

A SINGLE NATIONAL FRAMEWORK FOR THE REGULATION OF AGRICULTURAL CHEMICALS AND VETERINARY MEDICINES REGULATORY MODEL

EXECUTIVE SUMMARY

1. In 2008 the Productivity Commission released a report on the regulation of chemicals and plastics^[1]. In response, the Council of Australian Governments (COAG) directed the Primary Industries Ministerial Council (now the Standing Council on Primary Industries [SCoPI]) to develop a single national framework to improve the efficiency and effectiveness of the regulation of agricultural chemicals and veterinary medicines (agvet chemicals).
2. These reforms aim to address current variations in states and territory regulation, relating to:
 - licensing and competency requirements for chemical users and fee-for-service users^[2],
 - limited and inconsistent monitoring of chemical residues, including varying levels of integration with state, federal and private sector monitoring systems,
 - variation in access to chemicals restrictions, including off-label use restrictions and application of additional chemical controls,
 - compliance and enforcement of chemical use in accordance with registered and other permissible uses and,
 - record-keeping requirements for chemical use.
3. SCoPI is required to deliver a regulatory model, funding model and an Intergovernmental Agreement (IGA) for the proposed single national framework by December 2012.
4. Following extensive policy discussions and consultation with stakeholders, the proposed regulatory model contains harmonised models for licensing, training, access to agvet chemicals and a national produce monitoring program.
5. The proposed overarching governance arrangements for this framework specifies that:
 - control-of-use powers and responsibility is retained by states and territories with uniformity achieved through harmonised jurisdictional legislation,
 - there is increased jurisdictional involvement in governance of the Australian Pesticides and Veterinary Medicines Authority (APVMA)
 - arrangements are formalised through a recommitment to an amended IGA and
 - a new strategic policy committee for agvet chemicals is created under COAG/SCoPI to oversee the development and implementation of the national system, on the understanding that the new committee replace one or more of the current committees under the PISC framework.
6. The proposed licensing model details minimum harmonised requirements, where:
 - all fee-for-service providers (e.g. pest controllers, ground and aerial applicators, sheep dippers) are required to be licensed
 - both fee-for-service businesses and individuals within those businesses are required to be licensed
 - licensing will not be required for users of Restricted Chemical Products (RCPs) and Schedule 7 (S7) chemicals who are not operating a fee-for-service business (general users, including farmers), except when specifically required due to regional need

^[1] Productivity Commission, 2008.

^[2] Such as aerial and ground applicators, contract sheep dippers and urban pest controllers.

- licenses will be issued by the jurisdiction for registration of a business or for an individual, based on their primary location/residence
 - fees and charges will be set by each jurisdiction
 - all jurisdictions will automatically recognise licences issued in other jurisdictions and
 - individual jurisdictions will be responsible for auditing and compliance within their own state; and any suspension or cancellation of a licence or a right to operate in a particular jurisdiction will automatically apply in other jurisdictions.
7. In addition to the proposed licensing model, the following proposed harmonised minimum training requirements are included:
- All fee-for-service providers are required to hold, as a minimum, Australian Qualifications Framework (AQF) Level 3 competency determined to be appropriate for the occupation as a condition of licence.
 - All users of RCPs and S7 chemicals are required to hold, as a minimum, AQF Level 3 competencies determined to be appropriate for the use of the product (but with no licensing requirement).
8. To support proactive risk management, the framework includes nationally consistent recordkeeping of chemical use and user audits. Although some users of RCPs and S7 will not require licenses, these users will still be required to maintain records of chemical use. This element would also help to identify regional issues to inform produce monitoring, traceback and compliance programs.
9. The harmonised access to chemicals model is split into requirements for agricultural chemicals and veterinary medicines. The proposed veterinary prescribing and compounding rights model outlines a harmonised system which allows veterinarians to compound and prescribe an extension of label uses for prescription, non-prescription and unregistered veterinary products subject to certain conditions. The proposed access to agricultural chemicals model outlines minimum nationally harmonised access to chemicals provisions for allowing limited variations on approved use instructions for crops or situations (also known as 'off-label' use). This element also incorporates the nationally consistent recordkeeping arrangements for users of agricultural chemicals.
10. The proposed regulatory model contains a harmonised, enhanced national monitoring and trace-back program for chemical residues in produce. This model would provide a nationally consistent base level of produce monitoring to maintain confidence in the agvet chemical system, and appropriately identify risks and respond to adverse events. Produce monitoring would also provide the evidence necessary to evaluate the proposed access to chemicals arrangements and assist in providing vital data to inform future reforms. The proposed model would link directly with existing compliance and enforcement processes in the jurisdictions and the APVMA and build on existing industry and government-run schemes.
11. Following COAG agreement, implementation of the above proposed models is anticipated to take approximately 18 months.
12. The above proposed framework outlines the general models for the licensing, training, monitoring and access to agricultural and veterinary chemical models. Further details of these models will be determined during the reforms' implementation phases.
13. This implementation will require changes to state and territory control-of-use legislation. Some changes to Commonwealth legislation may also be required. Due to the different regulatory arrangements within each jurisdiction, harmonisation will be

best achieved through the development of consistent and uniform drafting instructions for the amendment of existing legislation and regulations.

14. Further stakeholder consultation will be undertaken on details of the proposed models as part of these legislative changes.