Efficacy and Safety Data Requirements

Registration of Grain Protectant Products

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Efficacy and Safety
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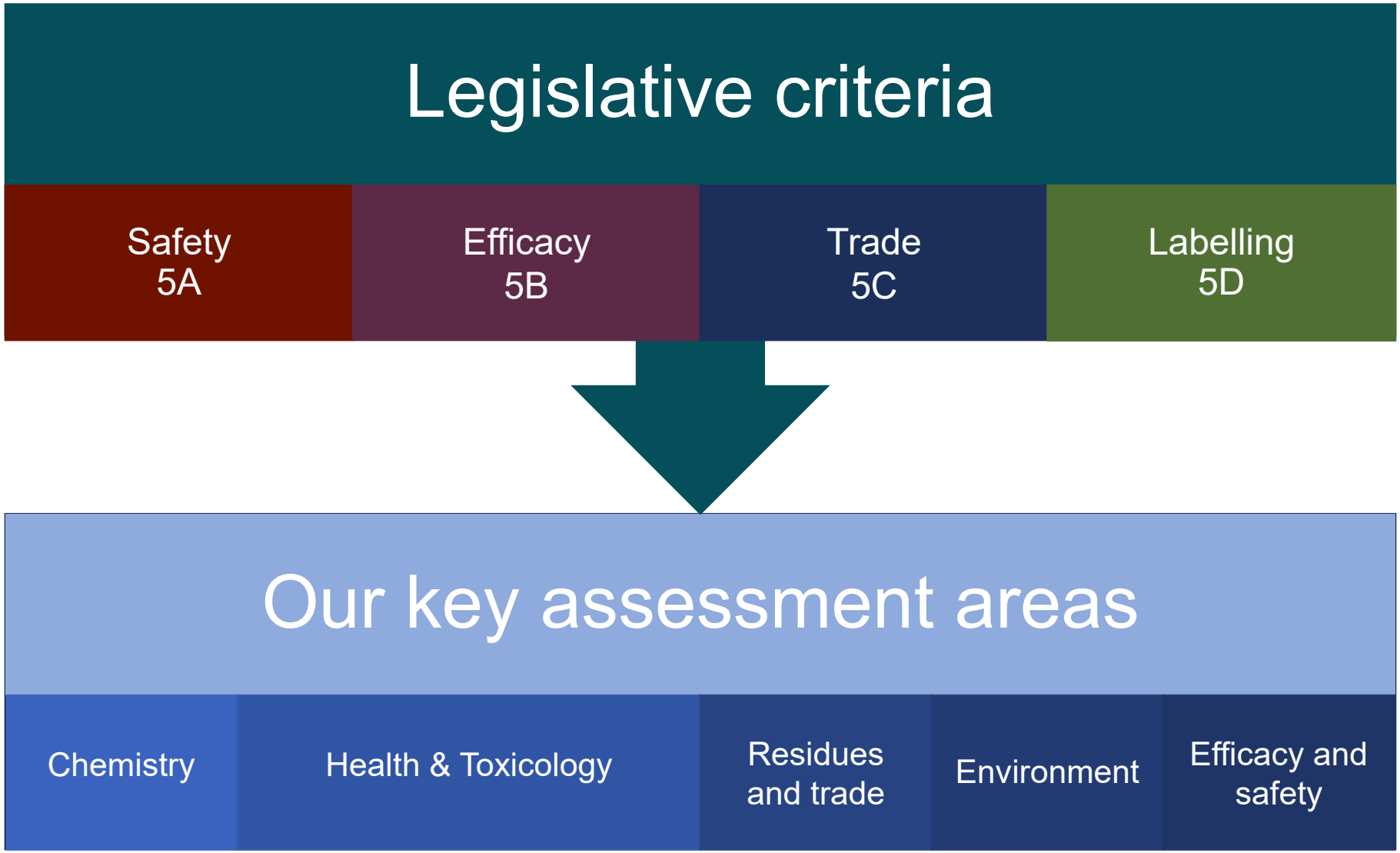
Australian Government
Australian Pesticides and Veterinary Medicines Authority

About the APVMA

- The Australian Pesticides and Veterinary Medicines Authority (APVMA) is the independent authority responsible for assessing and registering agricultural and veterinary (ag-vet) chemicals proposed for supply and use in Australia, with control up to – and including – the point of retail sale.
- State and territory governments are responsible for controlling the use of these chemicals (after sale).
- We take a risk-based, outcome-focused approach to regulation.


Legislative criteria
Safety
5A
Efficacy
5B
Trade
5C
Labelling
5D
Our key assessment areas
Chemistry
Health & Toxicology
Residues
and trade
Environment
Efficacy and
safety

What is ‘Efficacy and Safety’?

Efficacy: Capability of a pesticide to perform according to label claims when used in accordance with the label instructions.

Safety: The absence of any unintended adverse effect to target commodities, when applied according to the label instructions.

Assessed together to determine the total effects (positive and negative) of pesticide application.

Efficacy criteria

Based on type of product

For certain products considered to have a low-risk profile e.g. home/garden products, adjuvants, plant growth regulators etc.

Requires there to be products with the same active constituent, already registered and approved for the same use pattern.

Based on demonstrated effectiveness

Must meet the definition of an agricultural chemical product (*Agricultural and Veterinary Chemicals Code Act 1994*).

Submission of evidence e.g. providing data and/or valid scientific arguments from efficacy trials and/or nominating a relevant reference product.

Module descriptors

- Module descriptors explain what types of applications need which modules.
- Application fees and assessment periods are based on the modules and module levels

Module Item	Module description	Timeframe & fees
Efficacy and Safety 1	▪ New active constituent ▪ New combination of approved active constituents ▪ New formulation type ▪ Novel use patterns (a new crop in a new crop group/situation)	6 months ($4740)
Efficacy and Safety 2	▪ Formulation not consider 'similar' to existing registered product (E&S 3) or not covered by E&S 1. ▪ Related use patterns (a new pest or new crop within same crop group or situation) ▪ New domestic/home garden use	4 months ($1950)
Efficacy and Safety 3	▪ 'Similar' to existing registered product and 'bioequivalence' data and arguments	3 months ($1160)

Data requirements

Data requirements vary with the novelty of the active constituent, formulation and use pattern:

- New or first use of an active constituent in a major crop: may require approximately 10 trials per situation-pest combination
- Approved active constituent for use in the crop, or for minor commodities / pests: 3-4 trials per situation-pest combination.
- If the applicant nominates a ‘similar’ reference product, or applies for a minor / emergency use permit, a data reduction may apply (bioequivalence)
- If the applicant can nominate a ‘closely similar’ reference product, an Efficacy and Safety assessment may not be needed.

Closely similar vs. similar

Closely similar

- Same active constituents, concentration, and formulation type.
- Other constituents are same or perform similar function (if different).
- Label of the proposed product refers to the same use pattern as the approved label of reference product.
- Label of the proposed product includes similar instructions as the approved label of the reference product.
- Label claims of the proposed and reference products are the same or fewer/reduced in proposed product (if different).

Similar

- Same active constituents and formulation type.
- Label of the proposed product refers to the same use pattern as the approved label of reference product.
- Label of the proposed product includes similar instructions as the approved label of the reference product.
- Label claims of the proposed and reference products are the same or fewer/reduced in proposed product (if different).

‘Bioequivalence’ pathway

Establishing bioequivalence to a ‘similar’ product requires:

- A suitable reference product which is registered, without data protection
- A set of field trials that is **representative** of the reference label claims, with a focus on the hardest to control pests and the most sensitive commodities.
- Scientific argument to justify **extrapolation** from efficacy and safety demonstrated in field trials to the remaining use patterns

Changes to, or differences between, formulations that may be considered acceptable without requiring bioequivalence data include:

- small changes (up to 10%) of the same non-active constituents
- changes in the source or purity of active constituents,
- additions of or changes to minor constituents, such as dyes and preservatives

Bioequivalence is Bridging Data + Extrapolation

Compare the efficacy of a product, which is considered ‘similar’ to a reference product, in representative conditions, crops and pests.

Equivalent performance under these conditions can be extrapolated to the remainder of the use pattern.

Field and lab studies – Trial design and protocol in representative crops/pests.

Extrapolation to other crops and pests – APVMA Extrapolation guideline, crop groupings guideline, and scientific arguments.

Different situations and application methods will require separate trials – e.g., fumigation vs. auger spraying

Guidelines – Efficacy and safety

- APVMA – General guidance on demonstrating efficacy and safety including trial design and data analysis (Part 8).
- APVMA doesn't have any specific stored grain protection guidelines but refers to the following EPPO guidelines –
  - PP1/201 for fumigants, applied to control storage pests in storerooms, retaining structures, and transport including bulk storage (field).
  - PP1/202 for space and structural treatments of storerooms to control storage pests.
  - PP1/203 for protectants (other than fumigants), admixture of products to stored plant products to control storage pests.
  - PP1/204 for laboratory testing of both fumigants & protectants.

Efficacy evaluation – Lab and field trials

Fumigant/Protectant

- Experimental conditions – test organism, selection of commodity, trial conditions and design.
- Application of treatments – test product, reference product/industry standard product, and mode of application.
- Assessment, recording and measurements – meteorological data, time and frequency, direct effect on the commodity, and effects on other pests.

Integrated pest management practices to control storage pests

- Physical control: Aeration, temperature control and uniform grain moisture etc.
- Natural control: Diatomaceous earth, beneficial insects, botanical insecticides etc.
- Chemical control: Fumigation and grain protectants

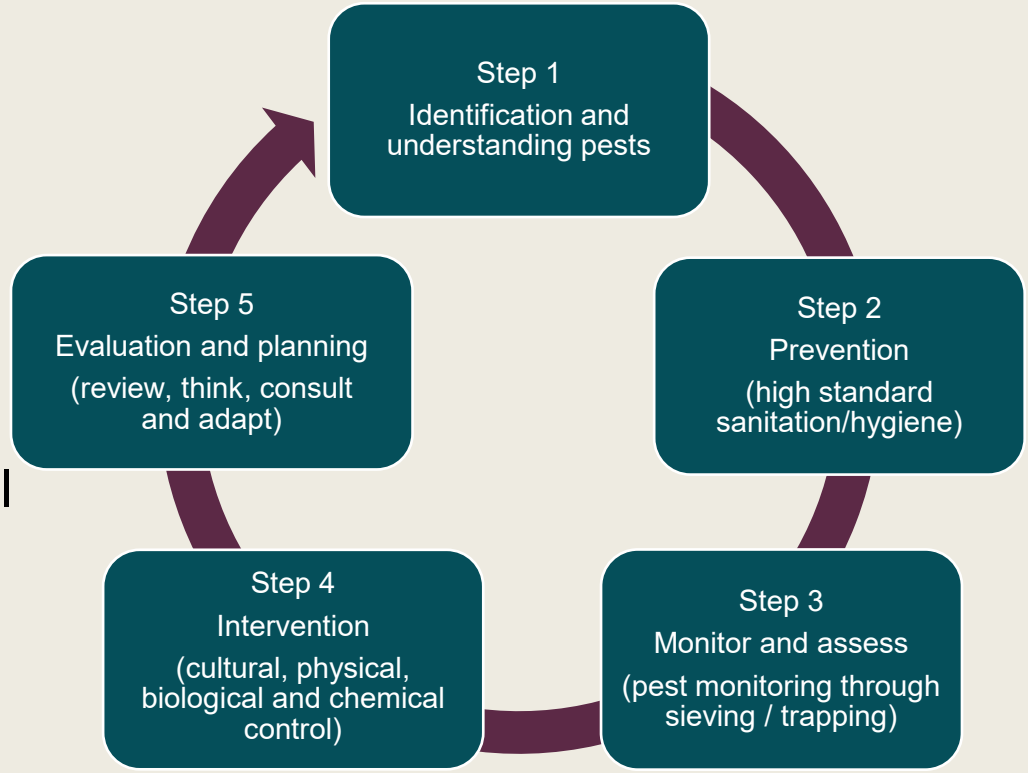


Figure: Principles and key components of an IPM strategy

Conclusion

The APVMA is the Australian Government regulator, which centralises the registration of all agricultural and veterinary chemical products into the Australian marketplace.

Our purpose is to provide safe and effective ag-vet chemical products for the Australian community while protecting Australia's trade and the health and safety of people, animals and the environment.

The registration process is evidence based and involves scientifically evaluating the safety, efficacy and trade risk of ag-vet products.

Contact information

For further information or engagement, you can contact us by email or post:

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