



Scope of a Review into the Operation of the APVMA Quality Assurance Scheme for Agricultural Active Constituents and Agricultural Chemical Products

Background

The Australian Pesticides and Veterinary Medicines Authority ensures the quality of active constituents used in agricultural chemical products in the Australian marketplace through the Quality Assurance Scheme for Agricultural Active Constituents and Agricultural Chemical Products [the Scheme]. The Scheme is based on the set of standards for active constituents. These standards set out the purity of the active constituent and the maximum allowable impurity level. The scheme was developed collaboratively with industry and has operated for the last few years.

Conditions of Registration of agricultural chemical products underpin the scheme. These conditions 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 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.

Reason for the review

The Scheme is the APVMA's 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 Scheme), and in so doing take account of:
 - a. The defined risks that were intended to be addressed by the Scheme;
 - b. The level of non-compliance with treatments to address those risks;
 - c. The resources and costs associated with implementation of the Scheme both for the regulated industry and the APVMA;
 - d. Any demonstrated changes in the compliance culture of the regulated industry resulting from introduction of the Scheme in 2006;
 - e. The policies of international regulators in relation to the quality of agricultural active constituents and the enforcement of standards;
 - f. 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 Scheme and consider whether:
 - a. The range of identified risks are relevant to the purpose of the Scheme;
 - b. The current legislative provisions provide adequate controls and allow the purpose of the Scheme to be achieved;
 - c. The standards and conditions underpinning the Scheme are sufficiently robust to ensure enforcement;
 - d. Alternative or additional legislative provisions are required to improve the efficiency or effectiveness of the Scheme;
 - e. The mix of structure, management responsibilities, delegations and resources allocation is the most appropriate to enable the APVMA to effectively enforce the Scheme.

3. Provide recommendations on:
 - a. The public value that will be delivered by the continuation of the Scheme in its present form;
 - b. Alternative operational initiatives to address identified risks, and
 - c. 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.

The review will:

- consider the operation and effectiveness of the Scheme
- assess the operation of the Scheme, and
- provide recommendations.

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. The CEO will determine what response to the recommendations will be pursued by the APVMA.

Further information on the Scheme can be found at:

<http://www.apvma.gov.au/agqa/agqa.shtml>