Listeria* were to be tested in the facility, it should be constructed to comply with PC2 level of containment at a minimum.

2.5.2 Department of Geology Laboratory (DOG)

The laboratory was situated in a ground floor building complex occupied by the Department and was approximately 6 x 7m of floor area with side benches and a central bench. It was viewed in a state of general dilapidation, ceramic floor tiles were missing or loose on the floor, and most benches and cabinets were wooden and in bad repair. The facility was built 40 years ago and has most likely not been adequately maintained since. The majority of this complex is derelict following an earthquake in the 1990s making many surrounding structures unsafe. A second adjacent laboratory room was mentioned, but we did not view this laboratory during our visit.

For this facility to be suitable for assessment to the ISO/IEC 17025:2005 standard for laboratory testing to take place, extensive refurbishment would be required to bring the facility building to an acceptable standard. This would include, but not necessarily be limited to, the removal of all current fixtures and fittings and then complete replacement of flooring, wall and ceiling materials, with new materials complying with acceptable international standards as set out in the aforementioned AS/NZ standards. New benching materials and sink units would be required and appropriate air conditioning for internal climate control would be required in order to maintain constant temperature and humidity levels. Consideration should also be given to the security of the facility such that unauthorised persons could not enter the facility unnoticed. If pathogenic materials e.g. *Salmonella*, or *Listeria* were to be tested in the facility, it should be constructed to comply with PC2 level of containment at a minimum.

2.5.3 Ministry of Health Laboratory (MOH)

The laboratory was on the same site and adjacent to the geology laboratory, described above. It is a two storey building, on a mainly derelict site, but due to previous earthquake damage, we cannot comment on the structural suitability of the site.

The facility consisted of an outer entrance area (approx. 4 x 4m) entered *via* a caged gate from stairs. This led to two main laboratory rooms one approx. 4 x 6m and one approx. 6 x 8m, with a small room approx. 4 x 4m.

The laboratory was not sealed to the elements with a broken window and a hole in the concrete wall, and there was significant insect infestation. Surfaces were painted laminate wood; the floor was of vinyl tiles and lifting in places. Cabinet doors were of wood, rotting and broken in places.

For this facility to be suitable for assessment to the ISO/IEC 17025:2005 standard for laboratory testing to take place, extensive refurbishment would be required to bring the facility building to an acceptable standard. This would include, but not necessarily be limited to, the removal of all current fixtures and fittings and then complete replacement of flooring, wall and ceiling materials, with new materials complying with acceptable international standards as set out in the aforementioned AS/NZ standards. New benching materials and sink units would be required and appropriate air conditioning for internal climate control would be required in order to maintain constant temperature and humidity levels. Consideration should also be given to the security of the facility such that unauthorised persons could not enter the facility unnoticed. If pathogenic materials e.g. *Salmonella*, or *Listeria* were to be tested in the facility, it should be constructed to comply with PC2 level of containment at a minimum.

2.5.4 COFELY Laboratory (UNELCO)

This laboratory was located on a UNELCO facility and was entered *via* an outer access controlled security perimeter fence. The laboratory building was on the ground floor and situated adjacent to an office and meeting room complex. The laboratory had two main rooms one for microbiology testing (measuring approx. 7 x 7m), and a separate laboratory (measuring approx. 7 x 10m) for chemistry testing. Both rooms were well appointed. The floor was of large ceramic tiles with grouted joints. Ceilings were solid and in very good condition. Walls were tiled and painted, in very good condition. Much of the benching in both laboratory rooms was constructed from stainless steel, manufactured by AlphaLine, and in excellent condition.

Some benching was constructed from wood with grouted ceramic tile bench tops. Some shelving was of wooden or wooden laminate construction.

An extraction fan was situated in the ceiling of the chemistry laboratory, and both rooms were air conditioned.

This facility was much closer to the standard required for ISO/IEC 17025:2005. Grouted ceramic tiles will be of concern and would need to be replaced by solid none porous materials, particularly for a PC2 facility suitable for pathogen testing. Wooden benches and cabinets would need to be replaced, and appropriate local fume extraction should be used. Laminar flow cabinets or externally vented fume extraction cabinets would be required.

2.5.5 VARTC, IRHO Plantation Laboratory, Santo

The laboratory facility was based in a standalone ground floor unit and is comprised of a main laboratory room (approximately 7 x 5m), with a smaller side storage room, (3 x 5m). The floor was concrete and painted but not sealed with cracks and wear showing through to bare concrete. There was a central bench and benches against the walls, surfaces were ceramic tile or painted and not suitable for pathogen testing work. Cupboards were of wooden construction. There was a hood with extraction at one end of the laboratory room, but no sash or doors are present, and it was unclear if the extractor was operational. There was no controlled access to the facility.

For this facility to be suitable for assessment to the ISO/IEC 17025:2005 standard for laboratory testing to take place, extensive refurbishment would be required to bring the facility building to an acceptable standard. This would include, but not necessarily be limited to, the removal of all current fixtures and fittings and then complete replacement of flooring, wall and ceiling materials, with new materials complying with acceptable international standards as set out in the aforementioned AS/NZ standards. New benching materials and sink units would be required and appropriate air conditioning for internal climate control would be required in order to maintain constant temperature and humidity levels. Consideration should also be given to the security of the facility such that unauthorised persons could not enter the facility unnoticed. If pathogenic materials e.g. *Salmonella*, or *Listeria* were to be tested in the facility, it should be constructed to comply with PC2 level of containment at a minimum.

2.5.6 Copra Processing Plant, Luganville, Santo

This facility was is a private laboratory operating at the COPSL copra processing facility. The laboratory space is approximately 5 x 5 m and carries out in-process determinations of free fatty acids, (FFA), content of the processed coconut oil. This determination is carried out by titration. The laboratory has a drying oven and a tintometer. There is no opportunity to use this facility for other

testing in its current state, and the operation and testing are self-contained for the processing plant. The crude coconut oil is shipped to Malaysia, where further purification and processing is carried out; therefore there is no requirement for food safety testing at this stage of the product. The by-product of copra meal, following oil extraction, is exported to Australia and Taiwan for use in animal food supplements.

2.5.7 Santo Meat Packers Abattoir Laboratory

This facility comprised two small rooms each 2 x 4 m accessed *via* a storage area. The floor material was vinyl and all cupboards and shelving units were of wooden construction. The room had a lot of cardboard storage boxes piled against the wall opposite the door.

For this facility to be suitable for assessment to the ISO/IEC 17025:2005 standard for laboratory testing to take place, extensive refurbishment would be required to bring the facility building to an acceptable standard. This would include, but not necessarily be limited to, the removal of all current fixtures and fittings and then complete replacement of flooring, wall and ceiling materials, with new materials complying with acceptable international standards as set out in the aforementioned AS/NZ standards. New benching materials and sink units would be required and appropriate air conditioning for internal climate control would be required in order to maintain constant temperature and humidity levels. Consideration should also be given to the security of the facility such that unauthorised persons could not enter the facility unnoticed. If pathogenic materials e.g. *Salmonella*, or *Listeria* were to be tested in the facility, it should be constructed to comply with PC2 level of containment at a minimum.

2.5.8 Department of Quarantine Entomology Laboratory

The entomology laboratory is situated within the Quarantine department building. It is approximately 7 x 7 m. This facility would not be required to achieve a standard for handling pathogens, although it is recommended that it operates to ISO/IEC 17025:2005, which ensures and maintains the integrity of any results published from a laboratory.

2.5.9 Proposed Laboratory Facility at the Department of Fisheries.

The Department of Fisheries are awaiting final government approval to construct a purpose built facility to enable testing, in particular histamine testing in tuna fish, to be carried out. The facility will be adjacent to the current fish processing plant operation in the wharf area of Port Vila. The laboratory will be single room approximately 10 x 10 m. The Director would like to see this facility operational by June 2012.

2.6 Conclusions Concerning Laboratory Facilities

Eight laboratory facilities in and around Port Vila on Efate Island and Luganville on Santo Island were visited and assessed; five laboratories were in the public sector and three were private operations (COFLEY, Copra Processing Plant Laboratory, Santo Meat Packers Plant Laboratory). None of these facilities would be in a state for immediate assessment against clause 5.3.1 of the ISO/IEC 17025:2005 standard for Laboratory Accommodation and Environmental Conditions. All the government laboratories visited would require major refurbishment to achieve the required standard for assessment to the ISO/IEC 17025:2005 standard.

It must be noted that no engineering or structural survey regarding the structural integrity of any of the laboratory facilities visited was undertaken by AsureQuality staff during this project visit, and we cannot comment on this aspect of the buildings visited.

The COFLEY (UNELCO) laboratory is closer to achieving the desired standard as set out in clause 5.3; however, some upgrade, as described above, would be required.

2.7 Report on Laboratory Equipment Inspected

A list of all the laboratory equipment and apparatus inspected is delineated in Table 2-2.

It should be noted that time did not permit each instrument to be assessed in detail to determine whether each individual piece of equipment was fully functional and appropriately calibrated for use in accredited testing. Comments in this table on functionality and the state of calibration referred to in this report are purely anecdotal and / or based on what we were able to see at the time of inspection. In order to determine the actual functional state of the equipment, it is recommended that manufacturer's instructions for operation and calibration are followed by a suitably trained and competent technician and a full assessment of the status of the equipment is undertaken.

It should be noted that in order to comply with ISO/IEC 17025:2005 standard for laboratory testing section 5.5 all equipment and its associated software, including that outside the laboratories control, required for testing and calibration activities are available and functioning properly (5.5.1), capable of achieving the required accuracy (5.5.2), has calibration programs established for measured quantities or values (5.5.2), is calibrated and checked before use (5.5.2), is operated by authorised personnel (5.5.3), has current instructions on maintenance available (5.5.3), is uniquely identified in all SOP's and supporting information (5.5.4). Comprehensive records (5.5.5) of the equipment should be maintained including manufacturer details, serial number, evidence that the instrument complies with the testing requirements it is being used for, calibration history and maintenance plan.

Detailed operating procedures should be available and readily accessed for each item of equipment (5.5.6 and 5.5.11), specific documentation should be readily available detailing out of service procedures (5.5.7), calibration status (5.5.8) and safeguards that are in place to prevent unauthorised adjustment of the apparatus (5.5.12).

2.8 Conclusions Concerning Laboratory Equipment Inspected

During our visits to the laboratory facilities 69 items of significant laboratory equipment were inspected or viewed. Information on a further seven items of equipment for another laboratory within the Department of Quarantine, which we did not visit, was also provided. In addition there were multiple items of glassware and plasticware, congruent with general laboratory equipment that one would expect to find in a laboratory environment. No comment will be made about items of glassware etc. other than to recommend that where items are used for volumetric determinations, i.e. volumetric flasks, pipettes, burettes and measuring cylinders etc., these items should be calibrated prior to use for measurement activities in the laboratory.

No evidence was found at the laboratories visited to indicate that any of the above points, required for instrumentation to comply with section 5.5 of the ISO/IEC 17025:2005, were being followed. The above discussion summaries only the key aspects of section 5.5, concerning the suitability for intended purpose of the existing laboratory equipment. To ensure compliance when preparing for audit, the full scope of requirements needs to be read and applied.

2.9 Security of Electrical and Water Services

For laboratories operating to ISO/IEC 17025:2005 accreditation, the security of electrical and water services is of importance to ensure that the laboratory facility and environmental conditions do not compromise the quality of results obtained at the testing laboratory.

Electricity supply to Port Vila is provided by diesel generation from the UNELCO power plant in the centre of Port Vila town. A backup UNELCO facility, also diesel generated, is situated on the road to the airport. The power supply is reported to have been stable for the last two years.

If electrical supply became an issue in future, a local diesel powered generator on site could be considered a useful backup, and if operated in conjunction with uninterruptable power supply units (UPS), could prove to be a robust way to achieve constant power supply and ensure that testing is not compromised.

UNELCO also supply town water within the Port Vila Urban area. The supply is chlorinated and tested to WHO potable water standards by the COFLEY laboratory based in the laboratory situated at the UNELCO backup power generation and research facility.

Gas supply in Port Vila is by bottled gas.

Table 2-2 List of major items of laboratory equipment observed

	Equipment	Comment
Food Technology and Development Centre – Analytical Unit		
FTC001	Analytical Balance	Not operating/calibrated – not able to comment on future suitability for use
FTC002	pH Meter	Not operating/calibrated – not able to comment on future suitability for use
FTC003	Colorimeter	Not operating/calibrated – not able to comment on future suitability for use
FTC004	Digestion apparatus	Not operating/calibrated – not able to comment on future suitability for use
FTC005	Incubator	Not operating/calibrated – not able to comment on future suitability for use
FTC006	Drying oven	Not operating – not able to comment on future suitability for use
FTC007	Bowl heaters	Not operating – not able to comment on future suitability for use
FTC008	Refractometer	Not operating/calibrated – not able to comment on future suitability for use
FTC009	Muffle Furnace	Not operating – not able to comment on future suitability for use
Ministry of Environment Laboratory		
MOE001	Incubator 37^{o}C	Not operating/calibrated – not able to comment on future suitability for use
MOE002	Incubator 47^{o}C	Not operating/calibrated – not able to comment on future suitability for use
MOE003	Water bath	Not operating/calibrated – not able to comment on future suitability for use
MOE004	Zeiss stereo microscope	Not operating – not able to comment on future suitability for use
MOE005	Sartorius top pan balance	Not operating/calibrated – not able to comment on future suitability for use
MOE006	MilliPore water purification unit	Not operating/calibrated – not able to comment on future suitability for use
MOE007	Refrigerator	Not operating/calibrated – not able to comment on future suitability for use
MOE008	Stirrer hotplate	Not operating – not able to comment on future suitability for use
Ministry of Geology Laboratory		
MOG001	Incubator 35^{o}C	Operating but not calibrated, available control charts last updated in February 2010
MOG002	Water filter unit	Operational
MOG003	Water Still	Not operating – not able to comment on future suitability for use

	Equipment	Comment
MOG004	Refrigerator	Operating but not calibrated, no control charts available
MOG005	Portable meter	Not operating – not able to comment on future suitability for use
MOG006	Heater/reactor block	Not operating – not able to comment on future suitability for use
MOG007	Colorimeter	Not operating – not able to comment on future suitability for use
MOG008	Portable Meter – pH	Not operating – not able to comment on future suitability for use
MOG009	Autoclave	Not operating – not able to comment on future suitability for use
MOG010	Colony Counter	Not operating – not able to comment on future suitability for use
MOG011	Eppendorf pipettes	Not operating/calibrated – not able to comment on future suitability for use
Cofley Laboratory at the UNELCO site		
COF001	Incubator	Operating but not calibrated, no control charts available
COF002	Incubator	Operating but not calibrated, no control charts available
COF003	Autoclave	Operating but not calibrated, no control charts available
COF004	Water bath	Operating but not calibrated, no control charts available
COF005	Filter unit	Operational
COF006	Water still	Operational
COF007	Refrigerator	Operating but not calibrated, no control charts available
COF008	Balance	Operating but not calibrated, no control charts available
COF009	Stirrer hotplate	Operational
COF010	Incubator	Operating but not calibrated, no control charts available
COF011	Reactor	Operational
COF012	Stirrer plate	Operational
COF013	Laboratory analyser	Operating but not calibrated, no control charts available
COF014	Incubator	Operating but not calibrated, no control charts available
COF015	Incubator	Operating but not calibrated, no control charts available
COF016	Microscope	Operational

	Equipment	Comment
COF017	Portable Spectrophotometer	Operating but not calibrated, no control charts available
COF018	Analytical Balance (4 dp?)	Operating but not calibrated, no control charts available
COF019	Top pan balance	Operating but not calibrated, no control charts available
COF020	COD reactor	Not operating – not able to comment on future suitability for use
COF021	pH Meter	Operating but not calibrated, no control charts available
COF022	Reference mass	Not calibrated to reference mass
Entomology Laboratory at the Department of Quarantine		
DOQ001	Microscope	Not operating – not able to comment on future suitability for use
DOQ002	Microscope	Not operating – not able to comment on future suitability for use
DOQ003	Microscope	Not operating – not able to comment on future suitability for use
VARTC, IRHO Plantation Laboratory, Santo		
IRH001	Centrifugal Freeze Drier	Not operating – not able to comment on future suitability for use
IRH002	Drying oven	Not operating – not able to comment on future suitability for use
IRH003	Centrifuge	Not operating – not able to comment on future suitability for use
IRH004	Refrigerator	Not operating – not able to comment on future suitability for use
IRH005	Water still	Not operating – not able to comment on future suitability for use
IRH006	Bowl heaters	Not operating – not able to comment on future suitability for use
IRH007	Stirrer hotplate	Not operating – not able to comment on future suitability for use
Copra Processing Plant Laboratory		
CPP001	Oven	Not operating – not able to comment on future suitability for use
CPP002	Heating mantle	Not operating – not able to comment on future suitability for use
CPP003	Tintometer	Not operating – not able to comment on future suitability for use
CPP004	Water Still	Not operating – not able to comment on future suitability for use
Santo Meat packers Laboratory		
SMP001	Autoclave	Not operating – not able to comment on future suitability for use

	Equipment	Comment
SMP002	Incubator	Not operating – not able to comment on future suitability for use
SMP003	Incubator	Not operating – not able to comment on future suitability for use
SMP004	Microscope	Not operating – not able to comment on future suitability for use
SMP005	Refrigerator	Operating but not calibrated, no control charts available
Quarantine Laboratory		
Equipment not viewed	Microscope (Olympus BH.2)	Not operational
Equipment not viewed	Portable Centrifuge	Operational
Equipment not viewed	Incubator	Not operational
Equipment not viewed	Water bath	Operating but not calibrated, no control charts available
Equipment not viewed	Water still	Not operational
Equipment not viewed	Autoclave	Not operational

3 Recommendations

Discussions with government department representatives, existing laboratory staff, producers and exporters highlighted the number and type of analyses currently undertaken in-country, those that have been conducted off-shore and those that stakeholders would like to be conducted in-country. This information was collated to provide a picture of the total testing requirements for Vanuatu for the next two–five years and is summarised in Appendix D. Additional information concerning export volume for the commodities of interest for the years 2008 to 2011 inclusive has been accessed from the Vanuatu National Statistics Office, November 2011 Statistics Update for Overseas Trade report.

Our recommended model for diagnostic service delivery is based on this information, together with our observations of the current testing capability in-country.

Within this section our recommendations are labelled R1, R2 etc. A summary of all recommendations can be found in Appendix A.

3.1 Options Based on Findings

The majority of testing requirements, as advised by stakeholders, is for routine microbiological and basic chemistry analyses. Based on our findings, a number of options aimed at providing laboratory testing facilities are potentially available. These options are restricted by the necessity for most microbiological tests to be started within 24 hours of samples having been taken and ideally sooner. For simple chemistry tests such as moisture determination, pH and cation/anion determinations, the testing time delay is less stringent but it would be beneficial to include this at the laboratory facility to have microbiological and basic chemistry testing capabilities at the same facility. Our research indicates that sufficient air transportation is available between Port Vila and Luganville to ensure that samples taken in either urban area could be delivered to a central Port Vila based laboratory within 24 hours of sampling. Details of logistics and indicative costs are set out in Appendix F.

Options available to achieve a central microbiology and basic chemistry testing laboratory in Port Vila include, but are not restricted to:

- Building a new central joint laboratory facility in the Port Vila area. This could incorporate all government departments into a single testing/diagnostic facility, and be funded either publically or through a public/private partnership.
- Consider a public/private partnership to expand and bring up to standard the existing COFLEY (UNELCO) Laboratory.
- Consider a public/charitable partnership with the Pacific International Trust Company Ltd PILCO. Our understanding is that PILCO are leading a charitable trust to facilitate a medical diagnostic testing facility to be based at the Hospital in Port Vila.

More complex chemistry testing requiring expensive instrumentation such as GC-MS/MS, LC-MS/MS, ICP-MS and HRMS should be outsourced to an international laboratory.

3.1.1 Recommendations for Laboratory Facility

Our recommendations based on the facilities visited would be to construct a new purpose-designed laboratory facility that will cater for existing microbiology and basic chemistry tests that are required and which can allow for future expansion in the volume of tests and testing scope within the

laboratory, **R1**. It is recommended that this facility is constructed and furnished to internationally recognised laboratory construction standards as described in the aforementioned AS/NZS standards, **R2**, and that the laboratory facility is constructed to a minimal of PC2 containment requirements. These standards are available for purchase from www.standards.co.nz/default.htm.

If the testing facility is to be able to provide internationally recognised and accredited test methods, and be able to respond to the increasing and potential testing scope required for overseas market access, aiming for a lower standard would severely hinder and compromise the ability of Vanuatu based exporters to satisfy overseas regulatory body market access requirements, both currently and in the future.

To be able to operate using internationally recognised testing procedures and use accredited test methods it is recommended that the facility operates to the ISO/IEC 17025:2005 standard, **R3**.

The development in Vanuatu of facilities and the purchase of equipment (e.g. GC-MS/MS, LC-MS/MS, ICP-MS/MS) to carry out more complex chemistry testing is considered to be too costly in terms of setup and the ability to train, maintain and accredit sufficient technical staffing capability. It is recommended that such testing be subcontracted to overseas test providers, **R4**. A list of ISO/IEC 17025:2005 accredited providers which can offer such services can be found by visiting the websites listed in Appendix E, for laboratories situated in Australia and New Zealand. Many other providers are available worldwide.

When considering the scope and type of testing that will be carried out in the proposed laboratory facility recommended be based in Port Vila, not all testing will require the same level of laboratory containment. However, it is recommended that for ease of operation, the overall facility is constructed with the highest required containment in mind as, if in the future, all of the facility needs to be at this standard, operation will be possible at no additional cost.

Microorganisms vary widely in their ability to infect humans, animals and plants or to spread in the environment. Therefore, all work undertaken with microorganisms should only be carried out after a thorough risk assessment has been conducted and after it has been demonstrated that any hazards are understood and controlled.

Currently the Vanuatu Government does not have any legislation or standards in place outlining requirements or guidelines relating to the standard of facility or safety in laboratories where microorganisms are handled. To achieve accreditation to ISO/IEC 17025:2005 standard, it is therefore recommended that the centralised laboratory in Vanuatu adhere to the standard applicable to New Zealand and Australian laboratories, AS/NZS 2243.3.

This standard classifies microorganisms according to the degree of risk they present and defines the level of physical containment required when working with these. The most common bacteria associated with food-borne illness are classified as either Risk Group 1 or Risk Group 2 and require a physical containment level 2 (PC2) facilities. To provide a complete service to Vanuatu stakeholders, it is recommended that the laboratory is designed and built to PC2 level.

Briefly, PC2 laboratories should be constructed in accordance with the following requirements as per AS/NZS 2243.3 Section 5.3:

(i) Floors shall be smooth, easy to clean, impermeable to liquids and resistant to commonly used reagents and disinfectants

(ii) Bench tops shall be able to withstand heat generated by laboratory procedures e.g flaming of equipment and heating of media
(iii) Open spaces between and under benches, cabinets and equipment shall be accessible for cleaning to prevent build-up of material providing refuge for microorganisms
(iv) Ceilings with a textured finish should be easily cleanable
(v) Structural joints should be minimised, but where used, shall be durable, impermeable, easy to clean and shall resist deterioration due to commonly used cleaning agents
(vi) Internal fittings and fixtures, such as lights, air ducts and utility pipes shall be selected and fitted to facilitate cleaning of any horizontal surfaces on which dust can settle
(vii) Windows shall be closed and sealed
(viii) Suitable containers shall be provided for collection, storage or disposal of infectious materials
(ix) Facilities shall be designed to prevent vermin infestation
(x) Furniture shall have smooth impervious seat coverings to facilitate cleaning
(xi) Facilities shall have dedicated hands-free operation type hand basins available inside each laboratory, near the exit
(xii) Facilities shall contain eyewash stations
(xiii) Facilities shall contain storage for PPE within the laboratory, near the exit
(xiv) Facilities shall contain storage for outer garments and personal items outside the laboratory
(xv) Appropriate backflow prevention for water supplies shall be installed
(xvi) Appropriate gas supplies shall be installed
(xvii) Adequate storage space shall be provided separate from work benches to allow for reference documents and papers, other than worksheets, to be used
(xviii) Facilities shall have separate report writing areas
(xix) Facilities shall display a sign near the entrance to the laboratory showing the biological hazard symbol and the level of containment together with hazard symbols as appropriate and any access restrictions
(xx) Facilities shall maintain an inward flow of air by forced extraction of laboratory air to minimise the spread of aerosols in the event of an inadvertent spill. Recirculation is permitted, but not into areas outside the PC2 facility
(xxi) A Class I or II biological safety cabinet shall be provided if work with microorganisms transmissible by the respiratory route or work producing significant risk from aerosol production is anticipated.

Chemistry and microbiological activities within the laboratory will need to be in separate rooms. It is also preferable to have separate rooms within the microbiology laboratory for media preparation, sample preparation and manipulation of live cultures, to prevent cross contamination of samples. Ideally, a one-way system would operate whereby samples would be prepared and broths / agar media inoculated in one room, incubated, read and manipulated in a different room. Incubated broths and agar plates with live culture should not be returned back to the sample preparation area.

Due to the hazardous nature of the laboratory working environment, personal protective equipment (PPE) is required to ensure the safety of staff and visitors. Appropriate PPE for a laboratory includes, but is not limited to, latex gloves, laboratory coats, safety glasses, heat resistant gloves, covered in shoes and dust masks. Specific test methods or sample matrices may require specialist equipment or precautions and a risk assessment should always be conducted on new work received or test methods undertaken. Additional protection for staff in the form of vaccinations may also be required.

3.1.2 Recommendations for Laboratory Equipment

It is recommended that all the equipment viewed should be assessed for proper functionality and be calibrated by a suitably qualified person, **R5.** This can be either an accredited agent or an agent of the equipment manufacturer. Once proper and accurate functionality of the equipment is established, correct operating procedures, calibration records, maintenance records etc., as required by section 5.5 of ISO/IEC 17025:2005, need to be created and maintained for each item of equipment. Also, a master schedule of all equipment for each facility needs to be prepared and maintained. In order to achieve this it is recommended that all current publically owned laboratory equipment should be collected and stored in a central, secure, environmentally controlled location to prevent any further damage or dilapidation.

Once equipment has been certified as fully functional and calibrated correctly for the range of measurement to be undertaken, there is no reason why the majority of the equipment viewed could not be used for testing purposes, in conjunction with the other requirements of an over arching QSM in compliance with ISO/IEC 17025:2005 requirements.

Any instruments that do not function correctly or are unable to be calibrated within the desired quantification range must be replaced if the laboratory wishes to continue to perform the associated testing.

Where possible future purchase of instrumentation should standardise on a single supplier (i.e. a single supplier for incubators, one for balances, etc.) as this will minimise the number of agents and suppliers required, and minimise the cost of travel should this be required for maintenance. Standardisation also assists with staff familiarity and training on equipment. For more complex equipment, especially that apparatus used to take quantifications or calibrations, a service contract, including annual preventative maintenance visits from the manufacturer or their agent is strongly recommended**, R6**.

Laboratory equipment in an ISO/IEC 17025:2005 laboratory will need to be uniquely identified with a maintenance and calibration schedule in place for each item. Specific major equipment required for the centralised Vanuatu microbiology laboratory includes:

(i) Incubators – heating and cooling, the number will depend on the analyses carried out and the temperature required for these.
(ii) Waterbaths – the number will depend on the analyses carried out and the temperature required for these.
(iii) Fridges x 3 – one for storage of pre-prepared media, one for holding of samples and one for storage of reference cultures and inoculated plates / broths awaiting confirmation.
(iv) Freezer x 1 – for storage of reference cultures.
(v) Autoclave x 1 – approximately 20L.
(vi) Hotplate x 2.
(vii) Microscope x 1 oil immersion.
(viii) Balances x 2 – one two decimal place for sample weighing and one four decimal place for calibration of pipettes.
(ix) Colony counter x 1.
(x) Water filtration unit and pump x 1.
(xi) Biohazard cabinet x 1.
(xii) pH meter x 1.
(xiii) Conductivity meter x 1.

(xiv) Deionised water unit.
(xv) Pipettes.
(xvi) Stomacher.
(xvii) Vortex.

Additionally for basic chemistry testing the following equipment will be required:

(xviii) pH Meter.
(xix) UV/VIS Spectrophotometer.
(xx) COD reactor.
(xxi) Moisture Meter.
(xxii) Stirrer hotplates x 2.
(xxiii) Chlorine meter.
(xxiv) Centrifuge.
(xxv) Colorimeter.
(xxvi) Conductivity meter.
(xxvii) Karl Fischer titrator.

3.1.1 Recommendations for Laboratory Staff Required

To operate efficiently a minimum of four trained staff would be required and would be trained in microbiology and basic chemistry techniques.

All microorganisms should be treated as potential pathogens and should be handled with standard microbiological techniques to protect the operator from infection, the environment and maintain the purity of the strain or isolate. Microbiology laboratory staff should, therefore, have undertaken training in aseptic technique and the safe handling of infectious microorganisms.

To gain accreditation to ISO/IEC 17025:2005 standard, the laboratory will need to have at least one staff member at Key Technical Personnel (KTP) level for each analyses it wishes to be accredited for. KTPs are appointed by the laboratory and will need to hold a tertiary qualification in science, have at least 6 months relevant laboratory experience, have a thorough understanding of laboratory quality management systems and demonstrate competence and the ability to trouble shoot problems in the analyses they are applying to be accredited for. Ideally more than one KTP would be available for each test carried out, this helps to ensure adequate cover for periods of illness and annual leave, and also provides for succession planning if staff were to move roles or retire, **R7**. To ensure local laboratory technicians are able to attain KTP status, it is recommended that an external microbiologist with suitable experience in an ISO/IEC 17025:2005 accredited laboratory be contracted for 6–12 months to provide training in-country during set up and initial operation of the laboratory.

Microbiological analyses take 1 to 10+ days to complete, and often require different steps to be carried out at strict time intervals to ensure growth of the micro-organism being isolated. This will necessitate the microbiology section of the centralised Vanuatu laboratory to operate seven days a week.

3.1.2 Recommendations for Microbiology Media Preparation

One of the most critical components of a microbiology test method is the microbiological media used; consistency and reliability are crucial to providing reproducible results. Current media in use in Vanuatu viewed by the inspection team was well past expiry dates and technicians advised there are often difficulties with receiving shipments from suppliers within a timely manner. Expired media used

for testing may not be able to effectively support growth of the desired microorganisms and can lead to a false negative or inaccurate result.

The IANZ Biological guide recommends a shelf life of three months for broths with screw capped lids, and two weeks for agar plates and broths with loose fitting caps. Further to this, some agars have selective ingredients that will shorten the shelf life of the media even further. Baird Parker agar, for example, contains egg-yolk and the prepared medium can only be stored for 5 days according to FDA BAM method.

It is therefore recommended that the centralised Vanuatu laboratory include suitable facilities and equipment to manufacture the majority of their own media from dehydrated powders.

3.2 Testing to be Conducted In-country

A range of diagnostic testing requirements was identified by various stakeholders visited and has been documented in Appendix D. Due to the complexity and high set up costs, some of these analyses will not be able to be conducted effectively in-country and should be conducted off-shore by an ISO/IEC 17025:2205 accredited laboratory. It is recommended that the testing able to be carried out effectively in-country is general microbiology and basic chemistry. A summary of the testing recommended to be conducted in-country and that which should be conducted off-shore can be found in Table 3-1.

Table 3-1 Summary of testing that was identified to be required by stake holders interviewed and which is recommended to be conducted in-country and off-shore

In-Country		**Off-shore**
Microbiology	**Chemistry – Simple**	**Chemistry**
Aerobic Plate Count (APC)	pH	NIP analyses
Bacillus cereus	Moisture	Histamine
Campylobacter	Water activity	Cyanide
Clostridium perfringens	Hardness	Vanillin content
Coliforms	Humidity	Pesticide residues
E.coli	Calcium	Antibiotic residues
Enterobacteriaceae count	Magnesium	Aflatoxins
Enterococci	Nitrate	Caffeine content
Faecal coliforms	Potasium	Other Metals
Faecal *streptococci*	Chlorine (free and total)	Veterinary Medicine residue
Heterotrophic Plate Count @ 22°C and 37°C	Sulphate	Persistent organic pollutants (dioxins, PCBs) residues
Lactic Acid Bacteria	Conductivity	Organic chemical residues (VOCs, SVOCs)
Listeria monocytogenes	Dissolved oxygen	
Pseudomonas aeruginosa	Turbidity	
Salmonella	Alkalinity	
Staphylococcus aureus	Ammonia	
Yeast and Moulds	Chloride	
	Chemical oxygen demand	
	Phosphorus	
	Suspended solids	

In-Country		Off-shore
Microbiology	**Chemistry – Simple**	**Chemistry**
	Total solids	

3.3 Laboratory Management Systems

In order to operate to the ISO/IEC 17025:2005 standard for laboratory testing certain management requirements must be met. Clause 4.1 describes the requirements of the organisation and 4.1.3 in particular describes the scope of the management system which must cover all activities in the laboratory's permanent facility, sites away from its permanent facility, and temporary or mobile laboratory facilities.

Items covered include, but are not restricted to, management of conflicts of interest (4.4.4), managerial and technical personnel (4.1.5a), customer confidentiality (4.1.5c), operational integrity (4.1.5d), organisation charts (4.1.5e), responsibility of authority (4.1.5f), laboratory supervision (4.1.5g), technical management (4.1.5h), quality management (4.1.5i), and appropriate communications to ensure the effectiveness of the management system (4.1.6).

Section 4.2 of ISO/IEC 17025:2005 describes the Management System or Quality Management System (QMS). In particular policies and procedures must be in place (4.2.1) to ensure the quality of all work carried out, these procedures must be communicated to staff, be available, understood and implemented.

There must be a quality policy statement (4.2.2) setting out the laboratory management commitment to good professional and quality service, stating what the standard of service will be and the purpose of the QMS.

Each laboratory must also have a Quality Manual (4.2.2, 4.2.5, 4.2.6) that defines the management system policies and objectives of the laboratory. The Quality manual must make reference to supporting procedures, including technical methods and procedures, and define the role and responsibility of the technical and quality managers. Section 4.2 of ISO/IEC 17025:2005 also covers aspects such as commitment to the management system by laboratory staff (4.2.3), customer requirements (4.2.4) and management of change to the QMS (4.2.7).

No evidence was found at any of the laboratories visited to indicate that any of the above points required for Management Systems, and in particular a Quality Management System (QMS) to comply with section 4.0 of the ISO/IEC 17025:2005, were being followed; if they were, there was no evidence to support this. The above discussion summarises only the key aspects of section 4.2 concerning Management Requirements. To ensure compliance when preparing for audit the full scope of requirements needs to be read and applied.

Copies of the following Standards should be obtained and read by any staff involved prior to embarking on the advancement of further laboratory testing facilities, **R8:**

- ISO/IEC 17025:2005 – General requirements for the competence of testing and calibration laboratories.
- AS LAB C 1 – Biological testing.
- AS LAB C 2 – Chemical Testing.
- AUS/NZ safety standards.

During our visits to laboratories it was clear that staff were not aware of the requirements of ISO/IEC 17025:2005 accreditation. We therefore make a recommendation that all existing laboratory staff, and those who may be already identified as future staff, should attend comprehensive instruction and training in the application of the above and any other relevant standards that will need to be applied, **R9**. The most cost effective way to approach this would be for appropriately qualified trainers to visit Vanuatu and provide training. Such training is offered by, for example, the New Zealand Quality College, which offers several courses including one titled “Laboratory Quality Management”.

This three-day course is particularly suited for staff new to a laboratory environment. It gives participants guidance and training in the skills needed to develop and implement an effective laboratory quality management system. The course is based on NZS ISO/IEC 17025:2005.

Upon completion of the course participants will have gained knowledge and an understanding of:

- Quality management concepts and culture, the elements of NZS ISO/IEC 17025.
- The development and the role of international standards.
- Method selection and validation.
- Selection, training and supervision of staff.
- Equipment management and calibration.
- Analytical variation and the uncertainty of measurement.
- Test records and reports.
- The accreditation process including signatory approval.
- The development, documentation and implementation of quality systems.

Alternatively, this training could be provided by consultancy with existing laboratory providers already operating to the required standard.

In order to be compliant with ISO/IEC 17025:2005, laboratories must demonstrate that their results are reliable and accurate at all stages of testing, and have a written quality management system detailing how they intend to achieve this. Quality systems should include, but are not limited to, procedures for:

(i) maintenance and calibration of equipment e.g. incubators, waterbaths, autoclaves, balances, pipettes, thermometers etc.
(ii) evaluation of all microbiological media e.g. pH checks, sterility checks, suitable recovery properties, ability to support growth etc.
(iii) evaluation of chemicals and test kits.
(iv) evaluation of laboratory glassware.
(v) evaluation of laboratory water.
(vi) verification of test method processes using suitably maintained reference cultures.
(vii) evaluation of test method effectiveness.
(viii) actions to be taken in cases of unsatisfactory results for any quality control procedures.
(ix) evaluation of test method uncertainty.
(x) environmental monitoring of the laboratory.

Significant work needs to be undertaken to prepare, write, install and operate a suitable quality system. Off-the-shelf quality systems for microbiology laboratories are able to be purchased, reducing the amount of time and effort required by the laboratory to become operational and reach accreditation standards. Instalment and operation of a quality system to achieve ISO/IEC 17025:2005 standard would need to be carried out by a suitably experienced microbiologist and it is recommended that such

a person be contracted for 6–12 months to prepare the laboratory. Similarly using an experienced chemist for chemical testing would be advantageous.

3.4 Technical Requirements for Accreditation and Day-to-day Operation

To gain accreditation to ISO/IEC 17025:2005 standard, laboratories must prove they are competent enough to carry out microbiological assays and chemistry testing to give reliable and reproducible results. All test methods will need to be reviewed to determine whether a full validation or verification is required. Methods developed in-house will need to be validated to prove they are scientifically robust enough to provide accurate and reproducible results. Internationally recognised methods, however, such as ISO, FDA, APHA etc. do not require a full validation – the laboratory only needs to carry out a verification to prove they are competent in performing the method.

Often the method required for each analyte is determined by the market access requirements of the importing country and the laboratory will need to have sufficient technical capability to undertake method validations or verifications as required. During initial set up of the laboratory there will be opportunity for staff to undergo training in the process of test method validation / verification but, for future method development, specialist technical advice on specific methods or sample matrices may be required.

Routine operation of the laboratory will require an experienced food microbiologist be available to problem solve issues relating to method performance, matrix interferences or contamination events.

3.5 Laboratory Consumables and Supplies

Various consumables, such as petri dishes, pipette tips, sterile bags etc. will be required to ensure the ongoing operation of the laboratory. Discussions with current laboratory staff indicated that these are currently ordered from New Zealand or Australia, but can take 1–2 months to arrive in country. Relationships with suppliers and robust purchase ordering systems will need to be developed to ensure these items are maintained and appropriate stock levels are always available. The implementation of a kanban system will assist with this.

During our visit in Port Vila, we assessed the Pacific Chemical Supply Company, and concluded that the stock of basic chemicals held by this company would not be suitable for accredited laboratory testing. These reagents were crude or technical grade chemicals, not analytical grade reagents which come with certificates of analysis and information on purity.

3.6 Laboratory Waste

Microbiological test methods are designed to isolate and purify bacteria through the use of agars and broths, often containing selective ingredients such as dyes and antibiotics. After the procedure has been carried out, tubes and agar plates of amplified bacterial culture will need to be disposed of in a responsible manner. This can be done by autoclaving on site followed by disposal of plates in general rubbish and decontamination of glassware in a dedicated wash-up area, or incineration off-site by a reputable waste disposal contractor. As there are no appropriate waste disposal contractors in Vanuatu, systems will need to be implemented to autoclave hazardous waste on-site prior to disposal.

3.7 Animal Serology Testing Services

In addition to microbiological and basic chemistry testing services, a capability to carry out serological testing on animal blood and tissue sample would be beneficial in monitoring the occurrence of diseases in animal herds.

This testing can be carried out using an enzyme-linked immunosorbent assay (ELISA) technique.

This testing for common diseases such as border disease, bovine viral diarrhoea (mucosal disease), bovine tuberculosis, infectious bovine rhinotracheitis, infectious bursal disease and Johne's disease (paratuberculosis) etc. can be carried out in a PC2 containment facility. This would require training and accreditation of staff in the relevant methods and appointment of a KTP. Due to the plate based nature of this testing, to be economically viable this testing should only be offered if test volumes are appropriate. Low test volumes would prove too costly due to the matrix nature of testing kits available.

3.8 Department of Quarantine Entomology Laboratory

With minimal investment this facility could be returned to an operational state. Three microscopes were viewed; however it was not clear that these were in working order. There is some need for phytosanitary inspection and entomology services in kava, and also a recently suspected outbreak of the infestation of honey bees with the potentially devastating varroa mite.

It is recommended that the Quarantine entomology laboratory seeks funding to bring its operation in line with the ISO/IEC 17025:2005 standard, **R10**. This will be required by certain overseas companies if accredited phytosanitary certificates are to be issued.

An ISO/IEC 17025:205 accredited entomology laboratorywith highly trained and experienced entomologists performing boarder control identification and related work could be contracted to assist in the refurbishment of the entomology laboratory facility and facilitate advanced training for staff.

3.9 Summary of Recommendations

In Summary our recommendations are that a multi-phased approach is adopted as follows:

- Up skilling and training of existing Vanuatu based laboratory technicians and managers.
- Building or refurbishment of a laboratory facility.
- Development of QMS and laboratory processes including detailed technical training and up-skilling of relevant staff.
- With the laboratory, systems and trained staff in place, inter-laboratory comparison programs (ILCP) will need to be completed to demonstrate that the laboratory results are as expected and that all laboratory systems are therefore under control. Note, although this would not be considered best practice, testing not endorsed by any accreditation could be conducted once all systems were in place but before ILCPs were conducted.
- The laboratory requests external accreditation to ISO/IEC 17025:2005 standard. Accreditation could be carried out by either NATA or IANZ representatives.

We make a recommendation that the above approach should be project-managed by an external laboratory consultant or consulting body, **R11,** who has existing experience in developing and operating to the ISO/IEC 17025:2005 standard and successfully completing external audits.

We also make a recommendation that consideration should be given to working closely with an existing laboratory to purchase an off-the-shelf QMS, **R12**. Although this approach will require an initial

outlay payment to the laboratory, the time saved in writing the QMS from first principles will be saved, and the QSM will already have passed the rigors of external accreditation audit, making the process less risky and easier to implement. AsureQuality has had experience in this approach with start-up laboratories in other countries and it has proved very successful.

It is also recommended that throughout the program of building and equipping ISO/IEC 17025:2005 standard facilities, trained and experienced laboratory staff from an external laboratory be contracted to work alongside the newly trained staff. This will assist with troubleshooting and provide further on the job training until such time as the local level of experience is well established. A minimum period of 6 to 12 months would be recommended, **R13**. It is also recommended that a relationship be developed, and a service level agreement put in place, whereby local staff could call upon assistance for matters arising, **R14**. This level of support would be useful for several years but could be reviewed annually depending on the performance of the laboratory.

By entering into service level agreements it may be possible to establish a broader, longer term working and support based relationship with a single external Laboratory to provide the higher end chemical testing. This scenario would need further investigation by all parties to understand the feasibility and sustainability of such an arrangement.

4 Costed Model for Diagnostic Service Provision

In order to provide a costed model for the provision of testing services, a number of assumptions and extrapolations have been made.

We have provided an indication of the cost of building and/or refurbishing a laboratory facility centralised in Port Vila, as recommended following the findings of this study. This estimation is based on our experience of the cost in New Zealand to build new or refurbish existing laboratory facilities in, and on, 2011 costs. It has been assumed that beyond the basic building construction, most fixtures and fittings would have to be shipped from overseas but no factor for shipping costs has been applied to this costing model.

It has been assumed that any equipment or apparatus purchased will also be shipped from overseas, and again no factor has been applied for shipping costs. These will vary depending on from where equipment is purchased. Estimated costs for new equipment are based on costs that we have in our records for similar equipment purchased with the last two years, or by obtaining new quotations from our preferred suppliers.

Where existing apparatus can be used the cost of servicing and calibrating existing equipment has been assumed to be 15% of the cost of a comparable new piece of equipment. Again travel costs for service agents or instrument engineers are not factored in to the figures as they may travel from different international locations.

4.1 Facility Requirements

As discussed, the facility required will need to be constructed to a minimum PC2 containment level. It will provide accommodation for microbiology (and possibly serology) and chemistry laboratory testing, with office space for up to six staff, including facilities such as rest rooms and toilets. No provision has been included for customer/visitor reception areas or for meeting rooms.

To adequately meet the requirements discussed in Section 5 the following areas will be required:

- Office space for 6 staff.
- Sample reception area.
- Chemistry laboratory.
- Microbiology media preparation and storage room.
- Microbiology sample preparation, plating and incubation area.
- Microbiology plate reading and reporting room.
- Wash up and storage area.
- Rest room and facilities.

Based on our experience this size of operation could be fitted into a floor space of 270m^2.

4.2 Staffing Requirements

To sustain ISO/IEC 17025:2005 accreditation and operate effectively on a seven day, 365 days per year service provision model, our experience indicates a minimum of four to six staff would be required. It would also be necessary for each test carried out to have at least two Key Technical Personnel (KTP) available. It is also assumed that one of the staff members will perform the laboratory management function, one staff member would also need to be appointed as having responsibility for

quality management, and one for technical matters. This model therefore assumes 6 staff using VT180,000 as an average monthly salary for a laboratory technician; salary costs for manager may be higher.

Training costs are based on figures obtained from the New Zealand Quality College to provide quality training courses, travel, and accommodation and sustenance costs will also apply for their staff travelling to Vanuatu to carry out training.

4.3 Accreditation Costs

Participation in ILCP rounds will be charged at the going rate for each particular ILCP round by the provider.

It is estimated that to gain ISO/IEC 17025:2005 accreditation, NATA or IANZ representatives would need to be on site for at least one week to assess the facility to this standard and then for a further week to assess the Quality system, testing methods and staff.

It should also be noted that to maintain ISO/IEC 17025:2005 accreditation, continued and regular participation in ILCP rounds will be required as will annual surveillance audits by the accrediting body (NATA or IANZ). For a facility of this size, annual audits should be no longer than 1–2 days duration.

For tests the laboratory carries out that are not required for overseas access purposes, it is possible that the specific test will not need to be accredited although a basic amount of test method validation will be required in order to comply with the overarching ISO/IEC 17025:2005 laboratory accreditation. This will reduce the ongoing cost of maintaining the laboratory accreditation.

Table 4-1 Approximate cost of lab construction and equipment purchase

Approximate Cost of Laboratory Construction and Equipment Purchase

	Per metre Sq	Size metre Sq	Cost A$
New Build[1]	$ 2,223	270	$600,287
Refurbishment	$ 1,170	270	$315,941
Design Costs			$90,000
Furnishings			$100,000
Staff Training Courses			$10,000
Accreditation Costs			$20,000

Equipment
New purchase

	Number	Unit Cost	
Microbiology			
Water baths	5	$ 2,184	$ 10,921.40
Incubators	4	$ 2,340	$ 9,361.20
Refrigerators	3	$ 1,560	$ 4,680.60
Freezer	1	$ 1,560	$ 1,560.20
Autoclave- 20L	1	$ 7,801	$ 7,801.00
Hotplates	2	$ 780	$ 1,560.20
Microscope- Oil immersion	1	$ 6,241	$ 6,240.80
Balance 2dp	1	$ 1,170	$ 1,170.15
balance 4dp	1	$ 2,340	$ 2,340.30
Colony Counter	1	$ 1,560	$ 1,560.20
Water purification Unit	1	$ 7,801	$ 7,801.00
Biohazard Cabinet (Class 2)	1	$ 19,503	$ 19,502.50
pH Meter	1	$ 1,482	$ 1,482.19
Conductivity meter	1	$ 1,950	$ 1,950.25
Deionised Water unit	1	$ 3,901	$ 3,900.50
Pipettes	6	$ 312	$ 1,872.24
Stomacher	1	$ 4,681	$ 4,680.60
Vortex	1	$ 780	$ 780.10
Chemistry			
pH Meter	1	$ 1,950	$ 1,950.25
UV Spectrophotometer	1	$ 23,403	$ 23,403.00
Moisture Meter	1	$ 2,340	$ 2,340.30
COD Reactor	1	$ 1,170	$ 1,170.15
Stirrer Hotplates	2	$ 780	$ 1,560.20
Chlorine Meter	1	$ 780	$ 780.10
Centrifuge	1	$ 7,801	$ 7,801.00
Colorimeter	1	$ 468	$ 468.06
Conductivity meter	1	$ 1,326	$ 1,326.17
Karl Fischer titrator	1	$ 4,681	$ 4,680.60
			$ 134,645.26
Equipment			
Use of existing[2]			$ 20,196.79

Table 4-2 Projected revenue per month based on anecdotal volumes of expected number of tests to be performed

		Test	Price per test	Volume per month	Total Revenue
Microbiology	**Water**	Total coliforms by MF	$14.04	45	$632
		Faecal coliforms by MF	$14.04	51	$716
		Enterococci *	$20.98	0	$0
		E.coli *	$20.59	44	$906
		Faecal streptococci	$9.75	1	$10
		HPC @ 22	$9.60	51	$489
		HPC @ 37	$9.60	51	$489
	Food	APC *	$14.43	109	$1,573
		Bacillus cereus *	$19.39	39	$756
		Campylobacter *	$29.60	8	$237
		Coliforms *	$17.71	33	$584
		E.coli *	$16.34	117	$1,912
		Enterobacteriaceae *	$17.71	1	$18
		Faecal coliforms *	$17.71	31	$549
		Lactic Acid Bacteria *	$14.78	1	$15
		Listeria monocytogenes *	$22.58	39	$881
		Psuedomonas aeruginosa *	$18.06	1	$18
		Salmonella *	$26.25	41	$1,076
		Staphylococcus aureus *	$16.85	39	$657
		Yeast and moulds *	$14.43	3	$43
Chemistry	**Water**	Alkalinity	$8.19	0	$0
		Ammonium	$12.87	0	$0
		Chloride	$18.88	1	$19
		Chlorine (free)	$3.74	4	$15
		Chlorine (total)	$3.74	0	$0
		COD	$39.32	0	$0
		BOD	$42.67	0	$0
		Hardness	$8.19	45	$369
		Nitrate	$9.83	1	$10
		Nitrite	$10.14	0	$0
		Sulpate	$10.22	1	$10
		Phosphorous	$9.28	0	$0
		Suspended solids	$8.19	0	$0
		Settleable solids	$8.19	0	$0
		pH	$4.91	1	$5
		Conductivity	$4.91	0	$0
		Dissolved oxygen	$2.18	0	$0
		Turbidity	$8.19	0	$0
		Iron	$9.44	0	$0
		Iodine	$9.28	0	$0
		Copper	$9.28	0	$0
		Silica	$19.50	0	$0
		Calcium *	$10.57	1	$11
		Magnesium *	$10.57	1	$11
		Sodium *	$10.57	1	$11
		Potassium *	$10.57	1	$11
		Nitrogen *	$21.57	0	$0
		Sulphide *	$72.28	1	$72
		Water activity *	$36.24	0	$0
		Moisture *	$24.34	2	$49
		Aflatoxins *	$101.37	1	$101
				766	**$12,254.12**

Table 4-3 Annualised Operating Summary

Annualised Operating Statement Summary

Projected revenue	$	147,049	
Direct labour	$	91,914	
Other costs	$	66,172	45%
Gross Margin	-$	11,037	

4.4 Discussion

All financial figures are expressed in Australian dollars (A$). The costing is based on a laboratory facility being a total of 270m^2 and based on having four FTE staff, other operating costs are estimated to be 45% of total revenue and are based on AQ experience from operating similar sized facilities in New Zealand. The test volume is extrapolated from data collected during visits to producers and exporters and based on overall export figures obtained from the Quarantine Department. Test prices are based upon prices obtained from within Vanuatu where possible; where this was not possible internationally benchmarked list pricing for a particular test has been used in this calculation.

In the annualised operating statement no account of depreciation of capital outlay has been considered.

Our recommended best course of action is to construct a new purpose built facility. The figure used to calculate this uses data from New Zealand obtained in 2011, as does the cost for the option to refurbish an existing facility. In our opinion, none of the laboratory sites visited would provide adequate space for this option be considered at these sites.

Our recommended plan therefore would cost A$600,287 to build a facility, including the required air handling infrastructure. Benching and other fixture and fittings would be an additional A$100,000 and design costs A$60k. Initial training and accreditation costs will be around A$30,000, depending on how this is addressed.

No consideration has been given to the cost of purchase of an existing QMS. If this were purchase from an existing overseas laboratory, negotiation would need to be entered into to arrive at a price.

Therefore to build a new facility as recommended, including all training and accreditation requirements the initial capital outlay required will be around A$960,000, assuming all new equipment were purchased. This cost can be reduced if existing facilities were found that were suitable for refurbishment and if existing instruments and apparatus were maintained, calibrated and used.

The figures used here are based on AsureQuality's experience operating laboratories in New Zealand, Australia and Singapore. There may be other costs unbeknown to AsureQuality incurred to carry out this exercise in Vanuatu.

5 Limitations

URS Corporation Pty Ltd (URS) has prepared this report in accordance with the usual care and thoroughness of the consulting profession for the use of AusAID and only those third parties who have been authorised in writing by URS to rely on the report. It is based on generally accepted practices and standards at the time it was prepared. No other warranty, expressed or implied, is made as to the professional advice included in this report. It is prepared in accordance with the scope of work and for the purpose outlined in the Contract dated 20 January 2011.

The methodology adopted and sources of information used by URS are outlined in this report. URS has made no independent verification of this information beyond the agreed scope of works and URS assumes no responsibility for any inaccuracies or omissions. No indications were found during our investigations that information contained in this report as provided to URS was false.

This report was prepared between April and June 2012 and is based on the conditions encountered and information reviewed at the time of preparation. URS disclaims responsibility for any changes that may have occurred after this time.

This report should be read in full. No responsibility is accepted for use of any part of this report in any other context or for any other purpose or by third parties.

Appendix A

Appendix A Summary of High Level Recommendations

Recommendation	Summary	Page
R1	Construction of new Laboratory facility based in Port Vila	21
R2	Adoption of AS/NZ laboratory construction standards	22
R3	Operate to ISO/IEC 17025:2005 standard	22
R4	High end testing should be sub-contracted to overseas accredited laboratories	22
R5	Existing laboratory equipment should be assessed for suitability of use and properly calibrated by a qualified technician	23
R6	Annual service contracts for all quantitative instruments advised	24
R7	A minimum of 2 KTPs should be trained for each test, KTPs can be accredited for multiple tests	25
R8	Relevant ISO/IEC 17025:2005 and AS/NZ safety and laboratory construction standards should be read and understood by laboratory staff	27
R9	Training in ISO/IEC 17025:2005 laboratory standard should be organised for relevant laboratory staff	27
R10	Refurbishment of DOQ Entomology Laboratory and staff training	30
R11	The overall process of improvement and construction of facilities and systems should be project managed by an external organisation	30
R12	Quality Management System should be purchased for an off the shelf provider or obtained by consultancy from willing existing laboratory providers	30
R13	Trained and experience laboratory staff should be contracted form overseas to assist in the set up and bedding in of the new facilities and systems (minimum 6–12 months)	30
R14	Developing a service level agreement with an overseas laboratory provider to service high end testing and provide ongoing support and consultancy for the new facility would be beneficial for staff continued support and training and assistance in trouble shooting	30

Appendix B Questionnaire Provided to Laboratories

B.1 Background Information

1. What regulatory agencies applicable to producers and laboratories are currently operating in Vanuatu? What is their scope?
2. Please provide market access requirements for current and immediate future markets. Are you aware of any imminent changes to these and if so, what are these?
3. Please provide information about products exported i.e. relative market share, current volumes, expected growth.
4. Please provide a list of producers, their size, products produced, volume of production, and locations.
5. Are there any potential export industries in the immediate future? What are these?
6. Please provide details of the water infrastructure on each island including supply, origin, quality and any treatment processes, and risks to supply / quality.
7. Are there any bio-security regulations / risks between islands?
8. Please provide details of the courier systems both internally and externally. Is there capability for cold transport of product / packages?
9. Please advise which laboratories we will be visiting. What is their size / capacity, location and accreditation status?
10. Are there any training providers in Vanuatu or nearby islands for laboratory staff?
11. What is the main source of power supply in Vanuatu? What comments can you make on the security of this?
12. Are there Government regulations relating to employment including health and safety regulations, that producers and laboratories must comply with? Please provide details.

Appendix B

B.2 Laboratory Specific Information

1. Please provide an organisational chart listing all staff and including a brief description of their qualifications and experience.
2. Please provide a copy of the organisation / management policies.
3. Does the lab have a quality management system? Please provide details or a copy of the manual.
4. Please provide a list of sample types, numbers of samples and who these are received from for testing.
5. What market access standards are you working to and for which industries? Please provide copy of the standard.
6. Please provide a list of all equipment and advise current maintenance / calibration procedures. Who / where are the equipment suppliers and repairers, and what is their level of service to you?
7. What are the consumables you buy and from whom?
8. Are any tests sub-contracted to another laboratory? If so, please provide details.
9. Does the laboratory carry out any sampling or other services? Please provide details.
10. What IT systems is the lab currently using?
11. Please provide a copy of a test report.
12. Are there any tests the laboratory used to carry out but doesn't any more, and are you intending to increase the scope of your testing? If so, please provide details of these.

Appendix C

Appendix C Market Access Testing Requirements

During our discussions with stakeholders, key export products, their current markets and intended markets were identified. Market access requirements for these was unknown by stakeholders, but the volume and type of analyses will have an impact on the diagnostic service delivery required.

The following table summarises testing requirements for the products and markets as researched by AsureQuality staff using various websites and standards. This summary is not intended to be a comprehensive list as requirements for some products and markets were unable to be located. AsureQuality recommends that exporters conduct their own research to determine compliance when exporting their product.

Product	Market	Requirement	Comment
Bottled water	Pacific Islands	pH, Conductivity, Turbidity, TDS, Alkalinity, Calcium, Magnesium, Hardness, Sodium, Postassium, Nitrate, Chloride, Sulfate, Maganese, Iron, Arsenic, Copper, Zinc, *E.Coli*. Usually also ongoing microbiological monitoring	According to Australian Bottled Water Standards http://www.hill-laboratories.com/page/pageid/2145845828
Cassava	Australia	Pesticide Residues MRL Limits listed on Food Standards website	Phytosanitary certificate & quality standards also apply – good guides available on WQA website
Yam	Australia	Pesticide Residues MRL Limits listed on Food Standards website	Phytosanitary certificate & quality standards also apply – good guides available on WQA website
Taro	Australia	Pesticide Residues MRL Limits listed on Food Standards website	
Honey	Noumea		
Coffee	Australia	Pesticide residues (Chlorpyrifos, Tebufenozide), Ochratoxin A	Does not need Nutritional Information Panel
	Europe	According to CODEX: Ochratoxin A (OTA), foreign matter, moisture, Pesticides, (certificate of origin),	Pesticides: - Aldicarb - Permethrin - Carbendazim - Prochloraz - Carbofuran - Propiconazole - Chlorpyrifos - Terbufos - Cypermethrin - Triadimefon - Disulfoton - Triadimenol - Endosulfan - Triazophos
	Taiwan	Caffeine (must be on label), Country of origin, energy, protein fat, carbohydrate (including dietary fibre) and sodium, other nutrients declared in the nutrition claim and other nutrients labelled by the producer voluntarily. Pesticide residues	
	United States	Coffee beans exempt from nutrition labelling, mould, pesticide residues, Ochratoxin A (OTA)	
	Japan	Pesticide Residues	
	Solomon Islands	No information found	
	Fiji	No information found	
	Malaysia	No information found	

Appendix C

Product	Market	Requirement	Comment
	New Zealand	Ochratoxin A (OTA), Pesticide residues (Chlorpyrifos, Tebufenozide)	
	Spain	See EU regulations	
	Germany	See EU regulations	
Kava	Guam	No information found	
	Gilbert Islands	No information found	
	United States		Legality is unclear – generally illegal for use in beverages or supplements of any kind
	Hawaii	No information found	
	Argentina	No information found	
	Noumea		
	New Zealand	No information found	
	New Caledonia	No information found	
	Fiji	CODEX	
Tuna	Japan	Antibacterial substances, residues, additives, pathogens	
	New Zealand	Histamine, pesticide & veterinary Medicine Residues, Pathogenic bacteria*: E.Coli*, TPC, Contaminants: Nitrofurans, fluoroquinolone	If canned or processed, nutritional panel information needed
	Hawaii	NIP, subject to HACCP criteria which seem to be pathogen surveillance, histamine	If canned or processed, nutritional panel information needed
	Australia	Histamine, pesticide & veterinary Medicine Residues, Pathogenic bacteria*: E.Coli*, TPC, Contaminants: Nitrofurans, fluoroquinolone	If canned or processed, nutritional panel information needed
Sea cucumbers	Asia	No information found	
Noni juice	China	No information found	
Breadfruit flour	New Zealand	No information found	
	Australia	No information found	

Appendix D Estimated Demand for Laboratory Services

The following table summarises the perceived laboratory testing requirements as advised by stakeholders during visits.

Company	Sample type	Testing requirements biological	Frequency	Testing requirements chemistry	Frequency	Comments
AzureWater	Water – finished product	Total coliforms	1 sample monthly	pH	1 sample monthly	May consider more frequent chemical composition if local
		Faecal coliforms	1 sample monthly	Calcium	1 sample annually	
		Faecal *streptococcus*	1 sample monthly	Magnesium	1 sample annually	
		HPC @ 37	1 sample monthly	Sodium	1 sample annually	
		HPC @ 22	1 sample monthly	Potassium	1 sample annually	
				Nitrate	1 sample annually	
				Chloride	1 sample annually	
				Sulphate	1 sample annually	
Vanuatu Direct	Process water	Faecal coliforms	5 samples monthly	Hardness	5 samples monthly	
	Vacuum packaged root crops (taro, yam, cassava)	Shelf life trial validation	Unknown	NIP	Once for each product	
		Product development	Infrequent	Cyanide	Infrequent	
		General micro	1 sample weekly	Water activity	Infrequent	
	Soil			Micro-nutrients	One off	
Tanna Coffee		None	–	Caffeine Content	One off	
Ministry of Health – Environmental Health Division	Assorted Foods from complaints	Pathogenic bacteria	50 samples annually			Swabs would be taken from food processors / food handling facilities and containers / imports at the border
	Human faeces, swabs, urine etc from food complaints	Pathogenic bacteria	50 samples annually			
	Assorted food imports	General micro	Unknown			
	Swabs	General micro	Unknown			

Appendix D

Company	Sample type	Testing requirements biological	Frequency	Testing requirements chemistry	Frequency	Comments
Forney Enterprises	Kava	General micro	Every batch – approx 6 per week	Kava lactone content	Every batch – approx 6 per week	
				NIP	One off	
	Rainwater	General micro	10 samples weekly	Hardness	10 samples weekly	
Vincent Lebot		None		Specialty components	Infrequent	
Department of Fisheries	Tuna			Histamine	1 sample monthly	
South Seas Commodities	Kava			Kava lactone content	Infrequent	
The Kava Store	Chilli, pawpaw jam, tamarind, black pepper, kava, canarium nut, terminalia nut	Shelf life	Once for every product	NIP	Once on every product	
Joseph Jacobe	Noni juice	General micro	2 samples annually	Humidity	2 samples annually	
				pH	2 samples annually	
				NIP	2 samples annually	
	Noni powder	General micro	1 sample monthly			
	Noni capsules	General micro	1 sample monthly			
	Tamanu oil			Acidity	2 samples annually	
Lapita Café	Chips from root crops (cassava, taro)	General micro	Unknown	Moisture	Unknown	
				NIP	Unknown	
	Breadfruit flour	Shelf life, product development	Unknown	NIP	Unknown	
	Rainwater	General micro	Unknown			
Gilbert Gibson	Honey	–		Moisture	Unknown	
				HMF levels	Unknown	
Venui Vanilla Co Ltd	Vanilla products	APC	10 samples annually	Moisture	10 samples annually	For every consignment over 500kg,

Appendix D

Company	Sample type	Testing requirements biological	Frequency	Testing requirements chemistry	Frequency	Comments
		E.coli	10 samples annually	Vanillin content	10 samples annually	an additional sample may be tested
		Yeast and Mould	10 samples annually			
		Total coliforms	10 samples annually			
		Salmonella	10 samples annually			
	Black and White Pepper	APC	10 samples annually	Moisture	10 samples annually	
		E.coli	10 samples annually			
		Yeast and Mould	10 samples annually			
		Total coliforms	10 samples annually			
		Salmonella	10 samples annually			
COPSL	Copra			Aflatoxins	1 sample monthly	
Dr Peter Hoyle Veterinarian	N/A	General serology capability	Project work			
		Brucellosis	Unknown			
		Leptospirosis	Unknown			
		Parasites	Unknown			
Santo Meat Packers	Beef cuts and offal	APC	9 samples weekly			
		E.coli	9 samples weekly			
	Hygiene swabs	APC	10 samples weekly			
		E.coli	10 samples weekly			
	Process water	General micro	4 samples monthly	Residual chlorine	4 samples monthly	

Appendix E Major ISO/IEC 17025:2005 Accredited Testing Laboratories Located in Australia and New Zealand

A full listing of Australian and New Zealand based ISO/IEC 17025:2005 accredited laboratories can be found on the following websites:

The **National Association of Testing Authorities**, NATA, provides assessment, accreditation and training services to laboratories and technical facilities throughout Australia and internationally.

http://www.nata.asn.au/

International Accreditation New Zealand, IANZ, is the New Zealand national authority for the accreditation of testing and calibration laboratories, inspection bodies and radiology services. IANZ also operate internationally.

http://www.ianz.govt.nz/

Appendix F Logistics Information

This Appendix contains information concerning sample movement between Luganville and Port Vila and International couriers from Port Vila and also indicative costs of the cost to send samples to New Zealand or Australia.

DHL freight rates (A$) between Port Vila and New Zealand (Auckland)

- 5kg $156.88
- 10kg $228.28

DHL freight rates between Port Vila and Australia (Melbourne)

- 5kg $235.08
- 10kg $333.58

The Air Vanuatu Domestic Flight Schedule, published in October 2011, is available at:

http://www.airvanuatu.com/media/63664/ns12%20-%20domestic%20schedule%20-%20issue%2001%20-%20effective%2026%20mar12%20-%2027%20oct12.pdf

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