



Australian Government  
Australian Pesticides and  
Veterinary Medicines Authority

# MRL ESTABLISHMENT IN AUSTRALIA

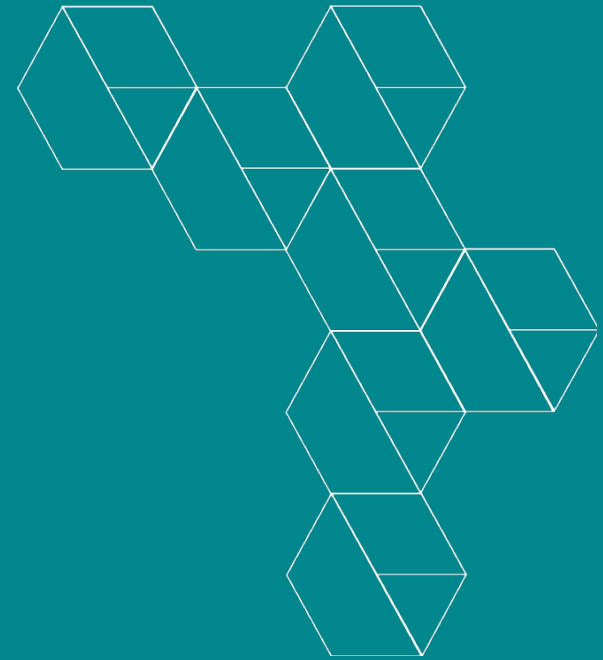


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2017 MRL Harmonization Workshop

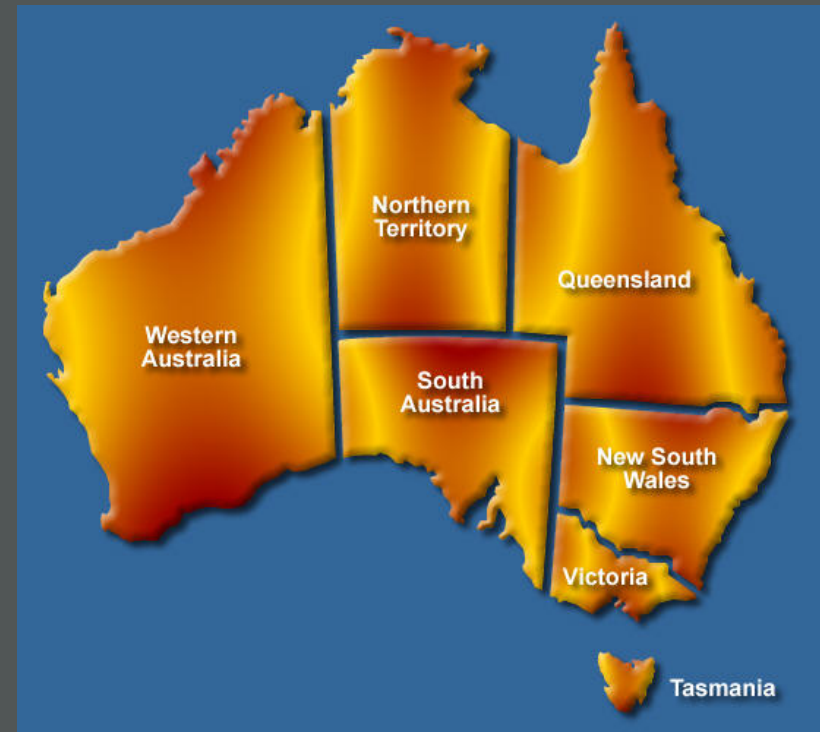
# Overview

- Regulatory Framework for pesticide use in Australia
- MRLs – why & how
- APEC import MRL guidelines



# *Commonwealth of Australia*

- Diverse in climate, environment and agriculture
- 1901 – ‘Federation’ of 6 independent states
- Federal system of government
  - . Powers divided between central (Commonwealth) Government and state governments



# Why are pesticides registered?

- *To provide safe crop protection products for farmers*
- *To protect the health of users of the pesticide*
- *To protect the environment*
- *To ensure that the pesticide does not damage the treated crop*
- *To ensure that the pesticide performs as claimed (efficacy)*

# Why are pesticides registered?

- *To protect the health of consumers of treated food*
  - *Residues expected from use pattern*
  - *Dietary exposure assessments*
- *To facilitate the international trade of treated produce*
  - *Agricultural exports are important to the Australian economy*
  - *Need to consider the MRLs of our trading partners*
  - *May need to consult with industry stakeholders for uses proposed for 'major export commodities'*
    - *Animal commodities: Cattle, sheep, pigs, goats, poultry*
    - *Grain commodities: Cereals, pulses, oilseeds*
    - *Horticultural commodities: Grapes (inc. wine and dried), citrus, pome fruit and stone fruit*
    - *Sugar cane and oaten hay*

# What is required to register a pesticide?

- *A proposed Good Agricultural Practice (GAP)*  
*Good agricultural practice in the use of pesticides (GAP) includes the nationally authorized safe uses of pesticides under actual conditions necessary for effective pest control. It encompasses a range of levels of pesticide applications up to the highest authorized use, applied in a manner which leaves a residue which is the smallest amount practicable (JMPR).*
- *A data package addressing all of the national regulators requirements*  
*OECD & JMPR guidance, consistent with many regulators requirements*
- *Minor use permits can be issued to provide chemical access for 'smaller' crops*

# What is the outcome of a registration?

- *Approval of a Good Agricultural Practice (GAP)*  
*Label instructions including withholding periods*  
*<https://portal.apvma.gov.au/pubcris>*
- *Establishment of Health Based Guidance Values*  
*ADI & ARfD - used in dietary exposure estimates*
- *Establishment of Maximum Residue Limits (MRLs)*  
*<https://www.legislation.gov.au/Series/F2012L02501>*

# A regulatory framework - Australia

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## APVMA

- Regulate agvet chemicals up to point of retail sale

## State/Territory Governments

- Regulate use of agvet chemicals

## Industry

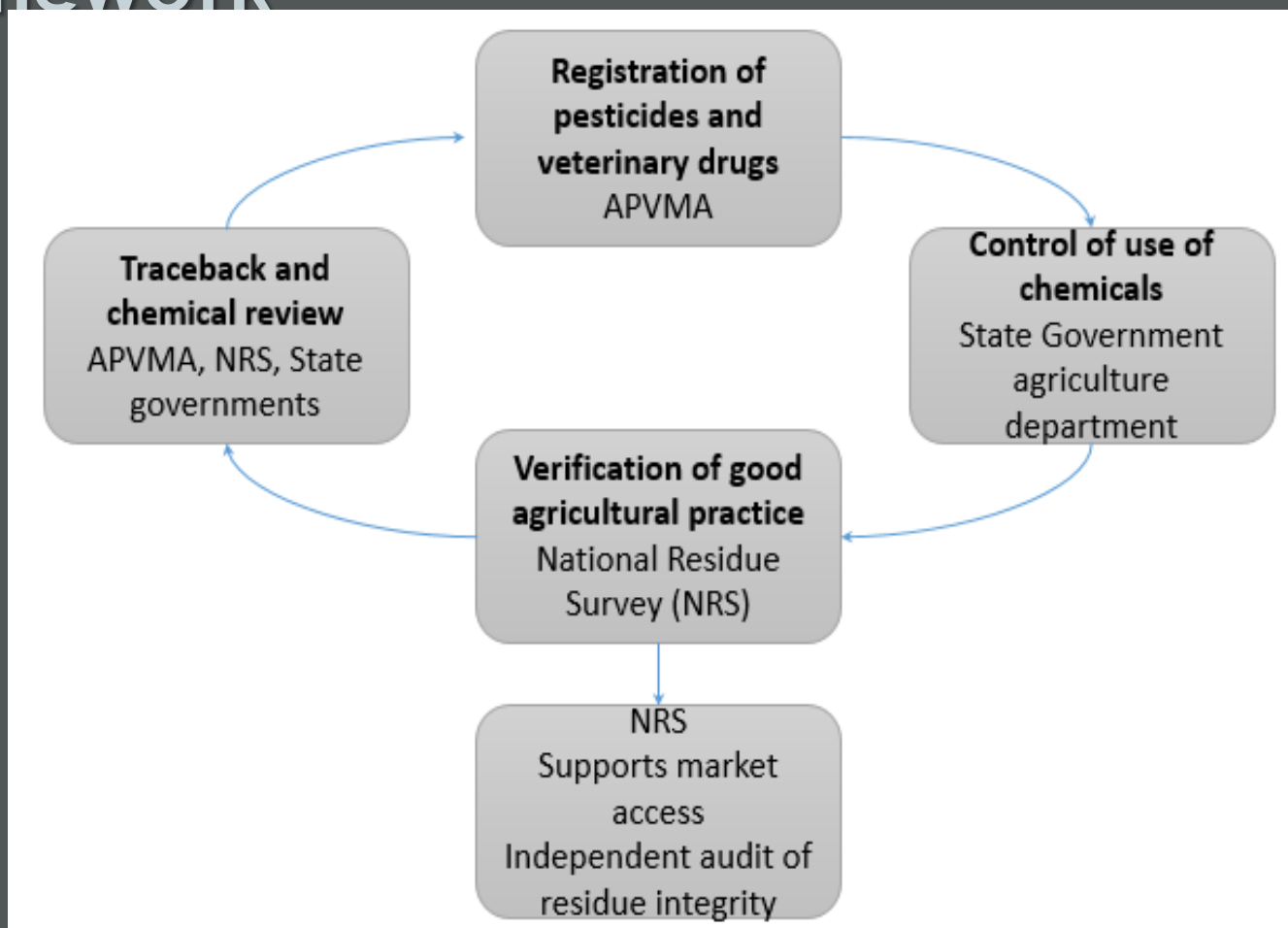
- Industry risk management programs

# How is use of pesticides monitored or controlled?

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- *Pesticides are required to be used according to label directions*
- *Record keeping  
auditing*
- *Monitoring compliance with Maximum Residue Limits (MRLs)  
MRL exceedances investigated by authorities*

# Australia's residue management framework



# Australia's residue management framework

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- The National Residues Survey (NRS)
  - Residue monitoring of chemical residues in food through the NRS is part of the Department of Agriculture's strategy to minimise chemical residues in agricultural produce.
  - The NRS facilitates the testing of animal and plant products for pesticide and veterinary medicine residues, and environmental contaminants for:
    - Animal commodities including cattle, sheep, pigs and goats
    - Grains including cereals, oilseeds and pulses
    - Horticultural crops including pome fruits and tree nuts

*<http://www.agriculture.gov.au/ag-farm-food/food/nrs>*

# What is an MRL?

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***Maximum residue limit (MRL)*** means the maximum concentration of a residue **resulting from the registered use** of an agricultural or veterinary chemical which is legally permitted or recognised as acceptable to be present in or on a food, agricultural commodity or animal feed

*Agricultural and Veterinary Chemicals Code Instrument No. 4  
(MRL Standard) 2012*

# MRL establishment

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- Australia has two MRL Standards

## *APVMA MRL Standard*

- referenced for control of use
- Contains MRLs to support approved uses in Australia
  - <http://www.comlaw.gov.au/Series/F2012L02501>

## *Schedule 20 of the Australia New Zealand Food Standards Code*

- referenced for sale of food
- Contains MRLs established by APVMA and import tolerances
- Jointly administered by Food Standards Australia New Zealand (FSANZ) and the APVMA
  - <https://www.legislation.gov.au/Series/F2015L00468>

# MRL establishment process

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- Once the APVMA is confident that a use is to be approved, the MRL Establishment process commences
- MRLs are established in the APVMA MRL Standard by legislative instrument and notification made in the APVMA gazette
- At the same time, public notification is made in the APVMA gazette that the APVMA is proposing to put the same MRLs into Schedule 20 of the Food Standards Code
- SPS notification also made, referencing that notice
- Following the consultation period, APVMA amends Food Standards Code

# MRL establishment – Inadvertent residues

- FSANZ now propose MRLs for ‘All other foods except animal food commodities’
- MRL to provide coverage for low levels of inadvertent contamination, but not allow for off label use
- The MRL applies to crops not otherwise listed
- Process involves consideration of dietary exposure
- The level will be determined on a case by case basis

<i>Permitted residue: Captan</i>	
All other foods except animal food commodities	0.1
Almonds	0.3

-<http://www.foodstandards.gov.au/code/proposals/Pages/P1027.aspx>

# MRL establishment – Harmonization requests

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- Food Standards Australia New Zealand (FSANZ)
  - Consider requests to harmonize Australian MRLs with MRLs established by Codex Alimentarius or by a regulatory authority in a recognized jurisdiction where the commodity is produced.
  - Dietary exposure and intake assessments performed in Australian context
  - Change made to Schedule 20 of the Food Standards Code
    - <http://www.foodstandards.gov.au/code/changes/limits/pages/default.aspx>

# APEC Food safety cooperation forum

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## **IMPORT MRL GUIDELINE FOR PESTICIDES**

*A guideline on possible approaches to achieve alignment of  
international MRLs*

[http://publications.apec.org/publication-detail.php?pub\\_id=1750](http://publications.apec.org/publication-detail.php?pub_id=1750)

# APEC Food safety cooperation forum

- Problem: Different pesticide uses, different MRLs -> trade disruption
- Development of a Food Safety Cooperation Forum MRLs Roadmap and principles at Beijing FSCF event in June 2014
- Developed a set of 4 broad principles to progress harmonisation of pesticide MRLs

# APEC Food safety cooperation forum

- 3 year funded project by Australia (2015 - present day)
- Development, and adoption, of an APEC Guideline on import MRLs for pesticides
- Three FSANZ-led workshops held to develop a Guideline
  - Sydney April 2015 (development and initial principles)
  - Cebu August 2015 (Guideline drafting)
  - Canberra February 2017 (implementation & training)
- Further initiatives to support the implementation of the Guidelines for import MRLs

# APEC Food safety cooperation forum - Broad principles

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1

Participation in the development of MRLs in Codex Alimentarius (Codex) via the Codex Committee on Pesticide Residues (CCPR)

2

Adoption of Codex MRLs in domestic legislation and trade

3

Work sharing, or exchanging data to support the establishment of pesticide MRLs by member economies, in cases where there is no domestic equivalent for a member economy

4

Develop unilateral “recognition”, or “import tolerances” where practical and appropriate, in domestic regulation of specific pesticide/commodity MRLs of trading partners on a case-by-case basis.

# APEC Food safety cooperation forum

- Principles underpinning the Guideline

Science-based using internationally accepted risk assessment methodologies

Protection of public health and safety of residues, not pesticide use considerations

Guideline is a reference tool

Emphasis on use of Codex MRLs, including supporting JMPR monographs, where such MRLs exist

# APEC Food safety cooperation forum

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- Guideline content

Section 1: Follows an extensive glossary of terms and introduces the purpose and scope

Section 2: Pesticide import MRL request/ proposal process

Section 3: Information/data required to support an import MRL request

Attachment 1: Template for data provision and explanations of data requirements

Attachment 2: Illustrative examples of different scenarios of import MRL requests

Attachment 3: Contact details for APEC member economies and links to useful resource materials

# QUESTIONS?

Thank you

