

ACCESS TO PESTICIDES

An Explanation for Minor Industries



RURAL
INDUSTRIES

Research & Development
Corporation

Contents

1. Do you need to control a pest in your crop?
2. What pest management options do you have?
3. Pest management decision tree
4. You need a pesticide
5. How do you find out what pesticides are available?
6. What do you do if there are no pesticides available?
7. Registering a pesticide
8. Applying for a permit
9. Using unregistered pesticides
10. Using the AgVet Chemicals Collaborative Forum
11. Summary
12. References



1. Do you need to control a pest in your crop?

You have inspected your crop and found that there is an unwanted pest causing damage.

A 'pest' can be a disease, insect, nematode, virus or weed. Damage from pests can show itself in a multitude of ways, including: poor growth, discoloured/deformed plants, spots/blotches on leaves and chewed plant parts.

For most crop production systems, effective pest management includes a complex process of inspection, identification, assessment and control strategies. Accurate pest identification is essential to ensuring that you are able to make correct decisions on the impact of the pest and the appropriate control strategy.

Rural supply retailers, farm consultants and sometimes the internet, can be excellent resources regarding:

- correct identification of the pest problem
- economic impact of the pest
- available pest management options.
- You need to be aware that with some pests, doing nothing is not an option; significant damage to your crop can occur if the pest is left uncontrolled.

The pest management strategy you choose will be influenced by:

- availability of pest control strategies
- complexity of the pest problem
- (potential) impact of the pest on the crop
- costs, risks and benefits.

Before any pesticide can be sold in Australia, the Australian Pesticides and Veterinary Medicines Authority (APVMA) must first ensure that the product is rigorously assessed for efficacy, safety and quality. For the manufacturer to register a product they are required to submit a comprehensive data package to the APVMA.

In most states of Australia, registered pesticides must only be used for the purposes specified on the product label. If a pesticide is required for the control of a pest which is not listed on the label, this is termed an 'off-label' use. Many off-label requests can be authorised by an APVMA issued permit.

Accessing the best information on pest management and pesticides is vital for your decision making.





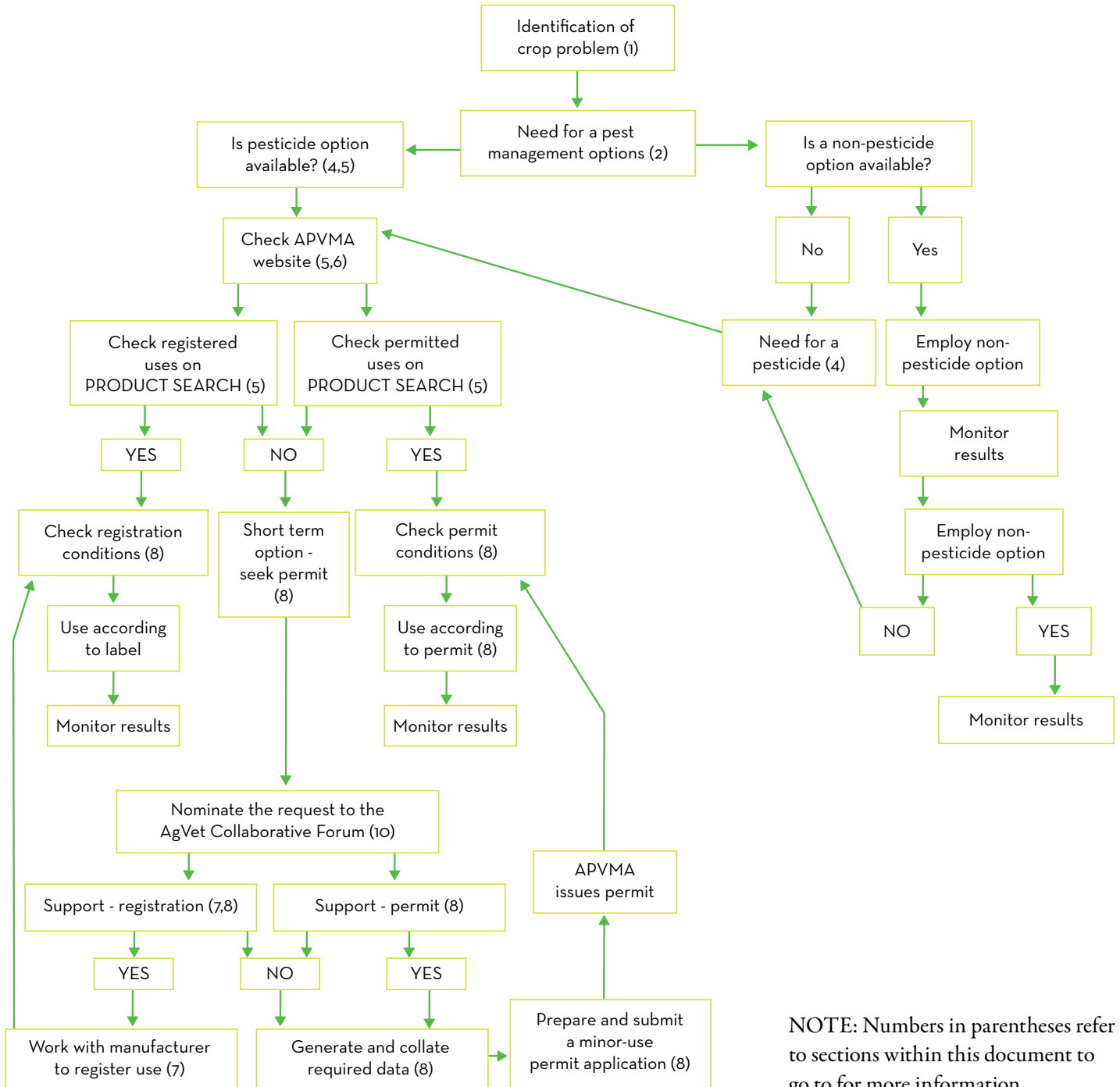
2. What pest management options do you have?

After the correct identification of the pest and deciding that it needs to be controlled, you have four options:

1. Do nothing.
2. Use a conventional pesticide – this approach uses all available registered pesticides for the control of the pest.

3. Use a biological pesticide – this approach uses various registered biological and organic pesticides, as well as beneficial organisms for the control of the pest.
4. Use integrated pest management – this approach uses all available control options including certain synthetic, biological and organic pesticides, as well as beneficial organisms for the control of the pest.

3. Pest management decision tree



NOTE: Numbers in parentheses refer to sections within this document to go to for more information

4. You need a pesticide

Once you have decided that a pesticide is required, the pesticide will be one of the following:

- registered with the APVMA for the required crop and pest
 - » Registration of the pesticide is predominantly undertaken by the chemical manufacturer and includes approval of label directions which specify how, and under what circumstances, the pesticide may be used to treat the relevant target pest or pests. Labels also give directions on clean-up, storage and disposal, and personal and environmental safety.
- permitted with the APVMA for the required crop and plant pest
 - » The minor-use permit system allows for approved off-label uses that are not listed on pesticide labels. It involves providing the APVMA with data to assess the safety and efficacy of the use. Permits are predominantly applied for by farmers, associations, consultants or government agencies.
- not registered or permitted with the APVMA for the required crop and plant pest
 - » If the pesticide is not registered or permitted for a particular use, then it is generally illegal to use that pesticide according to state law. However, certain exemptions do apply and these vary depending on each state.

5. How do you find out what pesticides are available?

The APVMA website (<https://portal.apvma.gov.au/>) is the most reliable source of pesticide information in Australia. It provides databases of registered and permitted pesticides with copies of most registered pesticide labels and permit documents. The website allows producers to 'search' for specific information targeted to their particular need.

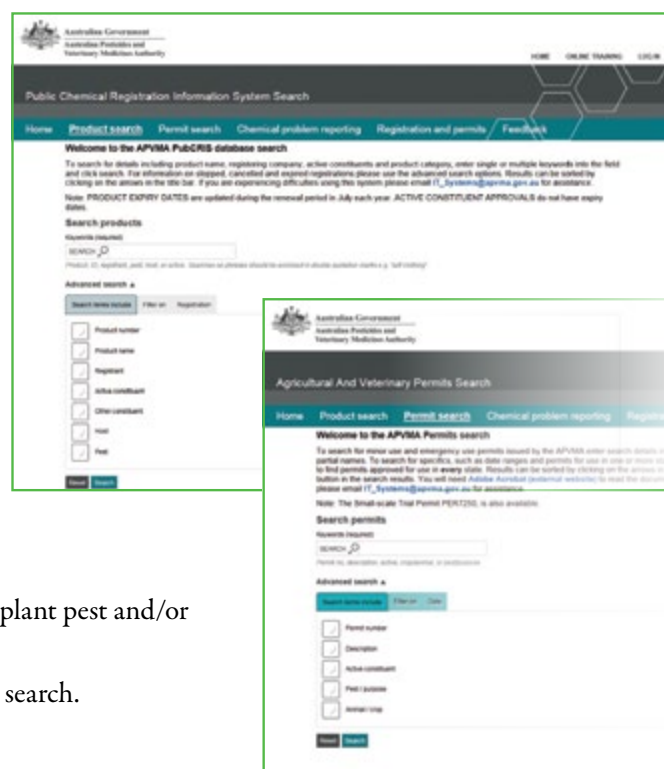
The information is the most accurate available in Australia.

APVMA Product Search (Pubcris):

This site (<https://portal.apvma.gov.au/pubcris>) is the Australian Government search facility that lists all registered pesticides.

How to effectively use the APVMA Product Search (Pubcris) web site:

- a. In the 'SEARCH' box, type the items you are looking search for: crop, plant pest and/or pesticide (e.g. rice, bloodworm, chlorpyrifos).
- b. Less information rather than more, is generally best in an initial search.
- c. Avoid common names for pests.
- d. The spelling used needs to be correct.
- e. Use the 'Advanced search' function to narrow the search field if desired.
- f. Once you have entered your search items, click on 'Search'.
- g. This will provide a 'Product list' with all registered products/pesticides that fall within your 'search' parameters.
- h. The list can then be sorted by product number, name or active.
- i. Copies of the product label can be viewed by clicking on 'View label'.



6. What do you do if there are no pesticides available?

It is often the case that no or limited appropriate pesticides are available for use with some agricultural crops (minor, new or emerging crops) or for specific situations in major crops (new pests, resistance, trade, etc.).

In these situations, the complex process of applying for a registered or permitted pesticide for use in your crop is often best left to experts in this area as the data required to comply with the APVMA regulations can be extensive.

7. Registering a pesticide

Registration of a pesticide is predominantly undertaken by the chemical manufacturer and includes approval of label directions which specify how, and under what circumstances, the pesticide may be used to treat the relevant target pest or pests. Labels also give directions on clean-up, storage and disposal, and personal and environmental safety.

This process cannot be undertaken by a grower or association, as it requires the collaboration of the chemical manufacturer to include the new use on a pesticide label.

If a grower would like the new pesticide use registered, then the process is:

1. Engage in discussions with the chemical manufacturer early to gain their acceptance of the proposed new use.
2. Engage in discussions with the APVMA early to determine what data is required for registration of the proposed new use.
3. Work with the chemical manufacturer to generate the required environment, efficacy, crop safety, residue, trade and/or OH&S data required for registration of the proposed new use.
4. Once all the required data has been generated, it needs to be collated and prepared into a registration submission. This is best prepared by a registration consultant.
5. Submit the registration submission to the APVMA with the associated fees.

Please note that the time required to generate the required data for the registration submission can range from 1–4 years, depending on the use. Also, the fees associated with generating the data plus the associated APVMA fees can range from a few thousand to hundreds of thousands of dollars.

8. Applying for a permit

The easiest and quickest method of accessing an unregistered or permitted pesticide is via the APVMA minor-use permit system:

- The APVMA minor-use permit applies to situations usually involving low acreage crops or small portions of high acreage crops.
- The APVMA emergency permit applies to situations where there is an outbreak of a new exotic disease or pest or other unforeseen event.

Any person, association or organisation can apply for a permit.

In situations where the whole industry requires an off-label use, the farmer organisation/association is the most suitable permit applicant and holder.

Preparation of the required data and submission to APVMA can be undertaken by an individual, industry association, consultant, government officer or chemical retailer. But with the increasing complexity of the information required by the APVMA in their evaluation of a permit application, it may be best to use the services of specialised consultants for this process.

An application must be completed and submitted to APVMA on-line (via the APVMA portal) with all the appropriate and necessary data to support the application.

8A. Who should apply for a permit?

In circumstances where a minor-use permit is required for an off-label use, the best option is for the whole industry to work together on the permit process, rather than an individual farmer.

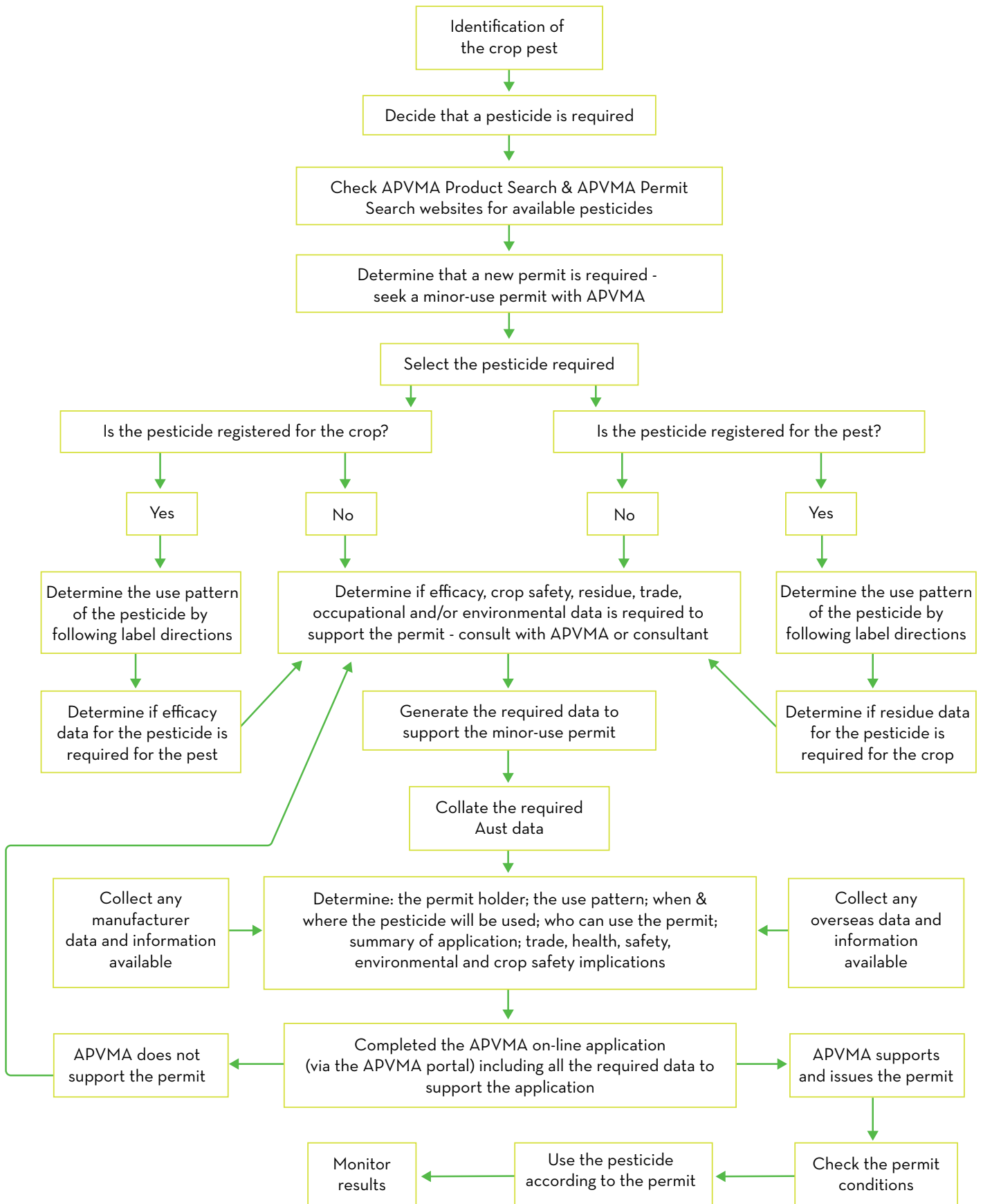
By the whole industry working together, it can prioritise its pesticide requirements and undertake the work that has the highest priority within the industry and therefore delivers the maximum benefit to most farmers.

The process of a whole industry working on its priorities also allows for collaboration with other industries and their priorities.





The Process for Applying for a New Permit





8B. Permit information required

Following is a list of key information required by APVMA for a new minor-use permit application:

1. Applicant and authorised agent details

2. Product trade name

3. Active constituent(s)

4. Active constituent(s) concentration (g/kg or g/L)

5. General details

- a. First date of proposed use
- b. Annual timing of use
- c. Proposed permit duration
- d. States/locations/regions required
- e. Who will use the permit?
- f. Scale of use

6. Proposed use

- a. Crop or situation
- b. Target disease, pest or purpose (include common and scientific names)
- c. Application rate
- d. Spray volume
- e. Addition of wetter
- f. Timing of application/growth stage
- g. Maximum number of applications
- h. Minimum re-treatment interval (days) between consecutive applications
- i. Application method
- j. Application equipment
- k. Proposed withholding periods
- l. Any special precautions/critical use comments

7. Justification for the proposed use

- a. Are any products currently registered or approved for the proposed use?
- b. Has an application been made to register the product?

8. Overseas registration

9. Registered product holder /manufacturer support

10. Executive summary (the purpose of the application)

11. Residues criteria

12. Trade criteria

13. Environment criteria

14. Toxicology and OH&S criteria

15. Target animal/crop safety criteria

16. Efficacy criteria.





8C. Generation of data

If there is limited efficacy, crop safety, residue and/or environmental data available from within Australia or from overseas sources to support the permit application, APVMA will require the generation of new Australian data.

The data can be generated by various sources including researchers, government agencies or chemical manufacturers.

As the data needs to be of a high scientific standard, sound financial planning of this process is required well before any trials are undertaken. Industry and/or manufacturer investment is required for this process.

For residue data generation (scientific field trials and analysis), the APVMA requires 'Good Laboratory Practice' (GLP) standard data for major crops. GLP trials can only be undertaken by accredited researchers. The list of major crops can be found on the APVMA website (www.apvma.gov.au/node/10931).



8D. Timelines and costs

The time taken for the APVMA to assess a permit application depends on:

- the complexity of the proposed use
- the risk assessment required.

In the majority of cases, the assessment of a minor-use permit application for a registered pesticide is ten (10) months and subject to a fee of \$350. Emergency permit applications are prioritised with assessments taking a few days to a few weeks. There are no fees associated with emergency permit applications.

8E. Role of the permit applicant

As an applicant, you need to:

- lodge the application for a permit electronically, using the APVMA portal
- pay all fees in relation to the application
- meet the requirements of the fit and proper person test
- respond to notices issued by the APVMA in the timeframe required
- notify the APVMA of any new information with respect to a pending application
- provide accurate information that is not false or misleading.

8F. Role of the permit holder

As a permit holder, you must:

- comply with all permit conditions (including permit timeframes and generating more data, when requested)
- continue to meet the requirements of the fit and proper person test
- provide information that is not false or misleading to the APVMA, when requested
- notify the APVMA of any new information (or more information) about the safety of the specified product a permit is held for.

8G. Permit jurisdiction

The APVMA usually issues permits for use in the Australian Capital Territory, New South Wales, Queensland, South Australia, Tasmania, Northern Territory and Western Australia. Permits are generally not issued for use in Victoria as their Control-of-Use legislation in most circumstances means a permit is not required to legalise off-label use in that state.



9. Using unregistered pesticides

Growers can encounter situations where severe losses from diseases, pests and/or weeds may occur if they do nothing to protect their crop. If there are no registered or permitted pesticides available to producers, they may consider using an unregistered product.

Farmers need to be aware of the possible consequences that can occur from the use of unregistered or not permitted pesticides. These can include;

- produce with unauthorised pesticide residues
- rejection of produce from local markets
- temporary exclusion from market access
- rejection of produce from export markets
- jeopardising of export trading arrangements
- fines and penalties.

10. Using the AgVet Collaborative Forum (AVCF)

In circumstances where a registration or minor-use permit is required by an industry, there is the opportunity to work through the AgVet Collaborative Forum (AVCF).

The roles of the RDCs and AVCF are:

- identify the 'need' (crop/pest) (AVCF)
- review and rank the proposal (AVCF)
- identify existing data (local and overseas) (RDC)
- determine the APVMA data requirements (efficacy, crop safety and/or residue data) (RDC)
- prioritise the project (AVCF)
- undertake the necessary data generation in collaboration with the industry (and possibly other industries) (RDC)
- prepare a submission to APVMA (RDC).

If your industry's project is successfully accepted by AVCF, then the project's management is overseen by AVCF, the chemical manufacturer and your industry.

11. Summary

Producers need access to effective pest management strategies to maximise yield and profit.

Pesticides are just one component in the crop protection toolbox, which should also include cultural, biological and mechanical pest management strategies.

Farmers need access to a suite of effective pesticides to minimise the impact of any pest attack on their crop; and also to minimise any risk of pesticide resistance developing. Therefore, crop planning, regular monitoring, access to the latest relevant information on pesticides, and discussions with pest management experts are all vitally important to producing a profitable crop.

Farmers do not always have legal access to the pesticides they require. Using the APVMA minor-use permit system provides an avenue for farmers to access unregistered pesticides. Information on registered and permitted pesticides can be found on the APVMA website (www.apvma.gov.au).

The selective use of pesticides to control pests plays an important role in increasing production, improving the quality of Australia's agricultural produce and enabling producers to earn reasonable returns on their investments.

Addressing pest management issues effectively, will help deliver high quality, healthy and affordable food for all consumers.

12. References

APVMA website: www.apvma.gov.au

NSW EPA website: www.epa.nsw.gov.au/pesticides/pestmngngnsw.htm

ISBN: 978-1-74254-852-4

RIRDC Pub. No. 16/006