

Australian Pesticides & Veterinary Medicines Authority (APVMA)

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“A Major Focus to Solve a Minor Problem”

- Australian regulatory mechanisms & requirements
- Minor Use definitions in Australia
- Applying for permits, data requirements
- Assessment process, fees and timeframes
- Some statistics, experiences and thoughts



Mechanisms for Approving New Uses

■ Registration

- Proponent = Manufacturer
- Uses reflected on product labels
- Focus is on economic return ~ major uses

■ Permits

- Minor Uses and Emergency Uses only
- Anyone can apply
- Uses not reflected on labels but via a Permit



APVMA Regulatory Role

- The APVMA must be satisfied that all uses approved will:
 - be effective for all uses proposed,
 - will be safe to humans, target and non-target species, and
 - will not pose unacceptable risks to the environment or trade with other nations

Product Registration, Permits and Chemical Review



What is a Minor Use?

Australian legislative definition

“a use of the product or constituent that would not produce sufficient economic return to an applicant for registration of the product to meet the cost of registration of the product, or the cost of registration of the product for that use, as the case requires (including, in particular, the cost of providing the data required for that purpose)”.

Generally speaking crops grown on a small scale or limited use within a major crop



What is a Minor Use?

APVMA Minor Use Guidelines

- Schedule 1: list major crops/situations
- Schedule 2: >10% and >10,000ha
- Schedule 3: data/regulatory costs > economic return



Applying for Permits

■ Who can apply?

- Anyone can apply
- Encourage peak industry bodies
- Some limited “minor use providers” – levy based (grain and horticulture)

■ How to apply?

- Determine data requirements
- Satisfy Schedule 1, 2 or 3 ?.
- Permit application form



Determining data requirements

We are generally not re-inventing the wheel

- Registered products are mainly proposed
- Use regimes are usually similar to existing label uses
- Target pests and diseases are often similar
- Related major crops already registered

- Therefore.....
 - can utilise existing risk assessments
 - Environmental impact and worker safety usually unchanged
 - Efficacy and Crop Safety – variable reliance
 - Residues ~ local, overseas data or extrapolations



Assessment of Permits for Minor Uses

- Determined by...
 - Technical and Agency screening determines reviewers

- Those involved in the assessment
 - APVMA
 - 8 State/Territory Dept. Primary Industries and Agriculture
 - Product manufacturers
 - Dept. Environment & Heritage
 - Office of Chemical Safety (toxicology and OH&S)



Assessment Timeframes and Fees

- Assessment timeframes
 - legislative 3 – 12 months (majority 5 - 8 months)
 - Vary depending upon assessment required
- Fees (introduced 1 July 2005)
 - \$320
 - Some exemptions apply for Govt. agencies



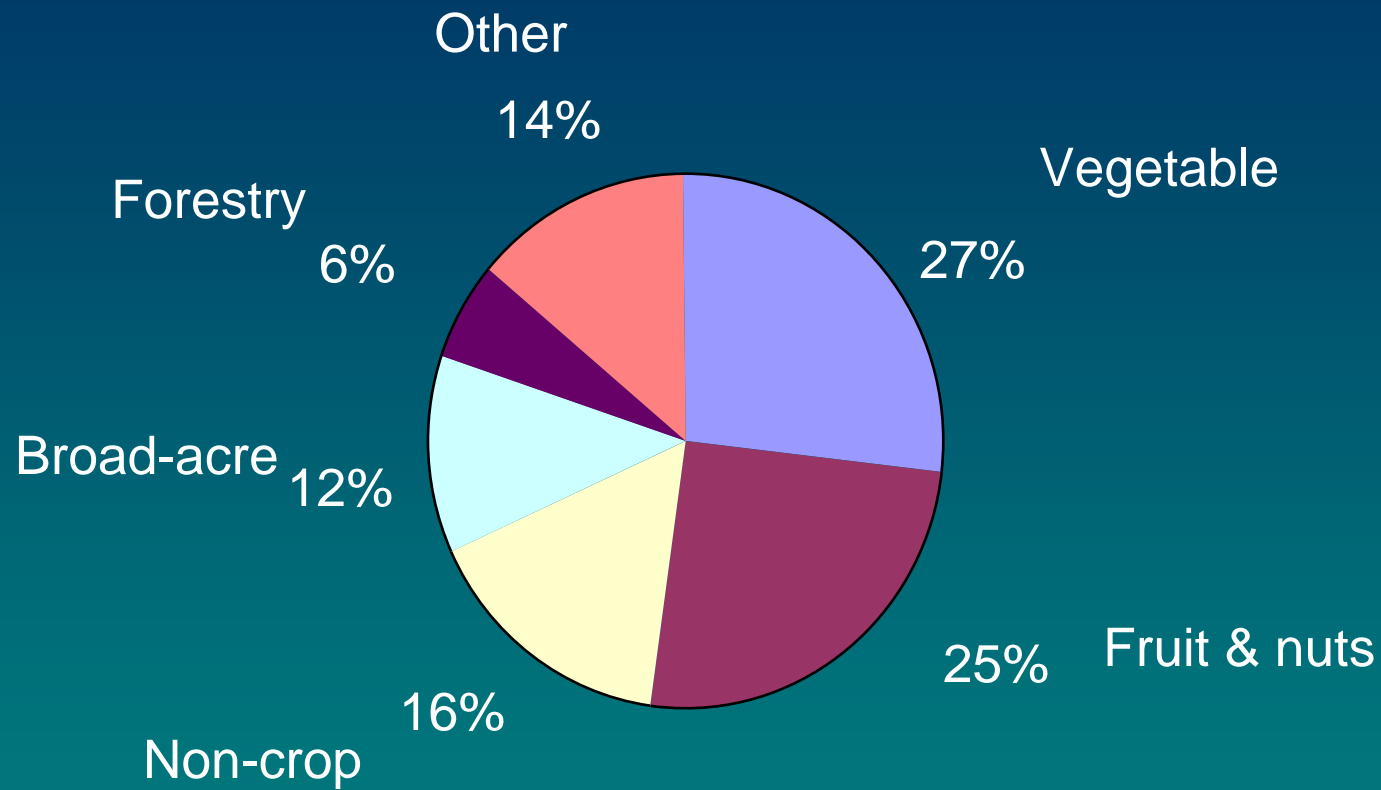
Applications submitted to APVMA

Agricultural (pesticides)

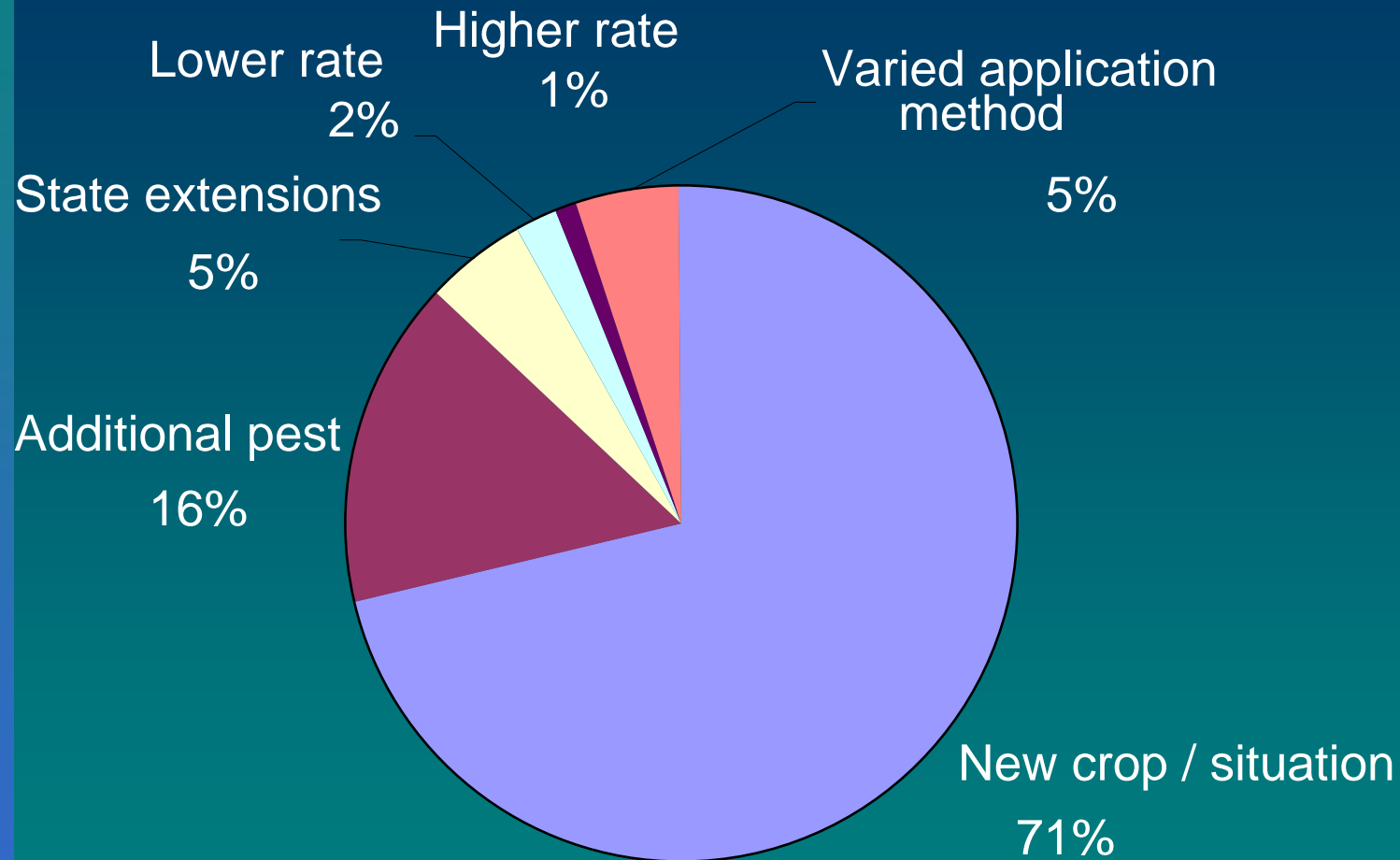
- Minor use approx. 521 permit applications/annum
- Applicants
 - Peak industry – 45%
 - Govt. – 35%
 - Individuals – 5%
- Sectors
 - Vegetable – 27%
 - Fruits and nuts – 25%
 - Non-crop – 16%
 - Broad acre – 12%
 - Forestry – 6%



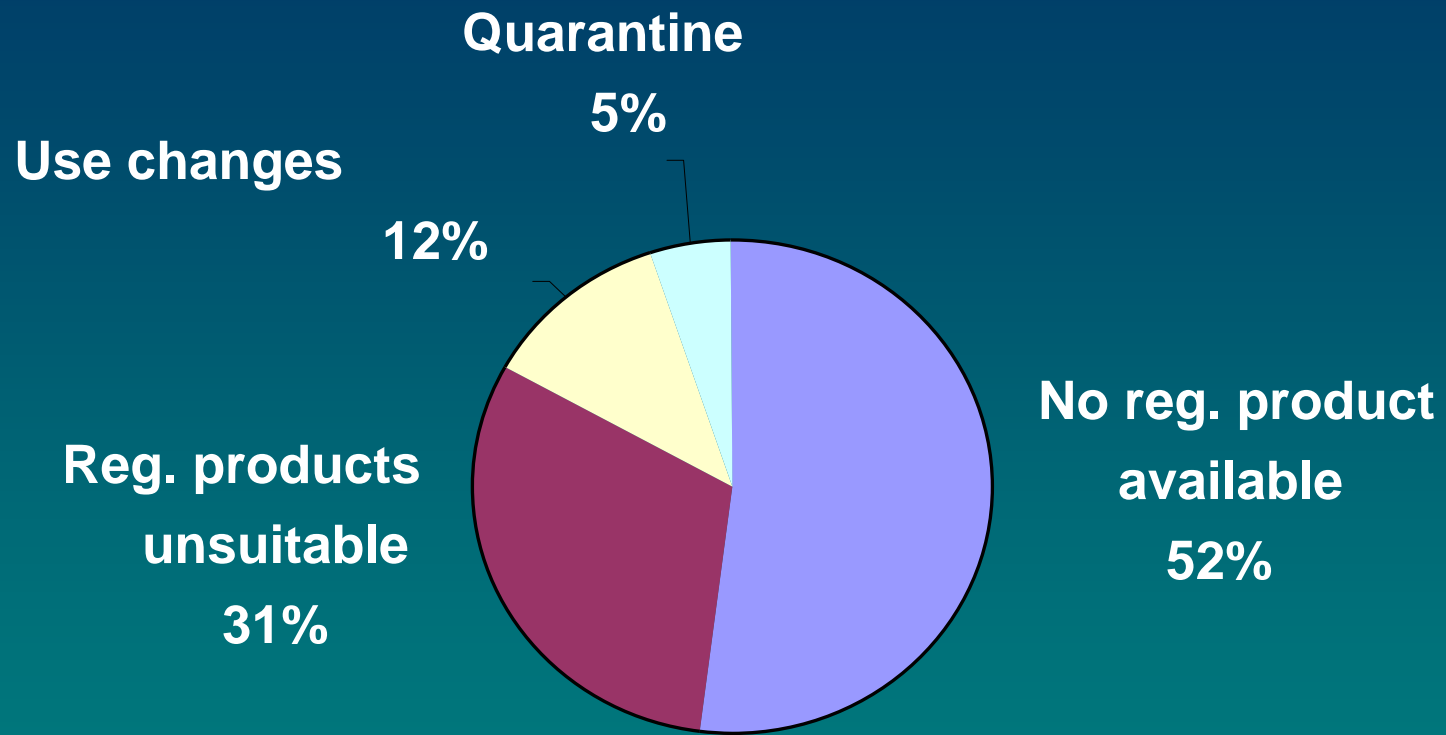
Major agricultural (pesticide) sectors applying for minor use permits



Purpose of minor use permit applications for pesticides



Justification and reasons provided in support of minor use permits



“A Minor Focus”

PRIMARILY APPLICANTS ARE THINKING.....

Almond Blueberries Linseed Custard apples Hazelnuts Longans Sage Silverbeet
Boysenberries Passionfruit Rosemary Cherries Safflower Bok choi Nashi Parsley
Spring onions Walnuts Endive Roses Pecans Celery Squash Peas Wasabi
Lentils Lemons Pistachios Tamarillo Coffee Lotus root Olives Jojoba Sunflowers
Plums Leeks Asparagus Rambutan Thyme Eggplant Capsicums Poppies Peanuts
Cucumbers Mushrooms Beetroot Kiwi fruit Mangoes Lavendar Cowpea Jackfruit
Pineapples Sweetcorn Brussels sprouts Avocado Manadarins Mungbeans Mangosteen
Garlic Lychees Sweet potato Zucchini Adzuki beans Chestnuts Durian Fennel
Snake beans Okra Spinach Taro Coriander Carambola Ginger Canola Loquat
Pawpaw Lemongrass Sesame Mizuna Pyrethrum Radish Snow peas Dragon fruit
Basil Mustard Mint Galangal Banana Kohlrabi Cauliflower Rhubarb Lettuce
Dill Tea tree Guava Mango Oregano Strawberry Sapote Tomato

.....BUT WHERE SHOULD THEY BE THINKING & WHY?



Difficulties encountered

- Large number of applicants and crops – little interaction
- Lack of regulatory knowledge/experience
- Limited technical knowledge of crop, pests and diseases
- Education can be lengthy – yet only after limited No. uses
- Can duplicate efforts/costs for quite similar and related uses
- Every need considered a similar complexity ~ stalls



Key groups from a Regulatory perspective

- Fruits
- Vegetables
- Grains (Cereals, Oilseeds & Pulses)
- Tree nuts
- Seeds for beverages and sweets
- Herbs and spices
- Ornamentals & Nursery
- Forestry
- Turf



Key groups from a Regulatory perspective

■ Fruit

- Citrus fruit
- Pome fruit
- Stone fruit
- Berries and other small fruits
- Tropical fruit

■ Vegetable

- Bulb vegetables
- Brassica vegetables
- Fruiting vegetables
- Leafy vegetables
- Legume vegetables
- Root and tuber vegetables
- Stalk and stem vegetables



Benefits from grouping needs

- Reduction in associated regulatory costs via:
 - Greater co-ordination & consolidation
 - Reduced duplication in gathering supporting information
 - Industry audits – identify common needs/trends
 - Targeted yet comprehensive research – fewer overall trials
 - Improved use and access to available data
 - Increase ability to gain registration for crop groups

Proposal under consideration

Development of a Minor Use & Specialty Crops Development Unit



A Major Focus

to Solve a

Minor Problem

