Department of Agriculture and Water Resources

Agricultural and veterinary (agvet) chemical regulation: Review of quality assurance (QA) arrangements – Final Report

December 2017

Executive summary

The Australian Government Department of Agriculture and Water Resources (the department) contracted GHD Pty Ltd to complete the project titled "A*gricultural and veterinary (agvet) chemical regulation: Review of quality assurance (QA) arrangements"*.

The project is an investigation of how agvet QA schemes support, or could potentially support, Australian regulatory activities to manage the risks associated with using agvet chemical products. It does not include a comprehensive review of all QA schemes but rather considers the operation of selected schemes from a wide range of agricultural industries to understand the current diversity and future opportunities.

The department nominated the following Australian industries and their respective QA schemes (or management arrangements) for investigation: poppies, poultry – eggs and meat, feedlot beef, antibiotic resistance in piggeries (in Australia and Denmark), barley, citrus and herbs (for export to Japan), macadamias, Freshcare and the schemes run by Coles and Woolworths. For comparison, the department also sought examples of instances in the United Kingdom, Canada and Denmark (and other OECD countries as appropriate) where agvet regulators legislatively recognise QA schemes, including an explanation of how this occurs, the benefits of that recognition to scheme participants, and the outcomes observed.

This project reviewed the selected QA schemes to provide an understanding of the extent to which they complement, overlap or exceed agvet chemical use regulation by state and territory jurisdictions. This provided insights on how these recognised QA schemes could potentially be used to support agvet chemical regulation in Australia, including the strengths and weaknesses of doing so.

Methodology

GHD completed the project via a combination of desktop reviews of the nominated QA schemes and regulatory compliance arrangements, and targeted consultation with scheme operators, industry organisations and state and territory regulatory agencies.

The desktop reviews included web searches to obtain information on each of the schemes which was supplemented by additional information following consultation with scheme operators. The consultation with the stakeholders was facilitated by a letter of introduction to the relevant contact persons from the department.

GHD analysed the information for each scheme using a rubric which provided a consistent, semi-quantitative analysis tool of the scheme elements. Scoring classifications for the rubric were constructed by GHD to reflect the degree to which each element was addressed within each QA scheme. The scoring within the rubric included elements within the scheme that demonstrated zero or minimal detail (score = 0) through to those schemes with comprehensive details (score = 4).

The elements of the schemes that were investigated are described in the table below.

QA Scheme Element	Description
Structure and operation	The details of the rules and standards related to agvet control of use, including the various modules and elements included and the standards required. May include performance indicators and scheme outlines may be publicly available to provide transparency.
Process for setting rules and standards	Schemes have varying arrangements for setting rules and standards - from reliance on industry only bodies to formal

QA Scheme Element	Description
	committees with members from industry, state/territory government regulatory agencies and independent experts.
Reference to international standards	Schemes may rely solely on standards set internally by the industry through to those which reference international standards, including WHO and FAO Codex Alimentarius standards.
Requirements for designated QA staff	Schemes may be silent on the required number of staff designated to perform QA roles through to the number specified according to the size of operation and described competencies.
Training	Schemes generally include requirements that individual staff are trained to the minimum standard required by agvet chemical regulations. In addition, schemes can nominate that staff demonstrate competence and also require additional QA training programs organised by the industry.
Record keeping	Agvet chemical users are required by regulation to keep certain use records. QA schemes may require more detailed records to be kept and maintained with various requirements on records being legible and retrievable. Also, records of audits and tracking of corrective actions may be stipulated.
Residue risks and testing	The registration of agvet chemicals by the APVMA includes a risk assessment that usage as directed will result in acceptable product residues. The National Residue Survey (NRS) samples and tests products, at industry expense, to confirm residue levels and thereby support access to international markets. QA schemes may require additional individual enterprise monitoring and processes for reporting adverse findings to state/territory regulatory authorities.
Off-label chemical use	Use of agvet chemicals outside of the conditions of registration. Off-label use may be allowed under an APVMA minor use permit, or through state and territory legislation
Audits and corrective actions	Schemes generally specify audit frequencies and requirements on the use of internal and/or external auditors. In addition, audits may be announced or unannounced and there may be directions on corrective actions for non-conformance and penalties depending on the severity of non-conformance.
Compliance reporting	Schemes have variable requirements for reporting on the level of compliance, including the percentage of members with Corrective Action requirements. Some schemes publish performance reports which are publicly available.
Complementarity with regulatory jurisdictions	Schemes may operate completely independently of regulators or include Memorandums of Understanding (MoUs) and/or Approved Arrangements providing co-regulation with states/territories whereby membership and certification within a scheme is deemed to satisfy regulatory requirements without additional compliance activities.
Future directions	Schemes may be relatively static in reviewing rules and standards while others complete gap analyses and revise elements in efforts to proactively adapt to changing market and regulatory requirements.

Results

The report includes a comprehensive analysis of each of the QA schemes that cover the nominated industries, including a completed rubric of the extent of development for each of the elements described above.

The table on the following page summarises the consultation findings by QA scheme operators, regulators and industry organisations with respect to QA schemes. The findings indicate differences in understanding between the respondent groups of the role of QA schemes in

relation to agvet chemical control of use, although all recognise the positive role the schemes play in providing assurance. This assurance extends well beyond control of use of agvet chemicals and refers more broadly to produce safety, human health and environmental protection. While such assurances are implicit for all Australian produce as part of compliance with state and territory legislation and regulation, QA schemes provide additional assurance to support market access.

Summary of desktop and consultation findings

QA Scheme Element	QA Scheme Operators	Regulators (states and territories)	Industry Organisations*
Structure and operation	• Varies depending on the industry • Broad enough to allow for differences in state regulations which also makes restrictions different for growers in different areas	• Regulators have varying knowledge of the QA schemes and are therefore uncertain of the schemes' ability to provide or supplement control of use • Jurisdictions adopt different approaches to QA schemes that limits their national application	• Generally little knowledge of specific QA schemes
Process for setting rules and standards	• QA schemes are market-driven which can enforce extra measures on growers • Generally remains broad enough to allow jurisdictional differences • Respond to changes in the industry or in public perception quickly	• Legislation is specific to the jurisdiction in question • Lack of resources and evidence can make changes to legislation slow to implement	• Consider that APVMA chemical permitting and registration processes are slow which can disadvantage Australian growers • Can represent growers or smaller industry organisations, particularly for unified applications to the APVMA for chemical registration
Reference to international standards	• Quality standards commonly employed • HACCP food safety system commonly employed • Reference to standards despite not adopting the standards	• Access to overseas markets facilitated from a government perspective through the National Residue Survey which gives confidence overseas, not via international standards	• No specific comments
Requirements for designated QA staff	• Variable • National Feedlot Accreditation Scheme (NFAS) very prescriptive • Codes of Practice silent	• No specific comments	• No specific comments
Training	• QA schemes generally include a comprehensive training element • Some require demonstration of competence	• National minimum training requirements are being established for all users of restricted chemical products and poisonous (Schedule 7) agvet chemicals	• No specific comments

QA Scheme Element	QA Scheme Operators	Regulators (states and territories)	Industry Organisations*
Record keeping	• All have minimum requirements with templates that comply with regulations • Some include more prescriptive evidence of records	• Regulators recognise the value of QA schemes in assisting to ensure good record keeping	• Information sometimes passed to industry organisations • Information within some organisations generally commercially confidential and not passed on
Residue risks and testing	• Varies by industry with the default being NRS, which supports international market access • Some QA schemes require individual to perform residue testing	• Concerned that selective samples are submitted for testing • Often late to learn of adverse residue results	• No specific comments
Off-label chemical use	• While schemes may be silent on off-label use, they support the permit approach incl. working with the APVMA in support of applications	• Variable regulations by jurisdictions potentially leads to confusion within nationally-based QA schemes • The Australian Government and the states and territories are exploring how to further harmonise off-label use	• Do not support off-label use unless under an APVMA permit because of potential reputational damage (see section 5.1.2)
Audits and corrective actions	• Internal and external auditing required • Announced and unannounced audit regimes • Sanctions for delays in completing corrective actions	• Auditing of growers by regulators not generally performed unless issues are flagged through residue testing • Regulators are divided as to whether co-regulation with QA schemes could reduce regulatory compliance visits	• Consider that unannounced audits are essential to ensure transparency and acceptance by consumers • Announced audits useful for continuous improvement by producers
Compliance reporting	• Very few schemes publicly report compliance (NFAS is one) • APIQ✓® and NFAS report according to MoUs	• Regulators are concerned that there is no requirement to report compliance issues (except where MoUs are in place)	• No specific comments
Complementarity with regulatory jurisdictions	• Examples where regulators accept certified producers as meeting jurisdictional requirements (MoUs)	• Regulators recognise that QA schemes may impose additional requirements on growers above regulatory requirements	• Support for efforts to avoid duplication to improve efficiency and cost effectiveness

QA Scheme Element	QA Scheme Operators	Regulators (states and territories)	Industry Organisations*
		• Acceptance by some jurisdictions of equivalence (or better) of certified producers complying with regulations	of schemes while still providing assurance to consumers
Future directions	• Market forces require continual adaptation by schemes to ensure they meet changes in consumer requirements concerning agvet chemical use	• Regulators recognise the adaptive requirements for QA schemes	• Organisations recognise the adaptive requirements for QA schemes

** Note that some industry responses may be contradictory as the groups consulted represent different sectors of the agricultural industries*

Potential for QA schemes to support agvet chemical regulation

This project examines a range of QA schemes to provide an understanding of the extent to which they complement, overlap or exceed agvet chemical use regulation by state and territory jurisdictions. The intent is to provide insights on how these recognised QA schemes could potentially be used to support agvet chemical regulation in Australia, including commenting on the strengths and weaknesses of doing so.

The following table summarises the current aspects of each QA scheme element that demonstrate evidence of how the schemes support regulation and also provides potential opportunities to strengthen that support. The table also presents the strengths and weaknesses of each QA element, and any future policy to incorporate QA schemes as part of a co-regulatory arrangement should be based on incorporating the strengths and eliminating or reducing the weaknesses.

Strengths and weaknesses of QA schemes to support agvet chemical control of use regulation

QA Scheme Element	Current and potential aspects that support regulation	Strengths	Weaknesses
Structure and operation	Current • All QA schemes include agvet chemical use as a component • Individual schemes vary in the extent of requirements (training, reporting etc.) however, it is understood that the majority reflect, at a minimum, state/territory regulations Potential • Include more explicit statements of the complementary role between schemes and regulation	• QA schemes recognise the importance of agvet chemical use as a component of their operations • Schemes apply nationally • Supply contracts could include QA scheme membership as a requirement (pseudo compulsory)	• Some schemes lack definitive statements and/or performance indicators demonstrating compliance with regulations in all jurisdictions • Schemes are voluntary and represent a proportion only of the particular produce
Process for setting rules and standards	Current • Schemes vary in the composition of boards/committees for setting rules and standards • Many have industry, government/regulator, research and consumer representatives in official and unofficial capacities Potential • Include regulators as members of rules and standards committees	• A multidisciplinary team ensures all perspectives of agvet chemical use are included	• Schemes are industry-based and may be reluctant to accepting government/regulator inputs
Reference to international standards	Current • Many schemes either adopt international standards or make reference to these standards Potential • More widespread adoption and reference to international standards to promote harmonisation	• International schemes such as GFSI and GLOBALG.A.P. are gaining wider acceptance • International regulators recognise QA schemes – e.g. in Canada CFIA has confidence that QA certification	• Regulators may not have sufficient knowledge of QA schemes to recognise certification of individual producers

QA Scheme Element	Current and potential aspects that support regulation	Strengths	Weaknesses
		results are within the CFIA's risk-based assessment continuum	
Requirements for designated QA staff	Current • Schemes vary in prescribing the number and competencies of QA staff Potential • Clear statements of numbers and competencies of QA staff based on size of operations	• Prescribed numbers and competencies of staff provide confidence to regulators	• Producer members vary from large to small operators and prescriptive requirements may add to compliance costs
Training	Current • All schemes include training elements for competency in agvet chemical use, but vary in the extent of training required and documentation Potential • National reforms will harmonise requirements • Minimum training requirements within QA schemes aligned with nationally harmonised requirements	• Recognition of training by scheme participants could be acknowledged by regulators as satisfying regulatory requirements thus reducing duplication and cost	• Regulators currently vary in training requirements for agvet chemical use and this would need consideration for nationally-based QA schemes
Record keeping	• Similar for training above	• Similar for training above	• Similar for training above
Residue risks and testing	Current • Most schemes do not have specific residue testing requirements, with exceptions being supermarkets, and Freshcare and Global GAP • NRS does not cover all produce and does not discriminate between QA and non-QA producers Potential • Agreement on residue testing regimes required for different purposes (e.g. food safety, environment)	• The opportunity for QA schemes to demonstrate superior residue risk outcomes could provide a market advantage	• Elevating residue issues may negatively impact market access for produce regardless of QA scheme participation

QA Scheme Element	Current and potential aspects that support regulation	Strengths	Weaknesses
Off-label chemical use	Current • Schemes are generally silent on off-label use and consequently audits may not address the issue. Work is underway to harmonise arrangements • Where schemes have legislated underpinning (e.g. poppies) there are strict rules in place Potential • Specific reference to off-label use, with harmonised regulations	• Schemes have flexibility to address off-label use which may be preferable where there are differences between jurisdictions	• Differences in regulations between jurisdictions may complicate the inclusion of off-label use until there is harmonisation • The inclusion could add to auditing costs and require additional training for auditors
Audits and corrective actions	Current • Schemes include minimum requirements for internal and external audits, including whether announced or unannounced • Corrective actions responses are stipulated including time period for completion with sanctions (including scheme disqualification) if not achieved Potential • Standardised approach to audit frequency and type (internal and external)	• Sanctions (incl. disqualification) are an incentive to ensure compliance • Announced audits promote non-threatening opportunities for improvement	• Announced audits reduce transparency and potentially undermine consumer confidence
Compliance reporting	Current • Schemes vary from non-disclosure to public disclosure (on a confidential basis) of the number of compliance issues, including the time period for completion of corrective actions • Individual supply contracts include sanctions for non-compliance, incl. loss of contract	• Public disclosure of corrective actions (individual names are confidential) and contractual implications of non-compliance ensure improved consumer acceptance of products	• Jurisdictions not being informed of compliance issues in a timely manner may have implications for the industry generally, and not just scheme participants (e.g. agvet chemical being consistently used not in accordance with label, with possible residue implications)

QA Scheme Element	Current and potential aspects that support regulation	Strengths	Weaknesses
	Potential • Adopt a process for reporting serious non-compliance to jurisdictions		
Complementarity with regulatory jurisdictions	Current • It is assumed that all schemes require minimum compliance with agvet chemical regulation • Certain jurisdictions accept scheme certification being compliant with regulation (MoUs) Potential • Widespread adoption of MoUs between schemes and jurisdictions	• Recognition by jurisdictions of scheme certification reduces duplication and leads to cost savings • International examples exist of jurisdictions accepting scheme certification for regulatory compliance	• National schemes need to demonstrate compliance for each jurisdiction in which regulations vary • This limits the extent to which MoUs are agreed
Future directions	Current • Schemes recognise the need to continually evolve and adapt to changing market requirements Potential • Flexibility by regulators to adapt to market requirements	• Schemes are industry-based and can quickly update standards to meet market requirements	• Changes may have regulatory implications and approvals by jurisdictions may be delayed, especially if changes to legislation are required

Conclusions

The schemes that were reviewed vary for industries with schemes that are highly regulated (poppies) through to those that recommend production based on codes of practice guidelines without any formal scheme compliance arrangements. All schemes include agvet chemical use modules that consist of a range of elements including training and record keeping. However, schemes vary in their requirements with respect to auditing, product testing (for residues) and off-label chemical use. It should be noted that regardless of scheme arrangements, all producers are required to adhere to state/territory control of use regulations as a minimum.

Similar to the variability between schemes in the way they address agvet chemical use, jurisdictions vary in the extent to which they recognise schemes as complying with (or exceeding) control of use regulations. Recognition varies from MoUs (or other forms of agreement) between jurisdictions and schemes through to no formal recognition. Where MoUs are in place, they are with individual jurisdictions and are not universally recognised by all jurisdictions.

The agvet control of use requirements are further complicated by differences in regulation between the jurisdictions, and this appears to impede co-regulatory recognition of what are generally national QA schemes. While this is being addressed by Australian governments which have re-committed to the development of nationally consistent regulation of agvet chemicals, including specific proposals around record keeping and training requirements and work to harmonise off-label requirements, it is unclear when such policies will be implemented and thereby positively enhance the co-regulatory opportunities between the QA schemes and states/territories.

GHD has identified a number of areas that QA schemes could consider that would enhance co-regulation for agvet chemical use (as described under “potential” in the above table).

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Acronyms and Glossary

Administrator For the purposes of this report, administrator denotes a person who is involved in the administration, management or organisation of a quality assurance scheme in an official capacity.

Agricultural chemical product is a substance or mixture of substances that is represented, imported, manufactured, supplied or used as a means of directly or indirectly; preventing infestation of any pest, destroying a plant, modifying a plant or pest, modifying another agricultural chemical product, or attracting a pest for the purpose of destroying it. It also includes a substance or mixture of substances declared by the Agvet Code Regulations to be an agricultural chemical product.

Agvet chemical is the term used to describe any agricultural or veterinary chemical.

ALFA (Australian Livestock Feeders Association). This is the peak industry body representing the cattle feedlot industry.

APIQ✓® is the pork industry quality assurance scheme which is owned and run by Australian Pork Limited (APL).

APVMA (Australian Pesticides and Veterinary Medicines Authority) is the Australian Government regulator of agvet chemical products up to and including the point of supply (usually retail sale).

ARTG Australian Register of Therapeutic Goods. Therapeutic goods must be entered on the Australian Register of Therapeutic Goods before they can be supplied in Australia. The regulatory framework is based on a risk management approach designed to ensure public health and safety.

AUS-MEAT Industry organisation which manages a number of meat industry product standards and also accredits and audits meat processing plants. AUS-MEAT provides audit services for the National Feedlot Accreditation Scheme (NFAS).

ChemCert An example of an industry based scheme that works with all industry sectors throughout Australia for the training, up-skilling and industry accreditation of users of agvet chemicals.

Codex Alimentarius Represents a collection of international food standards that covers the hygiene and quality of food including pesticide and veterinary drug residues. It is a joint initiative of the World Health Organisation (WHO) and the Food and Agriculture Organisation (FAO).

COSOP (Code of Sound Orchard Practices) The Macadamia Industry's best practice guidelines created by the Australian Macadamia Society for use by macadamia growers.

ESA (Egg Standards Australia) The quality assurance program for rearing and layer farms developed by Australian Eggs Limited (previously Australian Egg Corporation Limited).

FAO (Food and Agriculture Organisation) is a United Nations organisation involved in research, creating resources and promoting collaboration to promote food security and agricultural and rural development.

Freshcare An industry owned, not-for-profit, on-farm assurance program, established in 2000 to service the needs of the Australian industry. It is the largest on-farm assurance program in Australia and is recognised as providing access to major retailers in Australia.

FSANZ (Food Standards Australia and New Zealand) A statutory authority that develops food standards for Australia and New Zealand.

GFSI (Global Food Safety Initiative) A collaboration of the world's leading food safety experts from retail, manufacturing and food service companies, as well as international organisations, governments, academia and service providers to the global food industry. With a vision of safe food for consumers everywhere, it seeks to reduce food safety risks, audit duplication and costs while building trust throughout the supply chain.

GLOBALG.A.P. Integrated Farm Assurance A worldwide standard for Good Agricultural Practice with an internationally recognised standard that brings together farmers and retailers in the production and marketing of safe food. GLOBALG.A.P. is one of the four base schemes accepted for the supply of fresh produce to major retailers in Australia via HARPS (see below).

Graincare is a quality assurance program for grains (cereals, pulses and oilseeds) originally developed by Grains Council Australia (now Grain Producers Australia) in 2001.

HACCP (Hazard Analysis and Critical Control Points) program Generally used in the development of industry quality assurance programs to identify production risks and processes required to control risks.

Harmonisation The process of creating common standards across jurisdictions that may initially have different standards.

HARPS (Harmonised Australian Retailer Produce Scheme) A process to harmonise food safety certification requirements for the major retailers in Australia that recognises four base schemes as acceptable for certification by growers, packers and distributors: BRC Global Standard for Food Safety (for packers); SQF Code (Food) – Level 3; GLOBALG.A.P Integrated Farm Assurance; and Freshcare.

JAS-ANZ (The Joint Accreditation System of Australia and New Zealand) A government-appointed accreditation body for Australia and New Zealand responsible for providing accreditation of assessment bodies in the fields of certification and inspection.

LPA (Livestock Production Assurance) An Australian on-farm assurance program for livestock.

Minor use A use of a chemical product that would not provide sufficient economic return to holders of registration to include the use on the APVMA approved product label. Routinely addressed through a minor use permit from the APVMA, or where off-label use of a chemical product is permissible under state/territory legislation.

MoU (Memorandum of Understanding) A formal agreement between two parties which outlines the terms of an agreement but is not generally legally binding.

MRL (Maximum Residue Limit) The highest amount of a chemical residue that is legally allowed in a food product sold in Australia whether it is produced domestically or imported. MRLs help enforcement agencies monitor whether an agvet chemical has been used as directed to control pests and diseases in food production. The APVMA and FSANZ sets MRLs for agvet chemicals.

NATA (National Association of Testing Authorities) An organisation which provides assessment, accreditation and training to laboratories and other technical facilities.

NFAS (National Feedlot Accreditation Scheme) The quality assurance scheme used in the beef cattle feedlot industry, administered by AUS-MEAT.

NRS (National Residue Survey) An industry-funded activity whose core work is to facilitate the testing of animal and plant products for pesticide and veterinary medicine residues and environmental contaminants. The NRS is administered by the Australian Government Department of Agriculture and Water Resources. Product testing is done through either random or specifically designed sampling protocols. NRS programs encourage good agricultural

practices, help to identify potential problems and indicate where follow-up action is needed, and support access to international markets.

OECD (Organisation for Economic Co-operation and Development) Is an organisation which collects and analyses data, producing regular economic development projections and providing recommendations to governments.

Off-label use The use of agvet chemicals in a way which is different to uses approved on the label of the chemical product.

QA Schemes (Quality Assurance Schemes) This report considers formal QA Schemes for agricultural produce. Note that this report also considers management arrangements, codes and practices and standard operating procedures used by industries that may not be formalised as a QA scheme. For simplicity, this report refers to all of these arrangements as QA schemes.

Regulator A state or territory government (and staff) involved in the regulation of the use of agvet chemicals.

Residue(s) The remainder within agricultural produce of the active chemical constituent(s), metabolites or degradation products of the active constituent(s) of an agvet chemical product, arising from the direct use of the product or indirect exposure to the product.

Schedule 7 chemicals also known as Schedule 7 Poisons (Dangerous Poisons), have a high potential to cause harm at low exposure and require special precautions during manufacture, handling and use, and are restricted in their use.

Tasmanian Alkaloids Is an organisation of scientists and engineers that works with farmers in Tasmania to grow poppies and produce medicinal opiates, using Good Manufacturing Practice standards.

TGA (Therapeutic Goods Administration) The Therapeutic Goods Administration carries out a range of assessment and monitoring activities to ensure that the therapeutic goods (i.e. drugs and pharmaceutical products) available in Australia are of an acceptable standard. Their aim is to ensure that the Australian community has access, within a reasonable time, to therapeutic advances.

UKAS United Kingdom Accreditation Service, the national accreditation body for the United Kingdom, appointed by government, to assess organisations that provide certification, testing, inspection, and calibration services.

WHO (World Health Organisation) A United Nations organisation directing and coordinating international health concerns. This includes setting standards and promoting and monitoring their implementation, such as food safety standards.

WHP (Withholding Period) The minimum period of time that must elapse between the last application of an agvet chemical product and the harvest or slaughter of that crop or livestock species to which the chemical was applied.

Some of the terms used in this glossary have been adapted from the APVMA Definition of Terms. See: https://apvma.gov.au/definition-of-terms/

Acknowledgements

GHD acknowledges and thanks stakeholders who were consulted during the project and who provided valuable insights into the operations of QA schemes with respect to the control of use of agvet chemicals. Without your inputs the task of analysing the various elements of the schemes and the extent to which they complement regulation within the various jurisdictions would not have been possible.

Through your assistance, the project provides insights on how QA schemes could potentially be used to support agvet chemical regulation in Australia, with the outcome of improving efficiency through avoiding duplication of activities while still providing the product assurance required by customers.

1. Introduction

The Australian Government Department of Agriculture and Water Resources (the department) contracted GHD Pty Ltd to complete the project titled "A*gricultural and veterinary (agvet) chemical regulation: Review of quality assurance (QA) arrangements"*.

The project is an investigation of how agvet QA schemes support, or could potentially support, Australian regulatory activities to manage the risks associated with using agvet chemical products, including commenting on the strengths and weaknesses of doing so. It does not include a comprehensive review of all Australian QA schemes but rather considers the operation of selected schemes from a wide range of agricultural industries to understand the current diversity and future opportunities.

1.1 Background

The Australian Government, through the Australian Pesticides and Veterinary Medicines Authority (APVMA), and the states and territories, are involved in regulating the import, manufacture, supply and use of agvet chemical products to protect the health and safety of people, animals, plants and the environment.

The APVMA is primarily involved in regulating the import, manufacture and supply of agvet chemicals through the product registration process. Unless exempt, an agvet chemical product must be registered or granted a permit by the APVMA before it can legally be supplied, sold or used in Australia. Before an agvet product is registered for use by the APVMA, rigorous assessments are completed to determine the safe level/volume/method of use, target crops/pests and label instructions for the proposed use(s).

Complementing this registration process, the states and territories each regulate the control of use of agvet chemical products after the point of sale. This includes several interlinked activities, although the approaches taken to managing agvet chemical risks can differ within and across jurisdictions. The activities include:

- ensuring that chemicals are used legally – in line with labels
- formulating training requirements for licensing and the use of higher risk products
- licensing professional users
- monitoring licence compliance and chemical residues in produce and the environment; and
- conducting activities such as investigations, enforcement, compliance, education and extension.

In certain circumstances, "off-label" use of agvet chemicals is legally permitted. The APVMA can authorise off-label permits for minor uses. These are principally issued to grower organisations in situations where a gap exists in on-label (registered) uses. A permit describes the circumstances under which an agvet chemical can be used with similar instructions to those that would otherwise appear on a product label. Permits allow users to apply agvet chemicals which would otherwise be an offence in the individual state/territory (State Control of Use legislation). Approval of such permits adopts a risk-based approach whereby the prescribed use is considered to result in acceptable product and environmental safety.

State and territory government regulators also allow off-label uses of agvet chemicals under certain circumstances, and these are described in the report. The states and territories adopt different approaches in regulating the off-label use of agvet chemicals. Regulators are responsible for ensuring compliance by users of agvet chemicals on the basis that the

appropriate use of products results in produce that meets food safety, environmental and workplace health and safety requirements.

However, in response to market drivers, a number of agricultural industries have developed industry-based, voluntary QA schemes and/or best management practice arrangements which are designed to more explicitly demonstrate compliance with a range of standards and practices, with varying audit and compliance processes required to achieve certification of the produce. The schemes generally include elements for the responsible use of agvet chemicals.

For agvet chemical use, these standards include, at a minimum, that the produce has been grown in accordance with relevant state and territory regulation, but may also include additional requirements to facilitate improved market access. The implementation of each of the QA schemes varies, however each includes independent auditing and certification processes that provide assurance that the produce conforms with the scheme's standards.

As a result, with respect to agvet chemical use, QA schemes operate in parallel with regulatory requirements. There is uncertainty of the extent of overlap and duplication between the two, however where this occurs it is likely to result in inefficiencies leading to cost increases that could be avoided.

As part of Australia's ongoing agvet chemical regulatory reforms, there is a need to develop a national or harmonised approach across jurisdictions for the control of agvet chemical use, and this could include recognition of the role of QA schemes within the regulatory framework resulting in improvements to its efficiency, effectiveness and costs.

1.2 Purpose of this report

The purpose of this study is to comprehensively examine the nominated QA schemes, including a transparent and logical analysis of the potential for their use in support of agvet chemical regulation in Australia.

1.3 Terms of reference

The terms of reference for this project was to provide a detailed written report that:

- Identifies and documents select Australian/international industry QA schemes as they relate to managing risks associated with agvet chemical use.
    - Include schemes for poppies (Australian), poultry – eggs and meat (Australian), feedlot beef (Australian), antibiotic resistance in piggeries (Australian and in Denmark), barley (Australian), citrus and herbs for export (Australian, for export to Japan), treenut producers (Australian), Freshcare (Australian) and the schemes run by Coles and Woolworths (Australian).
    - For each selected QA scheme, identify and comment on:
        - how it is structured and operates
        - what international standards (if any) it is based on
        - training/competency arrangements, including initial training and how this is provided, what arrangements exist for ensuring maintenance of competency, and the capability requirements specified at an individual level and enterprise level
        - record keeping requirements, including at an individual level and enterprise level

- for residue risks / testing - the suite of chemicals on which analysis is carried out and the process for selecting them. Also, identify any triggers within the scheme for reporting adverse findings to regulatory bodies
- the approach to off-label agvet chemical use – including how the scheme ensures scientific validation of any proposed off-label use
- compliance and enforcement arrangements, including how the scheme addresses violations on an individual and group basis. Where a violative residue is detected, identify what entity carries out the risk assessment and the level of scientific/professional input. Where corrective action is required, explain how this happens and the mechanism for determining that it has occurred
- how the scheme has evolved from its initiation to now, including any specific incidents/events that may have triggered development or reform
- strengths and weaknesses, including any gaps
- future directions and anything else relevant to Australia's regulation of agvet chemical use, particularly related to control of use
- for the Australian-based QA schemes, identify and discuss any specific areas of potential overlap or duplication with the control of agvet chemical use activities managed by each state and territory. Also identify and discuss instances where QA schemes complement or contradict jurisdictional control of agvet chemical use activities.

- Investigates and comments on instances in the UK, Canada and Denmark, and other OECD countries as appropriate, where agvet regulators legislatively recognise QA schemes, including an explanation of how this occurs, the benefits of that recognition to scheme participants, and the outcomes observed.
- Analyses how these recognised QA schemes could potentially be used to support agvet chemical regulation in Australia, including commenting on the strengths and weaknesses of doing so.

The intention was to review QA schemes for each of the nominated industries. However, GHD found that not all of the nominated industries had formal QA schemes operating and other instances where broader QA schemes operated across several industries. Changes in the approach for reviewing each of the nominated industries are explained in the report.

1.4 Assumptions

For this report, GHD has obtained details of the QA schemes and the role of regulators from both publicly available sources and via targeted stakeholder consultation. While we consider the information is accurate, we have not independently verified the data.

1.5 Legal disclaimer

This report has been prepared by GHD for the department and may only be used and relied on by the department for the agreed purpose as set out above.

GHD otherwise disclaims responsibility to any person other than the department arising in connection with this report. GHD also excludes implied warranties and conditions, to the extent legally permissible.

The services undertaken by GHD in connection with preparing this report were limited to those specifically detailed in the report and are subject to the scope limitations set out in the report.

The opinions, conclusions and any recommendations in this report are based on conditions encountered and information reviewed at the date of preparation of the report. GHD has no responsibility or obligation to update this report to account for events or changes occurring subsequent to the date that the report was prepared.

The opinions, conclusions and any recommendations in this report are based on assumptions made by GHD described in this report. GHD disclaims liability arising from any of the assumptions being incorrect.

GHD has prepared this report on the basis of information provided by the department and others who provided information to GHD (including government authorities), which GHD has not independently verified or checked beyond the agreed scope of work. GHD does not accept liability in connection with such unverified information, including errors and omissions in the report which were caused by errors or omissions in that information.

2. Methodology

GHD completed the project via a combination of desktop reviews of the nominated QA schemes and regulatory compliance arrangements and targeted consultation with scheme operators, industry organisations and state and territory regulatory agencies.

The desktop reviews included web searches to obtain information on each of the schemes which was supplemented by additional information following a request to the scheme operators. The consultation with the schemes, regulators and industry organisations was facilitated by a letter of introduction to the relevant contact persons from the department.

The desktop review resulted in GHD completing an initial table which summarised the key elements of each scheme. The list of elements included:

- structure and operation
- any reference to international standards
- training/competency arrangements: at individual and enterprise level
- record keeping requirements: at individual and enterprise level
- residue risks and testing: suite of chemicals, triggers for reporting adverse findings to regulatory bodies
- approach to off-label agvet chemical use
- compliance and enforcement arrangements
- the evolution of the scheme and whether this included any trigger events
- strengths, weaknesses and gaps
- future directions in relation to the control of agvet chemical use.

This initial table (in many cases part-populated) was then emailed to each of the scheme contacts seeking feedback either by email, phone or a combination of both. The final versions of the summary tables for each QA scheme are provided in Appendix A.

GHD analysed the information for each scheme using a rubric which provided a consistent, semi-quantitative analysis tool of the various elements. Scoring classifications for the rubric were constructed by GHD for each of the scheme elements, with scores reflecting the degree to which each element was developed within each QA scheme. The scoring within the rubric ranged from zero or minimal detail for each element (score = 0) through to a comprehensive treatment (score = 4). This approach allowed the schemes to be compared for the particular attributes being investigated and then to further inform our analysis of the potential for particular schemes to support agvet chemical regulation.

The desktop reviews and consultation with the QA scheme operators were complemented by targeted consultation with regulatory authorities and industry organisations to seek their understanding of the current and potential roles of the nominated QA schemes with respect to the future direction of agvet chemical regulation in Australia. The department also provided an introductory letter to each of these stakeholders, and GHD completed interviews in person or by phone.

In advance of the interviews, GHD forwarded an email of the information sought as per the following:

1. Which of the following QA schemes is your department/organisation familiar with?
    a. Poppies

b. Poultry – egg

c. Poultry – meat

d. Feedlot beef

e. Piggeries (specifically related to antibiotic resistance)

f. Barley

g. Citrus for export to Japan

h. Herbs for export to Japan

i. Macadamias

j. Schemes run by Coles

k. Schemes run by Woolworths

2. For the schemes generally, and for individual schemes if different, what comments do you have on the following:

   a. Structure and operation

   b. Knowledge of any reference to international standards

   c. Training/competency arrangements: at individual and enterprise level

   d. Record keeping requirements: at individual and enterprise level

   e. Residue risks and testing: suite of chemicals, triggers for reporting adverse findings to regulatory bodies

   f. Approach to off-label agvet chemical use

   g. Compliance and enforcement arrangements

   h. The evolution of the scheme and whether this included any trigger events

   i. Strengths, weaknesses and gaps

   j.. Future direction of the schemes in relation to the control of Agvet chemical use

3. For QA schemes generally, or for individual schemes if different, are there any specific areas of potential overlap or duplication with the control of agvet chemical use activities included within the scheme and the control of agvet chemical use activities by your department/organisation?

4. For QA schemes generally, or for individual schemes if different, can you please identify and discuss instances where QA schemes complement or contradict jurisdictional control of agvet chemical use activities?

5. Does your department/organisation have any MoUs or other agreements with QA schemes with regard to agvet chemical use? Please provide details, including your thoughts on how the schemes meet your state's agvet chemical legislation requirements?

6. For QA schemes generally, or for individual schemes if different, what are your comments on how these recognised QA schemes could potentially be used to support agvet chemical regulation in Australia, including commenting on the strengths and weaknesses of doing so and the requirement for harmonisation of regulations between jurisdictions?

The feedback was captured and used in the analysis of the potential roles of the QA schemes for agvet chemical regulation.

In addition, GHD completed a desktop review of the structure and functioning of several overseas examples of QA schemes and food safety standards to inform the analysis of this report. Select schemes and standards from Denmark, Canada, the UK and New Zealand were reviewed, particularly where they were referenced in the course of consultation with Australian-based regulators and industry organisations.

3. Description of selected Australian-based QA schemes

Table 1 provides a list of the Australian-based QA schemes or management arrangements that were reviewed. Detailed information on each scheme is provided in Appendix A, with each scheme described according to the 12 elements listed in the terms of reference. The schemes vary for each of the elements under consideration with the variation related to a range of factors including the maturity of the scheme (number of years since inception), whether the scheme is a whole-of-industry model or a management arrangement between a limited number of producers and processors/marketing groups, and the relevant driving factors including public scrutiny and overseas market access.

Information from QA scheme administrators also provided perspectives and details on the strengths, weaknesses and gaps of their schemes and the potential for co-regulation. This information is included in the full templates, with an analysis of the opinions gained, and further analysis by GHD for the potential of quality assurance schemes towards harmonisation, provided in section 7.

A description of each of the elements within the QA schemes is provided in section 3.1.

Table 1 Summary of Australian QA schemes reviewed

Industry/product	Completed Template	QA scheme reviewed
Poppies	Appendix A-1	Tasmanian Alkaloids
Poultry – eggs	Appendix A-2	Egg Standards Australia for Rearing and Layer Farms
Poultry – meat	Not available	There is no industry-wide scheme. Quality assurance is administered between processors and growers and appended to contractual arrangements.
Feedlot beef	Appendix A-3	National Feedlot Accreditation Scheme (NFAS)
Piggeries	Appendix A-4	APIQ✓®
Barley	Appendix A-5	Graincare was used for the purposes of this study as an industry-wide QA scheme for grains which can be applied to barley. However, it is not commonly used in the barley industry where producers favour individual agreements with customers.
Citrus for export to Japan	See Appendix A-9	Citrus Australia advised that growers use the Freshcare QA scheme detailed below.
Herbs for export to Japan	See Appendix A-9	Herbs can be covered by the Freshcare QA scheme detailed below. The Australian Herb and Spice Industry Association has been included as an industry organisation for the purposes of this report.
Macadamias	Appendix A-6	The Code of Sound Orchard Practices was reviewed, however this is not an auditable QA scheme per se.
Schemes run by Coles		Coles declined to participate in the study.
Schemes run by Woolworths	Appendix A-7	Summary of several QA systems accepted by Woolworths.

Industry/product	Completed Template	QA scheme reviewed
Fresh produce *Freshcare	Appendix A-8	Freshcare was not originally included in the scope of works however it forms part of the QA systems for several of the horticultural industries under review.
Fresh produce **GlobalG.A.P.	Appendix A-9	GlobalG.A.P. was not originally included in the scope of works but is one of the benchmark quality schemes for access to Coles and Woolworths via HARPS.

3.1 Description of the elements within QA schemes

3.1.1 Structure and operation

QA schemes and their associated guidelines for the regulation of agvet chemicals are voluntary (with the notable exception of Tasmanian Alkaloids which requires farmers to use only Tasmanian Alkaloids approved chemicals). Most schemes have a variety of elements including management, training, food safety, chemical use, storage and handling etc. Generally the schemes provide opportunities for producers to demonstrate recognised, consistent practices which are then verified via independent auditing to provide assurance of quality to consumers and retailers.

Most of the selected QA schemes have entry level requirements for producers that require a demonstration of minimum compliance with the scheme standards. Other industries reviewed for the project operate according to best practice guidelines and/or Standard Operating Procedures (SOPs) that may be publicly available and do not require membership and certification via a formal QA scheme.

Typically schemes operate nationally and are open to all producers who voluntarily agree to comply with the scheme requirements. The schemes reviewed may not be the only schemes available to producers of each commodity. For example, as described in Table 1, Graincare is reportedly losing traction within the barley industry because of a preference for individual QA arrangements between producers and customers, where the auditable QA scheme is not perceived as adding any value for the grower and customer.

There is a proposal to develop a national QA scheme for the poultry meat sector that will incorporate antimicrobial stewardship as a key element. Currently, the industry operates on an individual contract basis between growers and processors, with each processor having their own unique commercial-in-confidence Standard Operating Procedures (SOPs) with which growers must comply. Processors undertake auditing of producers against the SOPs and non-compliance has contractual implications. GHD was not able to obtain examples of the commercial-in-confidence SOPs.

3.1.2 Process for setting rules and standards

The majority of QA schemes set their rules and standards internally, generally via a board (or similar) comprising growers and industry representatives. For example, Egg Standards Australia (ESA) reviews its standards internally but includes close consultation with customer groups. Other schemes include government (regulator) input - the National Feedlot Accreditation Scheme (NFAS) includes specialists in the industry and state government representatives from states with higher feedlot production. Industry research organisations can also play a role in the development of the industry standards such as for the macadamia Code of Sound Orchard Practices which was developed using research and development levy funds.

Certain schemes include flexibility in the range of standards included and this allows producers to opt in to those elements that suit their production and marketing arrangements. For example, the pork industry's scheme APIQ✓® has an option to allow accreditation for supply to Coles supermarkets. The APIQ✓® board sets the scheme's standards in conjunction with stakeholder consultation, including intentionally maintaining diversity of industry representation including small growers and retailers.

3.1.3 Reference to international standards

The application of different international standards by the schemes reviewed varies greatly, ranging from their use in the certification of the scheme, to providing a template or a benchmark, or to provide principles on which the schemes are based. For example, the NFAS was developed using the standard Codex Alimentarius International Food Standards which are endorsed by WHO and FAO. APIQ✓® makes use of the HACCP principles of the food safety system based within the Codex Alimentarius. Freshcare (for horticultural produce) also references international standards, particularly the Global Food Safety Initiative (GFSI).

A number of schemes make use of ISO9000 standards for quality management (Graincare and the Code of Sound Orchard Practices used by macadamia growers), while others make no reference to international standards, such as the ESA.

In contrast, poppy production via Tasmanian Alkaloids is completely regulated by the standards required by the International Narcotics Control Board.

3.1.4 Requirements for designated QA staff

The schemes vary in their stated requirements for the number and expertise of QA staff within individual business enterprises. For example, NFAS stipulates the number of trained QA staff based on the size of the operation, and all QA staff must have specific statements of authority. Freshcare requires training of all staff in quality assurance protocols, however one staff member is required to perform specific training. The pork industry and Tasmanian Alkaloids schemes make reference to all staff being trained in quality assurance while the other schemes reviewed do not mention the specific responsibilities staff members have in regards to quality assurance.

3.1.5 Training

All of the schemes include training of staff in various aspects of agvet chemical use, including endorsement of minimum chemical user accreditation based on state and territory regulations. Some schemes such as APIQ✓® provide detailed outlines of experience needed for staff to be deemed competent, while other schemes require that staff are "competent" without any specifications. Regardless of the specific level of training required, all QA schemes require legislated training to be adhered to, all staff to be trained for their role and records to be maintained of all staff training.

Some schemes provide external trainers and opportunities for growers to be trained as part of the QA scheme. For example, Tasmanian Alkaloids trains field officers who work with farmers in regards to agvet chemical use, while Freshcare requires that all participating businesses have at least one representative complete training provided by Freshcare.

One administrator noted that withholding periods following the use of agvet chemicals are one of the most important areas of training to ensure that a product complies with maximum residue limits, but that the relevant QA scheme did not include this training. Freshcare representatives indicated that further direction is required in the use of agvet chemicals particularly associated with the qualifications and training of users.

3.1.6 Record keeping

All QA schemes are very consistent in advocating good record keeping systems, with all placing particular emphasis on recording the use of agvet chemicals. Generally records must be kept for several areas of chemical application; application to crops, post-harvest chemical use, veterinary prescriptions, and other chemical use that could potentially impact the crop such as cleaning chemicals and pesticides used in storage areas. Some QA schemes provide templates to be completed, however all provide a thorough list of the details required on agvet chemical documentation. Tasmanian Alkaloids maintains chemical use records electronically by field officers on a central system. Generally record keeping processes among the schemes reviewed are confirmed by annual audits.

3.1.7 Residue risks and testing

Very few industries perform residue testing as an integral part of the QA schemes, with industries generally relying on the National Residue Survey (NRS) testing results to provide evidence that the whole of the industry (QA scheme and non-QA scheme producers) is meeting the MRL standards that are then used as a component for market access.

In some cases where MRL breaches are identified, information is shared between regulators and QA scheme administrators with a view to assisting regulators and the industry to understand non-compliance and improve farming practices if required. This study did not uncover information on potential differences in the use of NRS results between domestic and export produce.

In contrast, Freshcare is a notable example of a QA scheme that requires chemical residue testing. This requirement was in response to major supermarkets considering there was an unacceptable risk to the consumer unless there was evidence that produce met the required standards. In addition, there is high public scrutiny of supermarket produce quality.

As a result, Freshcare requires growers to provide samples to be tested to achieve QA scheme accreditation, and at least one grower provided residue test per year must be performed by a laboratory with National Association of Testing Authorities (NATA) accreditation to ISO/IEC 17025.

3.1.8 Off-label chemical use

QA schemes operate across jurisdictional boundaries and as such do not generally provide any advice in regards to off-label chemical use. None of the QA schemes reviewed endorsed off-label use unless specific provisions such as off-label permits were available. Because of differences between jurisdictions, this can sometimes be confusing. For example, macadamia growers in NSW cannot use some of the chemicals available to Queensland growers due to differences in off-label permits between the states. In addition, Victorian producers are permitted to use registered products off-label, as long as they accept full liability for their produce and do not violate any restrictions on the label. Most other jurisdictions require an APVMA permit to allow such off-label use.

For veterinary chemicals, off-label use and minor use permits are available on prescription from a registered veterinarian whose prescription powers are regulated by state legislation.

However, QA schemes and industries generally often play an active role in seeking off-label permits for the use of agvet chemicals. For example, Tasmanian Alkaloids plays an active role in the application of new chemicals, partnering with an agricultural research company in New Zealand that performs trials, residue testing and applies to the APVMA for off-label permits. This allows rapid turnaround of off-label permits for the short poppy growing season (refer to Appendix A-1 for details).

3.1.9 Audits and corrective actions

Auditing practices across QA schemes are generally set at a minimum of one internal audit, and one external audit by an accredited auditor, per year (this is the case for ESA, NFAS, APIQ✓®, Graincare and Freshcare). ESA further allows unannounced audits to be performed where a complaint is received from an outside party. The NFAS has the most rigorous audit schedule of the schemes reviewed, with additional potential for unannounced audits and "witness" audits to ensure consistency across the auditing process. The non-formal QA schemes (codes of practice) do not stipulate audit requirements.

The schemes vary as to whether auditors are trained according to standards stipulated in the scheme, are part of a wider auditing group, or are part of a national auditor accreditation body. Where co-regulation arrangements are in place between QA schemes and state regulators, growers have fewer audits as government and industry audits are conducted either concurrently or by only one party with subsequent sharing of information (refer section 3.1.11).

The audit sections within the QA schemes also include requirements for corrective action reports (CARs) to be recorded and maintained. The consequences of non-compliance are outlined, with major non-compliance or recurring non-compliance resulting in loss of accreditation in some schemes. Follow-up audits are generally required to ensure that corrective actions are implemented for all auditable quality assurance schemes. In general, schemes include time periods in which corrective actions need to be completed. For example, ESA requires corrective actions to be implemented within three months for a minor corrective action, and one month for a major corrective action and all corrective actions are required to be closed out by an auditor.

3.1.10 Compliance reporting

The two quality assurance schemes reviewed which have agreements with state governments (APIQ✓® and NFAS, detailed below in Section 3.1.11) are required to report non-compliances to the relevant government department on a confidential basis. While schemes generally do not publish reports on their operations because the information is deemed commercially sensitive, NFAS publishes an annual report of performance on its website, with the report including details of non-conformance.

A further exception is Tasmania Alkaloids which is a highly controlled scheme in which compliance reporting to regulators is mandatory.

3.1.11 Complementarity with regulatory jurisdictions

In general, state/territory agvet chemical regulations are considered to be the base requirements for all QA schemes, and as such the schemes are considered to complement regulatory requirements. There do not appear to be any areas of direct conflict between QA scheme requirements and agvet chemical legislation, despite the fact that the schemes are usually nationally based while regulations vary between jurisdictions. Scheme administrators identified that the QA schemes are not overly prescriptive because of the need to operate across jurisdictional boundaries. Record keeping and training requirements were identified as the main areas where similarity lies between requirements of quality assurance schemes and state legislation.

APIQ✓® and NFAS currently have co-regulatory arrangements in place with some states, and these arrangements demonstrate the potential for complementarity for other schemes in the future.

APIQ✓® currently has a Memorandum of Understanding (MoU) in place with the Victorian State Government and this allows producers with APIQ✓® certification to be audited only once, rather

than by both parties each year. APIQ✓® provides the state government with an annual report which summarises the number of growers participating in the scheme, the number of non-compliances and corrective actions issued to growers (on a confidential basis).

The NFAS has approved arrangements with the Victorian and Queensland governments in which all breaches of legislative requirements uncovered by NFAS audits are reported to, and designated the responsibility of, the relevant state authority. The MoU with the Queensland Government gives Queensland NFAS accredited feedlots a discount on their environmental licence fee. Joint audits of selected feedlots by the Queensland Department of Agriculture and Fisheries and AUS-MEAT auditors ensures consistency in standards between the two organisations.

With respect to the environment (i.e. in addition to any agvet arrangement) the Victorian Environmental Protection Authority (EPA) recognises NFAS audits as satisfying environmental auditing requirements for feedlots in Victoria. The Victorian Government has further approved AUS-MEAT (the NFAS auditor) under the *Livestock Management Act* as the Controlling Authority for determining that certified NFAS operators comply with the state's environmental standards.

3.1.12 Future directions

Consultation with quality assurance scheme administrators identified several strengths, weaknesses and gaps of the QA schemes along with some insight as to the underlying purpose of the scheme. The details of this consultation is included in Appendix 1 from discussion with administrators in the templates for each scheme. An analysis of these insights with further analysis of the potential of each scheme is included in section 7.

3.2 Comparative analysis of QA schemes

GHD constructed a rubric of each of the elements within the QA schemes that were important with respect to the control of use of agvet chemicals. A summary describing each element under assessment is provided in Table 2 below. This approach provides a semi-quantitative comparison of the elements between each of the QA schemes with the aim of providing insight into the future acceptance of schemes within a co-regulatory or complementary role with regulators.

Table 2 Summary of elements used to construct the rubric

QA Scheme Element	Description
Structure and operation	The details of the rules and standards related to agvet control of use, including the various modules and elements included and the standards required. May include performance indicators and scheme outlines may be publicly available to provide transparency.
Process for setting rules and standards	Schemes have varying arrangements for setting rules and standards - from reliance on industry only bodies to formal committees with members from industry, state/territory government regulatory agencies and independent experts.
Reference to international standards	Schemes may rely solely on standards set internally by the industry through to those which reference international standards, including WHO and FAO Codex Alimentarius standards.
Requirements for designated QA staff	Schemes may be silent on the required number of staff designated to perform QA roles through to the number specified according to the size of operation and described competencies.
Training	Schemes generally include requirements that individual staff are trained to the minimum standard required by agvet chemical regulations. In addition, schemes can nominate that staff

QA Scheme Element	Description
	demonstrate competence and also require additional QA training programs organised by the industry.
Record keeping	Agvet chemical users are required by regulation to keep certain use records. QA schemes may require more detailed records to be kept and maintained with various requirements on records being legible and retrievable. Also, records of audits and tracking of corrective actions may be stipulated.
Residue risks and testing	The registration of agvet chemicals by the APVMA includes a risk assessment that usage as directed will result in acceptable product residues. The National Residue Survey (NRS) samples and tests products, at industry expense, to confirm residue levels and thereby support access to international markets. QA schemes may require additional individual enterprise monitoring and processes for reporting adverse findings to state/territory regulatory authorities.
Off-label chemical use	Use of agvet chemicals outside of the conditions of registration. Off-label use may be allowed under an APVMA minor use permit, or through state and territory legislation.
Audits and corrective actions	Schemes generally specify audit frequencies and requirements on the use of internal and/or external auditors. In addition, audits may be announced or unannounced and there may be directions on corrective actions for non-conformance and penalties depending on the severity of non-conformance.
Compliance reporting	Schemes have variable requirements for reporting on the level of compliance, including the percentage of members with Corrective Action requirements. Some schemes publish performance reports which are publicly available.
Complementarity with regulatory jurisdictions	Schemes may operate completely independently of regulators or include Memorandums of Understanding (MoUs) and/or Approved Arrangements providing co-regulation with states/territories whereby membership and certification within a scheme is deemed to satisfy regulatory requirements without additional compliance activities.
Future directions	Schemes may be relatively static in reviewing rules and standards while others complete gap analyses and revise elements in efforts to proactively adapt to changing market and regulatory requirements.

Table 3 provides the rubric for each of the above elements. The classification and scoring ranges from situations in which QA schemes provide zero or minimal detail for the particular element (score = 0) through to a comprehensive description and associated increased confidence that the scheme has effective rigour for the element with respect to the control of use of agvet chemicals (score = 4).

Table 3 Rubric for comparison of QA schemes

QA Scheme Element	Score 0	Score 1	Score 2	Score 3	Score 4
Structure and operation	Not documented	Management arrangement between individual growers and purchaser/processor	Standardised national industry-wide management arrangement between growers and purchaser/processor	National, industry-wide QA scheme, with rules and standards, may or may not be publicly available document	National, industry-wide QA scheme, publicly available document with rules and standards, include Performance Indicators. Includes references to national standards and codes
Process for setting rules and standards	None	Product purchaser/processor sets grower standards	Product purchaser/processor and industry body jointly set grower standards	Industry and state/territory government regulatory agency members on committee	Industry, state/territory government regulatory agency and independent expert(s) as members of committee
Reference to international standards	No reference to national or international standards	Reference to one or more national standards	Reference to national standards and international trading bodies	Developed with reference to WHO and FAO Codex Alimentarius standards	Compliant with one or more WHO and FAO Codex Alimentarius standards
Requirements for designated QA staff	No reference to requirements for QA staff	General requirement that all staff are trained in quality assurance	Requirement for designated QA staff in the enterprise	Number of designated QA staff specified based on size of operation	Number of designated QA staff specified based on size of operation with specifically described responsibilities
Training	No training beyond state/territory legislated agvet requirements.	QA scheme outlines training requirements for the enterprise and staff in relation to agvet chemicals but training is not delivered.	QA scheme outlines training requirements for the enterprise and staff in relation to agvet chemicals, with training undertaken but in an *ad hoc* manner without competency testing	The enterprise and staff are trained in sound practical skills in relation to agvet chemicals and required to demonstrate competence	The enterprise and staff are trained in sound practical skills in relation to agvet chemicals and required to demonstrate competence. Staff attend additional QA training programs organised by the industry.

QA Scheme Element	Score 0	Score 1	Score 2	Score 3	Score 4
Record keeping	Not documented – assumed that minimum as required by state/territory legislation	Rudimentary records completed	Detailed records kept and maintained	Detailed records kept and maintained. Records are legible and retrievable. Records of audits and tracking of corrective actions	Detailed records kept and maintained. Records are legible and retrievable. Records of audits and tracking of corrective actions. Records maintained electronically and synchronise to QA scheme database
Residue risks and testing	Not undertaken or documented	Minimum requirements at industry level via NRS (National Residue Service)	NRS plus additional individual enterprise monitoring	NRS plus additional individual enterprise monitoring for internal corrective action	NRS plus additional individual enterprise monitoring and a process for reporting adverse findings to state/territory regulatory authorities
Off-label chemical use	No reference to off-label use	Reference to off-label use but with no directions on processes required	Off-label use requirements clearly documented	Off-label use requirements clearly documented with examples of permits and other authorisations listed	Evidence of current APVMA permits and/or authorisation by approved practitioner e.g. vet
Audits and corrective actions	Not documented	Unspecified audit frequency by internal auditors only	Unspecified audit frequency by external auditors. Audits announced. No formal recognition of auditors by regulatory authorities	Specified audit frequency (minimum annually) by external auditors recognised by regulatory agencies. Potential for unannounced audits. Clear corrective actions for non-conformance, with penalties for critical incidents.	Specified audit frequency (minimum annually) by external auditors recognised by regulatory agencies. Potential for unannounced audits, “witness” audits conducted to ensure auditor training/consistency. Clear corrective actions for non-conformance, with penalties for critical incidents. Corrective actions completed.
Compliance reporting	No reporting of scheme performance	Ad hoc reports of scheme performance	Annual report of the performance of the QA scheme - confidential	Annual report of the performance of the QA scheme, publicly available	Annual report of the performance of the QA scheme, publicly

QA Scheme Element	Score 0	Score 1	Score 2	Score 3	Score 4
					available. 3-5 year external review of scheme performance
Complementarity with regulatory jurisdictions	Conflict exists between QA scheme and legislated agvet chemical requirements	No conflicts identified but large gaps exist between legislated and QA agvet regulation requirements	Some small gaps exist between QA scheme and legislated agvet regulation	QA scheme deemed at least as rigorous as legislation, with the potential for co-regulation	QA scheme deemed rigorous enough in agvet chemical application to allow co-regulation and a co-regulation agreement is currently in place
Future directions	No assessment of future direction	Ad hoc assessment of gaps and potential update to existing standards	Formal internal assessment of gaps and a documented process of change	Formal industry/regulator assessment of gaps and a documented process of change – for internal use only	Publicly available report lists improvements to be implemented based on gap analysis and the need to continually adapt to changing market and regulatory requirements

Table 4 provides GHD's scoring for each QA scheme based on the rubric classification adopted in Table 3 above and the detailed descriptions of each of the schemes at Appendix A. We have avoided including a score total for each QA scheme because of gaps in the information available and a zero (or low) score may incorrectly indicate poor performance with respect to agvet chemical control when that is not the case. We have used the term "not verified" (NV) in the table where gaps exist.

Notwithstanding some data gaps, the information in Table 4 provides a sound basis for analysis of the potential of scheme elements, within a future co-regulatory framework, for the control of use of agvet chemicals. Specifically, the scoring rubric could be used to help determine policies in relation to: a) the level or standard required for elements/schemes to be 'recognised' in a co-regulatory sense; b) what activities at the state/territory and at the APVMA levels could be streamlined or potentially ceased; and c) mechanisms to monitor arrangements over time, with clear incentives for participating QA schemes. This is explored further in section 7.

Table 4 Scoring of QA scheme based on rubric classifications

QA Scheme Element	Tasmanian Alkaloids	ESA	NFAS	APIQ✓®	Graincare	COSOP	Freshcare
Structure and operation	2	3	4	4	3	0 (Best practice guidelines)	4
Process for setting rules and standards	4	2	3	2	2	4	2
Reference to international standards	2 (International Narcotics Board)	0	3	2	2	2	2
Requirements for designated QA staff	1	0	4	1	0	NV	2
Training	1	NV	4	2	4	NV	4
Record keeping	4	3	4	3	3	2	3
Residue risks and testing	4	1	4	1	1	1	3
Off-label chemical use	4	0	4	2	2	3	3
Audits and corrective actions	NV	4	4	3	3	NV	4
Compliance reporting	NV	NV	3	2	NV	NV	NV
Complementarity with regulatory jurisdictions	3 (controlled by regulators)	2	4	4	2	1	3
Future directions	NV	NV	4	4	0	4	NV

4. Regulators and QA schemes

As described in the methodology (section 2), regulatory functions of the state and territory governments and the APVMA were investigated with respect to the nominated QA schemes and control of use of agvet chemicals. Section 4.1 summarises the consultation findings with the regulators.

4.1 Consultation findings and analysis – Regulators

A desktop review was undertaken of the legislation and regulatory controls operating in each state followed by targeted consultation with the relevant regulators in each state. A set of standard questions were posed to each regulator and below is a collated summary of those responses.

4.1.1 Structure and operation

Generally, state regulators have only a general understanding of the various QA schemes, with some more detailed understanding of schemes operated by the larger commodity sectors (NFAS and Freshcare). They consider that the major supermarkets operate their own rigorous schemes with a focus on residue testing. As the information is usually treated as commercial-in-confidence there is limited information sharing with regulators. This project did not uncover instances where state regulators stated they would obtain value from this information.

4.1.2 Reference to international standards

Regulators have only limited knowledge of the international standards referenced within the QA schemes, although there was general awareness that some schemes would be referenced to international bodies in either setting the standards or for certification roles.

4.1.3 Training

With the exception of NSW, training and competency arrangements to manage agvet chemical risks are not currently mandated by the states except for the use of *Schedule 7* restricted poisons and for restricted chemical products (usually require attainment of level 3 competencies). NSW is currently in the process of repealing the *Pesticides Act 1999* and replacing this with a new Regulation 2017 that will include options for training requirements to ensure that users' qualifications and competency align with the risks associated with chemical use. One potential option is for agvet chemical users that are participating in a recognised industry-owned QA scheme to be exempt from undertaking re-training that is currently required at five-yearly intervals across several jurisdictions.

Regulators stated that training and competency in agvet chemical use are routinely stipulated in QA schemes, however regulator audits in some jurisdictions have found that users of agvet chemicals had not completed the necessary training and had not been adequately trained in their use. This suggests potential differences in perceptions between regulators and QA scheme operators.

States and territories are responsible for determining training requirements for agvet chemical users, however differences between states result in variable training requirements between states for a single chemical. Where incorrect use of agvet chemicals poses a high risk, as part of the registration process the APVMA can deem a product to be a restricted product, with jurisdictions then responsible for determining who is authorised to use it. The specific training requirements (if any) for such restricted products also rests with each jurisdiction and can differ.

It should be noted that at the recent Agriculture Ministers' Forum, ministers re-committed to the development of nationally consistent regulation of agvet chemicals and agreed to specific proposals around record keeping and training requirements (Agriculture Ministers' Forum, 2017).

4.1.4 Record keeping

Regulators acknowledged that the record keeping requirements for the QA schemes at the individual and enterprise level were generally very good and either align with or exceed the mandatory record keeping requirements as per the legislative requirements of the relevant state or territory.

It was recognised that the QA schemes require record keeping to be maintained. However for a few schemes the records did not go into sufficient detail relating to, for example, chemical names, weather conditions, wind directions, spray quantities etc. if the recording template did not specify that level of detail.

The APVMA may include mandatory record keeping requirements on labels for high risk chemicals or modes of application, such as for products subject to spray drift buffers. Some jurisdictions do not have additional requirements to keep records.

One regulator also noted that there is an anomaly in its regulation on the need to keep records of agvet chemicals that are not a direct application to a specific crop, for example when spraying crop perimeters.

As described above for training, agriculture ministers re-committed to the development of nationally consistent regulation of agvet chemicals and agreed to specific proposals around record keeping (Agriculture Ministers' Forum, 2017).

4.1.5 Residue risks and testing

With respect to chemical residues, regulators tend to be reactive and only become involved when there is a residue detection, for example from the NRS or when notified by external parties, such as a major retailer. In most jurisdictions (with the exception of Queensland), there is no requirement to directly notify the regulator of a non-compliance with respect to chemical residues. Regulators usually include the APVMA in addressing residue detections if it appears that residues are a result of use in accordance with label or permit instructions.

Exceptions to the above occur in Victoria and Queensland with both states funding their own residue detection programs to address those sectors they deem not to be adequately covered by the NRS. The Victorian scheme includes a trace back mechanism to the source of the problem to identify and rectify the cause. Queensland has a rigorous testing regime and legislation that requires supply chain participants to report any adverse residue test if detected.

Regulators in states/territories where residue testing is not as rigorous as Queensland and Victoria raised concerns about the validity and reliability of the sampling by growers and the suite of chemicals tested. They considered that certain QA schemes place the onus for collection and submission of samples on the grower and this enables selective sampling for testing. Concerns were also raised that non-compliances are not required to be reported to regulators who are then not aware of the issue unless reported by the NRS.

The APVMA works closely with the NRS on an informal basis and any unusual detections associated with use in accordance with label or permit instructions may prompt an APVMA chemical review. Private companies and QA schemes can do their own private testing but results are not required to be forwarded to the NRS. Residue detections by the major retailers can also have serious consequences for contracted growers.

4.1.6 Off-label chemical use

Off-label agvet chemical use refers to situations when a chemical is used in a manner that is not specified on the chemical's product label. Australian governments are collaborating to further harmonise arrangements for off-label agvet chemical use.

Unless state or territory legislation allows conditional access (see below), off-label use requires a minor use permit, via the APVMA, to allow for a range of uses, including:

- an unregistered product;
- a chemical product used at a rate higher than maximum rate on the label for that use;
- a chemical product used more frequently than the use intervals specified on the label for that use;
- uses in crops and situations not approved on the label;
- new application equipment; and/or
- a chemical product contrary to a specific restraint statement on the product label.

Generally it is illegal to use Schedule 7 chemicals off-label unless a permit has been issued authorising that use by the APVMA. There are variations between states and territories as to specific regulatory control requirements for restricted chemical use within each jurisdiction, including Schedule 7 chemicals (see Appendix B).

In most jurisdictions, while it is an offence to use a registered chemical product other than in accordance with its label conditions, there are some broad exceptions to this including:

- using a lower concentration, rate or frequency than specified on the label;
- applying the chemical to a different pest for the same crop than specified;
- using a different application method than specified;
- mixing a chemical with another chemical or fertiliser, provided the label does not expressly prohibit it.

In Queensland, these exceptions are referred to as ‘permitted off-label uses’.

South Australia allows for off-label use under an exemption scheme for the horticulture industry. It was introduced in 2004 because there were no APVMA permits for a substantial number of existing minor uses. To qualify, the grower must be part of a QA scheme, and the QA scheme must be approved by the SA Government. The exemption scheme does not cover major crops which will be exported, and exemptions for off-label use are not always granted.

Jurisdictions also raised concerns that the QA schemes do not specifically address off-label agvet chemical use, and as a result such use is generally not checked as part of the routine audit process and may only come to light if an issue arises.

4.1.7 Compliance reporting

Compliance and enforcement of QA schemes by regulators is not undertaken as the QA schemes are self-regulating and undertake their own compliance and enforcement. Compliance and enforcement by regulators is the same for all agvet chemical users except where MoUs are in place. For instance, NSW has not explored the opportunities for working with QA schemes on co-regulatory approaches.

It was acknowledged that compliance of the QA schemes by regulators would not only be challenging, but could also be seen as a negative if growers perceived that governments were too involved and could also lead to a lack of trust between government and industry. Regulators also raised concerns that the QA schemes do not appear to have mechanisms for identifying ongoing persistent problems.

5. Industry organisations

As described in the methodology (section 2), the study included examining the attitudes of industry organisations with respect to the nominated QA schemes and regulatory activities associated with agvet chemical control of use. Section 5.1 below summarises the consultation findings with the industry organisations.

5.1 Consultation findings and analysis – Organisations

5.1.1 Understanding of nominated QA Schemes

The understanding of the nominated QA schemes varies amongst the stakeholders consulted. A number have little understanding or involvement with the QA schemes, but all were generally supportive of industry based schemes. A limited number had detailed knowledge as they have had extensive involvement in the drafting of the standards and rules that underpin selected schemes. Industry stakeholders recognised the importance of these schemes to ensure access to international markets, and while the schemes might not reference specific international standards, the schemes must instead be acceptable to each of the international markets.

5.1.2 Off-Label use

Chemical industry stakeholders were not supportive of off-label use for a variety of reasons. These included potential damage to the reputation of the product chemistry and thereby damage to social licence, with inappropriate use of the agvet chemical being the cause of the adverse impact and not necessarily the underlying chemistry. Other chemical industry stakeholders cited the strictness of the label conditions developed by the APVMA, although in large part these are developed in consultation with the applicant and state regulators. This contrasts with producer stakeholders who consider that minor use chemicals need to be readily available as long as their safety has been determined from suitable evidence-based research.

For food producing animals, veterinary surgeons are authorised to use veterinary medicines off-label under prescribing rights and the owner is required to adhere to the necessary withholding periods. For non-food producing animals, the veterinary surgeon has absolute discretion unless it is a restricted product. Other issues cited within the livestock sector included the difficulties with registration of agvet chemicals for use not being available for multiple species (e.g. products registered for sheep but not goats) or for ancillary uses (e.g. Trisolfen is registered for pain relief for mulesing but not for general pain relief, for example for dehorning or castration in cattle).

Legislative differences with off-label use across jurisdictions poses challenges for QA scheme auditors.

5.1.3 Auditing, compliance and enforcement

Stakeholders made suggestions on improvements to the auditing processes of the QA schemes, and the adoption of HARPS in 2016 for fresh produce is an example of where the audit process was simplified. This resulted in the avoidance of the need to implement, maintain and be audited by multiple systems that are largely similar, including bespoke additional requirements that were time consuming, stressful and expensive. In addition, the availability of competent auditors was limited. The need to have a single audit of a base scheme plus HARPS that will satisfy all retail customers is estimated to lower costs, provide greater efficiencies in quality assurance and improve food safety outcomes across the entire fresh produce supply chain. It will also have positive outcomes for the certification sector, including improved retention of auditors.

The increasing adoption of digital technology could also be beneficial in completing audits and demonstrating compliance with all the elements of the QA schemes. The use of cloud software could provide real time access to check agvet chemical use. Confidence in remotely accessing records would reduce the requirements for auditors to be physically on site.

Increasing the frequency of unannounced audits was also suggested as a way to improve the integrity of the system with the GFSI Benchmarking Requirements (7th Edition) looking to incorporate unannounced audits to increase transparency and objectivity, for example with unannounced audits occurring once every 3 years with 24 hours' notice provided. At the same time, the continuation of announced audits is considered by some to promote continuous improvement in practices associated with agvet chemical use.

6. Review of overseas QA schemes

The following overseas QA schemes have been reviewed, as follow up to the QA schemes referenced by stakeholders during the consultation process.

6.1 Canada

The Canadian Food Inspection Agency (CFIA) recently announced its new policy related to private certification schemes in the context of food safety. Private certification schemes are voluntary systems that set process and product requirements as well as the means of demonstrating conformity with these requirements. Private certification schemes are a prominent part of the world food supply system and are increasingly being used by the food industry as a means of achieving food safety and other outcomes.

CFIA will use this information for risk-based planning and prioritisation within the regulatory framework, resulting in a more targeted compliance verification. CFIA points out that private certification is not intended to replace regulatory enforcement authorities; however, it may complement food safety regulatory oversight. CFIA will continue to verify compliance of regulated parties; the type, frequency, and intensity of the CFIA's oversight activities will be proportional to the risks that need to be managed. This new policy will initially apply to program design and delivery of CFIA's risk-based oversight of domestic and imported food, as it relates to food safety. However, CFIA is committed to expanding the scope to other aspects (such as labelling) and the plant and animal health programs, as applicable.

In implementing its new policy, CFIA will give consideration to four different categories of food safety certification schemes to accommodate the complexity and size of businesses.

6.1.1 Category 1 - CFIA-Assessed Programs

Any organisation/establishment that has completed evaluation by the CFIA for Food Safety Recognition Program (FSRP) is considered to meet CFIA food safety regulatory requirements. No further assessment is required. CFIA will consider certifications to FSRP within its risk-based assessment continuum.

6.1.2 Category 2 & 3 - International Private Certification Schemes

Category 2 schemes such as the Global Food Safety Initiative (GFSI) and the International Organisation for Standardisation (ISO) Food Safety Standards and the Category 3 scheme Hazard Analysis and Critical Control Point (HACCP) are recognised.

Certification to a GFSI-recognised food safety scheme, an ISO food safety standard and HACCP are certifications achieved without regulatory oversight. The CFIA has analysed the oversight or governance structure that exists within industry for the majority of such schemes and has concluded that the accredited certification oversight structure provides the CFIA with the confidence certification results are within the CFIA's risk-based assessment continuum.

6.1.3 Category 4: Other Private Certification Schemes

Where the oversight requirements for a private certification scheme do not fit one of the categories identified above, CFIA will undertake an assessment of the oversight structure that is in place to establish whether the CFIA has confidence in the oversight structure, and by extension, the certification result.

6.2 Denmark

Danish food safety legislation often exceeds that of other EU Member States, with full support of the industry. However, fulfilling legal requirements is only part of a wider remit and the delivery of high standards of food safety requires industry to take full responsibility for food safety.

The Danish commitment to producing safe food has been achieved through co-operation between farmers, the food industry and authorities, backed by an extensive program of research and development. Although strict controls have been a hallmark of the Danish approach, the industry has often been in advance of new food safety legislation. A good example is the Danish Salmonella Action Plans for pig meat, beef, poultry and eggs, which operate at each stage of the production chain and have been in operation since 1995.

At farm level, many strategies have been implemented to maintain healthy herds. Such programs reduce the presence of zoonoses as well as imposing strict biosecurity measures to prevent any spread of animal disease. Many Danish producers have a formal Health Advisory Agreement with their local veterinarian. A strategy is also in place to eliminate any unnecessary use of veterinary medicines. A high level of animal health therefore coexists with one of the lowest usages of medication among major livestock producing countries. The use of pesticides on all crops, including those grown for livestock feed, is also strictly controlled by legislation. Extensive surveillance programs confirm that residues in Danish meat (generally consistent with residues in Australian animal products) are virtually non-existent. Meat production is controlled by self-audit procedures in accordance with HACCP principles. Industry is responsible for the production of safe food, while the authorities perform a supervisory role ensuring that the agreed procedures are followed.

For some years there has been growing public concern about the development of antibiotic resistant bacteria. Although a separate issue is the use of antibiotics in the human population, the Danish agricultural industry acknowledges its responsibility to minimise the use of antibiotics in the rearing of its livestock. In addition to the initiatives taken to reduce use of veterinary medicines, the industry also stopped the use of all antibiotic growth promotants in 2000, six years ahead of the ban implemented across all EU Member States.

6.3 United Kingdom

The United Kingdom Accreditation Service (UKAS) is the national accreditation body for the United Kingdom, appointed by government, to assess organisations that provide certification, testing, inspection, and calibration services.

UKAS accreditation ensures that consumers, suppliers, purchasers and specifiers can have confidence in the quality and safety of goods, and in the provision of services throughout the supply chain. UKAS accreditation demonstrates that all aspects of this process can be evaluated, ensuring public safety and providing assurance that products and water are safe for consumption.

Samples, products, services, management systems or personnel can be evaluated against specified requirements by laboratories, certification bodies, and inspection bodies (collectively known as conformity assessment bodies). Conformity assessment is used to check that products are fit and safe for consumption against a standard, a code of practice or regulatory requirements.

6.3.1 Laboratories

UKAS accredits food and water testing laboratories to ISO/IEC 17025; *General requirements for the competence of testing and calibration laboratories* against a wide range of chemical and

microbiological scopes. The range of accredited scopes also includes packaging and environmental testing, sensory analysis, plant health, and veterinary microbiology.

6.3.2 Certification and inspection bodies

UKAS accredits certification bodies to provide compliance to food and water companies throughout the supply chain. These include UK Food Quality Assurance schemes, Red Tractor Assurance Schemes, BRC global standards, GlobalG.A.P. Integrated Farm Assurance, the Label Rouge Product certification scheme, Organic certification and HACCP. UKAS also accredits certification bodies to provide Food Safety Management Systems Certification to ISO 22000.

Inspection bodies are accredited to ISO/IEC 17020: *Requirements for the operation of various types of bodies performing inspection* throughout the supply chain in the provision of safe food and clean drinking water. This includes the inspection of pre-shipment, plant health, meat and slaughterhouses, and hotels.

6.3.3 Proficiency testing and reference material producers

UKAS accredits Proficiency Testing (PT) Providers for a range of chemistry and microbiological schemes to ISO/IEC 17043: *Conformity assessment - General requirements for proficiency testing*. These schemes involve food and water components, contamination and authenticity.

UKAS also accredits Reference Material Producers (RMP) to ISO Guide 34 for a number of materials including drinks, foodstuffs, animal feed, herbal medicines, and water.

6.4 Global Food Safety Initiative (GFSI)

The Global Food Safety Initiative (GFSI) brings together key actors of the food industry to collaboratively drive continuous improvement in food safety management systems around the world.

With a vision of “Safe food for consumers everywhere”, food industry leaders created GFSI in 2000 to find collaborative solutions to collective concerns, notably to reduce food safety risks, audit duplication and costs while building trust throughout the supply chain. The GFSI community works on a volunteer basis and is composed of the world's leading food safety experts from retail, manufacturing and food service companies, as well as international organisations, governments, academia and service providers to the global food industry.

Its collaborative approach brings together international food safety experts from the entire supply chain at Technical Working Group and Stakeholder meetings, conferences and regional events. They share knowledge and promote a harmonised approach with a shared vision of safe food for consumers everywhere.

Strategic direction for GFSI is provided by an industry-driven GFSI Board of Directors from retailers, manufacturers and food service operators. GFSI does not have a “membership” system as such; it is an open forum for collaboration comprised of various stakeholders associated with the food supply chain. The daily management of GFSI is undertaken by the Consumer Goods Forum (CGF), a global, parity-based industry network, driven by its members.

6.5 GlobalG.A.P.

GlobalG.A.P. is a worldwide standard for Global Good Agricultural Practice with the objective of safe, sustainable agriculture worldwide. It sets voluntary standards for the certification of agricultural products, encouraging producers, suppliers and buyers to harmonise their certification standards to GlobalG.A.P.

The purpose of GlobalG.A.P. is for members to create private sector incentives for agricultural producers worldwide to adopt safe and sustainable practices. Their mission is to globally connect farmers and brand owners in the production and marketing of safe food to provide reassurance for consumers through good agricultural practice.

GlobalG.A.P offer three main certification products named “localg.a.p”, “GLOBALG.A.P.” and “GLOBALG.A.P.+ Add-on”:

- GLOBALG.A.P. offers 16 standards for three scopes: Crops, Livestock, and Aquaculture
- localg.a.p. and GLOBALG.A.P.+ Add-on offer programs for developing customised solutions for members

GLOBALG.A.P. has more than 530 certified products and over 170,000 certified producers in more than 120 countries and works with more than 1,800 trained inspectors and auditors working for 154 accredited certification bodies to perform independent third-party producer audits and issue certificates. There is also an online database of certified producers.

GlobalG.A.P. also has a harmonisation program to benchmark international schemes and standards. Further information on GlobalG.A.P quality assurance may be found in Appendix A-10.

7. Analysis of the potential of QA schemes to support agvet chemical regulation

The above sections (and accompanying appendices) provided a description of selected QA schemes and their role in the control of use of agvet chemicals. The degree to which each scheme addresses a number of elements in support of the responsible use of agvet chemicals was provided by a rubric that provided a range of attributes, with the assumption that QA schemes with higher rubric scores were more likely to demonstrate aspects of agvet chemical use that would provide increasing confidence by the market of the safety of the produce, the environment and the workforce.

While the rubric is an imperfect tool for categorically stating that QA schemes with higher scores for each element result in increased assurance that produce meets the required standards for the use of agvet products, it sets parameters that can be used in discussion with regulators of the likelihood that certified scheme participants satisfactorily meet (and potentially surpass) regulatory requirements.

The results of the rubric can be combined with views of each of the stakeholder groups that were consulted for the project on the role of the various QA schemes and the issues that were raised with respect to regulation.

7.1 Summary of desktop and consultation findings

Table 5 provides a summary of the desktop and consultation findings which specifically addresses the potential of QA schemes to support agvet regulation. While there is clear evidence of complementarity between the schemes and state/territory regulation, there are several gaps which would need to be carefully considered.

The strengths and weaknesses of the various elements of the QA schemes to support agvet chemical regulation are further addressed in section 7.2.

Table 5 Summary of desktop and consultation findings

QA Scheme Element	QA Scheme Operators	Regulators (states and territories)	Industry Organisations*
Structure and operation	• Varies depending on the industry • Broad enough to allow for differences in state regulations which also makes restrictions different for growers in different areas	• Regulators have varying knowledge of the QA schemes and are therefore uncertain of the schemes' ability to provide or supplement control of use • Jurisdictions adopt different approaches to QA schemes that limits their national application	• Generally little knowledge of specific QA schemes
Process for setting rules and standards	• QA schemes are market-driven which can enforce extra measures on growers • Generally remains broad enough to allow jurisdictional differences • Respond to changes in the industry or in public perception quickly	• Legislation is specific to the jurisdiction in question • Lack of resources and evidence can make changes to legislation slow to implement	• Consider that APVMA chemical permitting and registration processes are slow which can disadvantage Australian growers • Can represent growers or smaller industry organisations, particularly for unified applications to the APVMA for chemical registration
Reference to international standards	• Quality standards commonly employed • HACCP food safety system commonly employed • Reference to standards despite not adopting the standards	• Access to overseas markets facilitated from a government perspective through the National Residue Survey which gives confidence overseas, not via international standards	• No specific comments
Requirements for designated QA staff	• Variable • National Feedlot Accreditation Scheme (NFAS) very prescriptive • Codes of Practice silent	• No specific comments	• No specific comments
Training	• QA schemes generally include a comprehensive training element • Some require demonstration of competence	• National minimum training requirements are being established for all users of restricted chemical products and poisonous (Schedule 7) agvet chemicals	• No specific comments

QA Scheme Element	QA Scheme Operators	Regulators (states and territories)	Industry Organisations*
Record keeping	• All have minimum requirements with templates that comply with regulations • Some include more prescriptive evidence of records	• Regulators recognise the value of QA schemes in assisting to ensure good record keeping	• Information sometimes passed to industry organisations • Information within some organisations generally commercially confidential and not passed on
Residue risks and testing	• Varies by industry with the default being NRS, which supports international market access • Some QA schemes require individual to perform residue testing	• Concerned that selective samples are submitted for testing • Often late to learn of adverse residue results	• No specific comments
Off-label chemical use	• While schemes may be silent on off-label use, they support the permit approach incl. working with the APVMA in support of applications	• Variable regulations by jurisdictions potentially leads to confusion within nationally-based QA schemes • The Australian Government and the states and territories are exploring how to further harmonise off-label use	• Do not support off-label use unless under an APVMA permit because of potential reputational damage (see section 5.1.2)
Audits and corrective actions	• Internal and external auditing required • Announced and unannounced audit regimes • Sanctions for delays in completing corrective actions	• Auditing of growers by regulators not generally performed unless issues are flagged through residue testing • Regulators are divided as to whether co-regulation with QA schemes could reduce regulatory compliance visits	• Consider that unannounced audits are essential to ensure transparency and acceptance by consumers • Announced audits useful for continuous improvement by producers
Compliance reporting	• Very few schemes publicly report compliance (NFAS is one) • APIQ✓® and NFAS report according to MoUs	• Regulators are concerned that there is no requirement to report compliance issues (except where MoUs are in place)	• No specific comments
Complementarity with regulatory jurisdictions	• Examples where regulators accept certified producers as meeting jurisdictional requirements (MoUs)	• Regulators recognise that QA schemes may impose additional requirements on growers above regulatory requirements	• Support for efforts to avoid duplication to improve efficiency and cost effectiveness

QA Scheme Element	QA Scheme Operators	Regulators (states and territories)	Industry Organisations*
		• Acceptance by some jurisdictions of equivalence (or better) of certified producers complying with regulations	of schemes while still providing assurance to consumers
Future directions	• Market forces require continual adaptation by schemes to ensure they meet changes in consumer requirements concerning agvet chemical use	• Regulators recognise the adaptive requirements for QA schemes	• Organisations recognise the adaptive requirements for QA schemes

* Note that some industry responses may be contradictory as the groups consulted represent different sectors of the agricultural industries

7.2 Strengths and weaknesses of QA schemes in supporting agvet chemical control of use regulation

Consultation with the various stakeholders identified in this report indicated that the characteristics of a quality assurance scheme underpin its potential for supporting agvet chemical regulation. Several administrators highlighted strengths of their scheme, while regulators typically indicated potential issues. Table 6 below and the following sections highlight the key characteristics of quality assurance schemes which are required for the scheme to potentially harmonise agvet chemical regulation in the relevant industry, and the weaknesses that lie within various structures of existing Australian quality assurance schemes.

Table 6 Strengths and weaknesses of QA schemes to support agvet chemical control of use regulation

QA Scheme Element	Current and potential aspects that support regulation	Strengths	Weaknesses
Structure and operation	Current • All QA schemes include agvet chemical use as a component • Individual schemes vary in the extent of requirements (training, reporting etc.) however, it is understood that the majority reflect, at a minimum, state/territory regulations Potential	• QA schemes recognise the importance of agvet chemical use as a component of their operations • Schemes apply nationally • Supply contracts could include QA scheme membership as a requirement (pseudo compulsory)	• Some schemes lack definitive statements and/or performance indicators demonstrating compliance with regulations in all jurisdictions • Schemes are voluntary and represent a proportion only of the particular produce

QA Scheme Element	Current and potential aspects that support regulation	Strengths	Weaknesses
	• Include more explicit statements of the complementary role between schemes and regulation		
Process for setting rules and standards	Current • Schemes vary in the composition of boards/committees for setting rules and standards • Many have industry, government/regulator, research and consumer representatives in official and unofficial capacities Potential • Include regulators as members of rules and standards committees	• A multidisciplinary team ensures all perspectives of agvet chemical use are included	• Schemes are industry-based and may be reluctant to accepting government/regulator inputs
Reference to international standards	Current • Many schemes either adopt international standards or make reference to these standards Potential • More widespread adoption and reference to international standards to promote harmonisation	• International schemes such as GFSI and GLOBALG.A.P. are gaining wider acceptance • International regulators recognise QA schemes – e.g. in Canada CFIA has confidence that QA certification results are within the CFIA's risk-based assessment continuum	• Regulators may not have sufficient knowledge of QA schemes to recognise certification of individual producers
Requirements for designated QA staff	Current • Schemes vary in prescribing the number and competencies of QA staff Potential • Clear statements of numbers and competencies of QA staff based on size of operations	• Prescribed numbers and competencies of staff provide confidence to regulators	• Producer members vary from large to small operators and prescriptive requirements may add to compliance costs
Training	Current	• Recognition of training by scheme participants could be acknowledged	• Regulators currently vary in training requirements for agvet chemical use and

QA Scheme Element	Current and potential aspects that support regulation	Strengths	Weaknesses
	• All schemes include training elements for competency in agvet chemical use, but vary in the extent of training required and documentation <u>Potential</u> • National reforms will harmonise requirements • Minimum training requirements within QA schemes aligned with nationally harmonised requirements	by regulators as satisfying regulatory requirements thus reducing duplication and cost	this would need consideration for nationally-based QA schemes
Record keeping	• Similar for training above	• Similar for training above	• Similar for training above
Residue risks and testing	<u>Current</u> • Most schemes do not have specific residue testing requirements, with exceptions being supermarkets and Freshcare • NRS does not cover all produce and does not discriminate between QA and non-QA producers <u>Potential</u> • Agreement on residue testing regimes required for different purposes (e.g. food safety, environment)	• The opportunity for QA schemes to demonstrate superior residue risk outcomes could provide a market advantage	• Elevating residue issues may negatively impact market access for produce regardless of QA scheme participation
Off-label chemical use	<u>Current</u> • Schemes are generally silent on off-label use and consequently audits may not address the issue. Work is underway to harmonise arrangements • Where schemes have legislated underpinning (e.g. poppies) there are strict rules in place <u>Potential</u>	• Schemes have flexibility to address off-label use which may be preferable where there are differences between jurisdictions	• Differences in regulations between jurisdictions may complicate the inclusion of off-label use until there is harmonisation • The inclusion could add to auditing costs and require additional training for auditors

QA Scheme Element	Current and potential aspects that support regulation	Strengths	Weaknesses
	• Specific reference to off-label use, with harmonised regulations		
Audits and corrective actions	Current • Schemes include minimum requirements for internal and external audits, including whether announced or unannounced • Corrective actions responses are stipulated including time period for completion with sanctions (including scheme disqualification) if not achieved Potential • Standardised approach to audit frequency and type (internal and external)	• Sanctions (incl. disqualification) are an incentive to ensure compliance • Announced audits promote non-threatening opportunities for improvement	• Unannounced audits reduce transparency and potentially undermine consumer confidence
Compliance reporting	Current • Schemes vary from non-disclosure to public disclosure (on a confidential basis) of the number of compliance issues, including the time period for completion of corrective actions • Individual supply contracts include sanctions for non-compliance, incl. loss of contract Potential • Adopt a process for reporting serious non-compliance to jurisdictions	• Public disclosure of corrective actions (individual names are confidential) and contractual implications of non-compliance ensure improved consumer acceptance of products	• Jurisdictions not being informed of compliance issues in a timely manner may have implications for the industry generally, and not just scheme participants (e.g. agvet chemical being consistently used not in accordance with label, with possible residue implications)
Complementarity with regulatory jurisdictions	Current • It is assumed that all schemes require minimum compliance with agvet chemical regulation • Certain jurisdictions accept scheme certification being compliant with regulation (MoUs)	• Recognition by jurisdictions of scheme certification reduces duplication and leads to cost savings • International examples exist of jurisdictions accepting scheme certification for regulatory compliance	• National schemes need to demonstrate compliance for each jurisdiction in which regulations vary • This limits the extent to which MoUs are agreed

QA Scheme Element	Current and potential aspects that support regulation	Strengths	Weaknesses
	Potential • Widespread adoption of MoUs between schemes and jurisdictions		
Future directions	Current • Schemes recognise the need to continually evolve and adapt to changing market requirements Potential • Flexibility by regulators to adapt to market requirements	• Schemes are industry-based and can quickly update standards to meet market requirements	• Changes may have regulatory implications and approvals by jurisdictions may be delayed, especially if changes to legislation are required

Table 6 identifies a range of issues that need to be considered for QA schemes to play a more supportive role in agvet chemical control of use regulation. The opportunities require changes on the part of the QA schemes themselves and also regulators.

The fact that certain QA schemes are recognised by regulators as delivering the required level of compliance with respect to specific components of the regulations demonstrates that the potential exists. Examples from the review of international schemes are further evidence of this approach, such as in Canada, where international private certification schemes including the Global Food Safety Initiative (GFSI) are recognised (see section 6.1.2).

In addition, examples of global industry initiatives such as GFSI and GLOBALG.A.P. demonstrate that industries generally are increasingly relying on QA schemes to provide quality assurance certification based on widely accepted standards that meet regulatory requirements in many countries.

In Australia, HARPS is an industry led system that seeks to harmonise food safety certification requirements for the major retailers, removing duplication and thereby reducing compliance costs.

A significant issue that remains is the voluntary nature of the schemes, and although scheme participants can demonstrate regulatory compliance and the safety of produce, non-scheme producers without the same checks with regard to the responsible use of agvet chemicals are potentially the weak link in the marketing chain. This can be overcome to some extent by the increasing reliance on supply chain verification (including branding of products).

However, it appears that auditing of non-scheme participants by jurisdictions to ensure basic adherence to agvet chemical use regulations suffers from a lack of resources available to verify compliance.

Table 6 highlights the opportunities within each of the QA scheme elements that could be considered to assist with regulating agvet chemical control of use. The schemes examined vary in the degree to which they explicitly address agvet chemical use and testing of produce. For example, for poppy production, Tasmanian Alkaloids includes very strict controls with farmers requiring a licence to produce, including specified agrichemicals and regular testing of produce for residues.

Alternatively, for macadamias, production is less stringently controlled with the Code of Sound Orchard Practices (COSOP) recommended as a guide which functions to provide growers with best practice advice to ensure quality outcomes.

The potential for co-regulation can only be considered through developing a much better understanding of QA schemes. There are instances where formal recognition already occurs via MoUs between schemes and jurisdictions (e.g. *APIQ✓®* and the Victorian government, and NFAS with both the Victorian and Queensland governments). However, there is potential for such recognition to be expanded, including an increasing number of schemes that satisfy agvet chemical use requirements and jurisdictions with MoUs or similar agreements with the schemes. Such recognition would provide additional incentives to scheme participants (and potential participants) for accreditation and it would also reduce jurisdictions' compliance requirements with respect to control of use of agvet chemicals.

8. Conclusions

This project reviewed a selection of agricultural, industry-based QA schemes to understand the elements related to managing the risks associated with using agvet chemical products. The intent was to establish whether QA schemes can support Australian regulatory activities around control of agvet chemical use.

The schemes were compared for a range of agvet chemical elements using a scoring rubric that was constructed to examine the full range of requirements necessary for certification. A desktop review of the schemes was supplemented by targeted consultation with stakeholders that comprised QA scheme administrators, government agencies and industry groups. GHD then analysed the key characteristics of QA schemes to consider the potential for schemes to support regulation, including the strengths and weaknesses of doing so.

The schemes vary, from highly regulated (poppies) through to those that recommend production based on codes of practice guidelines, without any formal scheme compliance arrangements. All schemes include agvet chemical use modules that consist of a range of elements including training and record keeping. However, schemes vary in their requirements with respect to auditing, product testing (for residues) and off-label chemical use. It should be noted that regardless of scheme arrangements, all producers are required to adhere to state/territory control of use regulations as a minimum.

Similar to the variability between schemes in the way they control agvet chemical use, jurisdictions also vary in the extent to which they recognise schemes as complying with (or exceeding) control of use regulations. Recognition varies from MoUs (or other forms of agreement) between jurisdictions and schemes through to nil formal recognition. Where MoUs are in place, they are with individual jurisdictions and are not universally recognised by all jurisdictions.

The agvet control of use requirements are further complicated by differences in regulation between the jurisdictions, and this appears to impede co-regulatory recognition of what are generally national QA schemes. While this is being addressed by Australian governments through national harmonisation reforms, which currently include record keeping and training requirements, it is unclear when such policies will be implemented to positively enhance the co-regulatory opportunities between the QA schemes and states/territories.

GHD has identified a number of areas that QA schemes could consider that would enhance co-regulation opportunities for agvet chemical use. These are listed in Table 7 below.

Table 7 Summary of potential areas to support agvet chemical regulation

QA Scheme Element	Potential aspects that support agvet chemical regulation
Structure and operation	Include more explicit statements of the complementary role between schemes and regulation Develop a better understanding by regulators of the QA schemes and gaps that inhibit co-regulation for agvet chemical use
Process for setting rules and standards	Include regulators as members of rules and standards committees
Reference to international standards	More widespread adoption and reference to international standards to promote harmonisation

QA Scheme Element	Potential aspects that support agvet chemical regulation
Requirements for designated QA staff	Clear statements of numbers and competencies of QA staff based on size of operations
Training	Minimum training requirements within QA schemes aligned with nationally harmonised requirements
Record keeping	Similar for training above
Residue risks and testing	Agreement on residue testing regimes required for different purposes (e.g. spray drift, food safety, environment, workplace health and safety)
Off-label chemical use	Specific reference to off-label use, with harmonised regulations between jurisdictions
Audits and corrective actions	Standardised approach to audit frequency and type (internal and external, announced and unannounced)
Compliance reporting	Adopt a process for reporting and resolving serious non-compliance to jurisdictions
Complementarity with regulatory jurisdictions	Widespread adoption of MoUs between schemes and jurisdictions
Future directions	Flexibility by regulators to adapt to market requirements

The findings provide an important input to Australia's ongoing agvet chemical regulatory reforms, with a view to developing a national or harmonised approach across jurisdictions for the control of agvet chemical use. This could include recognition of the role of QA schemes within the regulatory framework resulting in improvements to its efficiency, effectiveness and costs.

9. References

Agriculture Ministers' Forum (2017). Communique dated 26 July 2017 http://www.agriculture.gov.au/about/media-centre/communiques/ag-ministers-forum-july-2017 (accessed 30 August 2017)

APIQ✓ Reference Manual Version 4.2 (1/2017) Australian Pork Limited http://www.apiq.com.au/images/stories/2017_updates/apiq_reference_manual_v4.2_1_2017.pdf (accessed 2 June 2017)

APIQ✓ Standards Manual Version 4.2 (1/2017). Australian Pork Limited http://www.apiq.com.au/images/stories/2017_updates/apiq_standards_manual_version_4.2_1_2017.pdf (accessed 2 June 2017)

Australian Macadamia Society (2011). Best practice guidelines for the application of chemicals in macadamia orchards

Australian Macadamia Society (2015). Code of Sound Orchard Practices

APVMA (2010). APVMA response to the discussion paper "A National Scheme for Assessment, Registration and Control of Use of Agricultural and Veterinary Chemicals" February 2010

Egg Standards of Australia for Rearing and Layer Farms, April 2017. Australian Egg Corporation Limited (AECL)

Freshcare Food Safety & Quality (accessed 31 May 2017) Available: https://www.freshcare.com.au/standards/food-safety-quality/

http://mpi.govt.nz/food-safety/food-act-2014/http://mpi.govt.nz/food-safety/food-act-2014/ (accessed 14 July 2017)

http://mpi.govt.nz/food-safety/food-act-2014/New Zealand food safety program (accessed 14 July 2017)

http://www.agricultureandfood.dk/danish-agriculture-and-food/food-safety (accessed 14 July 2017)

http://www.agriexchange.apeda.gov.in/marketreport/Reports/Canada%20Rolls%20Out%20New%20Policy%20on%20Food%20Safety%20Private%20Certification_Ottawa_Canada_3-21-2016.pdf (accessed 14 July 2017)

http://www.apiq.com.au/index.php?option=com_content&view=article&id=16&Itemid=82 (accessed 31 May 2017)

http://www.apiq.com.au/index.php?option=com_content&view=article&id=21&Itemid=84 (accessed 31 May 2017)

http://www.apiq.com.au/index.php?option=com_content&view=article&id=96&Itemid=107 (accesses 2 June 2017)

http://www.globalgap.org/uk_en/for-producers-new/globalg.a.p./integrated-farm-assurance-ifa/crops-00001-00001/ (accessed 10 July 2017)

http://www.globalgap.org/uk_en/who-we-are/about-us/GlobalG.A.P (accessed 14 July 2017)

http://www.mygfsi.com/about-us/about-gfsi/what-is-gfsi.html (accessed 14 July 2017)

http://www.ukas.com/sectors/food-safety/# (accessed 14 July 2017)

http://www.ukas.com/sectors/food-safety/#United Kingdom Food Safety (accessed 14 July 2017)

https://www.aecl.org/quality-assurance/ (accessed 30 May 2017)

https://www.ausmeat.com.au/audits-accreditation/nfas-feedlot-assurance.aspx (accessed 30 May 2017)

https://www.schemesupport.com.au/about-us/ (accessed 30 May 2017)

National Feedlot Accreditation Scheme - Annual Report 2016

National Feedlot Accreditation Scheme (NFAS) Handbook Rules & Standards of Accreditation (August 2015 Edition, as amended). AUS-MEAT Limited. www.ausmeat.com.au/nfas/standards/default.html (accessed 30 May 2017).

National On-Farm Quality Assurance Manual Version 1 Rev 1 2001 (Graincare Manual)

Appendices

Appendix A – Quality assurance scheme details

Appendix A-1 Tasmanian Alkaloids QA summary (poppies)

Issue	Details
Structure and operation	Tasmanian Alkaloids are the manufacturer of narcotic raw materials for codeine, etc. Products go to other companies to produce pharmaceuticals. Testing procedures are used for pesticide residues. All products must be free from pesticide residues. There are very strict controls and the whole process is highly regulated. Higher standards of results are required, with regular testing. Tasmanian Alkaloids tell the farmer what agrichemicals they can use. Farmers must not use pesticides unless approved by Tasmanian Alkaloids. Farmers are approved and must have a licence to produce. Farmers must undergo a police and security check and can only farm in approved areas under licence, and can only sell to Tasmanian Alkaloids. All crop residue must be disposed of according to their licence. Tasmanian Alkaloids usually take the crop residues. All parts of the farming process are regulated except for the seed, which is provided by Tasmanian Alkaloids and who also take the seed back when the crop is harvested.
Any reference to international standards	The whole process is regulated according to the International Narcotics Control Board (INCB), which is part of the United Nations. Federal government representatives attend the international meetings. Agreement is made with INCB as to how much crop to grow and farmers must only grow the agreed approved quantities. All countries that legally grow poppy crops are part of INCB, under an international treaty. Implementation of the treaty is regulated by the State and Federal governments.
Training/competency arrangements: at individual and enterprise level	Field officers advising on the use of agrichemicals are usually university graduates, who also hold ChemCert qualifications. Tasmanian Alkaloids train the field officers so that they have a full understanding of agrichemicals for use on poppy crops. Agrichemical use is underpinned by Tasmanian Alkaloids research and development and approvals for use. Field officers work with farmers to make sure only approved agrichemicals are used.
Record keeping requirements: at individual and enterprise level	Record keeping is done electronically by field officers. There are requirements to keep records for agrichemical applications to comply with licences. Electronic records for residue testing are also maintained under Tasmanian Alkaloids' Crop Management System. There is full traceability as to the use of any and all agrichemicals.
Residue risks and testing: suite of chemicals, triggers for reporting adverse findings to regulatory bodies	There is testing of poppy products for routine chemicals that have been applied, such as herbicides, insecticides, fungicides and plant growth regulators. Any residue found in the product results in the product being rejected and an investigation undertaken. Testing includes organochlorines and organophosphates as standard but other chemicals not expected to be a residue, based on the agrichemicals applied, are not tested. Basically, growers provide the land and irrigation, and field officers provide all the advice as to how to grow the crop, application of agrichemicals and the controls required. This ensures that tight controls and management of chemicals and the crops are maintained to prevent any non-compliances for pharmaceutical production.
Approach to off-label Agvet chemical use	Tasmanian Alkaloids do require off-label use from time to time. For example, if a disease such as a particular type of mildew presents itself, Tasmanian Alkaloids need chemicals to treat the disease quickly. A contract company, Peracto, an agricultural research company located in New Zealand, work closely with Tasmanian Alkaloids and perform all the chemical trials for off-label use, test for residues and apply for off–label use permits. Tasmanian

Issue	Details
	Alkaloids must have an off-label permit for off-label chemical use. When developing a new chemistry, all residue data is obtained and permit for use is gained.
Compliance and enforcement arrangements	Compliance and enforcement has the potential consequence for the farmer to lose the ability to grow poppy crops. If a farmer fails to follow the set protocols and advice from Tasmanian Alkaloids, they will not be permitted to grow the crop again. The growing of the crop is State regulated and permitted, and is also regulated by the Chief Pharmacist of Tasmania. If there are non-compliances, the growing permit is withdrawn.
The evolution of the scheme and whether this included any trigger events	Trigger events – a chemical residue positive finding must be investigated under the QA scheme. New diseases will also trigger another look at agrichemistry. Tasmanian Alkaloids registers new chemicals with APVMA for unexpected use such as disease or pest outbreaks. Tasmanian Alkaloids are conscious of chemical resistance and are constantly looking at new chemistries to minimise resistance and to improve alkaloid yield.
Strengths, weaknesses and gaps	QA scheme works very well. Peracto know the compliance system very well. Peracto respond quickly to emergency situations such as a disease outbreak, which is very important as the crop only has a four month life. Peracto are very accommodating and responsive to Tasmanian Alkaloid's needs. Peracto also have access to other residue results from other agricultural chemical trials, which can be used by Tasmanian Alkaloids for their off-label permitting.
Future direction in relation to the control of Agvet chemical use	This is a small industry and more and more chemicals are becoming unavailable for various reasons, such as chemical resistance and they are no longer manufactured. Tasmanian Alkaloids would like to keep existing chemicals under review for minor use, as this provides them with more options. Chemical resistance is more of a problem and there is a need for more alternative chemicals to come through the approval process.

Appendix A-2 Egg Standards Australia for Rearing and Layer Farms summary (poultry – eggs)

Issue	Details
Structure and operation	Egg Standards Australia (ESA) is a voluntary quality assurance program for Rearing and Layer Farms, developed through an extensive consultation process with egg farmers to provide a practical mechanism to demonstrate compliance with egg production standards. It was established under the auspices of the Australian Eggs Limited (AEL). The primary objectives of ESA are: • To set out the requirements for best practice in the production of eggs • To provide a uniform mechanism for the verification of egg production practices • To provide a means of demonstrating best practice and continual improvement The ESA program is administered by Scheme Support Services (SSS). ESA is structured into three levels to enable egg farmers to join the program at the level that best suits their business needs and customer requirements. Level 1 – Basic: An entry level for egg farmers who are new to the egg industry or who have not previously participated in a quality assurance program. Egg farms certified at this level are audited to Level 1 compliance criteria. Level 2 – Core: An intermediate level suited to egg farmers with a more developed compliance system and record keeping procedures. Egg farms certified at this level must be audited against both Level 1 and Level 2 compliance criteria. Level 3 – Comprehensive: An advanced level suited to egg farmers with a fully developed compliance system and record keeping procedures, to meet the requirements of major retail customers. Egg farms certified at this level must be audited against all three levels of compliance criteria. There is no cost for an egg business to join the ESA program and access ESA resources. Once a business has implemented ESA and seeks certification, an annual $55.00 certification fee will be charged for each site. Egg farmers will also need to meet the actual cost of the annual compliance audit for each site. The scheme includes Management (M) and Production (P) elements, with those relating to agvet chemical use summarised below: **Management** M2 Documentation (see record keeping below), M3 Training (see training below), M4 Internal checks, audits and corrective action (see compliance below), M5 Suppliers - suppliers of materials and services that may introduce risk are identified, current specifications and/or Safety Data Sheets (SDSs) are available for all feed and chemicals supplied. **Production** P2 Inputs; P2.5 Chemical & veterinary medicines, P2.6 Pest control
Any reference to international standards	ESA is a private standard and is not accredited. It is not referenced to international standards and is to satisfy domestic and consumer requirements.

Issue	Details
Training/competency arrangements: at individual and enterprise level	**M3 Training element** M3.1 Training needs of the business are met (enterprise level) M3.2 Train all workers who complete tasks relevant to ESA (individual level). Includes that training is provided in the relevant language for workers, or pictorially. M3.3 Training records are kept
Record keeping requirements: at individual and enterprise level	**M2 Documentation element** M2.1 Verify compliance with ESA through relevant documents. M2.2 Legible records to verify compliance with ESA are kept. Includes any treatments/medications administered each day and all records relating to the previous two years of production (or longer if required by legislation or customers) are available on request. P2.5 Chemical & veterinary medicine - outlines the record keeping including best practice procurement and storage on premises and is used to ensure compliance with withholding periods.
Residue risks and testing: suite of chemicals, triggers for reporting adverse findings to regulatory bodies	No mandatory requirements for chemical testing under ESA. Supermarkets could have requirements through their own supermarket schemes.
Approach to off-label Agvet chemical use	No
Compliance and enforcement arrangements	**M4 Internal checks, audits and corrective action.** M4.1 Conduct internal audits to verify ongoing compliance with ESA. An internal audit is conducted at least annually, or wherever significant changes occur in procedures, to review compliance to all relevant sections of ESA. A record is kept. Internal audits are conducted by competent workers, and where possible, are independent of the practices being assessed. M4.2 Complete corrective actions for any non-compliance. A Correction Action Record (CAR) is completed when the requirements of ESA, certification rules or legislation are not being met. Reoccurrences of non-compliance are reviewed by the owner or appropriate senior manager. M4.3 Findings of external audits of ESA are reviewed and managed. M4.4 Complaints are recorded, reviewed and managed. M4.5 Where an infectious disease outbreak or a food safety issue has arisen, evidence of responses and actions taken must be kept. ESA audits are provided by the following Certification Bodies: AUS-QUAL Pty Ltd, BSI Group ANZ Pty Ltd, Merieux Nutrisciences Certification, SGS Australia Pty Ltd ESA requires that participating egg farmers are audited annually to maintain their certification. In addition, unannounced audits may be conducted at no cost to the farm in response to complaints received from an outside party. There is a detailed process to address minor corrective actions records (CARs), with time limits on rectification. Issue can escalate to major CARs if not satisfactorily addressed.

Issue	Details
	Major CARs are also raised when there is the potential to compromise food safety, animal welfare or the environment, or the potential to compromise the integrity of the ESA Program. Major CARs must be addressed within 28 days of audit and if not resolved within the nominated 28 day period, the egg farm's certification status will be placed in 'Certification Pending' within the ESA database until such time as the corrective action(s) are addressed. Egg farms are required to provide evidence in writing to their auditor of action taken to address corrective action(s), and in some circumstances a follow-up audit may be required. There are also Critical CARs for issues presenting an immediate risk to food safety, animal welfare, the environment, or a breach of legislation, or when the integrity of the ESA Program has been compromised. These must be addressed immediately; and the egg farm's certification status will be placed in 'Suspended' within ESA Online until the Critical CAR(s) have been addressed. Scheme Support Services (SSS) database manages all aspects from initial business registration, audit reporting and certificate issue. Australian Eggs is the owner of ESA and will be conducting a review of the scheme in 2018, in close consultation with stakeholders. Currently no public reporting of QA. There is the ability to search for certified bodies on website and outcomes of audits are private between egg farmer and certification body.
The evolution of the scheme and whether this included any trigger events	ESA replaces the previous industry scheme, Egg Corp Assured (ECA), providing greater clarity and a more robust set of compliance standards. The ESA is more prescriptive about what needs to be done to ensure compliance with QA Scheme
Strengths, weaknesses and gaps	Customer requirements are constantly changing and therefore the scheme must evolve accordingly. The model code of practice (MCoP) is being transitioned into Standards (mandatory) and Guidelines (not mandatory), with public consultation occurring at present (2017). The CoP is driven by animal welfare requirements which will impact on what is approved. Once complete, ESA will be updated to reflect changes.
Future direction in relation to the control of Agvet chemical use	The current ESA has a strong focus on the criteria needed to prove food safety, with Auditors only verifying the information provided to them.

Appendix A-3 National Feedlot Accreditation Scheme summary (Feedlot beef)

Issue	Details
Structure and operation	The National Feedlot Accreditation Scheme (NFAS) is an independently audited quality assurance scheme that was initiated by ALFA and is managed by an industry Committee the Feedlot Industry Accreditation Committee (FLIAC). AUS-MEAT administers the scheme through the Feedlot Industry Accreditation Committee (FLIAC). Organisations represented in the FLIAC are: AUS-MEAT Limited, Australian Lot Feeders Association (ALFA) – 2 nominees including the Chair, NSW Department of Primary Industries, QLD Department of Agriculture and Fisheries Forestry (DAF), Victorian Department of Economic Development, Jobs , Transport and Resources, Western Australian Department of Agriculture The NFAS Standards describe the processes by which the Australian feedlot industry, as a proactive self-regulated sector, has agreed to operate so as to demonstrate its commitment to animal welfare, environment, meat quality and food safety. To be accredited a feedlot operator must: ensure the feedlot is approved by the relevant authorities, at least one staff member must have attended a chemical user training course, have documented procedures in place, specifically for the feedlot which meet the requirements of the industry standards; maintain records that these procedures have been adhered to for all cattle prepared at the feedlot; and undergo an annual third party audit of these procedures, records and facilities at the feedlot. As at 31 May 2017 a total of 386 feedlots held accreditation in NFAS, including nine feedlots that are provisionally accredited. A further 56 are currently in Voluntary Suspension. The total approved capacity of NFAS Accredited Feedlots is 1,516,705 head/Standard Cattle Unit. The NFAS Standards comprise five standard Modules. Each Module contains one or more Elements which describe the required Outcomes, with Performance Indicators for each of the outcomes. The Modules (and elements related to agvet chemical use) are: 1. Quality Management System (QM), 2. Food Safety Management (FS), 3. Livestock Management (LM), 4. Environmental Management (EM), 5. Product Integrity (PI) (NFAS commented that that while NFAS is HACCP based, auditing against specific performance indicators enabled better consistency between auditors compared to auditing individual HACCP Plans that can differ between producers despite the outcomes being equivalent).
Any reference to international standards	The Food Safety Module in NFAS is based on the Livestock Production Assurance (LPA) module which was developed using the standard Codex Alimentarius International Food Standards endorsed by WHO and FAO. This process is outlined in a paper titled: “HACCP-based approach to the derivation of an on-farm food safety program for the Australian red meat industry” at the link below: http://www.sciencedirect.com/science/article/pii/S0956713505000617 HACCP approach was modified to allow a hazard analysis to be conducted at an industry level which could then be used to derive appropriate on-farm food safety control measures for cattle, sheep and goat production in Australia. Scientific information from a thorough chain risk profile of the red meat industry was used as a major resource for the hazard analysis. The process resulted in the identification of critical control points for control of (among others) the prevention of violations of maximum residue limits with agricultural and veterinary chemicals.

Issue	Details
Training/competency arrangements: at individual and enterprise level	Management Representative: the Enterprise shall appoint a member of management who, irrespective of other responsibilities, shall have responsibility and authority to: (a) ensure that the approved feedlot quality system is established, implemented, maintained and updated; (b) ensure the correct number of authorised QA Officers are maintained; and (c) report to senior management on the effectiveness and suitability of the approved feedlot quality system. Feedlots must have a specific number of QA Officers at the feedlot. The number required is related to the size of the feedlot. Each Quality Assurance Officer must hold a current Statement of Authority. AUS-MEAT will conduct examinations for Statements of Authority at the feedlot where the applicant is employed or engaged. The examination will generally be conducted in conjunction with a feedlot Audit. The certificate is issued in respect of a specified person and will continue to be recognised for that person should they move to another feedlot. To obtain a Statement of Authority an applicant must demonstrate to the satisfaction of the examiner sound practical skills in the following (among others):determining whether or not cattle, that are the subject of a NFAS Delivery Docket, are under any withholding period, veterinary medicine or other restriction The examiner must also be satisfied that an Applicant has demonstrated the ability to calculate Days on Feed and an overall understanding of the NFAS Rules and Standards including any recent amendments addressed by NFAS Advices. The rules cover withdrawal and reapplication for a Statement of Authority which can only proceed after a period of 28 days has elapsed from the date the Statement of Authority was withdrawn. Extra training over and above the standards is provided by ALFA via workshops etc. which many certified producers/staff attend.
Record keeping requirements: at individual and enterprise level	Accredited Enterprises must not make any “whole of life” claims or other assurances regarding the feeding history, drugs treatments, animal husbandry conditions, handling, and/or geographical references of introduced animals unless verifiable documentary evidence supporting those claims (such as written and signed statements from all previous vendors) is available. Records of the verifiable evidence shall be maintained. QM3 Quality Records - Records are kept that provide documented evidence of the enterprise’s compliance to the NFAS Standards. QM4 Document Control - All documents relevant to the NFAS Standards are controlled enabling the review of their currency and that out of date or superseded documents are withdrawn and replaced with the new version. QM5 Chemical Inventory - Only legally obtained and properly labelled chemicals are available for use on the property and that an accurate inventory of all chemicals purchased and stored on the enterprise is maintained.
Residue risks and testing: suite of chemicals, triggers for reporting adverse findings to regulatory bodies	LM7 Incident Reporting - Incident reporting requirements are undertaken when a reportable incident occurs. LM8 Contingency Reporting - Satisfactory actions are taken when an unusual emergency situation occurs. The industry contributes funds to the National Residue Survey (NRS).
Approach to off-label Agvet chemical use	Must have current permit or veterinary prescription/letter for use, including for example products beyond expiry date.
Compliance and enforcement arrangements	NFAS producers are exempt from LPA Random audits: the minutes of Meeting 1 of the LPA Standards Accreditation Committee on 2 August 2004 addressed equivalence with other QA programs to LPA.

Issue	Details
	One or more AUS-MEAT representatives will undertake accreditation Audits to ensure that the matters set out in the Feedlot's Quality System Manual are being complied with and, that: (i) the required number of Quality Assurance Officers are engaged or employed at the Feedlot; (ii) each Quality Assurance Officer understands the Quality System and the manner in which it must be applied to comply with NFAS requirements; (iii) product which does not conform to specifications can be detected, controlled, corrected, recorded and treated in accordance with procedures set out in the Feedlot's Quality System Manual; (iv) when monitoring of product associated with the Feedlot (eg. Veterinary medicine expiry dates) is undertaken by feedlot staff, sufficient and random samples are obtained to properly measure performance or conformance; (v) the activities and findings of staff are recorded on appropriate forms and reports as described in the Feedlot 's Quality System Manual; (vi) the Quality System Manual is approved by AUS-MEAT; and (vii) the NFAS Accreditation Rules and Standards including the mandatory reference material as detailed above at paragraph 3.2.1 are being complied with. The Audits are announced and scheduled with the Feedlot. Follow up Audits are conducted to ensure that non-conformances raised during an Audit have been corrected within the agreed time frame. AUS-MEAT Limited provides an annual report on the activities of the NFAS to the Feedlot Industry Accreditation Committee (FLIAC). As part of FLIAC's open communication policy of providing information on NFAS to all stakeholders, copies of the current NFAS Annual Report are available on the website. As the operator of NFAS, AUS-MEAT is involved in approved arrangements with the Queensland and Victorian State Governments. While these agreements are recognised as co-regulatory all breaches of legislative requirements are ultimately the responsibility of the relevant authority. A Memorandum of Understating (MoU) established with the Queensland Government in 2013 enables Queensland based NFAS accredited feedlots to receive a discount in their environmental licence fee. This agreement is based on the recognition of the annual NFAS audit as an environmental audit. Under the MoU, AUS-MEAT is responsible for ensuring feedlots are audited annually, providing quarterly reports outlining environmental non-conformances identified during NFAS audits and immediate notification to DAF of potential or actual environmental harm observed during an NFAS audit. As part of the ongoing commitment to the MoU, DAF and AUS-MEAT staff conduct joint audits of selected feedlots. This process ensures both organisations are inspecting the same environmental elements and addressing any adverse findings in a similar manner. The Victorian Government also recognises that NFAS auditors and inspectors for the Environmental Protection Authority (EPA) are addressing similar issues and generally accepts the annual NFAS audit, unless a specific environmental issue is identified. The Victorian Government has also approved NFAS in a Compliance Arrangement under section 11 of the Livestock Management Act with AUS-MEAT Limited as the Controlling Authority. Under this arrangement, feedlots must comply with specific animal welfare and transport requirements (as outline in the current NFAS Standards). AUS-MEAT is also required to provide an annual report to the Victorian Department of Economic Development, Jobs, Transport and Resources detailing the number of audits conducted, any non-conformances and the outcome of these non-

Issue	Details
	conformances. This report was provided in August 2016. No significant non-conformance were identified in the period covered by the report. MoUs with states and territories are 'Commercial in Confidence'. Unless otherwise specified NFAS audits are conducted annually. Auditors must have current registration as Food Safety Auditors with Exemplar Global, be current LPA Auditors and have an understanding of livestock production systems before they are considered to audit the NFAS program. AUS-MEAT provides NFAS Auditor training through a system of "buddy audits" prior to sign off. Focus group training is also provided for all of the Livestock Programs delivered by AUS-MEAT. As part of the ongoing auditor calibration activities, 'Witness Audits' are conducted. These audits are carried out by senior NFAS Auditors and are designed to ensure all Auditors continue to comply with the auditing requirements of the NFAS Standard. In 2016 three (3) Auditors participated in witness audits (an audit observed by a senior Auditor or external client to verify compliance to the audit process and Standard by the Auditor conducting the audit) on NFAS accredited feedlots. Non-conformances identified at audit are graded in accordance with severity in accordance with the NFAS Rules - namely Critical, Major and Minor. Feedlots are required to implement actions to address Major non-conformances within 30 days unless another arrangement is agreed to with the Auditor. The majority of non-conformances are closed within the 30 day period. Feedlots identified as taking longer to address the non-conformances are contacted by the Auditor to ensure the issue is closed. AUS-MEAT is also planning to use its automated mail merger system to generate overdue non-conformance letters as a reminder for feedlots that have not addressed issues raised at audit within the specified time. When a Critical Incident is identified by an Auditor, the Auditor must immediately inform the Program Manager who contacts the FLIAC Chair and the Committee members. Following a review of the incidents by the Committee, feedlot management and staff involved were required to show cause as to why their NFAS accreditation and individual Statements of Authority should not be withdrawn. These feedlots have since demonstrated that they have systems in place that will prevent the non-conformance from occurring in the future.
The evolution of the scheme and whether this included any trigger events	Commencing in August 1994 the NFAS was the first agriculturally based quality assurance program to be introduced in Australia and has provided a frame work for subsequent on farm systems. There was a need for the industry to demonstrate verifiable claims about feedlot beef to markets.
Strengths, weaknesses and gaps	AUS-Meat regularly sends out Advices & Circulars to accredited feedlots with updates to standards and other information. Strengths: provides a good baseline and is used as a conduit by feedlots for continuous improvement Weaknesses: a small minority flout rules and this can cause unacceptable consequences if there is media attention Gaps: there are ever increasing demands but NFAS continually adapts to address these. Following the overall review of the NFAS in 2015 it was agreed by FLIAC that a full review would be conducted every five years to ensure the Scheme remains relevant to industry.
Future direction in relation to the control of Agvet chemical use	Key projects commenced in 2016: As part of the recommendations from NFAS review sections of the NFAS Rules and Standards have been updated and are expected to be released in 2017 after final approval by FLIAC.

Issue	Details
	The NFAS Communication Strategy was developed during the year and will continue to be implemented in 2017. Increasing use of electronic tracking systems for livestock will improve monitoring and verification of performance. ALFA is proactive and continually looking at future requirements of markets and consumers. New standards on hard waste management (e.g. chemical containers) is planned for later in 2017.

Appendix A-4 APIQ✓® summary (Piggeries)

Issue	Details
Structure and operation	APIQ✓® is an on-farm quality assurance system based on managing farm risks by following Good Agricultural Practices (GAP), using the principles of Hazard Analysis and managing Critical Control Points (HACCP). APIQ✓® provides the framework and standards by which Australian pig producers can demonstrate they are responsible farmers who care for their animals, the environment and their customers, by following safe and sustainable practices. The Australian Pork Industry Quality Assurance Program (APIQ✓®) is the industry sponsored on-farm Quality Assurance (QA) program. QA Certification allows producers to demonstrate that they meet legal requirements, industry standards, customer specifications and export provisions. It requires producers to document procedures on-farm outlining how key tasks are carried out, monitoring the tasks, recording the results of those actions and checking that the results comply with the Standards. Certification enables producers to demonstrate that they are meeting relevant State and Federal legislation and following good agricultural practice. APIQ✓® also supports the requirements of the industry-wide traceability system, the PigPass National Vendor Declaration (PigPass NVD) by providing the supporting QA framework. The APIQ✓® Standards are outcome-focused and supported by Performance Indicators. Supplementary information is contained in the APIQ✓® Reference Manual, the APIQ✓® Compliance Guide for Producers and Auditors. Australian Pork Limited manages the program on the industry's behalf through APIQ Management (APIQM). A wide range of stakeholders have provided technical and policy input to the program, including producers, scientists, QA and audit experts, retailers and customer organisations, government, and supply chain members. The program was also trialled on-farm in different herd sizes and types of production systems. The APIQ✓® Standards are divided into seven Modules: 1. Management 2. Food Safety 3. Animal Welfare 4. Biosecurity 5. Traceability 6. Environment 7. Transport
Any reference to international standards	HACCP is an internationally recognised food safety system. The only relevant international standard which applies to this system is ISO 14001:2016 as part of the JAS ANZ system, from which APIQ✓® uses the formula to determine the number of audits to perform for producers with multiple sites, to ensure a representative sample.
Training/competency arrangements: at individual and enterprise level	1.1 F. Staff induction and training is conducted and recorded and ensures that: ─ New staff are inducted on commencement of employment and induction is completed within one (1) month. ─ New and existing staff are trained and competent in their required tasks and ongoing training needs are identified. ─ All staff are familiar with SOPs and WIs for their specific tasks. 2.2 E. Staff administering treatments to pigs are competent (Refer Performance Indicator 3.2 A). 3.2 A. Pigs are cared for by personnel who are skilled and competent in pig husbandry to maintain the health and welfare of animals as explained in the provisions of the Model Code of Practice for the Welfare of Animals – Pigs, or

Issue	Details
	personnel work under the supervision of a competent person. Competency may be demonstrated or assessed by the following methods: ─ Formal industry training in pig husbandry. ─ Individual skills assessment by a competent skilled person. ─ Documented work history outlining competency by recognising past experience or Recognising Prior Learning (RPL). 3.2 B. Staff training is recorded and evidence demonstrates that individuals are trained in or are being trained in their required tasks. ─ Training must be ongoing as responsibilities and practices change. 3.2 C. There is an induction program for new staff to become familiar with their tasks and staff are trained as required (Refer Performance Indicator 1.1 F). 3.2 D. There is a copy of the current Model Code of Practice for the Welfare of Animals – Pigs on file at the piggery and readily accessible to staff for reference. APIQ✓® Reference Manual includes a summary of what each state considers enough farm experience to deem competence.
Record keeping requirements: at individual and enterprise level	1.1 D. A system is in place to ensure that records and documents, including Standard Operating Procedures (SOPs) or Work Instructions (WIs), are maintained and current. Medicines and chemicals: 2.2 A. Records for pigs that are treated with medications and chemicals are kept for a minimum of three (3) years and specify: ─ The weight of the pigs to ensure they receive the correct dose ─ The name of the medication or chemical used ─ The date of treatment ─ The amount administered ─ Label directions/off label ─ WHP and Export Slaughter Interval (ESI). ─ Repetitive treatments; AND/OR ─ Non-response to treatment 2.3 C. There is a system in place that records all feed received and the medications in those feeds 2.4 A. A list of treatments (including medications, vaccines and routine husbandry products) used in the piggery is maintained and kept up to date. 2.4 B. Records of piggery medication and chemical use are available that specify or estimate pig weight (where relevant) and amount administered (Refer Performance Indicator 2.2 A).
Residue risks and testing: suite of chemicals, triggers for reporting adverse findings to regulatory bodies	2.1 E. Critical Control Points (CCPs), identified in the Pork On-Farm HACCP Plan, are monitored for identified food safety hazard indicators and corrective actions are taken where necessary. In Australia, Maximum Residue Levels are determined by Food Standards Australia and New Zealand (FSANZ) and are published in the FSANZ Food Standards Code. APIQ✓® does not require residue testing and does not report residue testing to regulatory bodies, however elements of chemical management such as a lack of veterinary prescription or poor records would be reported as a non-compliance to governments which have a co-regulation agreement (currently only Victoria).

Issue	Details
	In general, residue testing is not performed as part of the quality assurance process as this occurs as part of the National Residue Survey at abattoirs who reports findings back to APL who is the host of and is responsible for the PigPass system allowing APIQM to link back to and to assist a piggery when a residue is found.
Approach to off-label Agvet chemical use	2.2 C. Any off-label use of any medication or chemical, including any changes to WHPs or ESIs, is prescribed by a veterinarian and recorded in a manner consistent with the applicable veterinary prescribing legislation. Regulations for veterinary prescriptions of agvet chemicals vary state by state, therefore this is controlled by state legislation rather than this quality assurance system. The only element of this captured by APIQ✓® would be the records kept by producers which detail off-label prescriptions, as records are required to be kept under this system.
Compliance and enforcement arrangements	1.1 E. The enterprise must conduct and record an annual Internal Audit, approximately six (6) months but no later than eight (8) months, after their APIQ✓® Compliance Audit is conducted. The audit includes: – Review of the record keeping/SOP documentation to ensure they are maintained and current. – Any non-conformances are identified and recorded. – The appropriate corrective and preventative actions are taken as required and are recorded. – Outstanding non-conformances are scheduled to be addressed in a reasonable timeframe. Annual audits must be performed by an APIQ✓® registered auditor. Audits can be scheduled by location to allow for greater efficiency.
The evolution of the scheme and whether this included any trigger events	Most recent revision of Approved Standards (Version 4.3 7/2017) took effect July 2017. The pork industry used to have two different QA systems, PigPass and APIQ. PigPass assured traceability while APIQ included traceability, animal welfare and food safety. Calling a QA program PigPass caused confusion as the PigPass Vendor declaration system was also used by producers. This lead to confusion with producers using schemes for the wrong purpose. Both schemes were combined in 2010 with the creation of APIQ✓® to assure management, food safety, traceability, animal welfare and biosecurity. Several more modules have been added since the creation to incorporate management, transport and environmental factors and to give producers the ability to differentiate by production type. For example as indoor, free range or outdoor bred - raised indoors on straw. APIQ✓® has also been developed to include more verification options, including an option for producers to be certified for Coles. This came about due to the good relationship between Coles, APL and APIQM and because APIQ✓® Certification drives high animal welfare standards from Coles consumers.
Strengths, weaknesses and gaps	Strength: ease of access to Coles market, "To have Customer Specifications built into an industries QA program is a first for agriculture in Australia and fits with APL's responsibility to "*create the future farmers need*" as listed in the company values". This allows producers to avoid being audited by both Coles and APIQ✓®. Strength: compatibility of APIQ✓® with PigPass. PigPass is a mandatory component of APIQ✓®, it ensures traceability of pig movements and fulfils NLIS Pork and state legislation in providing documentation of pig movements. Strength: allowing the discretion of the veterinarian in prescribing medicines including off-label prescriptions means that this QA system works in every state despite differences in regulations for prescribing medicines in different states.

Issue	Details
	Strength: co-regulation with states. In Victoria there is a MoU between the Victorian state government (Department of Economic Development, Jobs, Transport and Resources (DEDJTR), previously under the Department of Primary Industries portfolio) which allows producers to be audited only once a year by APIQ✓®, with an annual report being supplied by APIQM to DEDJTR, fulfilling the state regulation audit requirements. This gives a strong link between the government and the quality assurance system, and is noted to be successful as it does not place extra burden on the quality assurance system, which is deemed adequate to fulfil state regulations surrounding agvet chemical use for pig producers. Strength: APIQ✓® aims not to place unnecessary burden on producers, which management believes contributes to its success. For example producers used to have to develop a full HACCP plan, but this requirement has been narrowed down to the trigger points which are deemed to be most important (risk-based rather than comprehensive planning).
Future direction in relation to the control of Agvet chemical use	APIQ✓® Standards and Performance indicators are reviewed by stakeholders of various sizes and types of production each year. Suggested improvements are approved by the APL Board and then released to industry. Standard 6.1, regarding licences and/or permits to operate, is currently under review. APIQ✓® aims to stay ahead of the curve for developments in pig production, rather than reactionary, for example changes in sow gestation stalls have changed under the APIQ✓® system along with piggery practice and driving market animal welfare forces. APIQM hopes to explore further co-regulatory opportunities on behalf of producers to streamline and minimise the cost and impost of regulations on producers while ensuring that their systems remain robust and sustainable.

Appendix A-5 Graincare summary (QA scheme for grains, applicable to barley)

Issue	Details
Structure and operation	Graincare is a quality assurance system developed by the Grains Council of Australia in partnership with the Grains Research and Development Council. It covers cereals, pulses and oilseeds. Growers register under Graincare and then must be audited against the requirements outlined in the manual. The Graincare program is most broadly categorised into three areas; management, chemicals and grains. It is broken down in this way to allow the grain component of the scheme to be used as an option, with livestock being another version as part of the wider National On-Farm quality assurance system. Therefore growers can be part of Graincare, Cattlecare and Flockcare, or other quality assurance programs such as Freshcare without duplication of management and general chemical quality assurance processes. Across all 3 modules incorporated into the 3 modules of management, chemicals and grains incorporated into Graincare, the following 13 areas are covered: • Paddock selection and preparation • Crop management • Persistent chemicals in soil • Paddock, crop and grain treatments • Obtaining and storing chemicals • Inputs and service suppliers • Harvesting and harvest equipment • On-farm storage and handling • Off-farm transport • Training • Internal auditing and corrective action • Quality records • Document control
Any reference to international standards	ISO 9002 is the basis of the National On-Farm quality assurance system. Graincare is based on the HACCP system which is an internationally recognised food safety management system.
Training/competency arrangements: at individual and enterprise level	Trainers operate in each state who run practical courses in regional areas on this Code of Practice. The scheme requires a Chemical Users course to be completed (if not already) within the first 6 to 8 weeks of beginning the scheme. Staff supervising the use of farm chemicals must hold a ChemCert or equivalent qualification. All staff on farms must be trained regarding the activities they are performing.
Record keeping requirements: at individual and enterprise level	Records of staff training must be maintained. Inspection/internal audit forms must be completed and maintained for all internal audits and detailed Corrective Action Reports should also be documented. A chemical storage stocktake should be performed every 6 months for veterinary chemicals and every 12 months for agricultural chemicals. Records of chemical use must be maintained, including the date, paddock, rate, method of application etc. and records of structural treatments for storage facilities and product after harvest such as insecticides or fumigants. Specific retention periods for different types of records are detailed in the Graincare manual; ChemCert for 2 years, farm chemical inventory for 5 years and paddock, crop and grain treatment records for 10 years.

Issue	Details
Residue risks and testing: suite of chemicals, triggers for reporting adverse findings to regulatory bodies	Soil testing is recommended to ensure that persistent chemicals in soil will not contribute to a violation of a maximum residue level. No specific residue testing occurs, hence the heavy reliance on good records of chemical application to determine withholding periods.
Approach to off-label Agvet chemical use	Only approved chemicals may be used and withholding periods must be observed. Chemicals may be used under off-label permits issued by the APVMA.
Compliance and enforcement arrangements	Qualified accredited external auditors conduct and audit in the first year to allow accreditation to be obtained. Then growers must perform two internal audits and have one external audit every year to maintain accreditation. Auditors are part of the Quality Society of Australasia. Non-conformities have a variety of implications under the scheme from increased auditing frequency through to irrevocable loss of accreditation.
The evolution of the scheme and whether this included any trigger events	Graincare was developed in 2001 as an On-farm National QA program.
Strengths, weaknesses and gaps	This quality assurance scheme has been identified as being in decline in use among barley growers. It is not seen as being necessary within the barley industry, in which individual supply agreements and relationships between producers and customers are seen as being enough to ensure quality. This scheme does not therefore have a driving market force.
Future direction in relation to the control of Agvet chemical use	As above, this scheme is not being driven by market forces therefore no future direction is apparent.

Appendix A-6 Code of Sound Orchard Practices summary (Macadamias)

Issue	Details
Structure and operation	The Code of Sound Orchard Practices (COSOP) is a guide which functions to provide growers with best practice advice to ensure quality in conjunction with other complimentary processes which occur in the Macadamia industry. For example, this system is often used in addition to grower-processor supply agreements, with processors performing auditing of grower quality. It is used by roughly 80% of macadamia growers as it fulfils export quality requirements and has a good reputation to enable access to overseas markets (80% of macadamias grown in Australia are exported). Where macadamias are destined for the domestic market, Freshcare is used in conjunction with the COSOP. The COSOP has been developed by the Australian Macadamia Society Limited (AMS), Office of Environment and Heritage (NSW) and Biosecurity Queensland. This reflects the states involved in the production of macadamias; NSW and Queensland. For advice on chemical use, the COSOP defers to the standards as set by the APVMA. This Code is supported by a series of best practice guidelines such as *Best practice guidelines for the application of chemicals in macadamia orchards*. The COSOP and all associated guidelines are voluntary systems, intending to assist macadamia growers to deliver good quality macadamias to processors.
Any reference to international standards	ISO 9001 quality management standards.
Training/competency arrangements: at individual and enterprise level	Pesticide users in NSW must have a current chemical use training card. The COSOP states that for application of any herbicides, rodenticides, insecticides and fungicides the person applying the chemicals must be “appropriately trained and accredited”. The AMS provides guides for macadamia sorting but specific requirements of different processors may vary, therefore there is no industry-wide standard training. Farm workers must be aware of Withholding Periods, but no official training is associated with this element.
Record keeping requirements: at individual and enterprise level	Record keeping is required by macadamia growers for elements such as fertiliser and pesticide application. Off-label permits must be kept where chemicals other than registered for use in macadamias is applied. It is recommended that a stock inventory is maintained of the chemicals stored, and annually checked. Pesticide records should be kept in accordance with legal requirements. Records of rejected nuts and the associated reasons are suggested to improve quality with good feedback systems for improvement. If flotation sorting is used and sanitising agents are added, they must be approved for food contact, monitored and records kept. Records of handling and transport may be required depending on the intended use of the macadamias (according to unique grower-processor agreements).
Residue risks and testing: suite of chemicals, triggers for reporting adverse findings to regulatory bodies	Residue testing does not occur as part of this QA system but the industry has been a participant in the National Residue Survey since 1996 and that testing is used in conjunction with the components of COSOP.

Issue	Details
Approach to off-label Agvet chemical use	Off-label chemical use is not tolerated unless an off-label permit from APVMA is followed. The COSOP defers many aspects of chemical pesticide application to APVMA regulations. Only chemicals Registered or covered by a Permit may be used, any other use by growers is illegal. Only approved chemicals are allowed at all stages of macadamia production e.g. *Use only cleaning and vermin control chemicals that are approved for use in food premises* (AMS 2015).
Compliance and enforcement arrangements	Producers are not audited centrally as part of the Code of Sound Orchard Practices. This function is performed by Freshcare if growers operate under Freshcare quality assurance, otherwise audits are conducted by processors to ensure quality practices and record keeping are satisfactory.
The evolution of the scheme and whether this included any trigger events	COSOP was initially created in 2007, and was completely revised and updated in 2011. The most recent version of the COSOP was created in 2015.
Strengths, weaknesses and gaps	Gap: the COSOP does not function as an accredited QA system per se. An independent QA system could function to level the playing field for growers, where legislative differences between NSW and Queensland currently means that chemical regulation is more stringent for NSW growers. Strength: the COSOP does not need to function as an auditable quality assurance scheme as the National Residue Survey results provide assurance to overseas markets from a history of 100% compliance of Maximum Residue Levels in the macadamia industry over the last 16 years.
Future direction in relation to the control of Agvet chemical use	The AMS is currently working with NSW DPI, other regional horticultural industries and Freshcare to explore options for the introduction of an industry wide independently audited approach.

Appendix A-7 Woolworths QA processes summary

Issue	Details
Structure and operation	Historically, Woolworths have their own QA scheme, known as the Woolworths Quality Assurance (WQA) program, which is in transition to the Woolworths Supplier Excellence Program, which includes HARPS for Produce. Woolworths is a member of a working group with Horticulture Innovation Australia to implement harmonised audit requirements in the Produce Industry and now accept HARPs, Global Gap & Fresh Care in the Produce Sector. For benchmarking, Woolworths use the Global Food Safety Initiative (GFSI) standards. Woolworths recognise current industry standards and bolt on their own requirements to the existing schemes.
Any reference to international standards	N/A
Training/competency arrangements: at individual and enterprise level	Woolworths commented that auditor competency is a huge challenge and Woolworths would like to see more rigour and support around auditing processes.
Record keeping requirements: at individual and enterprise level	Woolworths conduct their own chemical residue testing and maintain a database of results.
Residue risks and testing: suite of chemicals, triggers for reporting adverse findings to regulatory bodies	Woolworths conduct their own surveillance of growers for pesticide residue in addition to existing schemes. Woolworths growers as part of their certification are required to complete annual pesticide residue testing.
Approach to off-label Agvet chemical use	N/A
Compliance and enforcement arrangements	Woolworths conducts grower audits, targeted to their particular needs and they select the grower/suppliers to audit. Woolworths recognises audit schemes across the produce industry, for example: • Poultry eggs – RSPCA, organic and ACL • Poultry meats – RSPCA, Free range, AEFC, ACMF and organic • Feedlot beef – NFAS • Pigs (pork) – APL, APIQ✓®, Free range, Ausmeat and organic
The evolution of the scheme and whether this included any trigger events	N/A
Strengths, weaknesses and gaps	Woolworths have their own QA scheme requirements as the current third party schemes are more compliance based for Food Safety and they have further quality and process requirements in line with customer expectations. The Woolworths QA scheme strength is the level of QA surveillance with their suppliers and the ability to identify potential risk areas based on end customer complaints/feedback.
Future direction in relation to the control of Agvet chemical use	For their own schemes – Woolworths are phasing out the WQA and are replacing it with a supplier excellence program. This will also include global food safety standards and any additional QA requirements specific to Woolworths.

Issue	Details
	Woolworths would like to see a QA system that prioritises food safety, quality and meets all legislative requirements for each industry. Industries are very diverse and have completely separate risk profiles, which provides a challenge for the retailer. Whatever harmonised QA scheme is developed, Woolworths believes it needs to be delivered to provide trust and competency within the scheme. It would need to have government buy in and consider the risk factors. It should be best practice as end customers have very high expectations regarding the quality of the products they purchase. Before recognising any supplier standard or scheme, Woolworths would conduct independent benchmarking. Woolworths believe retailers must be involved in any harmonised scheme for successful implementation, as retailers bear the burden if anything goes wrong, as they are customer-facing. Retailers must be comfortable that the schemes are implemented to the right level and meet consumer expectations. Woolworths would like to work closely with governments and industries. Woolworths gather their own data based on end consumer complaints and can identify issues based on geographical information and substance of complaints. This data gathering is based on growing region and sales and provides the opportunity to avoid additional risks in other areas. Woolworths are considering environmental programs such as EnviroVeg and FreshCare for growers but have not made it a requirement as yet. Woolworths support government initiatives to harmonise QA schemes. They would like government to work closely with stakeholders (including them), to remove duplication while maintaining food safety.

Appendix A-8 Freshcare summary

Issue	Details
Structure and operation	Freshcare is an industry owned, not-for-profit on-farm assurance program, established and maintained to service the Australian fresh produce industry. Freshcare is currently the largest Australian on–farm assurance program for fresh produce; proudly providing on-farm food safety & quality and environmental certification services to over 5500 members nationally. The Freshcare Code of Practice Food Safety & Quality (FSQ) is an industry owned standard, describing the good agricultural practices required on farm to provide assurance that fresh produce is safe to eat and has been prepared to meet customer requirements. The Code identifies good agricultural practices required to: • identify and assess the risk of food safety hazards that may occur during land preparation, growing, harvesting and packing of fresh produce • prevent or minimise the risk of food safety hazards occurring • prepare produce to customer specifications • identify, trace and withdraw/recall produce • manage staff and documentation • review compliance. The requirements of the Code of Practice (FSQ), called elements, are grouped into two sections – Management and Food Safety & Quality. Specific compliance criteria and risk assessments are also included in the Code Appendix. The Management (M) elements, Food Safety & Quality (F) elements and Appendix information are all mandatory requirements for Freshcare Food Safety & Quality Certification. Each element describes the outcomes required, the practices needed to ensure compliance and records that may be required to demonstrate compliance. This forms the basis of Freshcare Training and together with the Freshcare Forms and Resources provides the foundations for the effective implementation of the Freshcare Program on farm. **Management (M)** M1 Scope and commitment M2 Documentation M3 Training M4 Internal audit and corrective action M5 Customer requirements **Food Safety & Quality (F)** F1 Hazard analysis F2 Growing site F3 Planting materials F4 Chemicals F5 Fertilisers and soil additives F6 Water F7 Allergens

Issue	Details
	F8 Premises, facilities, equipment, tools, packaging and vehicles F9 Animals and pests F10 People F11 Suppliers F12 Food defence and food fraud F13 Product identification and traceability F14 Recall
Any reference to international standards	Freshcare is currently being benchmarked to Global Food Safety Initiative (GFSI). GFSI provides an international benchmark model against which other standards can be assessed. The GFSI process enables customers to nominate to accept fresh produce from suppliers with any food safety system that is recognised as equivalent to GFSI - knowing that an agreed standard of compliance will have been achieved. Freshcare needs to have operated as an accredited certification system for at least 12 months before the full benchmark can be finalised (due for completion mid 2018). Freshcare is also being benchmarked to the GLOBALG.A.P. standard to assist Australian fresh produce businesses with export access.The change from a private industry scheme, to a more widely available accredited and benchmarked standard will ensure Freshcare remains a widely accepted food safety certification, for both domestic and export markets.
Training/competency arrangements: at individual and enterprise level	M3 Training M3.1 – Complete Freshcare Training M3.2 - Train all workers who complete tasks relevant to this Code of Practice to ensure a base level of food safety awareness. It is a requirement that all businesses participating in the Freshcare Food Safety & Quality program, have at least one business representative complete training. Freshcare training ensures each participating business has a full understanding of the Code and program requirements; how they are applicable to their business and what needs to be implemented and prepared to demonstrate compliance at audit. Freshcare training options include: group courses, one-on-one, and online (eLearning). F4 Chemicals outlines the chemical training requirements including: F4.3 - Train and authorise workers who store, handle, apply and dispose of chemicals. 1. Workers involved in the supervision of the storage, handling, application and disposal of chemicals: • have successfully completed a recognised chemical users course, or equivalent (See Appendix A-F4) • are competent in chemical storage, handling, application and disposal as specified by the Freshcare Code of Practice Food Safety & Quality. 2. Workers authorised to store, handle, apply and dispose of chemicals have been trained. 3. A register of workers authorised to store, handle, apply and/or dispose of chemicals is maintained and displayed in the chemical storage area. Approved Freshcare training includes: • Freshcare Food Safety & Quality Edition 4 Training

Issue	Details
	• Freshcare Food Safety & Quality 3rd Edition Training. Freshcare requires the following national competencies be included in all farm chemical user training qualifications: • Level 3 – AHCCHM303A – Prepare and apply chemicals • Level 3 – AHCCHM304A – Transport, handle and store chemicals.
Record keeping requirements: at individual and enterprise level	<u>M2 Documentation</u> M2.1 - Verify compliance with the Freshcare Code of Practice through relevant documents and records. F4.8 – Record all chemical applications 1. Records of all pre harvest chemical applications are kept and must include: • application date • start and finish times • location and crop • chemical used (including batch number if available) • rate of application and quantity applied • equipment and/or method used to apply the chemical • withholding period (WHP) or earliest harvest date (EHD) • wind speed and direction • name and signature of person who applied the chemical. 2. Records of all postharvest chemical treatments are kept and must include: • treatment date and time • produce treated • chemical used (including batch number if available) • rate of application and/or quantity applied • equipment and/or method used to apply the chemical • withholding period (WHP) (where applicable) • name and signature of person who carried out the chemical treatment.
Residue risks and testing: suite of chemicals, triggers for reporting adverse findings to regulatory bodies	F4.9 - Test produce for chemical residues to verify that chemicals are applied correctly, withholding periods are observed and produce complies with MRLs. 1. A chemical residue test is conducted before initial Freshcare certification and then annually, or more frequently, if required by a customer specification. 2. A chemical residue test is: • a multi-screen test that includes chemicals used in the spray program • conducted on a random sample of produce that has had all pre harvest and postharvest chemical treatments completed and is ready for sale and/or consumption • conducted by a laboratory with NATA accreditation to ISO/IEC 17025 for the analysis of chemical residues. 3. Chemical residue levels do not exceed: • Maximum Residue Limits (MRLs) as specified by Food Standards Australia New Zealand (FSANZ) • Maximum Residue Limits (MRLs) as specified by a customer and/or the importing country (where applicable).

Issue	Details
Approach to off-label Agvet chemical use	Off-label agvet chemical use is difficult to audit particularly as there is variation between states and more consistent approaches should be explored.
Compliance and enforcement arrangements	<u>M4 Internal audit and corrective action</u> M4.1 - Conduct internal audits to verify ongoing compliance with this Code of Practice. 1. An internal audit of all activities and records relevant to the Freshcare Code of Practice Food Safety & Quality is conducted at least annually. A record is kept. 2. Workers responsible for completing sections of the internal audit are identified and, where possible, are independent of the practices being assessed. M4.2 - Complete corrective actions for any non-compliance. 1. A Corrective Action Record (CAR) must be completed when the requirements of the Freshcare Code of Practice Food Safety & Quality, Freshcare Rules or legislation are not being met, as identified by: • routine activities • annual internal audits • annual external audits • a valid complaint received from a neighbour, customer or regulatory authority • produce identified as being contaminated, or potentially contaminated. 2. A Corrective Action Record must include: • description of the problem • cause of the problem • whether or not the problem has occurred before • short term fix (action taken to fix the problem) • long term fix (action taken to prevent the problem recurring) • confirmation that short term and long term actions are completed and effective • name and signature of person completing the review • date of the review. 3. Reoccurrences of non-compliance are reviewed by the owner or appropriate senior manager. The Freshcare Program offers benefits to both suppliers and customers. It verifies that an industry recognised food safety and quality program is followed. Certification to the Freshcare Program is achieved through independent third-party auditing to the Code of Practice by auditors working for approved Certification Bodies. Freshcare audits are provided by the following Certification Bodies: • AUS-QUAL Pty Ltd • BSI Group ANZ Pty Ltd • Merieux Nutrisciences Certification • SGS Australia Pty Ltd • Australian Certified organic • Sci Qual International Pty Ltd

Issue	Details
	The Freshcare Program meets the requirements of a wide range of customer groups and forms the basis of many approved supplier programs. Freshcare continues to work closely with key customer groups, maintaining a level of awareness of program developments and ensuring continued compliance with market requirements. Combined Audits All Freshcare Certification Bodies have auditors who are able to audit across a number of industry standards (not just Freshcare).
The evolution of the scheme and whether this included any trigger events	Freshcare is a customer driven and independent mechanism (all voluntary) with the aim of ensuring Australian products can get into key overseas markets. It was customer driven to provide them with the certainty that the products satisfy the clean and green image that underpins Australia's agricultural system. Freshcare standards are widely accepted by all sectors of the supply chain, from packing sheds and local retail stores to major retailers in both domestic and export markets.
Strengths, weaknesses and gaps	Freshcare is underpinned by key industry resources, including the The Fresh Produce Food Safety Guidelines, developed and managed by the Fresh Produce Safety Centre (FPSC) Freshcare continues to develop and work closely with similar programs worldwide, including n, GLOBALG.A.P., NZ GAP and Canada GAP all of which have the same underpinning science. In February 2016, the Freshcare Food Safety & Quality Standard was approved as an accredited standard by the Joint Accreditation System of Australia and New Zealand (JAS-ANZ). Benchmarking to both GFSI and GLOBALG.A.P. will ensure the ongoing recognition of the Freshcare program internationally. States need to have a common set of legislation as they relate to chemicals, particularly as auditors are rotated between states.
Future direction in relation to the control of Agvet chemical use	Further direction is required around qualifications and training for those required to use agvet chemicals. Also need to have consistency between permits and off-label use of agvet chemicals.

Appendix A-9 GlobalG.A.P. Integrated Farm Assurance summary

Issue	Details
Structure and operation	GlobalG.A.P. Integrated Farm Assurance Standard is a global quality assurance system that has several elements; General Rules and Control Points and Compliance Criteria (CPCC). The system is modular, with three levels; • All Farm Base Module: general farm practices which are always applicable • Criteria based on classification under either crops, livestock or grain • CPCC for a particular product or other additional aspects under one of the above three categories Organisations are required to have an organisational structure including individuals responsible for managing the quality management system, and performing internal audits. The person responsible for day-to-day management may not be the person responsible for internal audits.
Any reference to international standards	Laboratories used for residue testing to verify compliance with MRLs must be ISO 17025 accredited.
Training/competency arrangements: at individual and enterprise level	Internal auditors and inspectors must be competent according to specifications provided.
Record keeping requirements: at individual and enterprise level	Records of qualifications and training must be maintained. Records must be maintained for a minimum of 2 years and be made available upon request. Records may be maintained electronically as long as any requirements for signatures are adhered to. Records of audit findings and follow up corrective actions must be maintained. A list of chemicals that are allowed to be used in the country and on the crop in question must be maintained. Records of application must be maintained including: crop name, location, date and time, trade name and active ingredient of the chemical, pre-harvest interval. Records of other chemicals including soil fumigants, fertiliser and post-harvest treatments must also be maintained.
Residue risks and testing: suite of chemicals, triggers for reporting adverse findings to regulatory bodies	Annex CB. 4 Residue Analysis outlines requirements for residue analysis in more detail. A list of the Maximum Residue Levels for the intended markets and crops must be maintained, and where multiple MRLs are the intended buyer, the strictest must be complied with. Evidence of a residue screening system demonstrating compliance with MRLs identified must be supplied and traceable to the farm and GlobalG.A.P. registered crop.
Approach to off-label Agvet chemical use	Only chemicals that are authorised for use on the target crop in the country in which they are grown may be applied.
Compliance and enforcement arrangements	One internal audit and one external audit are performed annually. Corrective actions must be evaluated and have a documented timeframe.
The evolution of the scheme and whether this included any trigger events	
Strengths, weaknesses and gaps	Strength: this scheme may be applied anywhere in the world.
Future direction in relation to the control of Agvet chemical use	

Appendix B – Schedule 7 requirements by jurisdictions

State or Territory	Permit, licence, authority required for person, business, institution to:			Licence Premises	Domestic can:		Charges	Exemptions	Appendix J-Implementation	notes
	Obtain	Use	Sell	Storage	Obtain	Use				
QLD	Yes, Appendix 7 of the Health (Drugs and Poisons) Regulation 1996	Yes, Appendix 7 of the Health (Drugs and Poisons) Regulation 1996	Yes	Secured or specified by Chief Executive	Yes, provided not listed in Appendix 7 of the Health (Drugs and Poisons) Regulation 1996	Authorised only	Yes, except strychnine and cyanide permits	Certain exemptions for industrial, manufacturing uses and use in research	Not by reference, however Appendix J provisions are largely mirrored in Appendix 7 of the Health (Drugs and Poisons) Regulation 1996	Intent of Queensland legislation is not to impose restrictions on the use of Schedule 7 poisons in the industrial, manufacturing or research areas
NSW	Yes	Yes	Yes	In a room or enclosure to which the public does not have access.	No	No	No	Registered pesticides; scientific research; use for non-domestic purposes (other than highly dangerous substances)	No	
VIC	Yes for listed regulated Schedule 7 poisons	Yes for listed regulated Schedule 7 poison	Wholesale for all Schedule 7 poisons		Could for Schedule 7 poisons, but not for listed regulated Schedule 7 poisons	Could for Schedule 7 poisons, but not for listed regulated Schedule 7 poisons	Yes	Non listed regulated Schedule 7 products may have controls under AgVet control of use legislation and dangerous goods legislation.	No	
TAS	Yes (Appendix J)	Yes (Appendix J)	Yes (Appendix J)	Yes (Appendix J)	No	No	Wholesaler-Yes User-No (Appendix J)	If Dangerous Goods or pesticides permit issued	Yes	Restrictions only apply to Appendix J substances. Non Appendix JSchedule 7 not for domestic use.
ACT	Yes	Yes	Yes	Specified by Minister	No	No	No	Registered Pesticides	No	N/A
NT	Yes	Yes	Yes	Yes	No	No	$20 per annum for retail licence, $50 per annum for manufacturer or wholesaler, User Nil		Yes	
SA	No*	No*	Yes	Locked cage denying access to public	No	No	Yes	Yes**	Not by reference, however Appendix J provisions are largely mirrored in section 22 of the Controlled Substances Act 1984.	
WA		Yes	Yes				Yes	Specified groups eg primary producers	Implemented where appropriate	

Source: https://www.tga.gov.au/australian-state-territory-regulatory-controls-schedule-7-poisons. Accessed 05/12/2017

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Revision	Authors	Reviewer		Approved for Issue		
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