



Australian Government
**Australian Pesticides and
Veterinary Medicines Authority**

Pesticide Registration in Australia



James Deller
Director, Residues & Trade
The Australian Pesticides and Veterinary Medicines Authority

2019 Walnut Industry Symposium

Presentation overview

- Role of the APVMA
- Why are pesticides registered
- What is required for approval
- Registration and permits
- Permit-to-label and Crop groups
- Spray drift

A regulatory framework - Australia

APVMA

- Regulate agvet chemicals up to point of retail sale

State/Territory Governments

- Regulate use of agvet chemicals

Industry

- Industry risk management programs

Role of the APVMA?

- **Registration and Permits**
 - Product Registration
 - Variation of Registered products
 - Approval of Active constituents
 - Permits
- **Post approval**
 - Compliance (up to the point of sale)
 - Adverse Experience Reporting Program
 - Chemical Review

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*
 - *Establish Standards for Maximum Residue Limits*
 - *Dietary exposure assessments*



Why are pesticides registered?

- *To facilitate the international trade of treated produce*
 - *Will the use impact on the international trade for the commodity?*
 - *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: Cherries and other stone fruit, Grapes, Citrus and Pome fruit*
 - *Sugar cane and oaten hay*



What is required to approve use of a pesticide?

- *An application*
- *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 the requirements*

OECD & JMPR guidance, consistent with many regulators requirements

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>

Rate				Critical Comments
In the following table, all rates given for dilute spraying. For concentrate spraying, refer to the mixing/application section.				
Crop	Disease	Rate	WHP (days)	
Almonds (NOT Qld, NT)	Shot-hole (<i>Stigmia carpophila</i>) Stone fruit rust (<i>Tranzschelia discolor</i>)	160mL/100 L	-	Apply at bud-swell, bud-burst, shuck fall, cap fall. Apply every 10-14 days. Apply 1 week pre-harvest.
	Apricots (NOT Qld, NT,)		Brown rot - Fruit (<i>Monilinia fructicola</i>) Blossom blight (<i>Monilinia laxa</i>)	7
Shot-hole (<i>Stigmia carpophila</i>) Stone fruit rust (<i>Tranzschelia discolor</i>) Freckle (<i>Venturia carpophila</i>)		Apply at bud-swell, bud-burst, pink bud, shuck fall, cap fall, then every 10-14 days.	See also Additional Restraints for stone fruits.	
Cherries	Brown rot - Fruit (<i>Monilinia fructicola</i>) Blossom blight (<i>Monilinia laxa</i>)			Apply at bud-swell, bud-burst, pink bud, early blossom, full bloom. Apply 3 weeks pre-harvest and 1 week pre-harvest.
	Shot-hole (<i>Stigmia carpophila</i>) Stone fruit rust (<i>Tranzschelia discolor</i>)			Apply budswell, bud-burst, pink bud, shuck fall, cap fall then every 10-14 days. Apply 1 week pre-harvest.
	Transit Rot (<i>Rhizopus stolonifer</i>)			Apply 1 week pre-harvest.

- *Establishment of Maximum Residue Limits (MRLs)*

<https://www.legislation.gov.au/Series/F2012L02501>

What is an MRL?

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*

Registration or permit

1. Registration = Label Approval
 - Applied for by Manufacturers = market return influenced
 - Approved uses displayed on the product label
 - Outcomes are generally on major crops, fewer minor crop registrations

2. Minor Use Permits = Approval for Off-Label Use
 - Applied for by Growers/Users
 - Approval is granted in the form of a 'permit'
 - Emergency permits can be issued quickly if required

Walnuts are classified as a Minor Use Crop

- Australia has a list of major crops and considers by exclusion all other crops (not listed) as minor

Major food crops: almonds, apples, apricots, asparagus, avocados, bananas, barley, beans (french and runner), broccoli, cabbages, canola, carrots, cauliflowers, cherries, chick-peas, cotton, field peas, grapes (wine and table), green peas, nectarines, oats, onions, oranges, lettuce, lupins, macadamias, maize, mandarins, mangoes, melons (except watermelons), potatoes, peaches, pears, sweet peppers (capsicums), pineapples, plums, pumpkins, rice, sorghum, strawberries, sugarcane, sunflowers, tomatoes, triticale and wheat.

Major non-food situations: non-crop areas, commercial forests, fallow land, commercial and industrial areas, domestic and public service areas, ornamentals (when used as a group), bushland / native forests, turf areas, pastures and aquatic areas.

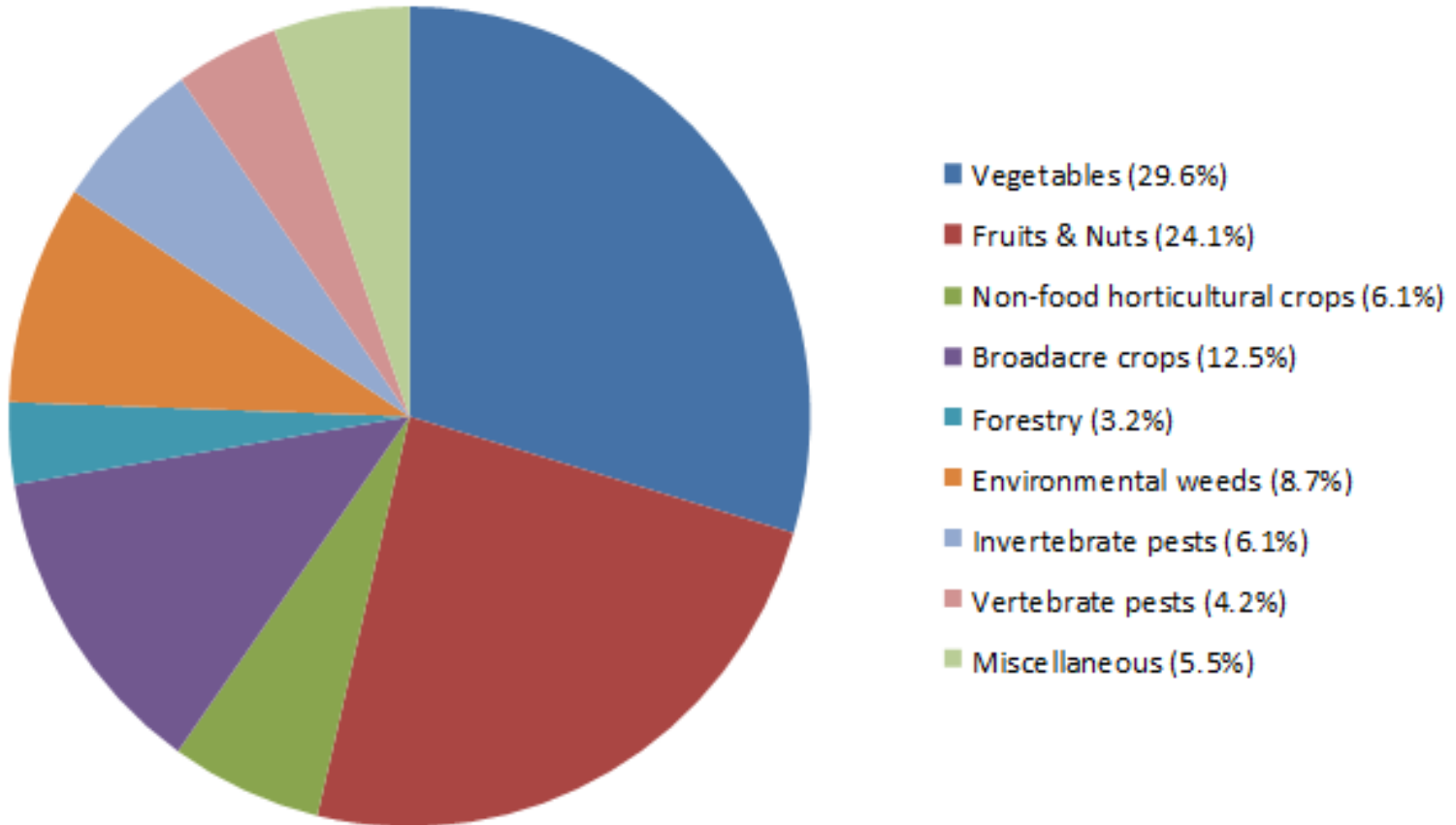
- Provisions also exist for consideration of minor uses in major crops

How minor use permits are processed

1. Growers/Users lodge permit application with APVMA
 - complete permit application form (proposed product & use details)
 - provide any supporting data/information (efficacy and/or residues)
 - pay fee = \$AU350
2. APVMA screen application
 - does it qualify as a minor use ?
 - what are the risk criteria needing assessment (how does the proposed use differ from what is already approved on label) ?
 - is there any supporting international data available ?
3. APVMA technical risk assessment (5-8 months)
 - often involves extrapolation of data and existing registrations in major crops to those minor crops
 - efficacy & residue extrapolations very common
 - use of expert judgement by external reviewers within state departments of agriculture

Minor Use statistics

Chart 1: Distribution of issued permits



What is a Permit?

- A 'permit' is a document issued by the regulator (APVMA) that outlines the use directions and conditions of the (off-label) minor use approval
- The permit contains;
 - The period in effect
 - The product which can be used
 - Who can use
 - The jurisdiction of use
 - Directions For Use & Withholding Periods
 - Any conditions
- All approved MU or emergency permits issued are available for downloading from the APVMA website

Permits issued for walnuts?

Search results (59 results)

Showing 1 - 20 of 59 results.

Items per Page Page of 3 [First](#) [Previous](#) [Next](#) [Last](#)

Permit No. ▼	Type	Description	Status	Issued date	Expiry date	Details
PER86916	AG	Ethephon / Walnuts (all cultivars) / To aid harvesting by promoting uniform nut fall	CURRENT	31-Oct-2018	31-Oct-2023	View
PER86671	AG	Dipel DF Biological Insecticide / Walnut / Heliothis and Lightbrown Apple Moth	CURRENT	01-Nov-2018	31-May-2021	View
PER86669	AG	Orius 430 SC Fungicide (tebuconazole) / Walnuts / Apical necrosis	CURRENT	04-Dec-2018	30-Apr-2020	View
PER81848	AG	APPLAUD INSECTICIDE / WALNUTS (ALL CULTIVARS) / FROSTED SCALE	CURRENT	08-Sep-2016	31-Jan-2020	View
PER85211	AG	pyraclostrobin / walnuts (all cultivars) / botryosphaeria	CURRENT	09-Oct-2017	31-May-2021	View
PER85782	AG	Orius 430 SC Fungicide / Walnuts (all cultivars) / Apical necrosis	CURRENT	01-May-2018	31-Oct-2019	View
PER85553	AG	Ethephon / Walnuts (all cultivars) / To aid harvesting by promoting uniform nut fall	SURRENDERED	27-Apr-2018	30-Jun-2019	View
PER85212	AG	Orius 430 SC / Walnuts (all cultivars) / Apical necrosis	CURRENT	05-Oct-2017	31-Oct-2019	View
PER84756	AG	Dormex Plant Growth Regulator / Walnuts (all cultivars) / To aid in the timing of budbreak and uniformity of flowering	CURRENT	01-Feb-2018	28-Feb-2023	View
PER81956	AG	DUPONT ALTACOR HORT INSECTICIDE / WALNUTS / HELIOTHIS, LIGHTBROWN APPLE MOTH	CURRENT	06-Nov-2015	31-Oct-2022	View

Permit to label?

- Project investigating the transfer of appropriate use patterns from permits to product labels (i.e. registration)
- Identification of permits for which sufficient data has been provided to satisfy the efficacy, safety and trade criteria
- Consultation with product registrants, permit holders and state/territory regulators for any information that would or would not support registration of these permit uses.
- Offers made to product registrants to include permit uses on labels – Labels will then be varied to include the minor uses
- Win-Win
 - More uses registered for growers
 - Less permit renewal applications for the APVMA to process

Crop groups?

- Project to make approval in entire crop groups easier
- Crop groups based on Codex crop groups
 - internationally recognized
- Representative crops now clearly defined
 - Data for almonds and macadamia nuts = tree nut group MRL

Crop Group 022: Tree nuts

[View all crop groups](#)

Commodity name	Codex code	Scientific name	Also known as	Representative crops
all commodities in Group 022	TN 0085			Almonds and Macadamia nuts

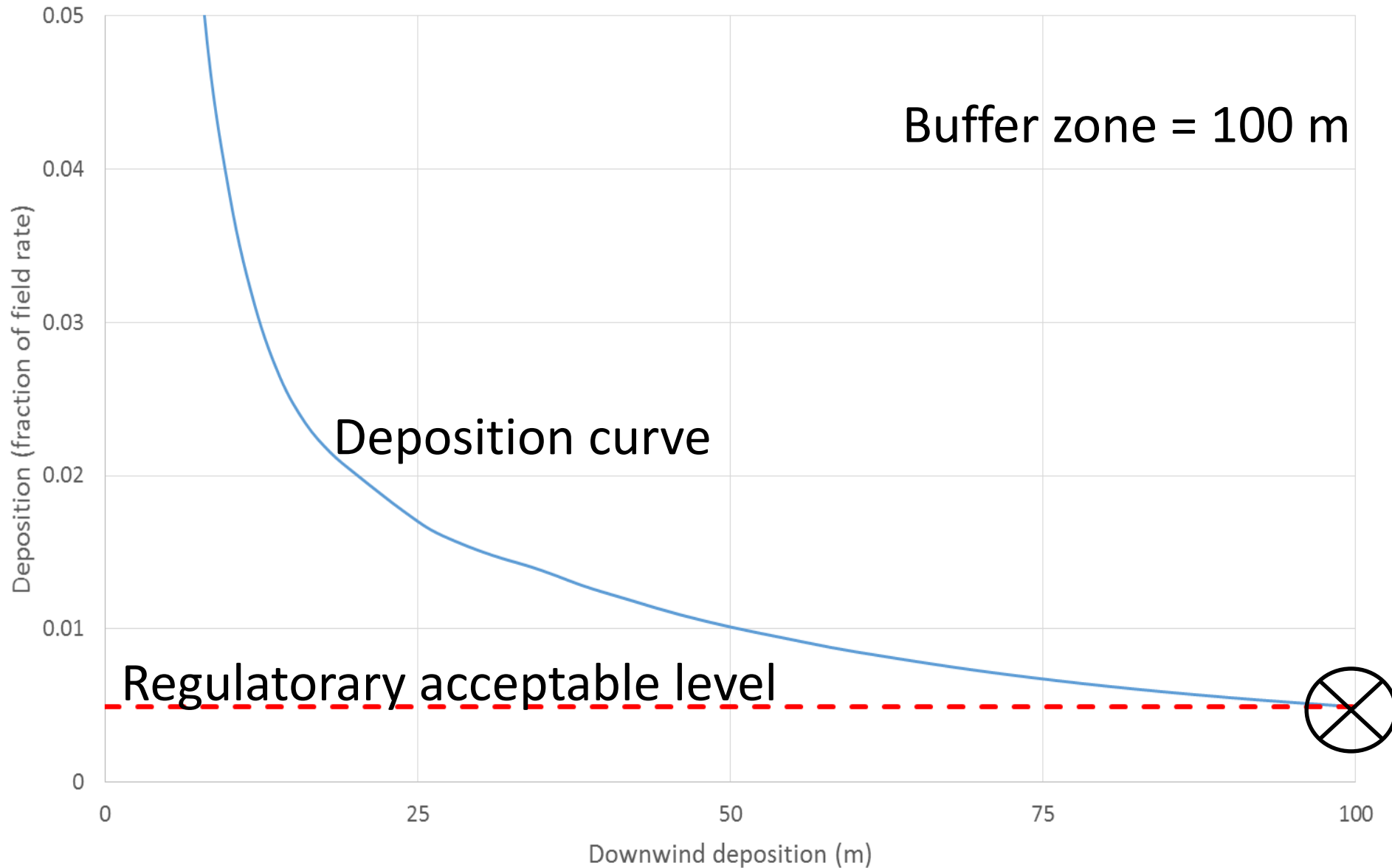
<https://apvma.gov.au/crop-groups>

Spray drift assessments

Need to know two things:

1. How sensitive are the areas being protected to the product (Regulatory Acceptable Levels)
2. What is the downwind spray deposition for the relevant application method (Deposition curve)

Buffer zone principles



Spray Drift - Background

- APVMA's current approach for addressing the risk of spray drift was implemented March 2010.
- Limitations
 - Lack of flexibility and ability to adopt Drift Reducing Technologies
 - Assessment based on worst case scenarios
No incentive to adopt best practice
 - Deterrent to including some types of applications when registering products.
- Project to develop a new spray drift regulatory framework began in 2013.

Spray Drift Consultation

- Initial consultation on the APVMA's proposed approach to spray drift management closed 30 March 2018
- APVMA revised proposal based on comments received
- Currently seeking supplemental comments for Stage 1 - close 8 March 2019
 - <https://apvma.gov.au/node/33726>

Main changes to the previous Consultation

- 'Spray drift management tool' not mentioned in label instructions
- Buffer zones are now all mandatory
- Release height now above the 'target canopy' rather than 'target'
- Expanded information related to spray drift inversions
- Changes to ground applications
 - Modified ground boom deposit curves (NWPPA review)
 - Maximum buffers for ground boom extended from 300 m to 400 m
 - Boom height reduced to 0.5 m and over 0.5 m option added
 - Wind speed 7, 14, 20 km/hr for both ground and air
- Changes to Aerial application
 - Release height for aircraft is based on 25% wingspan for fixed wing aircraft (4 m) or 25% rotor diameter for helicopters (3 m).
- No changes proposed for 'vertical sprayers' (orchard sprayers)

Case Study – Vertical Sprayers

Situation		Buffer Area	Buffer Distance for Vertical Sprayers (m)	
			Current policy	Consultation
SDRAM	Case study 2	Aquatic	60	40
		Vegetation	40	30
Product 3	Use 1	Aquatic	50	30
		Vegetation	10	10
		Livestock	80	20
Product 4	Use 1	Vegetation	20	15
		Livestock	80	15

Case Study - Aircraft

Situation		Buffer Area	Buffer Distance (m)					
			Fixed Wing			Helicopter		
			Current policy	Consult Dec 2017	Consult Nov 2018	Current	Consult Dec 2017	Consult Nov 2018
SDRAM	Case study 1	Aquatic	120	85	140	90	65	100
		Vegetation	750	300	400	500	210	230
Prod 1	Use 1	Vegetation	300	160	190	180	110	130
		Aquatic	50	55	75		50	60
Prod 3	Use 1	Aquatic	160	50	55	100	45	45
Prod 5	Use 1	Vegetation	750	300	400	500	210	230
	Mix 1	Aquatic	400	160	240	250	100	160
		Vegetation	>800	>800	>800	800	575	500
	Mix 2	Aquatic	15	NR	10	15	10	20
		Vegetation	>800	>800	>800	>800	600	550
	Mix 3	Aquatic	180	110	170	140	75	120
		Vegetation	>800	775	>800	700	425	375
	Mix 4	Vegetation	>800	>800	>800	750	550	450

NR – Not required

>800 – Use is not supported

Further Questions

- Thank you for the opportunity
- Any questions?

James Deller

02 6210 4750

James.deller@APVMA.gov.au