Accessing new chemicals through the APVMA permit process

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Before any pesticide can be sold or used in Australia, the Australian Pesticides and Veterinary Medicines Authority (APVMA) must ensure it is rigorously assessed for efficacy, safety (human and the environment), trade, and quality.

Manufacturers must conduct trials and submit comprehensive data packages to the APVMA to have their products assessed and registered in Australia. This process is expensive but works well for larger industries like strawberries, where the volumes of chemicals sold are economically attractive. It becomes tricky where chemicals are needed for smaller-scale crops or niche uses where the return on investment is lacking or in emergencies where a chemical is needed but there isn't enough time to develop data packages.

To allow smaller-scale crops to gain greater access to agrichemicals when needed, the APVMA has a **minor use permit** system that allows for approved off-label use of agrichemicals for specific purposes. There are currently 29 minor use permits for blueberries and 27 for Rubus. This permit system can also be used to allow limited uses of agrichemicals on major crops where registration for this use would not provide sufficient economic return to the manufacturer.

The APVMA **emergency use permit** system can be used when there is a genuine unforeseen need for a chemical product or active constituent.

Crop categories

Crops are categorised by the APVMA as minor or major according to the area under cultivation, the volume of production, dietary consumption, crop value, and export quantities.

Strawberries are considered a major crop, so minor use permits are not granted unless it can be demonstrated that the use will be limited to less than 10% of the national crop or 10,000 hectares (whichever is less) per annum, or that registering the minor use will not be economically viable for the manufacturer.

Blueberries, raspberries, and blackberries are currently considered minor crops and are eligible to apply for minor use permits, even if the use is for the entire Australian crop. The APVMA is currently reviewing the classification of industries and this 'minor' crop status may change in future.

Strategic Agrichemical Review Process

The Strategic Agrichemical Review Process (SARP) is a structured process that provides a view of current priorities and gaps regarding pest, disease, and weed control in horticultural crops. SARPs are conducted every four years and the latest berry industry SARP report was released in February 2024.

> Outcomes of the SARP ***may*** include pursuing chemical registrations with chemical companies, or minor use permits with the APVMA

The SARP involves a desktop study and industry consultation to:

- Identify the pests, diseases, and weeds affecting the industry, and prioritise them according to their impact and the current availability of effective control measures
- Evaluate all current registered and permitted chemical controls for their suitability in terms of efficacy, Integrated Pest Management (IPM), resistance management, residues, withholding period, trade, human safety, and the environment
- Identify gaps in pest and disease control strategies including gaps that may arise from future loss of chemistries
- Identify suitable new or alternative chemicals to address the gaps

Table 1 shows the list of diseases and pests that have been designated as 'high priority' in the 2024 berry industry SARP.

Table 1. Pests and diseases designated as 'high priority' in the latest Berry Industry SARP published in February 2024

Insects and Pests	Strawberry	Blueberry	Raspberry	Blackberry
Two Spotted Mite *(Tetranychus urticae)*	H	L	H	H
Broad Mite *(Polyphagotarsonemus latus)*	L	M	M	H
Red Berry Mite *(Acalitus essigi)*	L	L	M	H
Western Flower Thrips *(Frankliniella occidentalis)*	H	M	H	H
Green Vegetable Bug *(Nezara viridula)*	M	M	H	H
Rutherglen Bug *(Nysius vinitor)*	M	M	H	H
Green Stink Bug *(Chinavia hilaris)*	L	M	H	H
Green Mirid *(Creontiades dilutus)*	H	M	H	H
Brown Mirid *(Creontiades pacificus)*	M	M	H	H
Crop Mirid *(Sidnia kinbergi)*	M	M	H	H
Leafhoppers / Jassids *(Cicadellidae)*	M	M	H	M
Light Brown Apple Moth *(Epiphyas postvittana)*	M	H	M	H
Loopers *(Chrysodeixis spp.)*	M	H	H	H
Queensland Fruit Fly *(Bactrocera tryoni)*	H	M	H	H
Strawberry Aphid *(Chaetosiphon fragaefolii)*	H	L	L	L
Green Peach Aphid *(Myzus persicae)*	M	M	M	H
Leaf and Bud Nematode *(Aphelenchoides ritzemabosi)*	H	L	M	M
Chilli Thrips *(Scirtothrips dorsalis)*	M	H	M	H

Disease	Strawberry	Blueberry	Raspberry	Blackberry
Grey Mould (*Botrytis cinerea*)	H	H	H	H
Phytophthora Root Rot (*Phytophthora* spp.)	M	M	H	H
Fruit Rot (*Cladosporium* spp.)	M	M	M	H
Powdery Mildew (*Podosphaera* spp.)	H	L	M	M
Crown Rot (*Colletotrichum gloeosporioides*)	H	L	M	M
Downy Mildew (*Peronospora* spp.)	M	L	M	H
Charcoal Crown Rot (*Macrophomina phaseolina*)	H	L	L	L
Blueberry Rust (*Thekopsora minima*)	L	H	L	L
Stem Blight (*Neofusicoccum* spp., *Lasiodiplodia* spp. and *Botryosphaeria dothidea*)	L	H	L	L

To read the latest berry industry SARP report in full, visit the RESOURCE LIBRARY at berries.net.au/resource-library and Search for 'SARP'

Minor use permit process

New minor-use permits generally take 6-12 months to be assessed and issued once an application has been submitted. Application fees cost $350 and the permits are normally valid for 3-5 years before they must be renewed, or the use is added to the manufacturer's label.

Possible justifications for applying for a minor use permit:

- new disease, insect, or weed identified as a cropping issue
- no pesticide approved for the problem
- insufficient options for resistance management
- current pesticides ineffective due to resistance
- trade risk - current pesticides unsuitable where crop commodities will be exported
- IPM, environment, or WHS issues
- loss of pesticides due to removal from the market or chemical review restrictions
- market failure – insufficient return on investment for the manufacturer

A sound scientific argument, data, and evidence of support for the proposed use from the manufacturer, industry (e.g. industry SARP), and government officials, are also required to justify a new permit application.

Efficacy, crop safety, residue, trade, WHS, and environment data or argument must support the proposed use pattern prescribed in the permit application including application rates, method, frequency, and timing; pest density, withholding period, and applicable states/territories. Data already available in Australia and overseas (e.g. MRLs and use patterns) can be used. If there are gaps, local testing and trials may be required.

How long does it take?

Generating and analysing the data needed for a minor use permit can take 6 to 18 months. Putting all the required information into a permit application package can take another 0.5 to 2 months. That's up to 32 months (including the APVMA assessment timeframe) from when a potential product is identified to when it may be approved for use on a minor use permit.

Emergency use permit process

Emergency use permits are designed to support primary producers during emergencies or impending emergencies. They take 2-6 weeks to be assessed and issued once an application has been submitted.

Applications are free and permits are generally valid for 2 years before they must be renewed (usually as a minor use permit), or the use is added to the manufacturer's label.

Situations considered to be an emergency include:

- outbreak of an exotic pest or disease
- unusual weather patterns that have caused higher or more frequent pest or disease incursions

There must be evidence that the situation is a genuine emergency and of high priority. A written statement from the relevant state coordinator or government authority outlining the emergency and its impact (e.g. % losses, financial impacts) and supporting the proposed permit will be considered strong evidence.

Situations that are **not generally accepted** as an emergency include:

- a situation that has arisen because the applicant has not submitted a minor use permit application in sufficient time
- a pest, weed, or disease that has been allowed to thrive (contrary to sound agricultural practice) to the stage where urgent control or treatment is required
- the pest or disease generally recurs on a seasonal, annual, or other regular basis
- resistance to registered products has occurred, where the resistance has built up and been evident over time

Data and support from the chemical manufacturer are crucial for an emergency use permit application. If local data isn't available for the target crop(s) this can sometimes be extrapolated from other crops. Where available, MRL and other data from overseas can also be used.

How long does it take?

Identifying a suitable product or active ingredient to address the emergency, and collecting and extrapolating the relevant data can take 1 to 5 days.

Putting all the required information into a permit application package can take another 2 to 7 days.

That's up to 8.5 weeks (including the APVMA assessment time) from when a potential product/active is identified to when it may be approved for use on an emergency use permit.

More information

WATCH:

Minor Use Permit webinar (February 2024) with Peter Dal Santo - VegNET Tasmania
youtu.be/Q7RpH2u7jAw?si=2VMjVpkmbQVnzraP

VISIT:

APVMA Applying for Permits web page
www.apvma.gov.au/registrations-and-permits/permits

READ:

2024 Berry Industry SARP
Visit the RESOURCE LIBRARY at
berries.net.au/resource-library and Search for 'SARP'

Individuals (growers) or body corporates can apply for a permit via the APVMA online portal.

To allow equal access for all growers to chemistries suitable for berries, Hort Innovation has been contracted by Berries Australia to submit permit applications on behalf of the entire berry industry.

Preparation of the data needed to support the application can be undertaken by a grower, industry associations, consultants, government officers, or chemical retailers. Berry Industry Development Officers in each state are also available to help.

APVMA permit PER7250 allows small-scale trials with unregistered agricultural chemical active constituents or products so you can generate data on efficacy, residues, and crop safety.

Note: As there is no MRL, all produce treated under this permit must be destroyed.
permits.apvma.gov.au/PER7250.PDF

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