



Australian Government

**Australian Pesticides and
Veterinary Medicines Authority**



Guidelines for Determining Minor Use

May 2025

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Guide for determining a minor use

The Agricultural and Veterinary Code Regulations 1995 state that a minor use:

1. in relation to a chemical product or an active constituent, is 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).
2. in relation to a chemical product, is a use of the product where the following apply:
 - a) Instructions for that use are in the Register in relation to one or more registered chemical products
 - b) None of those registered chemical products is available for sale anywhere in Australia

What is a minor use?

A minor use can include:

- Use of a product on a speciality crop or animal grown on a small scale
- Infrequent use of a product on a major crop for the control of a minor pest or disease
- Use of a product on a major crop for the control of a minor pest or disease, where the use is restricted to a small proportion of that crop
- Change in use of a registered product (that would normally require an application for variation) to account for unusual seasonal conditions (for example, changes to the method or rate of application of the product)
- Use of a product on a newly emerging crop or livestock species

Guidance

Please note: The following are guidelines only. The final decision on which uses are determined to be a minor use rests with the APVMA.

1. Based on the list in Section 1, is the crop, animal or situation a minor crop, animal or situation?

- **YES** – then use is a minor use
- **NO** – go to 2

2. Does the use meet the criteria specified in Section 2 for a limited use within a major crop, animal or situation?

- **YES** – then use is a minor use
- **NO** – then go to 3

3. Would registration produce 'sufficient economic return'?

- **YES** – cannot be considered a minor use
- **NO** – then provide evidence as outlined in Section 3

*'Sufficient economic return' means in relation to the costs of obtaining registration for a specific use pattern compared to the returns to the manufacturer (registrant) from making the use available. This criterion is generally only available to registrants who are able to provide the necessary information as outlined in Section 3.

Section 1 – Major crops, animals and situations

These are based on current statistics regarding volume of production, area under cultivation or numbers of trees or animals and the value of crop or animal.

The following are deemed to be 'major'. All crops, animals or non-crop situations that are not included in the following list are considered 'minor'.

Table 1: Major crops/situations (agricultural chemicals)

Group	Crop or animal
Group 001 Citrus fruits	<ul style="list-style-type: none"> • Oranges • Mandarins
Group 002 Pome fruits	<ul style="list-style-type: none"> • Apples • Pears
Group 003 Stone fruit	<ul style="list-style-type: none"> • Apricots • Plums • Peaches • Nectarines • Cherries
Group 004 Berries and other small fruits	<ul style="list-style-type: none"> • Grapes (wine and table) • Strawberries • Blueberries
Group 006 Assorted tropical and sub-tropical fruit – inedible peel	<ul style="list-style-type: none"> • Avocados • Bananas • Mangoes
Group 009 Bulb vegetables	<ul style="list-style-type: none"> • Onions
Group 010 Brassica vegetables	<ul style="list-style-type: none"> • Broccoli • Cabbages • Cauliflowers

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Group	Crop or animal
Group 011 Fruiting vegetables – cucurbits	<ul style="list-style-type: none">• Melons• Pumpkins• Cucumber• Zucchini
Group 012 Fruiting vegetables – other than cucurbits	<ul style="list-style-type: none">• Peppers (capsicums)• Tomatoes
Group 013 Leafy vegetables (including Brassica leafy vegetables)	<ul style="list-style-type: none">• Lettuce
Group 014 Legume vegetables	<ul style="list-style-type: none">• Beans (French and runner)• Green peas (not including snow peas and sugar snap peas)
Group 015 Pulses	<ul style="list-style-type: none">• Chickpeas• Field peas• Lentil• Lupins
Group 016 Root and tuber vegetables	<ul style="list-style-type: none">• Carrots• Potatoes
Group 017 Stalk and stem vegetables	<ul style="list-style-type: none">• Asparagus• Celery
Group 020 Cereal grains	<ul style="list-style-type: none">• Barley• Oats• Rice• Sorghum• Triticale• Wheat
Group 021 Grass for sugar production	<ul style="list-style-type: none">• Sugarcane
Group 022 Tree nuts	<ul style="list-style-type: none">• Almonds• Macadamias
Group 023 Oilseed	<ul style="list-style-type: none">• Cotton• Canola

Non-food situations

- Agricultural non-crop areas (includes land associated with farmland but not used for regular cultivation and/or grazing)
- Commercial forests (includes plantations grown specifically for timber production)
- Fallow land
- Commercial and industrial areas (includes factories, factory land, industrial sites, parking lots, fuel tank farms, outside chemical storages)
- Domestic and public service areas (includes houses, residential subdivisions, schools, hospitals, restaurants, hotels, motels, cafes, rubbish tips and playground and recreational areas such as golf courses, municipal parks and gardens, etc.)
- Non-crop areas (includes areas of lands not being used or intended to be used for cropping or grazing)

These areas include industrial sites, timber yards, areas around farm buildings, along fences and roadsides, rights-of-way, storage areas, wastelands, vacant lots, cemeteries, etc.

- Ornamentals (when used as a group)
- Bushland/native forests (includes natural forest areas used for recreational/scenic purposes, national parks, etc.) except spot spray or spot treatment for control of invasive species.
- Turf areas (includes commercial turf farms, sports ovals, bowling greens, general lawn areas, etc.)

Other situations

- Pastures (herbage grown specifically for the purpose of being grazed by, or fed to, livestock. Pastures includes lucerne, medics, clovers and grasses, whether for grazing or seed crops. The word 'herbage' excludes crops such as cereals, oilseeds, vegetables and cole crops)
- Aquatic areas (includes irrigation channels, streams, lakes, dams, drainage ditches)

Table 2: Major animal species (veterinary chemicals)

Food-producing animals	Non-food animals (companion animals)
<ul style="list-style-type: none"> • Cattle • Sheep • Pigs • Chicken • Atlantic Salmon 	<ul style="list-style-type: none"> • Dogs • Cats • Horses

Section 2 – Limited use within a major crop, animal or non-crop situation

The APVMA acknowledges that a minor use may occur in a major crop, animal, or situation.

The following matrix can be used to classify uses based on the area, number of plants or animals to be treated, and the value of the commodity.

Please note that the following guidance **does not** apply to companion animals, as the ‘value of commodity’ can be difficult to quantify. Applicants seeking a minor use permit for a major companion animal species should refer to Section 3 below or seek further advice from the APVMA.

Table 3: Classification of minor uses based on treatment volume and value of commodity

		Area/number of plants/number of animals to be treated (per annum)		
		Low	Medium	High
Value of commodity	Low	Minor	Minor	More information required
	Medium	Minor	More information required	More information required
	High	Minor	More information required	Potentially major use – must demonstrate insufficient economic return

The following values have been developed based on data available for major crops and animals from the Australian Bureau of Statistics, ABARES and Hort Innovation. Parameters are based on the major crops in terms of size and value in each category.

Table 4: Classification of area and value for various commodities

	Low	Medium	High
<i>Broadacre crops</i>			
Area	<1,000 ha	1,000–10,000 ha	>10,000 ha
Value	<\$10 million	\$10–100 million	>\$100 million
<i>Horticulture</i>			
Area	<1,000 ha	1,000–5,000 ha	>5,000 ha
Number of trees	<50,000	50,000–1 million	>1 million +
Value	<\$10 million	\$10–75 million	>\$75 million
<i>Veterinary (note: does not apply to companion animals)</i>			
Number of animals – poultry	<1 million	1–50 million	>50 million
Number of animals – mammals	<10,000	10,000–1 million	>1 million
Production quantity – other e.g. fish	<10 kt	10–50 kt	>50 kt
Value	<\$25 million	\$25–500 million	>\$500 million

Situations where we will ask for more information

Some cases of minor use are clear-cut, for example, use on a very small scale or in a new industry. Other cases may require more evidence to satisfy the minor use criteria, and these requirements may change over time:

- Situations where pests have become more widespread, or use has potential to expand to other jurisdictions
- Situations where emerging industries have become more widely established and there may be a potential business case for registration
- Where the applicant is the holder of the product registration (see below)

The following information may be included in your application to support the minor use criteria

- Estimated scale of use (area treated, number of animals treated, amount of product used)
- A statement from product registrants stating the use would not be commercially viable to register
- Availability of management options, problem distribution, and frequency
- Evidence of industry need, e.g. SARPs, industry profiles
- Demonstration of a lack of suitable registered alternatives

The following conditions may be applied to your permit

- Reporting of scale of use under permit
- Evidence of discussions with product holders regarding registration of the use for permit renewal
- Generation of further data to support permit renewal

Case studies

Example A

An applicant wants to apply for use of an unregistered product in cattle to prevent toxicity from consuming a certain plant. As there are over 20 million cattle in Australia (ABS, 2021), the use is potentially major.

To support the application for a minor use permit, the applicant provides information on the areas where the plant is grown. Due to the limited growing area, only a small number of cattle stations have potential to be affected by toxicity from this plant.

For renewal of the permit, the Holder provides the APVMA with information on the sales of the unregistered product. These data demonstrate that only 200 bottles of product were sold each year. The use meets minor use criteria as the sales volume would not be expected to produce 'sufficient economic return' for the costs of registration.

Example B

An applicant wants to apply for use of a registered crop protection product for control of an insect in tomatoes. As tomatoes are considered a major crop, the use is potentially major. The applicant uses the matrix. According to ABARES the value of tomato production in 2021–22 was \$466 million. This is considered 'high'. The applicant wants to treat 40 ha. The potential for this use to expand beyond the proposed 40 ha is not great, because the purpose is to treat a specific pest outbreak unique to the applicant's site and growing conditions. This area is considered 'low'. According to the matrix, the use can be considered minor. The applicant will still need to provide information to justify [reasonable grounds](#) for issue of a permit, including demonstration that there are no suitable and effective alternative registered chemical products available for the same purpose.

Section 3 – Demonstrating economic return

When registration would not produce 'sufficient economic return'

Ordinarily, we will not issue a 'minor use' permit in relation to a product registrant or a person principally responsible for the development, manufacture, marketing, distribution or commercialisation of the chemical product that is the subject of the permit.

In these circumstances, the holder should apply for a new registration or approval, or to vary the relevant particulars or conditions of the registered chemical product or approved active constituent.

However, if the holder believes the use is a genuine minor use (i.e. would not produce sufficient economic return to meet the cost of registration), then the applicant **must** provide cost breakdowns to demonstrate this. Applicants are strongly encouraged to apply for pre-application assistance (PAA) to seek guidance on requirements for registration. The holder may then apply for a minor use permit, providing information as outlined below to demonstrate that there is insufficient economic return to consider registration of the product and/or use.

Demonstrating insufficient economic return – PAA recommended

'Sufficient economic return' means in relation to the costs of obtaining registration for a specific use pattern compared to the returns to the holder (registrant) from making the use available.

Applicants using this pathway are encouraged to seek [pre-application assistance](#) (PAA) from the APVMA to obtain technical advice on data requirements and assessment levels for registration. These should be addressed in the investment costs outlined below. A tier 2 PAA is recommended (meeting optional).

Applicants must supply full costs and projected incomes associated with a particular use covering a period of no less than 3 years.

Estimated economic return = (Expected retail sales units x profit margin per unit) minus expected registration costs.

Information required includes:

- Investment costs (includes but not limited to):
 - costs associated with data generation
 - costs of data analysis
 - internal costs including costs of label changes
 - [registration fees](#)
 - **total costs.**
- Return on investment (includes but not limited to):
 - expected sale units – taking into account:
 - the recommended average treatment rate
 - area or number of animals to be treated
 - frequency (number of applications per year)
 - adoption (number of consumers adopting)
 - expected retail sale price
 - sales margin (per cent)
 - **total income.**

The applicant must demonstrate that, based on the data in relation to the above, there is insufficient economic return to consider registration of the product and/or use.

A condition of the permit may be to provide evidence (e.g. annual return) to demonstrate actual sales and prices.

Guidance specific to Part 2 of the definition

Minor use may apply where a product is registered for a use but none of those registered chemical products are available for sale anywhere in Australia.

For unexpected supply issues, the use may be eligible for consideration under an [emergency use permit](#).

In your application you should provide:

- evidence that product is not available for sale (i.e. declaration from product holder)
- anticipated duration of product shortage
- evidence for lack of suitable registered alternatives.

Permits issued under part 2 of the definition of minor use will only be issued for a duration deemed suitable to bridge the gap in supply of registered product. If the registered product resumes supply before the permit expiry, the permit holder may be requested to surrender their permit.

Acronyms and abbreviations

Shortened term	Full term
PAA	Pre-application assistance
SARP	Strategic Agrichemical Review Process
