



Australian Government
**Australian Pesticides and
Veterinary Medicines Authority**



AGQA SCHEME REVIEW

DRAFT REPORT

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OPPORTUNITY FOR COMMENT

You are invited to comment on this draft report into the operation and future directions of the AgQA Scheme.

Written responses should be sent to the APVMA by **5pm, Friday 7 May 2010**. Please provide submissions by email to agqa_review@apvma.gov.au.

All submissions will be publically available on the APVMA website unless they contain confidential commercial information (CCI). Such submissions should clearly indicate they contain CCI in either the submission or the associated email.

The final report will be prepared after the review team has considered the submissions.

SCOPE OF THE REVIEW INTO THE AGQA SCHEME

Reason for the review

The Quality Assurance Scheme for Agricultural Active Constituents and Agricultural Chemical Products (the AgQA Scheme) is the Australian Pesticides and Veterinary Medicine Authority's (APVMA) primary compliance activity to provide quality assurance of agricultural active constituents. In recent months, the APVMA has received consistent feedback that the scheme is labour intensive, too focussed on paperwork and does not adequately address the concerns about the quality and specification of agricultural chemical products supplied to the market after registration assessment.

Terms of reference of the review

The terms of reference of the Review are:

1. Review the operation and effectiveness of the Quality Assurance Scheme for Agricultural Active Constituents (the AgQA Scheme), and in so doing take account of:
 - The defined risks that were intended to be addressed by the AgQA Scheme
 - The level of non-compliance with treatments to address those risks
 - The resources and costs associated with implementation of the AgQA Scheme both for the regulated industry and the APVMA
 - Any demonstrated changes in the compliance culture of the regulated industry resulting from introduction of the AgQA Scheme in 2005
 - The policies of international regulators in relation to the quality of agricultural active constituents and the enforcement of standards
 - Views of relevant stakeholders, including the regulated industry, the Department of Health and Ageing and APVMA staff.
2. Conduct an assessment of the operation of the AgQA Scheme and consider whether:
 - The range of identified risks are relevant to the purpose of the AgQA Scheme
 - The current legislative provisions provide adequate controls and allow the purpose of the AgQA Scheme to be achieved
 - The standards and conditions underpinning the AgQA Scheme are sufficiently robust to ensure enforcement
 - Alternative or additional legislative provisions are required to improve the efficiency or effectiveness of the Scheme
 - The mix of structure, management responsibilities, delegations and resources allocation is the most appropriate to enable the APVMA to effectively enforce the AgQA Scheme.
3. Provide recommendations on:
 - The public value that will be delivered by the continuation of the AgQA Scheme in its present form
 - Alternative operational initiatives to address identified risks
 - The most appropriate legislative regime for proper, efficient and effective enforcement of those initiatives.

Details of the review

This will be achieved by detailed consideration of the relevant issues and include the views of agency regulatory personnel, community and industry. The review will be open and transparent, with consultation and targeted engagement with regulatory personnel, industry, end users and the broader community.

Who will conduct the review?

The review team will consist of the APVMA Compliance Manager and a project officer attached to the Compliance Section. The Program Manager Regulatory Strategy and Compliance will provide general direction to the review team. The overall management of the Review will be the responsibility of the Program Manager, Regulatory Strategy and Compliance.

A draft report with draft recommendations will be prepared for final consultation with regulatory personnel, industry and community sectors.

The review team will then prepare a final report to the Chief Executive Officer (CEO). The CEO will determine what response to the recommendations will be pursued by the APVMA.

Further information on the AgQA Scheme can be found at: <http://www.apvma.gov.au/agqa/agqa.shtml>

GLOSSARY OF TERMS AND ABBREVIATIONS

Active	The active constituent in a product
AgQA Scheme	APVMA's Quality Assurance Scheme for Agricultural Active Constituents and Agricultural Chemical Products
Agvet	Agricultural and veterinary
Agvet Code	Schedule to the <i>Agricultural and Veterinary Chemicals Code Act 1994</i>
Agvet Legislation	Agricultural and veterinary chemicals legislation incorporating the Acts, Regulations and Instruments
APVMA	Australian Pesticides and Veterinary Medicines Authority
DoC	Declaration of Composition
Excipient	Any ingredient other than an active constituent that is part of a formulated product. Non-active constituents are added at the time of manufacture for various reasons. For example, excipients improve formulation characteristics such as stability, solubility and spreadability.
GMP	Good Manufacturing Practice
NCR	APVMA's Non-Compliance Report
National Registration Scheme for Agricultural and Veterinary Chemicals (NRS)	The NRS sets out the regulatory arrangements for the management of pesticides and veterinary medicines in Australia. The APVMA administers the scheme's legislation in partnership with state and territory governments, and with the active involvement of other Australian government agencies.
Parent products	Parent products provide the active constituent used in the production of progeny products.
Progeny products	Progeny products utilise a registered chemical product as the source of their active constituent, either through repacking or reformulation via dilution.
Regulatory activities	Activities involved in administering regulations
Site Independence	Exclusion for the requirements of active constituent approval evaluation for a specific site of manufacture. Active constituent would only be required to comply with a standard for quality.
2004 RIS	The 2004 Regulatory Impact Statement — <i>Regulation of Agricultural Chemical Product Quality by Conditions of Approval and Registration</i> .

EXECUTIVE SUMMARY

This review examines the operation and effectiveness of the AgQA Scheme and provides a number of strategic directions that could be implemented to strengthen the scheme before amendments to the Agvet Legislation and Code are considered.

In the context of this review, the Australian Pesticides and Veterinary Medicines Authority (APVMA) has jurisdiction over the importation, manufacture, supply and advertising of agricultural chemical products and active constituents in Australia. The APVMA ensures the quality of active constituents used in agricultural chemical products in the Australian marketplace through its Quality Assurance Scheme for Agricultural Active Constituents and Agricultural Chemical Products (the AgQA Scheme).

Context of the AgQA Scheme

The AgQA Scheme is based on a set of standards for active constituents. These standards set out the purity of the active constituent and the maximum allowable impurity level. These standards are incorporated in the Conditions of Registration along with other information that the APVMA deems necessary to ensure the quality of agricultural chemical products.

As such, the Conditions of Registration underpin the scheme. These conditions hold product registrants responsible for ensuring the active constituents in agricultural chemical products are sourced from an APVMA listed manufacturing site. They also require that the active constituents meet the relevant APVMA standards, where such a standard exists.

Under the scheme, the APVMA monitors compliance with the Conditions of Registration through product record call-ins and on-site company record inspections, and the accuracy and validity of these records through product batch sampling and testing.

The Operation and Effectiveness of the AgQA Scheme

The majority of products have active constituents that conform to standards but many registrants fail record keeping and continuity conditions. Compliance with these conditions has improved over the life of the AgQA Scheme. However, the current scheme only considers the quality of the active constituent and it does not place any onus on the product registrant to ensure the quality of the final product supplied to the market.

The APVMA devotes considerable resources to administering the AgQA Scheme as part of its evaluation, registration and compliance activities. The efficient and effective utilisation of these resources could be improved in a number of ways through greater collaboration between different programs in the APVMA, setting standard Conditions of Registration for different product types and introducing more flexibility to compliance activities.

Improving the efficiency and effectiveness of the AgQA Scheme

As part of the review, three industry workshops were held during November 2009. It was the intention of these workshops to gather insight into industry's experience of and feelings towards the scheme.

The attendees at the workshops spanned the full spectrum of stakeholders from multinational manufacturers to low-volume, local manufacturers. Active constituent approval holders, consultants and farmers were also among the attendees.

The majority of attendees expressed satisfaction with the intent and aims of the AgQA Scheme. However, much debate focussed on the practical aspects of the scheme, and possible limitations of a focus on the quality of active constituents. There were also concerns raised that while the scheme had

increased compliance and record keeping, significant scope remained for information falsification and avoidance of legislated requirements.

AgQA Scheme – Future Directions

Stakeholder workshops indicated that the AgQA Scheme has strengthened the quality of active constituents and agricultural chemical products supplied to the Australian market. As such, termination the AgQA Scheme was not considered an option, unless it was to be replaced by more comprehensive scheme, such as a full ‘Good Manufacturing Process’ (GMP) style system¹.

There was unwillingness to proceed down a full GMP style system for agricultural chemical products based upon the relatively small size of the Australian market and absence of international equivalents. The changes proposed for the Conditions of Registration and Conditions of Approval are intended to move the AgQA Scheme towards a more comprehensive licensing model without imposing excessive regulatory burden. Any changes to the current scheme should remain mindful of competition in the market for quality agricultural chemicals within Australia, and the trade implications and factors faced by primary producers.

After considering the points presented during the workshops, it is apparent that significant improvements are possible. The majority of opinions have supported the concept that the AgQA Scheme does not extend far enough (especially with regard to the quality of products), and with some amendments could become a more comprehensive quality assurance scheme for agricultural chemical products from the manufacture of active constituents through to the point of retail sale.

Current operational difficulties in undertaking activities associated with the AgQA Scheme may be overcome by strengthening the Conditions of Approval, Conditions of Registration and the links between them. Introducing more flexibility in the conduct of compliance activities, such as incorporating AgQA compliance work into the broader Compliance program, would allow resources to be appropriately allocated to priority areas of need.

Summary of strategic recommendations

This review into the AgQA Scheme recommends the following strategic directions.

STRATEGIC DIRECTION 1 – Conditions of Approval and Conditions of Registration

The Conditions of Approval for active constituents and the Conditions of Registration for agricultural chemical products be amended to strengthen the quality of agricultural chemical products and active constituents contained therein.

At a minimum,

- the APVMA should identify a standard for all active constituents
- approval holders and registrants should regularly update information held by the APVMA
- approval holders should provide their support for an active constituent to be incorporated in an agricultural chemical product
- Conditions of Registration should require compliance with the particulars of the Register of Chemical Products, and relevant product specifications (including packaging) and site of manufacture/formulation

¹ A ‘Good Manufacturing Process’ (GMP) accreditation, monitoring and audit system exists to ensure the quality of veterinary medicines. By comparison with the AgQA Scheme, the GMP system is very resource intensive.

- Conditions of Registration should directly align with the Conditions of Approval (so that changes to active constituents do not inadvertently lead to breaches of the Conditions of Registration).

STRATEGIC DIRECTION 2 – Standardised Conditions of Registration

A standardised set of Conditions of Registration be developed for different types of agricultural chemical product registrations, such as:

- stand-alone products
- progeny products (repack or dilution only)
- low-risk products

In addition, flexibility be retained to allow the APVMA to apply unique Conditions of Registration where appropriate.

STRATEGIC DIRECTION 3 – Compliance with the AgQA Scheme

Sampling and testing programs be expanded to include:

- agricultural chemical products — quality of active(s); level of toxicological impurities; and product specifications as provided to the APVMA
- field sampling at all stages of the production process up until the point of retail sale
- multiple batches of a single product.

The APVMA should also provide guidance on the expectations of registrant's record keeping and the areas where record keeping deficiencies will result in critical and major non-compliance.

STRATEGIC DIRECTION 4 – Administration of the AgQA Scheme

A dedicated team is formed to undertake coordination and administration of the AgQA Scheme. This team would:

- have input in the design of enforceable Conditions of Registration
- be responsible for post-registration activities
- provide a single point of contact, within the APVMA and between the APVMA and industry, for all matters relating to the AgQA Scheme.

The Draft AgQA Scheme Review also makes several supporting recommendations to underpin the strategic recommendations for the operation of the scheme. These encompass issues related to Conditions of Approval, Conditions of Registration, compliance activity and the administration of the scheme. These recommendations are listed in table 3 in chapter 6.

1 OVERVIEW

1.1 Purpose

The ANAO *Better Practice Regulation Guide* suggests that regulators should routinely assess effectiveness and efficiency of programs and suspend or vary those programs found not to be performing. The Australian Pesticides and Veterinary Medicines Authority (APVMA) concurs with this approach and has reviewed the operation and effectiveness of a number of programs and schemes in response to the ANAO review of APVMA operations.

This review of the Quality Assurance Scheme for Agricultural Active Constituents and Agricultural Chemical Products (the AgQA Scheme), conducted by the AVPMA, evaluates the operation and effectiveness of the scheme taking account of the risks, resources and relevant compliance concerns. As part of a detailed consideration of the relevant issues, it incorporates the views of agency regulatory staff and industry stakeholders, as well as international active constituent quality assurance models.

1.2 Context

The APVMA ensures the quality of active constituents used in agricultural chemical products supplied to the Australian marketplace up until the point of retail sale through the AgQA Scheme. The AgQA Scheme is based on the set of conditions that relate to standards for active constituents published on the APVMA website. These standards set out the purity of the active constituent and the maximum allowable impurity level.

The AgQA Scheme was developed collaboratively with industry in 2004 and has operated since 2005. It was introduced to improve the quality of agricultural chemical products by developing Conditions of Registration for these products and their active constituents. The scheme was seen as a solution to the problem of agricultural chemical products failing to meet specifications and quality standards without resorting to complex and time-consuming legislative amendments.

Since its introduction, the APVMA has received consistent feedback that the AgQA Scheme is labour intensive, too focussed on paperwork and does not adequately address the concerns about the quality and specification of registered agricultural chemical products supplied to the market. This review identifies those issues that have not been adequately managed by the current scheme and provides directions to further strengthen the quality of agricultural chemical products.

THE AGRICULTURAL CHEMICALS INDUSTRY AND THE ROLE OF THE APVMA

The agricultural chemical industry in Australia comprises about 600 companies or persons supplying about 6000 products to farmers, contract applicators, pest controllers and householders. These products broadly include herbicides, insecticides and fungicides for use on farm crops; similar products for use in home situations; water treatment products including swimming pool treatments; products for treating algae and mould; preventing rot and infestation in marine structures; and other products. The businesses involved range from major multinationals through substantial Australian companies to small businesses and sole traders. For many of these businesses, agricultural chemicals represent only a part of their product range. The total sales volume in these products was over \$1.9 billion in 2008-09.

As there are inherent hazards present in chemicals that are intended to kill living organisms, Australian law requires that a risk assessment be carried out before such products are allowed into the market and used. The principal laws applying at the Commonwealth level are the *Agricultural and Veterinary Chemicals (Administration) Act 1992*, which establishes the Australian Pesticides and Veterinary Medicines Authority (APVMA) and defines its powers, and the *Agricultural and Veterinary Chemicals Code Act 1994*, with its schedules. The latter is known as the Agvet Codes and provides detailed operational arrangements and powers for the control of agricultural chemicals. It is rendered national in its scope by complementary legislation in each State and Territory. States and Territories have further powers under their own legislations to control use of these products once marketing authorisation is given.

The APVMA is the Australian Government authority responsible for providing supplying authorisations for agricultural chemical products. It provides these authorisations after it has completed a risk assessment as part of the registration process as set out in the Agvet Codes. In making this risk assessment, the APVMA requires applicants for registration to provide substantial scientific data about the chemical proposed. Advice from other government agencies, such as the Commonwealth Departments of Health and Ageing, and Environment, Water, Heritage and the Arts, and State agriculture departments, form an important part of the APVMA's considerations.

The Agvet Codes require that the APVMA be satisfied, among many other criteria, about the quality² of a proposed agricultural chemical product. In particular, the APVMA is required to separately approve the active constituent(s) which are to be included in the product to provide the desired biological effects.

The current framework includes a requirement that each source of manufacture of an active constituent have separate approval by the APVMA. Particular categories of product application require confirmation of the proposed active constituent quality in the product — for example, a batch analysis for an active from an approved site. This confirmation of quality may be given without reference to, or knowledge of the approval holder for the active constituent, and hence may be seen by the approval holder as bypassing their interests and 'free-riding' on their approval.

In order to fully and properly discharge its statutory duties, especially s.14 of the Agvet Codes, the APVMA needs to be able to ensure that the quality of each agricultural chemical product in the marketplace is maintained in accordance with that approved at the time of registration. The AgQA Scheme was intended to strengthen the quality and assurance regime for agricultural chemical products in the Australian market.

² 'Quality' described in the 2004 RIS refers to the composition of an active constituent or agricultural chemical product established at time of approval or registration, and assessed at that time by the APVMA as meeting the legislative criteria for approval or registration.

2 OVERVIEW OF THE AGQA SCHEME

The APVMA ensures the quality of active constituents used in agricultural chemical products in the Australian marketplace. It does this through the Quality Assurance Scheme for Agricultural Active Constituents and Agricultural Chemical Products (the AgQA Scheme). The scheme utilises Conditions of Registration that refer to standards for active constituents which set out the purity of the active constituent and the maximum allowable impurity level.

Conditions of Registration for agricultural chemical products underpin the scheme. They require that the active constituents contained in the agricultural chemical product meet the relevant APVMA standard for the active constituents in the product. Product registrants are responsible for ensuring the active constituents in agricultural chemical product are sourced from an APVMA-listed manufacturing site.

Under the AgQA Scheme, the APVMA monitors compliance with the conditions through product record call-ins and on-site inspections of company records. The APVMA assesses the accuracy and validity of these records through product batch sampling and testing.

The AgQA Scheme was developed collaboratively with industry and has operated for the last five years, but the APVMA has received consistent feedback that the scheme is labour intensive, too focused on paperwork and does not adequately address the concerns about the quality and specification of agricultural chemical products supplied to the market after registration assessment.

2.1 History of the AgQA Scheme

There is a provision for manufacturers of chemical products to be licensed under the *Agricultural and Veterinary Chemicals Code Act 1994* (the Agvet Code). However at the commencement of the National Registration Scheme (NRS) in 1995, it was decided to temporarily exclude licensing requirements for manufacturers of agricultural chemical products until a measure of good manufacturing could be established. While the APVMA and previous working groups have considered a formal licensing scheme for manufacturers of agricultural chemical products, the exclusion from such requirements has been maintained because:

- there is limited demonstrable risk to public health, the environment, efficacy or trade of not having a licensing scheme
- none of Australia's major trading partners of comparable regulatory standard require licensing of agricultural chemical manufacturers.

As such, Australian manufacturers of agricultural chemical products could be seriously disadvantaged by a licensing scheme and indicated that the introduction of such a scheme may force them overseas.

The regulatory framework administered prior to the introduction of the AgQA Scheme placed the emphasis on the AVPMA deciding whether active constituents and chemical products were suitable to be supplied — in other words, the framework was limited to only the giving or refusal of an approval. It did not include:

- Any formal licensing requirements for the manufacture of active constituents or chemical products
- Any offence provisions for the supply of active constituents that do not meet the approval requirements
- Any obligations on manufacturers of active constituents or chemical products to conduct testing of substances or to retain records relating to the manufacture and testing of those substances.

As a result, the ability of the AVPMA to undertake enforcement action on registrants and approval holders in regard to product quality was limited to responding to complaints once non-compliance had

occurred, often with serious consequences, rather than supporting and ensuring proactive attainment of compliance by industry participants.

In addition, there were limited consequences, and possibly rewards, for registrants and approval holders that were willing to undertake adverse conduct, such as fabricating paperwork or supplying products of uncertain quality, as the likelihood of detection was seen as low, and regulatory consequences light, even if detected.

The shortcomings of this regulatory framework were highlighted in a number of incidents between 2002 and 2004 where agricultural chemical products failed to meet specifications and quality standards. In addition, there were concerns about the integrity and quality of agricultural chemical products and active constituents imported from some manufacturing sources in countries such as China, India, other parts of South East Asia and South America.

As a result, four options for improving the quality and assurance regime for agricultural chemical products without implementing a licensing scheme were considered in the 2004 Regulatory Impact Statement — *Regulation of Agricultural Chemical Product Quality by Conditions of Approval and Registration* (the 2004 RIS).

The options considered in the 2004 RIS were:

- enhanced compliance monitoring by the APVMA
- self-regulation by manufacturers of agricultural chemicals
- Conditions of Approval and/or Condition of Registration
- legislative provisions for actives and products (see box for more information).

The APVMA's preferred long-term option in 2004 was the adoption of legislative provisions for active constituents and products through:

- approval of each active constituent with a detailed manufacturing and compositional specification, and require persons supplying or using the active constituent in a chemical product to comply with that specification
- incorporation, in the Agvet legislation, of an offence provision to address any instances of non-compliance as identified above
- provision, in regulations, of the requirements for quality assurance for agricultural chemical products.

However, it was noted that this legislative option would take a number of years to progress, and that these amendments were a low-priority compared to other planned amendments to the AgVet legislation.

In response, the APVMA decided to proceed with a non-legislative, interim solution, based on the option to strengthen the Conditions of Approval and Registration for active constituents and products respectively. This scheme, known as the AgQA Scheme, was designed to allow the commencement of improvements in the quality of agricultural chemical products that do not require legislative change. This review evaluates the effectiveness of the non-legislative, interim solution (the AgQA Scheme) and identifies any issues that continue to be a problem, or have arisen since the introduction of the AgQA Scheme. The outcomes of this review will inform the discussion to determine what legislative changes, if any, are necessary to strengthen the regulatory regime to ensure quality of agricultural chemical products in Australia.

NON-LICENSING OPTIONS FOR IMPROVING THE QUALITY AGRICULTURAL CHEMICAL PRODUCTS

The APVMA developed four options for improving the quality agricultural chemical products from previous working parties that were evaluated in the 2004 RIS. The current AgQA Scheme was developed as an interim solution to towards the full implementation option 3.

OPTION 1 – ENHANCED COMPLIANCE MONITORING BY APVMA

This option envisaged a substantial and on-going monitoring program (ex-factory or in the market). A sampling model would be developed, and issues that could influence the sampling rate might include potential risk of products, volumes of sale, cost of sampling and testing, and other factors which would need to be identified for this option to be evaluated in detail.

Issues relevant to the effectiveness of this option include:

- the level of monitoring at which there is a reasonable probability that most non-compliances would be detected
- the scope of testing – what compounds would be screened for, and whether analysis would be quantitative or qualitative
- the level of monitoring and sanctions that would provide an incentive for industry to adopt measures, such as quality assurance, to ensure compliance

OPTION 2 – SELF-REGULATION BY MANUFACTURERS OF AGRICULTURAL CHEMICALS.

Under this proposal, the industry would develop their own guidelines for the manufacture of agricultural chemical products. The guidelines would provide for an industry-written code of practice. The code of practice would incorporate production methods to a level ascertained as practicable by industry, and the industry would operate a process to audit companies and accredit those in compliance.

There would not be formal sanctions should the code be disregarded or broken, but publicity and marketing strategies would be used to support the scheme and make compliance attractive to companies.

OPTION 3 – CONDITIONS OF APPROVAL OR REGISTRATION

Under this system, the APVMA would impose requirements on registrants for regular sampling and analysis of their products as Conditions of Approval of the active constituents and registration of the agricultural chemical products. The APVMA would subsequently require the approval holder and/or registrant to demonstrate compliance with these conditions. The APVMA has powers to impose conditions that it considers appropriate for approvals or registrations, and powers to suspend or cancel approvals or registrations for breaches of these conditions.

This option allows the APVMA to set conditions as part of the risk assessment and management process, ensuring that testing is relevant to statutory criteria and information used at the time of registration or approval. Monitoring and compliance aspects would need additional consideration.

OPTION 4 – LEGISLATIVE PROVISIONS FOR ACTIVES AND PRODUCTS

The legislative provisions required would be:

- Inclusion of an offence provision in the Code, similar to s. 83, which deals with agricultural chemical products, creating an offence of supply or use an active constituent not complying with approval particulars, especially the Declaration of Composition for the active, and
- Inclusion in Code Regulations of provisions as to what QA measures, such as testing and record-keeping, are required of agricultural chemical manufacturers.

There has been general support for this proposal at the policy level, however achieving legislative changes could be a lengthy process.

This option comprises an offence provision for substandard actives together with regulations for quality assurance of agricultural products. It represents a strong solution to the issue, and would need to be the subject of a detailed regulatory impact statement (RIS) when legislation is being drafted. However, because of the delay involved in agreeing and achieving legislative change in the Agvet legislation, with all States and Territories involved, this option has represented a 'do nothing' or status quo option in the medium term.

2.2 The structure of the AgQA Scheme

The Quality Assurance Scheme for Agricultural Active Constituents and Agricultural Chemical Products (the AgQA Scheme) is based on a set of standards for active constituents (actives). These standards set out the purity of the active constituent and the maximum allowable impurity level.

The initial objectives of the AgQA Scheme were to establish practices for the approval of active constituents and registration of chemical products that:

- assure a consistent level of quality in those actives so that the products are effective when used as directed (as specifically required by the Agvet Codes s. 14 (3) (f)), and that their use does not endanger people, animals or plants, the environment or Australia's international trade (s. 14 (3) (e))
- allow for the use of enforcement powers in a clear and transparent manner by the APVMA, when a person does not comply with those rules or a product does not comply with the required quality criteria.

The AgQA Scheme was designed to improve:

- transparency — registrants and applicants should know what is required of them.
- fairness — products of like degree of risk should be subject to a like degree of control. Control measures should be achievable by small business. Large importers should be subject to similar control levels to local manufacturers. The requirements should be only those considered necessary to meet APVMA legislative criteria.

The AgQA Scheme was intended to address these objectives through setting and enforcing the Conditions of Registration on all agricultural chemical products containing an active constituent for which there is an APVMA standard. These Conditions of Registration set out the record keeping requirements that ensure the quality of active constituents contained in registered chemical products.

The APVMA monitors compliance with the Conditions of Registration under the AgQA Scheme through three distinct activities. Compliance requirements may consist of one or more of the following.

- Data call-ins — a desk-based audit of the records required under the Conditions of Registration
- Company visits — compliance officers make inspection visits to registrants' premises to monitor records required under the Conditions of Registration
- Sampling and testing of agricultural active constituents — a formal sampling and testing program is conducted to provide assurance that the records under the Conditions of Registration are valid and accurate.

Registrants with non-compliant records and/or products may be subject to enforcement action by the APVMA depending on the nature of the failure, its significance and what risks the failure may represent.

Conditions of Registration

Conditions of Registration underpin the AgQA Scheme. Conditions of Registration are applied at the time the APVMA registers an agricultural chemical product. The conditions set out the registrant's responsibilities for ensuring the quality of agricultural active constituents.

Under the conditions, the product registrant must ensure the active constituent is sourced from an APVMA approved manufacturing site listed in the Record of Approved Active Constituents.

The conditions also require that the active constituents meet the relevant APVMA standards. Among other things, these standards set out the purity and the maximum concentration for specified impurities.

The product registrant or a nominated third party must keep records for each batch of active constituent used in each batch of registered product. The records include batch analysis records, the name and address of the manufacturing site for that batch of active constituent. The records must be made available to the APVMA on request and must be kept for two years after the manufacture of the agricultural chemical product.

The APVMA considers requests for variations to the standard Conditions of Registration on a case-by-case basis. New applicants or existing registrants must provide additional information to support any proposals for alternative conditions.

Certain active constituents might be excluded from the requirements of APVMA approval where they are considered to be low risk with few safety concerns. In addition, the Conditions of Registration relating to active constituents are applied but not considered relevant in cases where the product only contains active constituents for which a standard does not exist.

Where an active constituent is contained in a manufacturing concentrate and a standard for the manufacturing concentrate does not exist, it is the responsibility of the registrant to establish compliance with APVMA standards for the active constituent.

2.3 Defined risks associated with the quality of agricultural chemical products

There are a number of defined risks associated with the manufacture and use of agricultural chemical products that the AgQA Scheme was intended to address.

2.3.1 Broad risks

Broad risks related to the quality of an active constituent or agricultural product include:

- The likelihood of harm to humans exposed to the product or its residues
- The likelihood of harm to the environment
- The likelihood of harm to subject crops or animals
- The consequences on Australia's trade with other countries, including the impact of residue levels
- The impact of a product not being effective for the purposes described on the label.

Ameliorating these broad risks appears to be an appropriate justification for the continuation a quality assurance scheme for agricultural chemicals in the absence of a more comprehensive licensing scheme for manufacturers of these products.

2.3.2 Specific risks

A number of defined risks were explicitly intended to be addressed by the AgQA Scheme.

- Toxicological impurities in excess of allowed concentration — OH&S risks to handling of products and end users; residues of impurities that remain on foodstuffs and commodities.
- Purity of technical grade active constituent is higher/lower than the standard — If lower, the product may be ineffective or have a high level of impurities that are considered toxicologically significant. If higher, the product may be phytotoxic for target crops. These matters are of particular concern where product is formulated to independent of the purity of the active constituent.
- Substitution of approved active constituent with an inferior active constituent — Gives rise to the risks set out above for toxicological impurities and non-compliance active constituent purity.

Substitution of active constituent presents a risk to the National Registration Scheme (NRS) as it encourages product manufacturers to seek approval using expensive high quality material and then circumventing the approval by using less expensive, lower quality material. Nominating fictitious manufacturing sites and submitting false documentation also presents a risk to the NRS as registrants may achieve market advantages over compliant registrants.

- Nominating fictitious manufacturing sites and submitting false documentation to demonstrate compliance — Gives rise to the risks set out above for toxicological impurities and non-compliance active constituent purity. Such actions also undermine the integrity of the NRS if they result in market advantages over compliant registrants.

In addition, specific types of manufacturers of agricultural chemical products may be more susceptible to the risks outlined above.

- Small to medium size manufacturers — these manufacturers may not have robust and rigorous testing and record keeping procedures for their actives and hence may manufacture products that have actives that do not conform to the standards.
- Manufacturers/registrants that source actives internationally — registrants/approval holders who import products/actives may not test the quality of the actives themselves, but may rely on third parties (such as the active manufacturer) to provide records the quality of these products/actives. Of particular concern are products/actives that are sourced from Asia (particularly China, India and Malaysia).

The AgQA Scheme was intended to reduce the risks associated with these specific manufacturers and, in general, has been relatively successful in promoting better record keeping and conduct within these organisations, as well as the broader agricultural chemical manufacturing community.

Arguably, the most important defined risk that the AgQA Scheme does not address is that of product quality, both at the time of manufacture and in the market.³ In its present form, the AgQA Scheme only requires that manufacturers of agricultural chemical products ensure the quality of the actives used in the manufacturing process, not the final product. There are no Conditions of Registration relating to the quality of the products manufactured, and, hence, no assurance that the characteristics of the final product (excluding the quality of the active and impurity levels) are consistent through time, especially when the manufacturing process may have changed substantially.

Introducing a regime for the quality of products, either at the time of manufacture or when imported (in the case of imported products), would provide a more rigorous program for ensuring not only the quality of actives is maintained through the production process and reducing the incidence of products with high levels of toxicological impurities but other physio-chemical attributes. The end result to be a greater assurance (for the APVMA and the community) of the quality of the product supplied to the Australian market.

³ State and territories have responsibility for compliance with 'control-of-use' regulations — that is, after retail sale.

3 THE OPERATION OF THE AGQA SCHEME

The APVMA's main role in regard to the AgQA Scheme is to monitor the compliance of the registrants of agricultural chemical products with the Conditions of Registration. Instances of non-compliance result in the APVMA seeking remedial action (such as product suspension or recall) and/or criminal penalties (such as prosecution).

Administratively, the operation of the scheme is spread over three programs within the APVMA — Chemistry, Pesticide Evaluation and Compliance. It is difficult to determine the costs to the APVMA of administering the AgQA Scheme as the associated activities are integrated into the general activities of each program.

3.1 Level of non-compliance

The APVMA uses a variety of methods — data call ins, company visits, and sampling and testing of active constituents — to ensure registrants are compliant with the Conditions of Registration. Not all registrants or products are evaluated each year for compliance with the Conditions of Registration; the APVMA schedules compliance activity based on adverse experience reports, non-compliance reports and previous failures of agricultural quality assurance record keeping.

Since the introduction of the AgQA Scheme in 2005, the APVMA has conducted data call-ins on 155 products, company monitoring visits on 215 products and 15 sampling and testing programs⁴ on active constituents. Products reviewed under these compliance activities represent around 10 per cent of the total number of registered agricultural chemical products.

3.1.1 Record keeping and auditing

APVMA staff have examined the records for 786 batches from 370 products since the inception of the AgQA Scheme. Compliance monitoring has focussed on three aspects of records kept by registrants (see tables 1 and 2).

- Quality (Active constituent meets the standard) — Record particulars are examined to determine if the purity and impurity levels comply with the APVMA standard. Of the 786 batches examined, 783 complied for both purity of the active constituent and level of toxicologically significant impurities.
- Quality (Adequate records kept for active constituent) — The AgQA Scheme requires the keeping of records that can demonstrate that a batch product supplied by the registrant contains the active constituent for batch analysis results presented to substantiate compliance of the active constituent. These records must contain all of the particulars required by the Conditions of Registration. Missing records, missing particulars or irrelevant particulars can break the link between the product and the active constituent. While this does not indicate a non-compliant active constituent, it does not allow the APVMA to be assured that the nominated active constituent is contained in the subject product. During the period of the operation of the AgQA Scheme, only 359 batches have met these requirements.
- Continuity of Records — Records must contain linking information, such as batch numbers, on all documents. If documents contain correct particulars but cannot be linked, then it is not possible for the APVMA to be assured that the nominated active constituent is contained in the subject product. Since 2004, compliance with continuity requirements has only been achieved for 394 batches.

⁴ Only 14 active constituents were actually sampled and tested as there were no registered products available to be tested for one active constituent.

These results show that registrants are paying particular attention to records showing compliance of the active constituent with the APVMA standards. However, there are problems with registrants failing to obtain and keep records that establish links between the quality of the active and its incorporation into a specific product batch.

Adequate record keeping and continuity of records, while showing a low level of compliance, have continuously improved over the life of the program. Results from compliance activities undertaken since 2007 have indicated a higher level of compliance since the focus of compliance activities moved away from purely educative.

Over the course of the scheme the APVMA has moved its focus from data call-ins to company visits for record audits. The APVMA has found a significant increase in the compliance with record keeping requirements during these visits.

TABLE 1: AUDITS OF RECORD KEEPING – DATA CALL-INS

YEAR	NUMBER OF PRODUCTS	NUMBER OF BATCHES	ACTIVE MET APVMA STANDARD (% OF BATCHES)	ADEQUATE RECORDS (% OF BATCHES)	CONTINUITY OF RECORDS (% OF BATCHES)
2005-06	88	170	168 (99)	8 (5)	10 (6)
2006-07	54	72	72 (100)	23 (32)	24 (33)
2007—2009 ⁵	13	19	19 (100)	12 (63)	19 (100)
TOTAL	155	261	259 (99)	43 (16)	53 (20)

TABLE 2: AUDITS OF RECORD KEEPING – COMPANY MONITORING VISITS

YEAR	NUMBER OF PRODUCTS	NUMBER OF BATCHES	ACTIVE MET APVMA STANDARD (% OF BATCHES)	ADEQUATE RECORDS (% OF BATCHES)	CONTINUITY OF RECORDS (% OF BATCHES)
2005-06	44	100	100 (100)	23 (23)	30 (30)
2006-07	115	234	233 (99)	192 (82)	184 (79)
2007—2009 ³	56	191	191 (100)	101 (53)	127 (67)
TOTAL	215	525	524 (99)	316 (60)	341 (65)

3.1.2 Sampling and testing to confirm the validity of records

To address concerns about the validity of record keeping documents provided to the APVMA — particularly batch analysis results — it was decided that the APVMA would also take samples of market ready product along with batch analysis results for the active constituent contained in the products and

⁵ The compliance program for the AgQA Scheme was disrupted between 2007 and 2009 due to staff turnover and other priorities within the APVMA compliance section. As such, compliance activity that was started in 2007-08 was completed in 2008-09. No AgQA compliance activities were initiated in 2008-09.

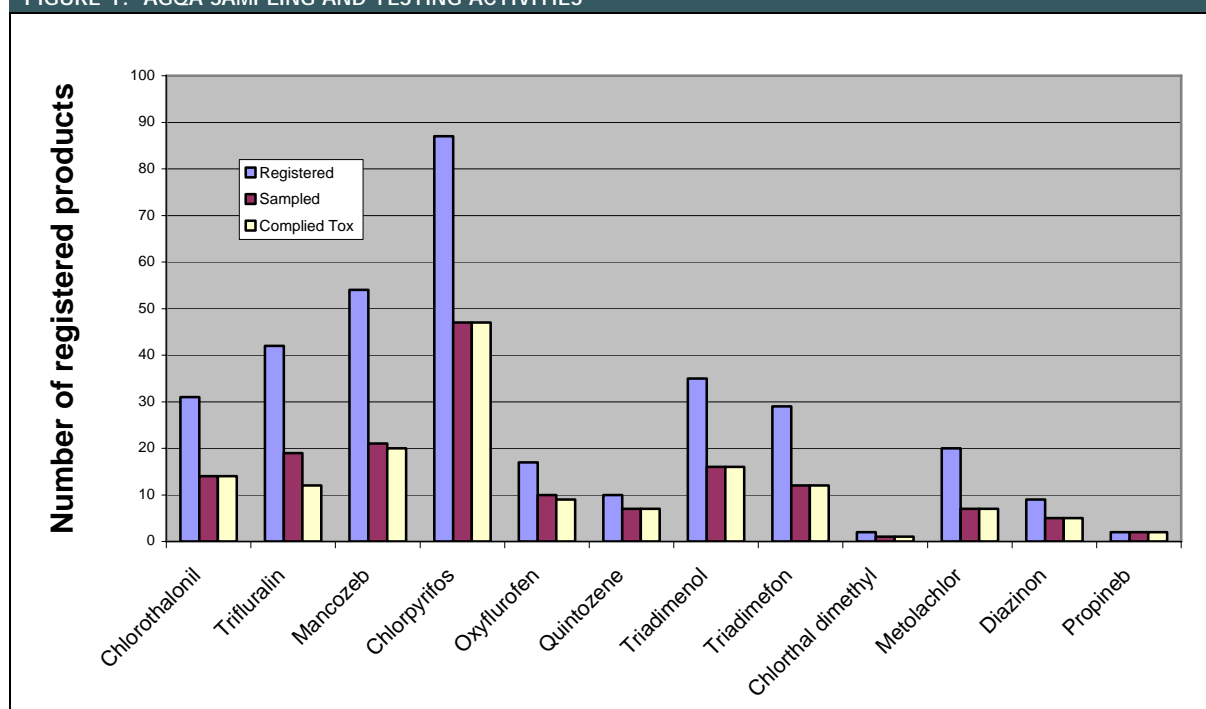
have the product analysed to determine if the batch analysis results were consistent with the quality of the active constituent contained in the product.

The sampling and testing program focuses on products that contain actives with known and regulated toxicological impurities as these products present a high risk to users and the wider community. This limits the scope activities of this program have been limited as only 21 per cent of registered products have standards that set out impurity levels. Figure 1 shows the results of analysis and compliance standards where results are available. Very few products failed to meet the standard and acceptable explanations were available in some instances where non-compliance was found.

Two testing programs, pyrimethanil and glyphosate, remain incomplete while the APVMA awaits the results from analysis. In another program, products containing diclofop were not available during the sampling time resulting in that particular program being abandoned.

The result from sampling and testing activities suggest that the active constituents are primarily compliant with APVMA standards with very few instances of non-compliance detected.

FIGURE 1: AGQA SAMPLING AND TESTING ACTIVITIES



3.2 Non-compliance actions and penalties

In relation to the AgQA Scheme, the APVMA has issued 3 testing orders under s. 99 of the Agvet code and, more recently, entered into 2 deed polls with registrants that were deemed non-compliant. In addition, numerous warning letters have been issued for products where the records have been found to be technically non-compliant but where the risk from non-compliance is low. Registrants that have been issued with warning letters were also identified as priority targets for compliance activity in subsequent years.

Since the introduction of the AgQA Scheme, the APVMA has not penalised registrants to full extent possible for non-compliance with the Conditions of Registration. The two main reasons for this are that:

the quality of almost all the active constituents investigated for non-compliance have met the APVMA standard; and, the vast majority of non-compliance breaches are related to record keeping issues, which are considered low-risk. In addition, the focus of AgQA compliance activities during the first two years of the scheme was on education, rather than enforcement.

There are significant costs associated with the enforcement arising from non-compliance activity and only a limited likelihood of success if enforcement action is contested in the Administrative Appeals Tribunal. As such, in the relatively few cases where major breaches of non-compliance have been found under the AgQA Scheme, the APVMA has been reluctant to prosecute or utilise the complete spectrum of regulatory tools available.

NON-COMPLIANCE ACTIONS AND PENALTIES AVAILABLE TO THE APVMA

The current penalty regime for non-compliance with the Conditions of Registration for agricultural chemical products is the same as the broad penalty regime for non-compliance under the Agvet Legislation and Codes. There is a provision under the Agvet Legislation and Codes for the APVMA to fine and prosecute registrants in cases of non-compliance under the criminal justice system. In addition, the APVMA can also issue stop supply and recall orders for product batches that are found to be non-compliant.

While this penalty regime can be used for cases of minor non-compliance (for example, sub-standard record keeping), the APVMA is often reluctant in using this approach for the following reasons.

The penalties are not commensurate with the nature of the non-compliance activity. For example, the maximum penalty for the supply of a registered chemical product in contravention of the conditions of listed registration is 300 penalty units (currently \$33 000) for an individual or 1500 penalty units (\$165 000) for a corporation.

The APVMA utilises recalls and compliance notices as cautionary, protective measures rather than imposing these measures as a form of punishment (although remedying non-compliance may incur costs).

The costs of pursuing non-compliance can be large and are often not cost effective, especially when decisions may be overturned at the Administrative Appeals Tribunal (AAT).

The major problem the APVMA faces in its penalty regime for non-compliance is that the penalties available are not proportionate to the offence and/or the size of the corporation. In addition, the APVMA does not currently have access to deterrents that are appropriate for all types of non-compliance that are dealt, such as moderate penalties for major non-compliance.

There are inherent problems with the current criminal penalty regime — such as the two-year statutory timeframe, which is often not long enough for detecting offences, assembling evidence and commencing prosecution.

Different legislative powers may include the introduction of civil penalties, in addition to criminal penalties, for non-compliance with the Agvet Codes. This issue is much broader than just the AgQA Scheme, however, there does appear to be a need for a variable penalty regime that the APVMA is comfortable to pursue.

3.3 Resources and costs associated with the AgQA Scheme

3.3.1 Cost to industry

Information regarding the costs of the AgQA Scheme for industry was garnered from the review workshops in late 2009. However, industry representatives were not specific on the costs associated with compliance activities.

Most registrants indicated that there was an initial cost at the introduction of the AgQA Scheme to align quality testing and records with the Conditions of Registration. In addition, there was also an increase in staffing (specifically, regulatory managers and chemists) to produce ongoing records to comply with the Conditions of Registration. Many large, international companies report that significant resources are still being employed to align their global reporting systems with Australian requirements.

Other than direct reporting requirements as part of the Conditions of Registration, industry participants noted that small delays in the compliance activities of the APVMA could have a significant impact upon

a specific registrant and the industry in general. For example, an advantage may be achieved through non-compliance activity that is often not corrected in a timely manner following detection by the APVMA.

While industry may have incurred greater costs as a result of the AgQA Scheme, it was acknowledged that these requirements have improved the quality control procedures for registrants and, as a result, registrant's satisfaction of the quality of the agricultural chemicals released to the market.

3.3.2 Costs to the APVMA

There are three distinct sections within the APVMA that manage the AgQA Scheme and each are responsible for a separate component.

- The Chemistry section is responsible for giving approvals, setting Conditions of Approval and setting active constituent standards.
- The Pesticide Registration section is responsible for developing the Conditions of Registration and administering the application process.
- The Compliance section is responsible for ensuring that registrants adhere to the Conditions of Registration.

It is difficult to accurately determine the costs associated with the AgQA Scheme as these activities are included with general activities of the Chemistry, Pesticides Registration and Compliance sections. As such, it is not possible to separate out the cost of the AgQA Scheme to the APVMA for either Regulatory Strategy & Compliance or Pesticides Program.

In the Compliance program where there is some information available, the cost of auditing records for the AgQA Scheme is estimated to be about \$100,000 each year. This includes staff time in preparing for and conducting audits and reporting results. The cost of sampling and testing consists of staff costs of about \$50,000 per year and the costs for laboratory analysis that, over the life of the program, have been about \$250,000.

The most variable impact on APVMA resources is programming AgQA compliance activities into the broader compliance monitoring activities and the return on staff input relative to the risks addressed by pursuing compliance activity.

In the case of the AgQA Scheme, it can be said that the APVMA spends considerable time regulating a mostly compliant facet of active quality in registered products. However, there are considerable deficiencies with the record keeping practices of many product registrants and concerns over the veracity of some information provided to the APVMA.

4 IMPROVING THE EFFECTIVENESS OF THE AGQA SCHEME

As part of the review, three industry workshops were held during November 2009. It was the intention of these workshops to gather insight into industry's experience of and feelings towards the scheme. This section collates the ideas presented by all stakeholders for improving the scheme. Ideas presented that did not garner support from the forum in which they were raised have been excluded from comment here.

The attendees at the workshops spanned the full spectrum of stakeholders from multinational manufacturers to low-volume, local manufacturers. Active constituent approval holders, consultants and farmers were also among the attendees.

The majority of attendees expressed satisfaction with the intent and aims of the AgQA Scheme. However, much debate focussed on the practical aspects of the scheme, and possible limitations of a focus on the quality of active constituents. There were also concerns raised that while the scheme had increased compliance and record keeping, significant scope remained for information falsification and avoidance of legislated requirements.

In addition to the risks highlighted by the APVMA, industry noted the following as risks any quality scheme should address:

- environmental risks
- equality of registrants — that is, a level playing field
- 'down stream' implications for farmers — for example, residue levels in produce.

An increase in measurable outcomes was also recommended. It was noted that the measurements employed by the APVMA currently could not provide clear indication of the value of the scheme through increased product quality.

The attendees were clear in asserting that any system that is employed by the APVMA to ensure the quality of products must be applied equally to all parties in the Australian marketplace. There should be no differentiation between local manufactured product and imports, and no regulatory burden that would decrease the local chemical manufacturing industry.

The United States and New Zealand models for ensuring the quality of agricultural chemical products are also reviewed to provide guidance on alternative regulatory practices and assist in strengthening the AgQA Scheme.

4.1 Quality of agricultural chemical products

Conditions of Registration and standards for active constituents form the basis of ensuring the quality of the agricultural chemicals used in Australia. Concerns have been raised, both within the APVMA and in industry consultations, that the Conditions of Registration, including standards for actives, are not robust enough to ensure the quality of agricultural chemical products.

The main areas identified where there could be improvements in the quality assurance regime for chemical products are:

- Active constituents — including standards and site of manufacture
- Agricultural chemical products — appropriate Conditions of Registration for different registration types, quality testing of products and record keeping.

Conditions of Active Constituent Approval

The APVMA standards for active constituents and the Record of Approved Active Constituents are integral to the AgQA Scheme and are referred to in the Conditions of Registration for agricultural chemical products.

Standards for actives

Currently, around 430 of the 650 active constituents with APVMA approval for agricultural products are required to conform to a standard set by the APVMA. However, there are inconsistencies between the APVMA standards and those provided by the Food and Agriculture Organisation (FAO) and this topic was raised on numerous occasions. For example, the APVMA standard for pirimiphos-methyl contains only one toxicological impurity, whereas the FAO standard lists five toxicological impurities.

There was agreement that for specific instances a scientific justification may exist for differences between standards. In general, however, it is widely agreed that if an international standard exists for an active constituent, it should be adopted by the APVMA.

A formal review of all standards was accepted as not being appropriate. However once a standard has been determined, regular review to ensure currency of these standards was raised as a strong tool to ensure Australia remains at the forefront of chemical product quality.

The ideas above for active constituent standards were supported by all stakeholders and are consistent with the current policy of the APVMA.

While stakeholders agreed on the need for active constituent to meet a standard, concerns were raised that there might be other tools which better reflect active quality in addition to batch analysis results, e.g. declaration of composition (DoC) lists all the impurities not just those of toxicological concern.

There was some support for enforcing the quality of an active constituent as detailed in the DoC, but it was accepted that this might require the publication of the DoC for each site. This release of information may comprise commercial-in-confidence. The review team considers that retaining standards for actives remains an appropriate way to ensure their quality.

It was also noted that a number of active constituents are currently excluded from the need of APVMA approval, including manufacturing site and standard conformance. A proposal to require compliance with a standard for these actives, while retaining the exclusion of manufacturing site assessment, received tentative support. The review team considers that a requirement for all actives to meet a standard is an appropriate means to ensure that 'commodity chemicals' which are incorporated into agricultural chemical products are of sufficient quality to ensure the effectiveness and safety of the product.

A similar limitation was identified for the emerging area of bio-pesticides and the need for a form of active quality assurance in combination with product quality assurance. There are concerns that the development of standards might not be appropriate and the link to specific sites of manufacture may not be relevant. While these products are within the scope of the AgQA Scheme, the scheme was not designed to address the issues of how to develop standards for these actives and their associated products.

Site of active constituent manufacture

The site of active constituent manufacture is considered fundamental to ensuring the quality (including evaluation of all manufacturing impurities) of an active constituent contained in products that are supplied to the Australian marketplace. Registrants of agricultural chemical products must source active constituents from an APVMA approved site of manufacture where an APVMA standard exists.

However, sourcing an active constituent from an approved site does not currently require consent from the approval holder(s). As such, product registrants may circumvent the approval holder and source material from the approved site independently, which effectively reduces the value of holding an approval for an active constituent.

In addition, there are concerns of who is held responsible when an active does not meet APVMA standards. It was accepted that the obligation rests with the registrant to ensure the quality of the active constituent incorporated into their product. However, the approval holder for the site may be held responsible in broader terms even though there may be no contact between the non-compliant product and the approval holder. In addition, the inclusion of 'traders' within APVMA records as either active constituent manufacturers or product formulators does not ensure the responsibility of manufacture can be correctly assigned and confuses this issue further.

Under the current scheme, the APVMA cannot determine the manufacturing site for an active incorporated into a specific product prior to a record audit. Various stakeholders raised this as a significant shortcoming. For example, there have been human health concerns about the quality of milk and paint products from overseas manufactures in recent years. Should a similar need arise for urgent action in an agricultural product from a specific site the APVMA action, such as recall, may be unnecessarily delayed, with a consequent risk to community health.

Increasing the links between the Conditions of Approval and the Conditions of Registration was considered a worthwhile improvement to the AgQA Scheme. Segments of industry raised the point that the current value of holding an active approval is negligible. Mandating that registrants be required to gain consent from the approval holder to use an active from a specific site, and advise the APVMA prior to inclusion within the product, would enable the APVMA to re-establish clear obligations for actives and products that do not meet standards. In addition, it would allow swift and appropriate action to be taken, if required.

The review team considers continuing to require that actives be sourced from approved manufacturing sites is an important component to ensuring the quality of agricultural products. However, confusion over who is responsible if the quality of an active is not up to standard could be made clearer by requiring that active constituents source from an approved site have the consent of an approval holder for that active at that site.

It was noted that any proposed amendment to the scheme that may adversely impact access to, or restrict trade in, active constituent (for example, requiring active sourced solely through the approval holder) would not receive support from industry. However, under this arrangement competition need not decrease as there is no limitation on the number of approval holders for a site of active manufacture and the process for gaining APVMA approval is relatively straightforward and not prohibitively expensive.

Workshop participants proposed to remove details of the site of manufacture from the publicly available Record of Approved Active Constituents. This would increase the importance of active constituent approvals and give approval holders control and responsibility for the active within the Australian marketplace. It is noted that the requirement to keep this information, and its availability to any person, is detailed within s.17 of the Agvet Codes. No proposal to amend or alter legislation was presented on this topic.

It was proposed that the APVMA again require notification of active constituent source variation, and a letter of support from the approval holder. This notification and APVMA approval would occur prior to supply of product to the Australian market. Under this proposal, registrants may include as many active sites within the original approval as necessary, assuming that supporting documentation is presented.

The idea of 'site independence' was raised as an alternative policy. For this to still retain the quality of active supplied to Australia, noting that the impurity profile of material is fundamental to the toxicological profile, an increase in the minimum purity standard for all actives was mooted. The increase suggested was in the order of minimum purity for all active constituents of greater than 98 per cent. However, the review team considers this impractical (when considering international practice) and has the potential to disadvantage the Australian industry and wider community.

In addition, recent issues of false, or erroneous, sites within the Record of Approved Active Constituents were highlighted as an area not adequately addressed within the scheme. Workshop attendees identified the inclusion of 'incorrect' information within the APVMA records as a major risk to active constituent quality. This was considered to significantly devalue the overall goals of the scheme and the value of records supplied in support of the Conditions of Registration, including consent from approval holders.

The APVMA considers that approvals for active constituents and having correct information in the Record of Approved Active Constituents (the Record) remain essential for ensuring the quality of agricultural chemical products.

It was proposed that other sources of information (such as company records, export permits or government accreditation) be employed to establish the authenticity of sites of manufacture. Physical sites visits may also be appropriate to minimise the risk of false information within the Record but it was acknowledged that this might be difficult in the case of international sites of manufacture. As the Australian market is relatively small, most international site of active manufacture would also supply other jurisdictions and would therefore be required to verify the site in other regulatory systems. For example, the APVMA could accept US EPA Establishment Number documentation to establish the veracity of manufacturing sites.

Other areas of concern related to incorrect addresses, numerous differing addresses for the same site and inclusion of chemical 'traders' listed as a manufacturer. Any change to the AgQA Scheme should seek to increase APVMA assurance in the robustness and veracity of information provided to it.

It is the review team's view that a comprehensive review of sites of manufacture for active constituents should be undertaken to confirm the veracity of the information listed in the Register of Approved Active Constituents.

Other issues related to the Conditions of Active Constituent Approval

Workshop attendees wished to see an end to the perpetuity of approvals and a requirement for regular registration. The issue of perpetuity of an approval is considered outside the scope of this review. The review team is broadly supportive of ending this practice in relation to active approvals.

Under the AgQA Scheme, manufacturers of active constituents may change their site, processes and/or formulation through the Conditions of Approval without the knowledge of the product registrant. However in many cases, product registrants do not have direct contact with active manufacturers and are not informed when changes occur. Registrants of 'progeny' products (that is, repackaged or relabelled products) are particularly affected by such changes that may lead them to breach the Conditions of Registration inadvertently. Increasing the reliance on the Conditions of Approval would allow the active requirements for a site to vary without the need to vary multiple registered chemical product conditions. In addition, adopting such an approach would reduce the need for product registrants that do not have a direct connection with the approval holder (that is, they source active constituents from a third party — manufacturer directly or trader) to amend their Conditions of Registration to remain compliant.

It was suggested that batch samples of actives could be submitted with the original approval (or re-assessment) application. This would allow the APVMA to develop a compositional fingerprint of each active site and allow determination of active constituent source. However, there are likely to be substantial costs associated with testing the samples and compiling a database and it is unclear how this would substantially contribute to improving the quality of active constituents in light of other proposed changes.

There were also concerns raised about the accuracy of information contained within the Record, particularly the composition of actives where the manufacturing process may have changed significantly since the approval was obtained. It was proposed that a regular review of the Record be conducted which would involve the submission of a current DoC and possibly re-assessment of multi-batch analysis against the DoC. This would also allow the Record to reflect the most recent advances in manufacturing process and ensure that the quality of actives was consistent with updated standards.

Concerns regarding data-protection and access to data submitted by approval holders by third parties were noted. These concerns are not shared by the APVMA which considers that the processes it employs to protect confidential commercial information are appropriate.

Conditions of product registration

Conditions of Registration are the main tool by which the APVMA ensures the quality of agricultural chemical products. During consultations, a number of issues were raised concerning the Conditions of Registration including:

- Appropriate Conditions of Registration for different product types — repacks and dilutions of registered products ('progeny' products).
- There is no testing of products — both actives and overall — to determine if the level and quality of the active is maintained in the final formulation. This may be particular problem for imported, formulated products where there are concerns about the quality of the active constituent used (including the manufacturing source of the active).
- Record keeping — greater clarity for registrants regarding APVMA expectations, both overall and for specific aspects (such as the results of standards testing).

Appropriate Conditions of Registration for different registration types

The need to ensure that appropriate Conditions of Registration are applied to products was a continuous theme in many of the workshops. Concerns existed that the default 'one size fits all' approach was too broad and that there may be some inconsistency with registrants proposing the Conditions of Registration for a product.

Having similar types of products with different Conditions of Registration is not conducive to an efficient and effective regulatory regime, unless there is a valid reason for a product having unique Conditions of Registration. The concept of grouping of similar types of registrations (such as relates to different categories of regulation or regulatory risk) has merit in that it achieves the appropriate conditions for the most number of products with the least regulatory burden.

Concern was raised regarding the treatment of 'progeny' products within the current scheme. 'Progeny' products utilise a registered chemical product (the 'parent' product) as the source of their active constituent, either through repacking or reformulation via dilution. The registrants of these products have no relationship with the active constituent site of manufacture and may be unable to provide records to comply with the Conditions of Registration.

If a product starts its regulatory life as a progeny product (that is, the active is sourced from a registered product), then it should remain so for the life of its registration. However, if a progeny product decides to

become a 'stand-alone' product (such as, by changing its formulation or sourcing active from an approved site) then it is the review team's view that it should be required to reapply for registration. Currently these progeny products are given category 8 (repack) approval on the understanding that the product initially meets APVMA standards but registration details can be easily changed so that these products bear no resemblance to the 'parent' product. For example, the 'active' may be sourced from any approved site or the product formulation may be significantly altered. Requiring progeny products to re-apply for registration (i.e. variation or new product) when they wish to become 'stand-alone' products will reduce the problems associated with the current system whereby all products are treated equally post-registration, regardless of their original registration category.

As a result, it is proposed that a separate set of Conditions of Registration be developed for 'progeny' products. The conditions would link a progeny product to a specific 'parent' product for its source of active constituent and require records relating to batches of 'parent' in product to be kept. The justification for these reduced conditions is that all details regarding active constituent quality could be confirmed in the 'parent' product.

If standardised Conditions of Registration were developed for different types of registration, consideration would also need to be given to what conditions would be appropriate for products which have a low risk associated with active constituent. For example, products with an essential oil as the active, in low concentration, may be considered lower risk than other 'classical' agricultural chemical actives.

As such, there could be three broad types of standard Conditions of Registration for stand-alone products, progeny products and low-risk products. In addition, the APVMA should continue to have the flexibility to apply unique Conditions of Registration where it deems that it is appropriate.

End-use product testing

The current process of holding the registrant accountable for active constituent quality should be extended to include product quality as the AgQA Scheme is intended to ensure quality up until the point of retail sale. The most appropriate way of achieving this is by requiring the quality of agricultural chemical products themselves to be tested, rather than just the quality of the active constituent.

There was overwhelming support from industry representatives for the expansion of the AgQA Scheme to include product testing. It was raised that the original scope of the scheme, as discussed during its implementation in 2004, was to expand from active constituent to products. The general consensus was that the introduction of a quality control requirement for products would be of benefit to all stakeholders — industry, consumers and government.

While a product focussed scheme in the absence of active constituent considerations was raised, the majority of all workshops believed a continued focus on active constituents, in conjunction with product quality testing, would strengthen the quality of agricultural chemical products in the Australian market.

Discussion on product quality also included a request for the APVMA to test products against the specifications and details submitted in support of a product registration. The physio-chemical properties to be assayed were not discussed in depth, but would include active constituent level and other properties relevant to product use. The proposed tests for products are not intended to be resource intensive and are already being undertaken by those product manufacturers that have rigorous quality control systems.

Record keeping

Many attendees acknowledged that the AgQA Scheme, and its associated record requirements, had increased the quality control procedures within the industry. In turn, this increased the satisfaction of registrants regarding the quality of the product released to the marketplace.

Comments from industry relating to record keeping varied from “onerous” to “easy, part of normal business practice”. Those stakeholders with presence in wider international markets raised concerns of the cost for complying with local requirements in a global marketplace. In these instances, a greater discretion should be afforded to the APVMA when auditing records.

It was proposed that the APVMA proscribe a form for the records it requires. This concept was supported by smaller registrants and could clarify and simplify compliance requirements for record keeping as part of the Conditions of Registration. It was noted that the APVMA should be flexible and develop appropriate conditions for establishing product quality where registrants have rigorous quality assurance systems and can demonstrate ongoing compliance for established products. The cost to rewrite systems for the multinational business systems represents a prohibitive cost based on the value of the products sold in the Australian market.

Other issues related to the conditions of product registration

Concerns were raised regarding the appropriateness and value of the various criteria within the Conditions of Registration, in particular the ‘dates of analysis’ and ‘dates of importation’. It was suggested that if this information is not significant enough to form the basis of a Compliance action (including prosecution) then the criteria should be removed. The review team considers that any criteria that does not add significant value in establishing the quality of the material is inappropriate to mandate.

The attendees also raised the difficulties they have experienced in varying Conditions of Registration. It was stated that the pre-registration/evaluation and post-registration sections within the APVMA differ in their understanding of how and when conditions may be varied. Industry sectors advised that it was currently considered easier to change a supply system than work with the APVMA to have the relevant Conditions of Registration on a product varied.

During the registration process, if a company identified that the Conditions of Registration are not appropriate then they should be able to change them before a product is registered, not have to wait until registration application is approved before submitting such documentation to change.

Any increase in the level of rigour in the evaluation of active constituent sites of manufacture should be mirrored in the sites of product formulation. While the active constituent is a major component of the end use product, the final product quality is also highly dependent upon the process control of the formulation site. The review team agrees that it is desirable to register sites of product manufacture, in conjunction with a requirement for product testing, to illustrate physical continuity between the use of the active constituent and manufacture of the end product.

Suggestions were made to require a minimum level of competence/qualification for registrants (or an approved person in the case of a company) of chemical products. However, the majority of workshop attendees did not support this concept citing concerns about the restriction of trade and free-market principles. The review team considers that these concerns are sufficient to not require registrants to have a minimum level of competence or qualifications.

4.2 Compliance activity

The APVMA undertakes compliance activity to ensure the quality of agricultural chemical products through its Compliance program. Workshop attendees provided an array of comments on the types and

frequency of compliance activity in relation to the AgQA Scheme. In addition, views were also sought on whether the current penalty regimes were appropriate and if there was a need for the APVMA to provide information to educate industry on the expectations of the scheme and how to satisfy them.

While some comments were received which indicated a preference for reduced testing of previously compliant sites, the majority of stakeholders welcomed APVMA audits and testing (even of compliant sites) to ensure the quality of active constituents.

Audits and planning

Several areas were addressed in the workshops relating to the audit practice and outcomes of the APVMA.

The level of planning and development required by all parties prior to conducting an audit was identified as an area of concern. The introduction of ways to streamline this process — for example, prescribed forms or consistent audit practices — were identified as means of improving the effectiveness of the audits and the efficiency with which they can be conducted.

Broad agreement was reached relating to the need for the APVMA to indicate the importance of non-compliance across the different Conditions of Registration — that is, whether non-compliance is critical, major or minor. This would allow registrants to focus corrective action and devote resources appropriately to the most important areas. The APVMA also needs to educate industry in what response to expect from different types of non-compliance with the Conditions of Registration — for example, a critical non-compliance event may result in significant compliance action (such as, a recall or suspension) whereas a minor record keeping error may just result in a warning letter.

Areas of the industry suggested the issue of prescribed (standardised) forms was potentially beneficial. It was acknowledged that significant administrative issues existed to align global manufacturing processes APVMA reporting requirements. However, the benefit of standardised forms to specific segments of the agricultural chemical product market was also understood and general support existed for the development of a template record by the APVMA. While its use would not be mandatory, the guidance it may provide to certain aspects of the industry was considered to be invaluable.

In addition to seeking a greater consistency in audit practice, the workshop attendees indicated they would welcome greater discretion by APVMA compliance officers when reviewing records. It was generally accepted that audits should act as a trigger for further compliance focus and action. It is noted by the review team that breaches for low-risk, non-compliance in records are already give discretion by Compliance.

The inclusion of greater details — such as formulation and product specifications, and site of formulation — within the audit was strongly supported by various stakeholders. These would be assessed against the information within APVMA records (including the Register of Chemical Products and the Record of Approved Active Constituents). The focus is to ensure that the product released to the market represented the product evaluated by the APVMA at time of registration. The review team considers that compliance with these details could be incorporated into the Conditions of Registration for a product.

Concerns were again raised in the ability of a 'paper-based' system to detect and respond to false or fraudulent records. In particular, where the information already exists within APVMA records, the difficulty in submitting false or misleading information increases if the depth of records required to be kept also increases. As such, strengthening the Conditions or Registration to further illustrate continuity in product manufacturing could enable greater detection of false and erroneous records.

Sampling and Testing

The sampling and testing programs conducted by the APVMA have been constrained by resources and the need to deploy (or re-deploy) compliance resources on a priority basis.

The results presented for the testing programs were well received. It was noted that while the results for specific programs had been compromised by matrix interference, the broad trend across all programs was compliance with APVMA standards for the quality of actives, including toxicological impurities.

It was suggested that product specification testing might be a more accurate representation of quality than a limited focus on active constituents with toxicologically significant impurities — around 80 per cent of actives do not contain an impurity of toxicological concern.

The delay between sampling and the release of results was also highlighted as being too large to allow the APVMA to undertake timely remedial action. Part of the delay was the size of the testing program with concerns raised regarding the percentage of registered products included within a testing program (currently around 50 per cent). The review team considers that steps should be taken to reduce this timeframe, including undertaking smaller, more targeted programs. However, there will always be some limitations in the time between sampling and testing results becoming available as the APVMA relies on commercial contractors to undertake testing.

While it was acknowledged that testing of the active from the site of manufacture represents the best means of assuring quality, it was understood this posed significant logistical and legislative issues for the APVMA. Product testing provides an additional mechanism to combat these issues, given that increasingly actives and fully formulated products are being imported.

When Compliance is conducting future sampling and testing programs of any form, the point was raised that sampling products on a regional rather than a national basis may be more beneficial. Regional sampling could also incorporate taking samples from the field (that is, retail outlets) to allow a more comprehensive testing regime which has the ability to test quality from the active source through to retail locations. To ensure that economies of scale are maintained, multiple batches of single products should be taken. The added benefit of testing multiple batches is that a wider picture of product manufacture quality is achieved and this may highlight systemic problems within a product's manufacture.

Information pertaining to the transport and distribution of chemical product nationally would remove the APVMA reliance on industry to inform the location of product for sampling. This is particularly relevant should entire actives be sampled (as per the current system). A requirement to 'harvest' this logistical information from industry is considered by the review team to have merit, but falls outside the scope of this review.

Education

Several stakeholders raised concerns regarding a lack of understanding regarding the requirements of the scheme and their post-registration obligations. One reason for this is the lack of formal documentation that explains what the AgQA Scheme is and the obligations of product registrants. The review team considers that it would be useful for the APVMA to develop a formal publication outlining the aims, expectations and processes associated with the AgQA Scheme.

Several workshop attendees noted that individual company's understanding of the APVMA requirements increased after the completion of an audit. The review team considers that this represents a justification for an increase in physical company audits, rather than relying solely on desk based processes, such data call-ins.

Any change to the AgQA Scheme as a result of this review must also be accompanied by a strong educational component to assist the industry understand their responsibilities with regard to compliance. However, all cases of non-compliance should still be dealt with consistently and fairly to promote better industry behaviour in the future.

The lack of understanding and relevance of the scheme and its components within sections of the APVMA (and wider regulatory environment) was also raised as a point of major concern. A single area of responsibility, such as a dedicated AgQA team, was raised as a potential solution. The review team supports this idea as essential to improving the efficiency, and effectiveness, of the scheme.

Regulatory Action

General comments were received relating to the apparent lack of transparency in APVMA Compliance activities. It was acknowledged that legal constraints existed in relation to many of these activities (due to commercial-in-confidence or legal-in-confidence issues) but where possible comment should be made.

While it was noted that as a result of testing, products had been withdrawn from supply or further testing orders issued to ensure quality but no specific regulatory action (such as product suspension or prosecution) had been undertaken by the APVMA in relation to the AgQA Scheme. This apparent lack of clear regulatory action was perceived as a significant shortcoming of the scheme.

The lack of a level playing field between those who have amended processes to comply with AgQA requirements in comparison to more recalcitrant parts of industry was raised. It was understood that an educational focus had existed within APVMA compliance activities until 2007 (half the life of the AgQA Scheme). However, a clear position now exists within stakeholders that this education role must be secondary to regulatory action for significant non-compliance.

The review team considers that any compliance action must be swift and decisive as even short delays can have significant impact on the supply chain and increase the risks to the broader community. As a result, action should be taken promptly provide surety to the market of product quality. This would also provide a signal to other registrants that the APVMA takes non-compliance seriously.

Workshop attendees proposed that the response to non-compliance should be proportionate to the seriousness of the deficiency in the record. Where a critical non-compliance in the records (or other aspects in any future scheme) is identified, product recall should be an immediate consideration. Major non-compliance in the first instance should take the form of a formal warning (public or confidential as appropriate). Repeated instances should escalate the matter to critical non-compliance.

The review team and all stakeholders are supportive of strong action, including production suspension and approval withdrawal, where the submission of false or misleading information is identified by the APVMA.

Legislation

The AgQA Scheme was originally introduced as an alternative to legislative changes to the Agvet Legislation and Codes. The scheme works within the legislative remit of the APVMA and utilises the current penalty regime as prescribed by legislation.

Feedback from workshops indicated that there were only a few areas where legislative change may be required to increase the penalty options for varying degrees of non-compliance, particularly in the area of major (but not critical) non-compliance (the middle tier of the Ayres-Braithwaite regulatory triangle).

However, it was noted that legislative change would be a lengthy process and may be avoided with amendments to the current scheme. If the legislation does not allow the APVMA to undertake appropriate action, then legislative change should be considered. For example, workshop attendees indicated there may be a need for legislative change to include excipients within appropriate offence provisions, in the event that the scope of the AgQA Scheme is extended to include product testing.

On balance, the review team considers that there are some amendments to the AgQA Scheme that can be made to strengthen the quality of agricultural chemical products. As such, legislative change is not considered necessary at this time.

4.3 Administration and governance

Industry stakeholders and consultations within the APVMA highlighted concerns about the internal management of the AgQA Scheme. For example,

- there is no overarching coordinator for the AgQA Scheme who can assist registrants both pre- and post-registration, particularly the Conditions of Registration and record keeping requirements
- the development and application of the Conditions of Registration should be more closely aligned with the monitoring and enforcement expectations
- the APVMA may not have the capacity to establish the veracity of information prior to its acceptance, such as records of active constituent quality and/or foreign manufacturing sites, given the APVMA's policy that information submitted is taken *prima facie* and is assumed to be correct unless there is other information to the contrary

Structure and resources

Although different parts of the APVMA have various degrees of input into the AgQA Scheme, it is the Compliance program that arguably has the largest role in ensuring the quality of active constituents and agricultural chemical products through its record keeping audits, sampling and testing programs, and general activities.

Ideally, a dedicated team to administer the AgQA Scheme should be formed with responsibilities for working between programs to set appropriate Conditions of Registration in the pre-registration process, and administering post-registration compliance activities. A dedicated team to co-ordinate the operation of the AgQA Scheme would provide greater consistency, both within the APVMA and with external stakeholders, and could be an initial point of contact for inquiries related to the Conditions of Registration for agricultural chemical products.

Consideration may be given to expanding the scope and regularity of compliance activity related to the AgQA Scheme. For example, this could include auditing all product registrants and/or sampling and testing all actives on a rolling five-year basis. However, this cannot be achieved unless further resources are devoted to compliance section to undertake this activity. The review team does not consider regular and comprehensive compliance activity necessary, as the industry is generally compliant with active constituents while record keeping and continuity are the main issues. In addition, the proposed changes to other parts of the AgQA Scheme are envisaged to strengthen record keeping and continuity aspects.

The resources devoted to the AgQA Scheme could be better utilised if more flexibility was introduced into the auditing and testing regime. That is, auditing and testing activities associated with the AgQA Scheme should be incorporated into the general activities of the Compliance program, which can then pursue potential non-compliance concerns (whether generated externally or internally) according to priority, rather than being a separate area of compliance activity with specific aspirational targets.

Regardless of changes to compliance activities related to the AgQA Scheme, the review team considers that a dedicated AgQA team would still be required to promote greater consistency within the APVMA and industry.

4.4 International regulations imposed on the quality of agricultural chemical products

International initiatives were raised as means for ensuring the accuracy and authenticity of records within the current scheme. Industry feedback is that the use of government issued export certificates and site registration may assist in validating the existence of a specific site of manufacture.

The United States (US) and New Zealand (NZ) have different models for ensuring the quality of active constituents in agricultural chemical products that could inform the discussion on how improve the AgQA Scheme.

4.4.1 US Environmental Protection Agency Establishment Number

A person or business that produces pesticides must have a separate number assigned by Environmental Protection Agency (EPA) for each producing location. The EPA Establishment Number of the final establishment in which the product was produced must appear on the label or immediate container of each pesticide product released for shipment from the producing establishment.

Each facility that produces and distributes any pesticide must complete an annual report that lists the names, types, registration numbers, amounts of pesticide produced or repackaged, and the amounts of the produced or repackaged products that were sold during the previous calendar year. Even if a facility produces nothing, it must still submit a report.

Foreign establishments that import pesticides to the US must also submit a report to EPA. The amount reported should only be that amount which is imported into the US, not to other countries.

This scheme addresses an issue that confronts the APVMA in that the location of establishments, the active constituents used and the products produced are all verified. Incorporating these aspects of the US scheme into the AgQA Scheme may significantly strengthen the validity of product formulation sites and capability information.

4.4.2 NZ Scheme for responsible manufacture

The NZ scheme for ensuring the quality of agricultural chemicals is overseen by the New Zealand Food Safety Authority (NZSFA) and focuses on the idea of a 'responsible manufacturer'. The scheme was introduced in January 2010 and requires that all agricultural chemical products have a party designated as the 'responsible manufacturer'. It is possible that this party is not the owner of the registration but under contractual obligation to the owner.

The 'responsible manufacturer' ensures the quality of the product released to the market and must maintain records relating to the manufacture of the product and source of some or all of the components of the formulation. These records can then be audited and the 'responsible manufacturer' held accountable for deficiencies.

NZSFA is also capable of sampling products direct from the marketplace to undertake specification testing to ensure quality.

5 RECOMMENDATIONS

Should the AgQA Scheme continue in its present form?

Stakeholder workshops indicated that the AgQA Scheme has strengthened the quality of active constituents and agricultural chemical products supplied to the Australian market. As such, termination of the AgQA Scheme was not considered an option, unless it was to be replaced by a more comprehensive scheme, such as a full 'Good Manufacturing Process' (GMP) style system⁶.

There was unwillingness to proceed down a full GMP style system for agricultural chemical products based upon the relatively small size of the Australian market. The changes proposed for the Conditions of Registration and Conditions of Approval are intended to move the AgQA Scheme towards a more comprehensive licensing model without imposing excessive regulatory burden. Any changes to the current scheme should remain mindful of competition in the market for quality agricultural chemicals within Australia, and the trade implications and factors faced by primary producers.

After considering the points presented during the workshops, it is apparent that significant improvements are possible. The majority of opinions have supported the concept that the AgQA Scheme does not extend far enough (especially with regard to the quality of products), and with some amendments could become a more comprehensive quality assurance scheme for agricultural chemical products from the manufacture of active constituents through to the point of retail sale.

Current operational difficulties in undertaking activities associated with the AgQA Scheme may be overcome by strengthening the Conditions of Approval, Conditions of Registration and the links between them. Introducing more flexibility in the conduct of compliance activities, such as incorporating AgQA compliance work into the broader Compliance program, would allow resources to be appropriately allocated to priority areas of need.

Alternative Operational Initiatives

In a separate meeting after the completion of the workshops, the following scheme was proposed as an improvement on the current model. Much of the scheme mirrors that of the NZ model, and is predicated on the idea that movement towards product quality, in addition to active quality, is a logical progression.

A revised AgQA Scheme would continue to be underpinned by Conditions of Registration but these conditions would be strengthened by requiring that the registrant also maintain records relating to:

- compliance with product specifications, including active content and other parameters as determined by the APVMA
- site of product manufacture
- formulation
- method of manufacture
- site of active constituent manufacture
- compliance of active constituent with APVMA standards.

The registrant would be required to ensure the quality of each batch of product, or have in place legal arrangements allowing a third-party to fulfil this role. In either case, the registrant would be responsible for the life of the product up to the point of retail sale.

⁶ A 'Good Manufacturing Process' (GMP) accreditation and monitoring system exists to ensure the quality of veterinary medicines. By comparison with the AgQA Scheme, the GMP system is very resource intensive.

In addition, registrants would be required to notify the APVMA of the sites used to source active constituent and have this information included within the Register of Chemical Products. A letter of support must accompany this notification from an approval holder for that manufacturing site. This information must be provided to the APVMA prior to inclusion of material in product.

Approval holders for active constituents would be required to submit on a regular basis a current Declaration of Composition and information pertaining to current manufacturing processes at each site, primarily to ensure the veracity of information provided to and held within the APVMA but also to ensure that the quality of actives was consistent with updated standards. Where the information provided is different from that in APVMA records, the site approval should be suspended pending a formal application for review and evaluation.

Legislative Regime

The review team considers that substantial legislative change is not required at this stage as there are a number of non-legislative amendments that could be enacted to strengthen the current AgQA Scheme.

However, the APVMA response to the discussion paper “*A National Scheme for Assessment, Registration and Control of Use of Agricultural and Veterinary Chemicals*” notes:

“...the Agvet Code reflects the prevailing regulatory philosophy that existed in 1994. The APVMA considers that the current compliance powers are inadequate as they do not contain the full breadth of powers that are available to other modern Commonwealth regulators. Modern regulatory compliance frameworks contain a mix of administrative, civil and criminal enforcement tools. In general terms, the current administrative enforcement tools in the Agvet Code are less than ideal. The lack of a civil penalty regime is a major weakness.” (APVMA 2009, p. 14)

As such, there may be a case for rethinking the penalty regime as set out in the Agvet Legislation and Codes. Specifically, there appears to be justification for allowing the APVMA to issue infringement notices as part of its array of penalties for non-compliance infringements that are significant but not worth undertaking prosecution.

However, amendments to the Agvet Legislation and Codes take significant time for consultation and implementation, and would have to be considered in a broader context than just the AgQA Scheme. In light of this, the APVMA should continue to pursue non-legislative changes to the AgQA Scheme by implementing more appropriate Conditions of Registration and provide adequate resources to undertake comprehensive compliance action in a timely manner.

6 AGQA - FUTURE DIRECTIONS

The review team recommends the following strategic directions to shape the AgQA Scheme as it moves from an interim solution to being more permanent quality assurance solution. It is the intent that the proposed changes will increase the relationship between a registrant and their product (or approval holder and active constituent) and is inspired by the New Zealand concept of a responsible manufacturer.

To achieve the principle of responsible manufacture, it is necessary to establish where the onus lies within the formulation process for quality product. For active constituents, this requires a return to a greater involvement of the approval holder with products incorporating their material. For product registrants, this means stronger quality assurance protocols within all aspects of formulation and assurance of quality at product release.

It is the review team's position that Strategic Directions 1 through 4 be implemented to strengthen the quality of agricultural chemical products and their active constituents. The supporting recommendations expand on the strategic directions and outline the potential benefits and costs associated with proposed changes to the AgQA Scheme.

6.1 Strategic recommendations

This review into the AgQA Scheme recommends the following strategic directions.

STRATEGIC DIRECTION 1 – Conditions of Approval and Conditions of Registration

The Conditions of Approval for active constituents and the Conditions of Registration for agricultural chemical products be amended to strengthen the quality of agricultural chemical products and active constituents contained therein.

At a minimum,

- the APVMA should identify a standard for all active constituents
- approval holders and registrants should regularly update information held by the APVMA
- approval holders should provide their support for an active constituent to be incorporated in an agricultural chemical product
- Conditions of Registration should require compliance with the particulars of the Register of Chemical Products, and relevant product specifications (including packaging) and site of manufacture/formulation
- Conditions of Registration should directly align with the Conditions of Approval (so that changes to active constituents do not inadvertently lead to breaches of the Conditions of Registration).

STRATEGIC DIRECTION 2 – Standardised Conditions of Registration

A standardised set of Conditions of Registration be developed for different types of agricultural chemical product registrations, such as:

- stand-alone products
- progeny products (repack or dilution only)
- low-risk products

In addition, flexibility be retained to allow the APVMA to apply unique Conditions of Registration where appropriate.

STRATEGIC DIRECTION 3 – Compliance with the AgQA Scheme

Sampling and testing programs be expanded to include:

- agricultural chemical products — quality of active(s); level of toxicological impurities; and product specifications as provided to the APVMA
- field sampling at all stages of the production process up until the point of retail sale
- multiple batches of a single product.

The APVMA should also provide guidance on the expectations of registrant's record keeping and the areas where record keeping deficiencies will result in critical and major non-compliance.

STRATEGIC DIRECTION 4 – Administration of the AgQA Scheme

A dedicated team be formed to undertake coordination and administration of the AgQA Scheme. This team would:

- be involved in the development of enforceable Conditions of Registration
- be responsible for post-registration activities
- provide a single point of contact, within the APVMA and between the APVMA and industry, for all matters relating to the AgQA Scheme.

6.2 Supporting recommendations

The AgQA Scheme Review also makes supporting recommendations as detailed in Table 3.

TABLE 3: SUPPORTING RECOMENDATIONS				
CATEGORY	RECOMMENDATION	AREA TO BE ADDRESSED	BENEFITS	EXPECTED AREAS OF COST
CONDITIONS OF APPROVAL	The APVMA nominate standards for all active constituents even when no standard exists. These standards should also clarify if the active constituent is to be sourced from an APVMA approved manufacturing site.	Inconsistency in requirement for active constituents supplied within the Australian market to conform to quality standards (including impurity levels), thus allow poor/low quality material to be utilised by the Australian public	Having standards for all active constituents will ensure quality product is released to the Australian market. It will also allow the APVMA to audit all registered chemical products.	APVMA staff time
	Active constituent standards developed by the APVMA be aligned, where applicable, with Food and Agriculture Organisation (FAO) standards (or other appropriate international standards).	Inconsistency between Australian and international standards imposes increased burden on active constituent manufacturers	Utilising international standards creates a level playing field for manufacturers of active constituents and agricultural chemical products. As Australia is only a small market, this approach is considered to be appropriate.	APVMA staff time
	Where appropriate, the Conditions of Approval be utilised to reflect variations at the source of active constituent manufacture. The Conditions of Registration should be amended to reflect the Conditions of Approval for the site of active constituent manufacture.	It is unclear from reading the APVMA standards the need to source material from approved sites. This will be exacerbated with the development of standards for all agricultural active constituents.	This change will eliminate the need for registrants to change the Conditions of Registration when there are changes to the active constituent.	APVMA staff time
	Approval holders be required to submit Declaration of Composition for active constituents from each site and information pertaining to current manufacturing processes on a regular basis.	Amendments or changes to the manufacture process are not routinely evaluated by the APVMA, and rely upon the approval holder voluntarily advising when they become aware, Changes in the processes or impurity profile can impact the quality of supplied material.	This change will: <ul style="list-style-type: none"> ensure that the information held by the APVMA remains current assist in identifying any areas that require a more detailed submission by the approval holder 	Industry resources APVMA staff time

Continued

TABLE 3 (CONTINUED): SUPPORTING RECOMENDATIONS				
CATEGORY	RECOMMENDATION	AREA TO BE ADDRESSED	BENEFITS	EXPECTED AREAS OF COST
CONDITIONS OF REGISTRATION	<p>The Register of Chemical Products for a registered chemical product are to reflect the source(s) of the active constituent(s) and the site(s) of formulation.</p> <p>Consent from each site of active manufacture and product formulation is required prior to its inclusion on the Register of Chemical Products.</p>	<p>Absence of linkage between sites of active constituent manufacture and inclusion within product.</p>	<p>This change will mean the information contained in the Register should be accurate and there will be an onus on the product registrant to ensure that this information is accurate and updated. If it is not accurate, this will allow the APVMA to undertake compliance action.</p>	<p>Industry resources</p> <p>APVMA staff time</p>
	<p>Active constituent may only be sourced with the support of the approval holder. This support may be given once, can be withdrawn at any time and does not require the sourcing of material through the approval holder.</p> <p>This support is to be provided to the APVMA and includes endorsement to utilise information previously supplied by the approval holder. The support remains in place until the approval holder seeks its removal.</p>	<p>The continued responsibility for the quality of active constituent supplied from a site of manufacture is unclear.</p> <p>The ability for the APVMA to respond to quality concerns from a specific site of active constituent manufacture is hampered by a requirements to seek information of active constituent inclusion after incorporation into product, and subsequent supply to the market.</p>	<p>The re-introduction of this requirement will create a link between the quality of an active constituent and its use in a chemical product. This means that the approval holder will be responsible for the quality of the active constituent in the supplied chemical product.</p>	<p>Industry resources</p> <p>APVMA staff time</p>
	<p>The existing Conditions of Registration be amended to <u>remove</u> requirements for:</p> <p>Dates of Analysis</p> <p>Dates of Importation</p>	<p>Specific criteria within the Conditions of Registration do not add significant value to establishing the quality of the incorporated active constituent.</p>	<p>This information is not considered important enough to undertake compliance action. As such, it is not considered important enough to be part of the Conditions of Registration.</p>	<p>APVMA staff time</p>

TABLE 3 (CONTINUED): SUPPORTING RECOMENDATIONS				
CATEGORY	RECOMMENDATION	AREA TO BE ADDRESSED	BENEFITS	EXPECTED AREAS OF COST
CONDITIONS OF REGISTRATION	<p>The existing Conditions of Registration be amended to <u>include</u> requirements for:</p> <ul style="list-style-type: none"> • Ensuring the quality of product batches (including compliance with stated product specifications) • Information regarding the identity and address of the formulator to conform with that listed on the Register of Chemical Products <p>All other Conditions of Registration be included within a single document (for example, packaging conditions).</p>	The quality of supplied products is dependent upon more than the active constituent quality,	<p>This information will allow the APVMA to ensure that chemical products are formulated or manufactured at an APVMA approved site and meet quality standards. This will help ensure the quality of chemical products, not just active constituents.</p> <p>Including all Conditions of Registration in a single document will reduce the regulatory burden on the APVMA and industry.</p>	<p>Industry resources</p> <p>APVMA staff time and resources</p>

TABLE 3 (CONTINUED): SUPPORTING RECOMENDATIONS				
CATEGORY	RECOMMENDATION	AREA TO BE ADDRESSED	BENEFITS	EXPECTED AREAS OF COST
STANDARDISED CONDITIONS OF REGISTRATION	<p>The development of standardised Conditions of Registration for different types of products:</p> <ul style="list-style-type: none"> • Group 1: Stand-alone products — conventional (non-progeny) products that require comprehensive information for registration • Group 2: Progeny products —products which are repacked or relabelled • Group 3: Products of low quality risk — products which do not have quality standards and/or products containing natural oil extracts as the sole active constituent <p>In addition, the APVMA should retain the ability to apply unique Conditions of Registration where it deems appropriate.</p> <p>The standardised conditions would be detailed in a 'Compendium of Conditions' that would detail the Conditions of Registration for each tier, including reference to the Conditions of Approval and a requirement to manufacture and/or formulate in accordance with the particulars supplied to the APVMA.</p>	<p>In appropriate Conditions of Registration place excessive burden upon registrants and APVMA resources.</p> <p>The APVMA currently develops unique conditions on a case by case basis., where it is identified by the registrant as necessary.</p> <p>The potential interrelationship between the Conditions of Registration and Conditions of Approval is not currently utilised,</p>	<p>Standardised Conditions of Registration will:</p> <ul style="list-style-type: none"> • create a level playing field for similar types of products • reduce the time spent by industry and APVMA staff in creating and assessing Conditions of Registration <p>allow Conditions of Registration to be amended (in the Compendium) without the need to change the Conditions of Registration for each product individually</p>	<p>APVMA staff time and resources to apply new Conditions of Registration</p>

Continued

TABLE 3 (CONTINUED): SUPPORTING RECOMENDATIONS

CATEGORY	RECOMMENDATION	AREA TO BE ADDRESSED	BENEFITS	EXPECTED AREAS OF COST
SITE AUTHENTICATION	<p>Information be provided by approval holders and registrants to establish the veracity of any site of manufacture or formulation where this information is not already held by the APVMA. This information may take the form of government accreditation, registrant affidavit or other international documentation (such as a US EPA establishment number). This information must support both the address and the activity of the site.</p> <p>The responsibility for information submitted to the APVMA would rest with the registrant or approval holder. Where this information cannot be provided, the site is to be removed from the Record of Approved Active Constituents and/or the Register or Chemical Products.</p>	<p>Potential submission of false, misleading or otherwise erroneous material to the APVMA, in particular in relation the site of manufacture or site of formulation.</p>	<p>This change will address concerns that false or misleading information regarding manufacturing and formulation sites is being provided to the APVMA.</p>	<p>Industry resources</p> <p>APVMA staff time</p>
RECORD AUDITS	<p>The APVMA prepares a template and checklist for the records it expects registrants to keep. Registrants may use these templates and checklists as the record system or as a guide for their existing systems.</p> <p>The APVMA is to identify the areas in records that are critical and major with regard to non-compliance. Outcomes of audits must adequately reflect the seriousness of non-compliance.</p>	<p>Aspects of Industry, in particular small to medium size businesses, are unclear on the nature of the records required for compliance with the Conditions of Registration.</p> <p>All aspects of the conditions are given equal weight from identification of product through to quality of incorporated active constituent. Industry is not given indication of the areas of record keeping that require urgent attention to ensure quality of product.</p>	<p>Checklists and templates provide greater certainty for industry as to the APVMA's expectations of record keeping to comply with the Conditions of Registration.</p> <p>Conveying clear expectations establishes a baseline from which appropriate action may be taken in cases of non-compliance.</p>	<p>APVMA staff time</p>

Continued

TABLE 3 (CONTINUED): SUPPORTING RECOMENDATIONS

CATEGORY	RECOMMENDATION	AREA TO BE ADDRESSED	BENEFITS	EXPECTED AREAS OF COST
SAMPLING AND TESTING	<p>The APVMA expand its testing programs beyond the quality of incorporated active constituents to include:</p> <ul style="list-style-type: none"> testing of products for active constituent content, impurities of concern and other parameters determined as relevant for product quality focus on regions, registrants or active constituents, as appropriate field sampling (retail outlet, production or storage facility) of product yet to be supplied to the consumer multiple batches of a single product, where available. 	<p>A single batch of product may not represent the true quality of the entire batch or product as a whole.</p> <p>Reliance upon registrants for product artificially controls the samples, and not reflective of the product available to the market..</p> <p>Active constituent is not the sole determinant, nor indicator, of product quality.</p>	<p>Widening the scope of sampling and testing will allow the APVMA to ensure quality is controlled over the entire process of manufacturing and supplying agricultural chemicals to the Australian market (to the point of retail sale).</p>	<p>APVMA staff time and financial resources</p>
ADMINISTRATION AND GOVERNANCE	<p>The APVMA consolidate the administration (pre- and post-registration) of the AgQA Scheme in a single program with a dedicated team, noting that specific functions (including application of conditions and evaluation of data) may rest in other programs.</p> <p>With consideration to the post-registration function, the most appropriate area to undertake the overall administration of the scheme is Compliance. This proposal to include the development of appropriate database facilities.</p>	<p>Responsibility for the scheme is split across three sections. Industry raised issues that differing and often contradictory view points are expressed by the APVMA in relation to the Conditions of Registration.</p> <p>The application of enforceable Conditions of Registration is essential</p>	<p>Consolidating the administration of the AgQA Scheme will provide:</p> <ul style="list-style-type: none"> a single portal for contact with regard to the scheme for industry and the APVMA increased capacity for Compliance to undertake a more proactive role in developing appropriate and enforceable Conditions of Registration. 	<p>APVMA staff time</p>

TABLE 3 (CONTINUED): SUPPORTING RECOMENDATIONS				
CATEGORY	RECOMMENDATION	AREA TO BE ADDRESSED	BENEFITS	EXPECTED AREAS OF COST
ADMINISTRATION AND GOVERNANCE	The requirement for a specified number of audits, site visits, and sampling and testing programs be removed from the AgQA Scheme. Such activities should be part of the general compliance activities.	The use of formal targets constrains APVMA Compliance activities in wider arenas.	This change would allow Compliance to more flexibility respond to priority areas of need and allocate resources where appropriate.	No costs