



Australian Government  
Department of Agriculture  
and Water Resources

# Australian Agvet Chemical Regulation and Policy – Minor Use



Dr Joseph Morrall/ Agvet Chemicals Policy section

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# 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



Source: arabstoday.net

# 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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