National regulation

The Australian Government’s *Agricultural and Veterinary Chemicals (Administration) Act 1992* implements the National Registration Scheme.

- The National Registration Scheme is a partnership between the Commonwealth and the states & territories.

- The Australian Pesticides and Veterinary Medicines Authority (APVMA) is an independent Commonwealth statutory authority. It regulates *up to* supply.

- States and territories are responsible for controls on products *after* supply.
Responsibilities in the regulatory system

**APVMA**
- Registers new chemicals and products
- Reviews existing chemicals
- Issues permits for some unregistered uses
- Conducts compliance for registration

**State & territory governments**
- Control of use of chemicals after sale
- Enforces training and licencing requirements

**Chemical users (farmers & pest controllers)**
- Ensures safe use – follow label and/or permit directions
- Complies with training & licencing and access requirements
- Stores and disposes of chemicals safely and report adverse experiences

**Manufacturers & distributors**
- Complies with registration requirements
- Develops voluntary industry codes and chemical stewardship

Source: Department of Agriculture and Water Resources
Scope of APVMA assessment

Statutory criteria for all registered product

• Safety
• Efficacy
• Trade
• Labelling (relevant label particulars)

In practice

• APVMA must be satisfied, not legislated how - providing flexibility
• Generates MRLs and GAP instructions
• Initially supported with data, but subsequent products may rely on chemical similarity
• Criteria applies equally to registration and off-label, minor use, permits
Minor Use in Australia

• Small market
• Small returns on investment
• Australia highly generic-centric market

Strategies to address

• Funding for research
• Collaborative forum
• Australian crop grouping
• Reduced application burden, fees, data and timeframes
• Permits for off-label use
• Permit to label use migration
• Harmonisation of control of use laws
Minor Use Strategies

Funding for research

• RDCs provided $ for $ matching in research funds (~$200 million pa)
• Improved access to agvet chemical program
  • $14.4 million from 2014
  • ~$6 million supported 126 research grants in chemical use.

Collaborative forums

• Replicating aspects this meeting, strengthening engagement between growers, researchers and chemical manufacturers

Australian crop grouping

• Formally incorporated into assessment
• Extend beyond residues and address safety, efficacy, trade and label criteria
Minor Use in Strategies

Harmonisation of control of use – Label directions

- Same crop, different pest is allowed
- Rates of application up to the label limits allowed
  - Concentration
  - Frequency
- Tank mixing is allowed
- Provide flexibility to the grower to respond to their pest pressures
- Flexibility to use different application equipment than stated on the label
- Current project will harmonise treatments of label stated pests in non-label crops

Reduced application burden

- Application fees are 40% of assessment cost
- People other than registrant can seek to amend label, or hold a label approval
Minor Use Strategies

Permit

• Anyone can seek authority to use a product in a manner different to the label
  • Routinely used by grower industry
• Does not require registrant support or involvement
• Decision is APVMA, criteria are the same as for registration
  • Registrant does not have power of veto
• Nature of permit allows specific conditions to manage risk
• $350, will achieve a lawful use and MRL
  • Currently 1000 minor use permits in place

Permit to label

• Australian government is supporting the APVMA to identify those uses that could be included on labels without any further regulatory requirement.
Thank you

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