Australian Government
Australian Pesticides and Veterinary Medicines Authority

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Environment (Part 7)

1. Introduction

This document sets out the considerations that applicants should make when submitting environmental data as part of applications for:

- registration of an agricultural chemical product
- variation or extension of a registration of an agricultural chemical product, or
- a permit to use an agricultural chemical product.

Generally, the Australian Government Department of the Environment evaluates environmental data on behalf of the states or territories, and then advise the APVMA.

You should submit the following information to allow an adequate assessment to be made about the potential environmental impact of the active constituent and related products:

- the expected volume of use
- the expected exposure, behaviour and fate of the active constituent(s) when the agricultural chemical product is used as proposed
- the potential harmful effects on birds, mammals, aquatic life (fish, invertebrates, algae and higher plants), terrestrial invertebrates (honeybees and other non-target arthropods, earthworms), soil microbial processes, and non-target terrestrial plants.

This information is important in establishing whether the risk to any of these organisms posed by the proposed use of the product may be considered unacceptable or whether there are other concerns due to the behaviour of the substance in the environment.

This document covers a very broad range of data elements. However, in many cases the data that are relevant will be a subset of these, and should be tailored to the nature of the proposed application and the anticipated environmental exposure pattern. Decisions regarding which data are relevant are based primarily on the expected environmental exposure. It is unrealistic to recommend uniform data dossiers for environmental assessments, as agricultural chemical products vary widely in their environmental properties and in the ways that they are introduced into the environment. Considerable variation in the nature of the receiving environment can also be expected for different applications. This will be discussed in more detail under the heading 'Relevant data'.

1.1. Reference materials

The details of documents referred to in this chapter (including codes and standards) are provided in the References section. Applicants should be aware that many of these documents are updated regularly, and thus should make sure they use the latest edition.

The Environmental Risk Assessment Guidance Manual for agricultural and veterinary *chemicals* (EPHC 2009—referred to in this document as the Risk assessment manual or RAM), developed through the Environment Protection and Heritage Council, is a useful document that provides more detailed explanations of how data are used in the assessment process. This is available from the National Environment Protection Council website.

The guideline for the registration of biological agricultural products is currently being reviewed and will be re-published following that process. This guideline will be a useful document to provide more detailed guidance when registering biological agricultural products.

2. Overview of the assessment process

Under the legislation relating to agricultural and veterinary chemical registration, the APVMA, when granting or refusing an application, needs to consider whether the proposed use of an active constituent or product, in accordance with the instructions for its use, may have unintended effects that are harmful to 'animals, plants or things or to the environment' (see the Agricultural and Veterinary Chemicals Code Regulations 1995 under the APVMA legislative framework). It is the Environment Protection Branch in the Department of the Environment that generally provides advice to us on the environmental aspects of applications.

The practices used in undertaking environmental risk assessments for the APVMA are described in the RAM. Environmental risk assessment consists of:

- an exposure assessment to arrive at a predicted environmental concentration or estimated environmental concentration (PEC/EEC)—to do this, considerations include the method of use of the product, scale of use, situations in which the product is used, and fate of the active constituent in the environment. Various models may be used for which specific information is relevant; for example, to estimate concentration in surface waters from spray drift or runoff. For existing chemicals, monitoring data may also be considered.
- an effects assessment to identify and classify the hazards to the environment and to determine the most sensitive, reliable endpoints in the various compartments
- risk characterisation, relating the PEC/EEC to the most sensitive endpoints to determine whether or not the risk is acceptable and, if not, consider refinements of the process or models and if or how risks may be mitigated by appropriate label advice or other action (see Figure 1).

In Figure 1, the risk quotient (RQ) is the (most sensitive) endpoint divided by the PEC/EEC. For agricultural chemicals the acute RQ should be less than 0.1, as there is an inbuilt assessment factor of 10 (see page 75 of the RAM) for most species. The same relationship is also used for chronic risk assessments, except that no-observed-effect concentrations (NOECs), or no-observable-effect levels (NOELs), or no-observable effect rates (NOERs) are used rather than the acute endpoints such as lethal concentration (LC50), or effect concentration (EC50), or inhibition concentration (IC50), or lethal rate (LR50) (depending on the endpoint), and that the chronic PEC/EECs are used, together with the RQ that should be less than 1.

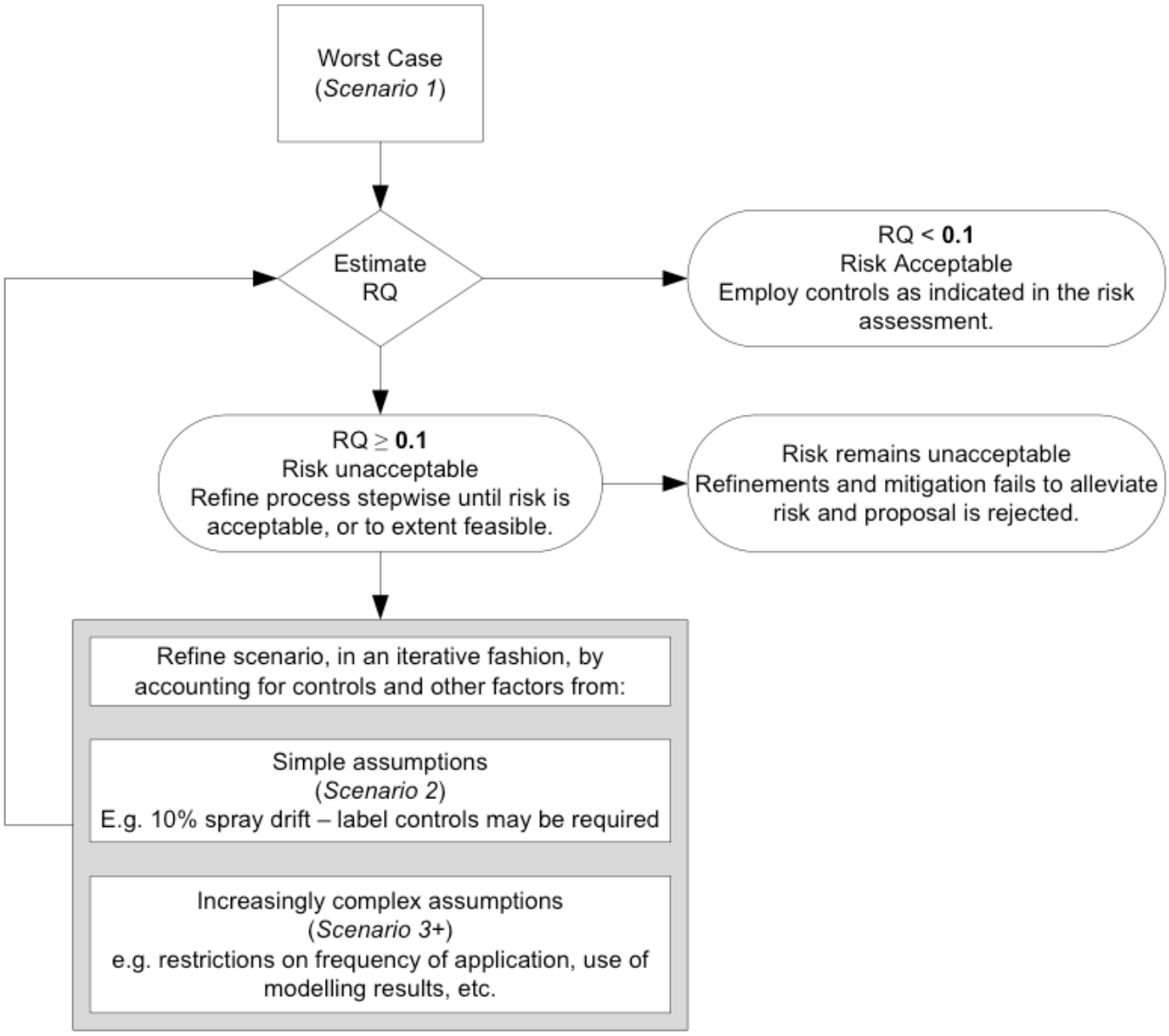
In addition to evaluating toxicity hazards to non-target organisms, consideration is given as to whether there are other concerns due to the behaviour of the substance in the environment, including persistence in soil, sediment, water or the atmosphere, bioaccumulation, potential to move into groundwater or, for volatile or gaseous substances, the potential to affect the ozone layer or act as a greenhouse gas in the atmosphere, or to be transported to remote areas.

In assessing risks to the environment, the whole life cycle of the active constituent is taken into account. Consideration is given as to whether there is any environmental exposure in Australia as a consequence of the manufacture of the active constituent or formulation and the packing of the product. Assessment of the fate of the active constituent, once released to the environment, includes consideration of:

- the rate of degradation
- the means by which degradation occurs
- the identity and amount of degradation products produced and their further degradation
- the mobility of the active constituent and major metabolites/degradates (defined as substances formed from the active constituent occurring at levels more than 10% of the applied active constituent in environmental media).

Effects of major metabolites/degradates on non-target organisms are are also considered, depending on the environmental medium in which they are formed (soil, sediment, water or biota).

Figure 1: The iterative approach to determine risk acceptability



As well as assessing data provided by the applicant, consideration is given to information available from other sources, such as literature searches and foreign environmental agency reports (for example, from the United States Environmental Protection Agency (US EPA) or European Food Safety Authority (EFSA) reports).

2.1. Environmental risk assessment

As stated above, the risk assessment is a synthesis of the results from the evaluation of the exposure and the toxic effects. Depending on the degree of environmental hazard, consideration may be given to actions to minimise the environmental risk. For example, the APVMA may impose:

- specific restrictions—such as, 'do not apply on steep country above 20% or 11 degrees'
- other label instructions and warnings—such as, toxic to aquatic life.

This section provided an overview of Australia's environmental risk assessment process. The following section considers the specific data elements to enable a full environmental risk assessment.

3. Types of applications

The nature of the application determines which assessment module in Part 7 (Environment) is relevant. Each module refers to the same broad set of environmental data elements, but the actual data element varies depending upon the nature and extent of environmental exposure from the proposed use pattern and the anticipated environmental behaviour of the product.

4. Relevant data for applications

The relevant environmental data you should provide for an application depend largely on the product's expected environmental exposure. You should provide sufficient data to allow us to make an adequate environmental assessment and draw a conclusion about whether or not your submission would satisfy the APVMA test (that the proposal would not be likely to have an unintended effect that is harmful to animals, plants or things or to the environment).

You should address all of the data elements discussed in this chapter. If you do not provide data to address a specific element, you should request a data waiver against the specific element and justify the waiver with a valid scientific argument; for example, by demonstrating that environmental exposure to this group of organisms will be minimal.

4.1. Comments applicable to all applications

4.1.1. Quality of submitted studies

Data quality directly influences how confident our risk assessors can be in the results of a study and the conclusions they may draw from it. Therefore, your environmental fate and toxicity studies should be of sufficient quality for the study to be relied upon for regulatory decision-making. The process of determining the quality of data takes into consideration three aspects—adequacy, reliability and relevance of the available information to describe a given assessment endpoint.

Detailed information on how the quality of studies is determined and rated can be found in Chapter 4 of the RAM. To be suitable for regulatory purposes, your study should be of sufficient quality to achieve either a rating of:

- fully reliable, or
- reliable with restrictions

according to the Organistion for Economic Co-operation and Development (OECD) approach, as used by the Department of the Environment (as described in Chapter 4 of the RAM).

4.1.2. Level of documentation

The documentation you provide should be complete, well organised and be presented in sufficient detail (for example, inclusion of raw data on concentrations measured or individual animal responses) to allow independent scientific assessment.

You should supply copies of original reports. Summaries, or reprints of published material, usually do not contain sufficient detail and may, therefore, only be suitable if they contain sufficient detail to allow independent scientific assessment and achieve an acceptable reliability rating.

4.1.3. Request for waiver of a data element

If you believe that a particular data element in the guidance documents and forms located on the OECD website (see Section 6.1 of web version) or list in Chapter 3 of the RAM (EPHC, 2009) is not necessary, you should maintain the data heading, request a data waiver for the specific data element and provide a valid scientific argument as to why you have not submitted the data. In some circumstances, model data based on structure–activity relationships (SAR) may be suitable for submission in lieu of test reports, particularly where models have been validated.

4.1.4. Adverse reports

You should not omit reports, including published material, that could adversely influence the outcome of an environmental risk assessment. If you consider that such reports reach unsupportable conclusions, you should clearly justify this in the application.

4.1.5. Details of other regulatory applications

Your application should include details of any regulatory applications you have made for the same product to other regulatory bodies in Australia or overseas. Where available, you should provide the results of those applications and subsequent regulatory decisions (for example, copies of assessment reports, or links to where these and/or regulatory decisions may be found). If any data in those submissions have been rejected by an overseas regulatory body, you should identify this and provide justification to support why you have included the study in question.

4.1.6. Formulation data

Formulation toxicity is an important consideration. The types of formulation data is covered in Parts III A 9 & 10 of the comprehensive guidance documents and forms located on the OECD website.

The Department of the Environment usually focuses on data about the active constituent (for example, for aquatic toxicity), but formulation data may be more important for toxicity to honeybees, non-target arthropods and non-target vegetation, as these come into direct contact with spray or spray drift (as opposed to water or soil where there is more time for the formulation components to separate before exposure occurs). If results are available for the formulation and the active constituent, the Department of the Environment will generally use the most sensitive value in its risk assessments.

Formulation data is also more relevant where the toxicity is modified by the formulation (eg slow release, encapsulated formulations), and for combination products involving two or more active constituents. In these cases, the formulation results are generally more appropriate for use in the determination of the risks.

4.2. Chemistry and manufacture

For applications where environmental data are recommended, Part 2—Chemistry and Manufacture data are also relevant.

Chemistry and manufacture data are important because details of the chemical and physical properties of the active constituent, in particular, are important to allow complete environmental evaluation of the product. This can be particularly important for Reduced and Limited assessments, where both environmental fate and effects may be inferred from, for example, data on water solubility and partition coefficient.

4.2.1. Basic data elements used in environmental risk assessments

The basic data elements with which you should comply for environmental risk assessment include:

- fate and behaviour in the environment (environmental exposure)
- hazard—effects on non-target species (environmental hazard).
- Aspects of these are explained in more detail below.

4.2.2. Environmental fate and behaviour

Environmental fate and behaviour data describe the degradation of active constituents, through abiotic and biotic mechanisms, and their mobility and likely transport and final destination in the environment. These data are used to help estimate the predicted environmental concentrations in different environmental compartments—vegetation, soils, sediment, water, air and animals—as appropriate, based on the proposed use pattern and physicochemical properties of the chemical.

4.2.3. Environmental effects

Environmental effects data are obtained from tests on standard organisms, representing organisms that are likely to be exposed to the agricultural chemical product or to residues arising from its introduction into the environment. These data are used in conjunction with the anticipated environmental exposure and environmental fate data to determine the potential risk to non-target organisms, and the need for precautionary label statements or other risk management measures to minimise the potential for harm.

Tests for effects on non-target species include studies on short-term acute, subacute, reproduction, simulated field and full field effects. For the results, a hierarchical or tier system should be followed by the applicant. Under this system, the results from the lower-tier laboratory tests are used to determine the need for higher-tier testing, such as full field studies, based on the potential for the chemical to cause harmful effects.

Individual data elements and the circumstances in which they are likely to be relevant are discussed in more detail below.

4.2.4. Data that may be needed for any particular application

The relevant level of data for a submission is generally proportional to the potential for environmental exposure arising from the proposed use pattern. For example, for any proposal that includes broadacre, the full data set will generally be relevant, unless the Department of the Environment has previously assessed the chemical. If this is the case, the data set should only need to be updated and supplemented as appropriate.

The use pattern, together with its scale of use, type of formulation and mode of application are all relevant considerations when conducting environmental assessments.

4.2.5. Factors determining relevant data

Table 1 gives an idea of the potential for environmental exposure arising from four factors related to exposure. Each column is arranged in approximate decreasing order of potential environmental exposure, from high at the top, to low at the bottom. Note that it is important to read down the columns rather than across the rows. Also the sequence down the rows should be viewed as indicative rather than definitive. Taken as a whole this may be used as an indicator of the extent of environmental data from the four factors likely to be relevant.

Table 1: Factors relating to environmental exposure

<table>
<tr><th colspan="2"></th><th>Use pattern</th><th>Scale of use</th><th>Formulation</th><th>Application method</th></tr>
<tr><td rowspan="7">Potential Environmental Exposure</td><td rowspan="3">More</td><td>Grain and fibre crops</td><td>Broadacre</td><td>ULV</td><td>Aerial</td></tr>
<tr><td>Fruit crops</td><td rowspan="2">Multiple applications</td><td rowspan="2">EC</td><td>Mister</td></tr>
<tr><td>Vegetable crops</td><td rowspan="2">Boom</td></tr>
<tr><td>↑</td><td>Forestry</td><td>Irrigated crops</td><td>WP</td></tr>
<tr><td>↓</td><td>Pasture, turf and seed crops,</td><td rowspan="2">Single application</td><td>Fumigants</td><td>Baiting</td></tr>
<tr><td rowspan="2">Less</td><td>Antifoulants, rodenticides</td><td rowspan="2">Granules</td><td rowspan="2">Seed dressing</td></tr>
<tr><td>Glasshouse crops</td><td>Small acre</td></tr>
</table>

		Premises	Home gardens	Individual baits	Backpack

ULV = ultra-low volume; EC = emulsifiable concentrate; WP = wettable powder

The following scenarios, based on information in Table 1, are provided to demonstrate relevant data for various levels of environmental exposure. These scenarios are not exhaustive, and are indicative only. However, they may be used as an example and a guide for your decision-making process. Additionally, you may wish to make an application for pre-application assistance or a technical assessment.

4.2.6. Variations in relevant data—example scenarios

When addressing the data relevance, you may decide not to provide data, or provide minimal data, for a particular data element, because of the use pattern or indications from other data. For example, if the chemical's volatility is low, then dissipation-in-air studies would not be relevant; or if acute toxicity studies indicate the chemical is practically non-toxic, then short-term and chronic studies may not be relevant, unless it was persistent, or there were good reasons to suggest the acute chronic ratio is very high, such as with insect growth regulators. If you wish to use this reason or scientific argument for the waiver of data, you should clearly state this.

The mode of application of a chemical, as illustrated in the examples above, can often decide the extent of environmental exposure. For instance, if the chemical is to be aerially sprayed, then the data relevance (both fate and toxicity) are likely to be high because this application type has the potential for widespread environmental exposure to non-target areas and non-target organisms. Misters or air-assisted sprayers in orchard situations are also likely to have potential for widespread environmental exposure to non-target areas and for these you should therefore submit a similar degree of fate and toxicity data.

Scenario 1: Insecticide

Use pattern	Scale of use	Formulation	Application
Grain and fibre crops	Broadacre	Ultra-low volume	Aerial

For example, if you want to register a new insecticide that is aerially sprayed onto broadacre crops, you should address all data elements, given the wide dispersive exposure pattern. In addition, you should also place special emphasis on the potential for overspray and spray drift, as well as for run-off in surface water and the effect on non-target invertebrates.

For crops where integrated pest management (IPM) is routinely practiced, such as pome fruits, screening studies that are not following good laboratory practice may be useful in addition to the standard laboratory tests. Non-target organisms that should be considered include bees and earthworms, predators, parasites, and detritus feeders. Field efficacy studies addressing impacts on non-target organisms or screening tests for activity of metabolites will also be useful for environmental assessment.

Scenario 2: Herbicide

Use pattern	Scale of use	Formulation	Application
Grain and fibre crops	Irrigated	emulsifiable concentrate	Boom

For sugar cane, cotton or summer grain crops that are irrigated, even if the product is applied by boom spray, you should address most of the fate data requirements because of the potential for movement off-site in surface water (either as release of tail waters or storm water). The data should be reflective of soils typical for the area for the latter cases, most notably the heavy cracking clays.

In contrast to Scenario 1 above, is the situation where an applicant registers a herbicide to control pre-emergent weeds that will be applied as a blanket spray by low-boom spray, with a coarse spray. Based on the proposed crops for which this will be applied, the soils may range from a light sandy loam to heavier silt loam. In this scenario it is clear that the chemical has the potential, if moderately water soluble and applied at a high rate, to be transported in surface waters or leach to groundwater while the potential for spray drift is comparatively low.

Scenario 3: Insecticide or fungicide seed dressing

Use pattern	Scale of use	Formulation	Application
Grain and fibre crops	Broadacre crop	emulsifiable concentrate	Seed dressing

In contrast to Scenario 1, Scenario 3 deals with a situation in which, if the formulation were a granule or the application was as a seed dressing, there will not be a high degree of drift or spread of the chemical off target. However, there would be a greater relevance for avian toxicity studies because of the greater potential for poisoning birds from ingesting granules and treated seeds. A wider range of bee studies may also be relevant if the insecticide or fungicide is translocated to the pollen or nectar.

Scenario 4: Residential or commercial rodenticide

Use pattern	Scale of use	Formulation	Application
Rodenticides	Single application	Individual baits	Baiting

If the product is a rodenticide and put out as field bait, then avian and non-target mammalian toxicity data would be relevant, but aquatic data would be less relevant because exposure to aquatic life is expected to be very low when the bait is used according to label directions. If the product is used on residential or commercial premises, then avian and non-target mammalian toxicity data requirements are potentially lower, due to the lower environmental exposure. However, some data are still relevant, particularly for anticoagulants, due to the length of time taken for the target animal to die, and the potential for dead or dying animals to move into the open. Further, it should be made clear if there are attractants in the formulation or baits that might result in non-target organisms being attracted to the baits.

Scenario 5: Poultry shed insecticide

Use pattern	Scale of use	Formulation	Application
Premises	Single application	wettable powder	Backpack

For a poultry-shed insecticide, limited environmental chemistry and fate information may be relevant, such as some biodegradation (that is, metabolism or transformation) studies, especially those performed using relevant (that is, soil) test systems. A request for data waiver for mobility studies (e.g. volatility and leaching potential) could be justified with a suitable argument as the insecticide will be applied to building surfaces, with an expected very-limited exposure to soil.

If, however, the insecticide was expected to contaminate chicken litter (for example, because of different management practices or use pattern), then more biodegradation, mobility and field dissipation studies would be relevant because of the potential use of the litter as fertiliser. Similarly, only a limited set of environmental toxicology would be relevant because of the insecticide's generally low environmental exposure, unless contaminated litter was subsequently used as a field dressing.

4.2.7. Other issues

For chemicals (and their major metabolites/degradates—defined as substances formed from the active constituent occurring at levels more than 10 per cent of applied active constituent) that may persist in the environment (identified through laboratory studies on hydrolysis, photolysis, metabolism studies, and frequency of application), field accumulation studies will be relevant, particularly if exposure is high, and there is likely to be carryover of residues in soil, etc. between years or seasons. This can be tested through the use of some basic modelling using the half-life (see Chapter 5 of the RAM). In this case, the scale of field use (that is, broadacre versus glasshouse) is not likely to be sufficient justification to request a data waiver of these data elements, as a chemical used at high rates might be very persistent and mobile, and therefore of possible concern in its potential to accumulate and/or leach to groundwater, even if used in glasshouses.

Field dissipation studies, or other studies performed for 'realism' or 'environmental relevance' such as microcosms or mesocosms, should test a typical or representative end-use product relevant to the formulation proposed in Australia.

In summary, all data elements are likely to be relevant for active constituents in products that are used in broad scale applications, and it is mainly in the specialty areas that a data waiver for certain data elements may be applicable.

4.2.8. Other areas of toxicity testing

The areas of environmental risk assessments for which relevant data have changed over the past decade include:

- testing of the toxicity of pesticides to honey bees and other managed insect pollinators – details are provided in the APVMA's *Roadmap for insect pollinator risk assessment*
- ecotoxicity tests for at least four algal species and an aquatic plant species—these should be included for all herbicides and fungicides due to the potential for harm to these species from these types of pesticides (fewer data points may be adequate for other types of pesticides)
- information on toxicity to non-target terrestrial plants—for which data for herbicides are particularly relevant, but is also important for fungicides. In particular the need to extrapolate from a limited set of tested plants, usually other crop species, which emphasises the value of obtaining incident data during trialling and testing the active constituent and its proposed formulations, should be noted,
- sediment testing— this is an important area of toxicity in the aquatic environment, particularly for insoluble persistent pesticides. As noted in Chapter 6 of the RAM, the route of exposure is an important factor. Where exposure is primarily through chemical bound to soil or sediment (for example, run-off in the sorbed state), data based on OECD test guideline (TG) 218 are more appropriate as the test is performed with the substance pre-mixed with the test sediments. However, in the case of exposure directly to the water column (for example through spray drift), data based on OECD TG 219 using spiked water is more appropriate.

4.2.9. Combination toxicity testing

Combination toxicity data are relevant for formulations containing two or more active constituents, to allow assessment of the toxicity from the combination product. The extent of relevant combination toxicity data will depend on both the exposure and toxicity; for example:

- for a seed dressing combination, aquatic toxicity may not be relevant
- for birds, combination toxicity may not be relevant if toxicity of both actives is low
- for aquatic toxicity, relevance might depend on whether one active constituent's toxicity swamps the other
- for aquatic toxicity, if one group (say algae) is 100 times more sensitive for both actives, only that level should be tested
- if the taxonomic groups that are most sensitive for the individual active constituents are not the same, formulation data is relevant for all three taxonomic groups (see RAM, page 44).

Data are also relevant for all deliberate (mandatory) tank mixes where the draft label's directions for use or critical comments says 'must always be applied with X'. This can apply to all applications or only in certain circumstances. These data are not expected if directions are only present on another part of the label which says 'Compatible with…' or 'May be tanked mixed with…'. Given the variable extent of mandatory tank mixing that may appear on labels, an estimation of toxicity based on the concentration addition (CA) equation in the application is generally more acceptable than for combination formulations.

5. Data evaluation

You are encouraged to conduct your own environmental risk assessment, based on the expected environmental exposure arising from the proposed use volume and pattern, and the data or argument submitted to address relevant data elements. This assessment is highly recommended, as it identifies which data elements require particular attention. The risk assessment forms part of the crucial determination of which elements are relevant for a particular application, as described above under the heading 'Data that may be needed for any particular application'.

This risk assessment corresponds to point 3.3 of the Main document (active substance and formulated product dossiers)) in the tier III overall summary and assessment known as Document N under the OECD format. The risk assessment should be based on a concise summary of the data presented in the active substance and formulated product dossiers, supported with a statement of your overall assessment of the dossier and the conclusions you believe should be reached on the basis of the data and information you have provided. That statement should have regard to the weight of the evidence available (the extent, quality and consistency of the data) and the criteria and guidelines for environmental evaluation and decision making used by the APVMA. These criteria and guidelines are described in the Four step process below.

5.1. Four step risk assessment process

As described in the RAM (pages 8–10), the environmental risk assessment is a four-step sequential process:

- step 1—problem formulation
- step 2—an environmental exposure assessment to determine the concentrations of the chemical that are likely to occur in the environment
- step 3—an environmental effects assessment, consisting of an evaluation of toxicity data for organisms that are likely to be exposed, based on the exposure assessment, to determine the concentrations that are likely to be harmful to these organisms
- step 4—an environmental risk characterisation that integrates the outcomes of the exposure and effects assessments to determine whether the use of the chemical according to label directions is likely to be harmful to non-target organisms in the environment.

The exposure and effects assessments are interdependent, in that the exposure assessment will determine which data elements are relevant for environmental effects, while the effects assessment will determine the level of detail and refinement relevant for the exposure assessment.

The procedures followed for environmental risk assessment are discussed in more detail below. The discussion is deliberately presented from a general perspective, as it is unrealistic to prescribe a specific procedure due to the variability of environmental exposures and risks across different products and use patterns. Further, some product types, such as antifoulants, have very specific data elements that do not pertain to crop protection chemicals. Such examples are presented in more detail below under the heading Specific recommendations for particular proposals.

6. Step 1—Problem formulation

Before any assessment work is undertaken it is paramount that a thorough understanding is obtained regarding the purpose of the application and the crucial issues, so that the assessment is relevant and irrelevant issues are avoided.

7. Step 2—Environmental exposure assessment

The amount of chemical likely to be released to the environment is a central tenet of environmental exposure assessment. The Department of the Environment considers the chemical in the context of 'cradle-to-grave'. The environmental exposure assessment will determine which compartment(s) of the environment (air, soil, water and biota) will be exposed to the chemical, and the likely level of exposure through its use as stated on the proposed product label and predicted market volume. This includes consideration of environmental exposure arising from the manufacture or formulation, and from disposal of excess or spent chemical (for example, dipping solutions, after appropriate treatment), unused product, and empty containers.

7.1. Amount of chemical to be used

In your application, you should provide the estimated quantity (in tonnes or litres) of chemical or product to be imported, manufactured, formulated or repacked up to, and including, market maturity.

7.2. Manufacturing plant (active constituent) and formulating plant (product)

For active constituents where the manufacturing plant is located in Australia, and for all product formulation and packaging processes taking place in Australia, you should provide a brief summary of the following:

- details of the release of the chemical to the environment resulting from all manufacturing, formulation and packaging operations (for example, from disposal of bulk containers and rinsings from cleaning machinery). This will include total amounts released to water, air and land, concentrations in effluent streams, and the control technology used to minimise release.
- the proposed means of disposal of waste product arising from manufacturing, formulation and packaging operations (eg spilled material and off-specification batches).

7.3. Use and application

To allow an accurate assessment of the environmental hazard, you should provide information about label claims (uses) and application methods to determine which environmental compartments are likely to be exposed to the chemical. Therefore, information on the following may be relevant:

- details of the method of application (for example, granules incorporated into the soil; type of spraying [ground directed, ground boom, ground misting, aerial]; baits or lures; fumigation; dipping)
- details of factors influencing mobility or transport or spray drift of the product (for example, droplet size, and equipment used,)
- fundamental characteristics of the environment that may influence transport and degradation of the chemical (for example, irrigated pasture or crop, type[s] of irrigation, soil types and range, rainfall, cropping system and area under cultivation to that crop).

Crop profiles are particularly useful when the active constituent is only proposed for restricted uses or limited applications, as the characteristics of the environment can play an important role in deciding the amount of fate and toxicity data required.

7.4. Product disposal

You should provide information on disposal of:

- empty containers
- unused product
- diluted-for-use chemical.

The applicant should consider developments in these areas. The National Farmers Federation (NFF), CropLife Australia, Animal Health Alliance (Australia) Ltd, VMDA and the Australian Local Government Association (ALGA) have together developed the following initiatives:

- DrumMUSTER as the solution to the safe collection and recycling of cleaned chemical containers
- ChemClear for the collection of unwanted rural and agricultural and veterinary chemicals.

General label statements for the proper disposal of product and used containers can be obtained from the Agricultural Labelling Code. Furthermore, part of the Department of the Environment's assessment and advice to the APVMA may include appropriate label disposal instructions for the particular product under assessment.

7.5. Spent dipping solution disposal

The following criteria for disposal of spent dipping solutions to land have been adopted by the APVMA based on 10 active constituents used in dips and following their drafting and approval by its Registration Liaison Committee:

- the half-life in soil is less than 10 days at the likely concentrations following dip disposal, and/or

- the active constituent(s) should be able to be denatured safely, quickly and completely (more than 98 per cent in two hours) prior to disposal
- if repeat applications are to be made to the same site and denaturing is not possible, these should not occur until four half-lives have passed
- the spent dip should be evenly spread over flat land at a rate not exceeding 100 000 litres per hectare for spent sheep dips and 20 000 litres per hectare for spent fruit dips
- the disposal site must be dedicated and adequately bunded (the soil should be at least 15 centimetres high).

While an examination of the data holdings and label statements of all current active constituents and their associated products used in dipping is being undertaken, any application for new active constituents or extension of existing actives and associated products to be used in dips should be accompanied by:

- data in the above areas to allow assessment of whether disposal to land is feasible, and/or
- the drafting of suitable label statements.

7.6. Predicted environmental concentration

Chapter 5, Environmental exposure assessment of the RAM provides a more detailed discussion of the predicted environmental concentration, and provides guidance and more details on the range of environmental chemistry and fate tests. In particular, it provides details for the determination of estimated or predicted environmental concentrations (PECs).

A key element of the exposure assessment is the spray quality, as this is one of the determinants of drift, and a key input in models used to estimate the amount of drift at different distances from the point of application. Spray quality parameters need to be clearly defined on product labels. Applicants should refer to the APVMA operating principles in relation to spray drift risk (APVMA 2008).

You should estimate PECs in water, air, soil, vegetation and/or animals depending on the use pattern. If no such exposure is expected in any compartment, applicants can request a data waiver and provide this as an argument for not providing particular data elements. For example, aquatic exposure would not be expected from the use of household rodenticides. Therefore, toxicity data for aquatic life would not be relevant for such an application; although you should provide such data if they are available.

7.7. Tiered PECs

The environmental exposure assessment is a stepwise or tiered process under which PECs are first determined under worst-case conditions using simple screening models. If the initial PECs are at harmful levels, based on the environmental effects assessment, they are progressively refined to reflect more realistic exposures. In this way, the analysis for a particular chemical will be kept to a minimum, allowing resources to be directed towards chemicals with the greatest potential for causing ecological harm.

7.8. PEC_{Water}—Spray drift

The initial estimates of the predicted aquatic concentrations (PEC_{Water}) are based on the scenario of direct application to a water body that is three metres wide and 15 centimetres deep, at the maximum cumulative rate per crop cycle. You should supplement the short-term (acute) PECs with long-term (chronic) PECs if the chemical is persistent or applied repeatedly within a season. Then, refine these estimates as necessary to reflect exposure through spray drift, again using progressive refinement from an initial worst case assumption that this represents 10 per cent of the maximum proposed rate. More realistic exposures are then modelled as needed. Refer to the APVMA spray drift website for further information on spray drift policy.

7.9. PEC_{Water}—Run-off and drainage

Spray drift may not be the most significant route of aquatic contamination for many chemicals, particularly those that are persistent and mobile, and are widely used within a catchment. An OECD based model (Probst et al. 2005) has been developed by the Department of the Environment that considers the edge-of-field concentration, and we recommend you use this model to assess run-off and drainage. The model considers that the application rate, topography—in particular the

slope of the field to which the pesticide is applied—the magnitude of the rainfall and run-off events, and the persistence and mobility of the chemical are the most important factors. Additionally, placement of the pesticide, an allowance for the heterogeneity of fields and pesticide bound to suspended sediment are also considered.

Based on data available, the model considers a worst-case scenario of a 100 millimetre rainfall event with 20 per cent of that water running off. On a hectare basis this results in 200 cubic metres of run-off water. An initial screen that does not consider the properties of the chemical should be performed. Depending on the likely topography of the cropping scenario, the run-off water is assumed to carry 5 or 10 per cent of the applied chemical, once heterogeneity of the field is allowed for. Consideration is given to the interception and retention of the applied chemical by foliage for foliar applications. Suspended sediment bound pesticides are generally only considered for sparingly soluble chemicals with solubility of less than one milligram per litre. This screen can be used to exclude low risk chemicals from further consideration.

7.10. Refined run-off PECs

If the predicted aquatic exposure from the screening model for run-off indicates that aquatic organisms may be exposed to harmful concentrations of the chemical, you should refine the assessment of the edge-of-field concentration.

Exposure scenarios for run-off and drainage are more complex than those for spray drift because the properties of the chemical and of the soils where it is used will influence the mobility and stability of the chemical, and consequently the levels of aquatic exposure.

The OECD-based model assumes three days degradation of the chemical and the adsorption/desorption coefficient (K_d) value, usually based on the organic carbon partitioning coefficient (K_{oc}) of the chemical and the organic carbon content of soil as determined by ANRA (2001). The modelled, refined edge-of-field concentration may also be compared with any actual studies of run-off of the chemical of interest. Dilution of the edge-of-field water is considered in 1500 cubic metres of environmental water, which is equivalent to a one hectare water body of 15 centimetres deep, or the daily flow of a low-flow primary stream. Initially, it is assumed that the water body is entirely fed by a 10 hectare field that is 100 per cent treated at the maximum rate.

Refinement of the model considers partitioning of the chemical to sediment using the same model as that used for determining the PEC sediment as outlined in the RAM. The model is being further developed to consider the fate of the chemical in water and more hydrologically realistic catchments that consider the likely use pattern of the chemical in the catchment.

7.11. $PEC_{Sediment}$

As noted above, for hydrophobic chemicals rapid partitioning to the sediment may be expected. The PECsediment may be estimated from the PECwater based on the partition coefficient. More information about estimating the PECsediment can be found in the RAM.

7.11.1. PEC_{Soil}

PECs in soil are usually based on the maximum proposed application rate, as effects on soil organisms in treated areas need to be evaluated. A soil depth of 10 centimetres is generally assumed, but this may be decreased for chemicals that sorb strongly to soils, or increased for more mobile chemicals. PECs in soil can be refined where needed by considering the persistence of the chemical in soil.

7.11.2. PEC_{Food}

Concentrations on vegetation should be estimated using the modified Kenaga nomogram (Pfleeger et al., 1996). The nomogram may also be used, with qualification, to estimate residues on insects. These estimates are used to evaluate dietary risks to non-target organisms such as birds and mammals. The highest residues generally occur on foliage, and can be used as the basis for an initial risk assessment based on the assumption that only treated foliage is consumed.

The risk assessment can be refined as needed, for example by considering a more realistic diet including insects as well as vegetation. The nomogram can be used to estimate residues on insects, based on those for fruits and seeds, but caution is needed as there are limitations in using fruits and seeds as surrogates for mobile organisms such as insects.

8. Step 3—Environmental effects assessment

The main outcome of the environmental effects assessment is to identify suitable effects endpoints for subsequent use in the risk characterisation. The reliability of the individual study is also considered.

Again, the amount of relevant data is likely to be dependent upon the extent of exposure to the various environmental compartments (air, water soil, sediment and biota, including plants), and the toxicity of the active constituent and products containing it, to organisms inhabiting these compartments. If the exposure is low to a particular environmental compartment, limited data will be relevant, particularly if the toxicity to representative organisms from the compartment is also low. Conversely, if the exposure to a particular compartment and the toxicity to representative organisms inhabiting this compartment are both high, a much more extensive suite of toxicity tests will be relevant.

Chapter 6, Environmental effects assessment of the RAM provides a detailed discussion of this topic, including a very wide potential range of environmental effects tests.

8.1. QSARs versus field testing

The RAM also mentions the possible use of quantitative structure–activity relationships (QSARs). As noted, these are generally less useful in predicting toxicity of pesticides as opposed to industrial chemicals due to their relatively complex structures and because they have specific modes of action that are not easily incorporated into general structural relationships.

You should use verified models in these situations using QSAR calculations.

On the other hand, field testing studies such as microcosms or mesocosms are potentially very powerful tools in defining toxicity in actual or real-life situations; in particular, for testing any mitigating effects such as reduced toxicity in the presence of sediment as opposed to testing in clean laboratory tanks or vessels. Microcosm testing is the preferred approach.

9. Step 4—Environmental risk characterisation

Chapter 8, Risk characterisation of the RAM provides a detailed discussion of environmental risk assessment; the basic principles of which are outlined below. Applicants are encouraged to consult the RAM for further detail or clarification. Please note, however, that this chapter of the RAM is not in the order of the internationally agreed OECD format.

9.1. Risk quotient (RQ) method

The approach followed for environmental risk assessment is based on that used by the US EPA, as originally developed by Urban and Cook (1986). This is often referred to as the quotient or risk quotient (RQ) method. It compares the PEC as the numerator with the toxicity as the denominator. Acute toxicity is usually expressed as the median lethal concentration (LC50) or median effect concentration (EC50). For plants, a more sensitive measure (for example the EC25) may be used. Chronic toxicity is usually expressed as the NOEC. The objective is to ensure that the quotient does not exceed levels of concern.

9.1.1. Toxicity exposure ratio (TER) method

The approach followed by the European Union entails the determination of the toxicity exposure ratio (TER), which is the inverse of the risk quotient. Under this approach, the TER must be maintained above levels of concern. While the APVMA would prefer that applicants use the risk quotient method, it will accept risk assessments based on the TER approach, particularly for major data submissions in the agreed OECD format.

9.1.2. Level of concern (LOC)

The level of concern (LOC) that is generally adopted by the APVMA for risk assessment of acute toxicity to aquatic organisms (fish, invertebrates, algae and aquatic plants), terrestrial animals (birds, mammals and invertebrates) and plants is generally 0.1. As noted in the comparison tables in Section 8.9 of the RAM, this is often more conservative than the approach of the US EPA, though the US EPA's level of concern (unity = 1.0) for chronic toxicity is adopted by the APVMA. This contrasts with the stricter LOCs adopted by the EU.

9.1.3. The iterative approach

When assessing risk, it is generally the situation that every case cannot be accounted for, so the applicant should follow an iterative process (refer to Overview of the assessment process) by considering:

- a worst-case scenario such as a direct overspray to shallow water; and, if needed,
- a series of refinements that account for other factors and results in setting more realistic scenarios at each step, such as the 10 per cent spray drift followed by spray drift modelling (refer to Figure 1 above).

9.2. Mitigating risk

Where levels of concern are exceeded, the applicant should propose measures such as label instructions to mitigate the risk. For example, labels could require the observation of unsprayed buffer zones downwind of the treated area to protect sensitive aquatic or terrestrial environments.

9.3. Deterministic versus probabilistic risk

As the quotient method is deterministic, it can only indicate the possibility of harmful effects, and not their probability or extent. The size of the quotient bears no relation to the ecological significance of any harm that may be caused by exposure to the chemical.

You have the opportunity to present further data or argument where you consider that any harm arising from exposure to the chemical will be limited. For example, if exposures are transient and the affected organisms have a high reproductive capacity, you may present data or argument to support a more relaxed approach to mitigation than would result from rigid maintenance of quotients below levels of concern. The overriding consideration is protection of populations and ecosystems, rather than individual organisms.

Chapter 10, Probabilistic risk assessment of the RAM provides a discussion and comparison of OECD, US EPA and EU approaches to this emerging tool for conducting environmental risk assessments. Probabilistic risk assessment methods provide more information on the probability and extent of harm associated with the use of a chemical. Such methods provide a more realistic and often less conservative basis for determining the risk, and the nature and extent of any measures that may be necessary to mitigate the risk, but generally need to be supported by a much larger database. The APVMA suggests that you use this method if you have sufficient data. Probabilistic approaches to risk assessment used by applicants will be evaluated on their merits.

9.4. Secondary exposure risk

Secondary exposure effects are emerging areas of risk assessment, particularly through the terrestrial food chain and its importance in bioaccumulative and persistent pesticides.

10. Specific recommendations for particular proposals

The APVMA recommends that you submit a comprehensive data package for products with specific-use patterns and/or situations, because of their intrinsic nature. Examples include:

- cooling system antifoulants and similar products
- timber preservative treatments (see OECD Scenario document)
- biotechnology products (see Reference materials for further details)
- products containing nanomaterial
- swimming pool products.

While it is not possible to address all of these specific-use patterns in this document, an example of a specific-use situation (marine antifoulant paints) has been addressed below to demonstrate the provision of additional data elements.

10.1. Marine antifoulant paints

For assessment of a marine antifoulant paint it is important to have a comprehensive set of fate data relevant to the fate of the active constituent(s) in estuarine or marine situations, and of ecotoxicity data relevant to estuarine or marine species. The application dossier should also indicate clearly the method of use and types of vessels that are to be treated with the product.

The risk assessment will compare predicted and, if available, measured levels of the active constituent with ecotoxicological endpoints. Marina and harbour situations or other scenarios will be considered, as appropriate for the intended use of the paint.

10.2. MAMPEC model

Modelling is used to predict concentrations in water and sediment arising from release of the active constituent during the life of the coating. According to the procedures discussed in the Emission scenario document for antifouling products (OECD 2005), the MAMPEC model will be used by the Department of the Environment. In the absence of reliable MAMPEC scenarios for representative Australian harbours and marinas, scenarios for major New Zealand harbours and marinas will be considered by the Department of the Environment (Gadd et al. 2011), in addition to OECD default scenarios (van Hattum et al. 2002). You may also wish to submit your own modelling using MAMPEC or other models.

Certain information on the physicochemical properties and environmental fate of the active constituent is important for modelling with MAMPEC, as described in the model and related guidance documents (van Hattum et al. 2002 and 2011, Baart et al. 2008, CEPE Anti-Fouling Working Group 2003)

10.3. Release routes

Information is also important on the release rate of the active constituent from the coating. Generally, the steady-state release rate is first considered, as discussed in OECD (2005). Annex 2 to that document (CEPE Anti-Fouling Working Group 2003) explains other methods how the release rate may be determined, including the use of ASTM/ISO laboratory methods to measure the release rate, field tests, and the European Paint Industry (CEPE) mass balance calculation method.

You should submit available results from such testing with the same or very similar paints, but we will compare these results with calculated results by the CEPE method to determine the most appropriate value for further modelling. You should provide various parameters if you are using the CEPE method, as these are often not evident from the product label or associated information.

10.4. CEPE input data

You should ensure that you provide all the necessary information to enable us to calculate the release rate, or to confirm a release rate which you have already calculated. As indicated in Appendix 1 of CEPE Anti-Fouling Working Group (2003), the input values for the equations that can be used include:

- the dry film thickness
- the specified lifetime for that dry film thickness
- the weight fraction of the active ingredient in the biocide
- the concentration of the biocide in the wet paint
- the solid volume ratio (volume of dry paint versus the volume of wet paint in per cent)
- the specific gravity of the wet paint.

10.5. Monitoring data

If monitoring data are available (including published scientific papers), you should submit these together with a discussion or risk assessment of the levels that have been found in the environment relative to ecotoxicity data.

10.6. Emission scenario documents

An Emission Scenario Document (ESD) is a document that describes the sources, production processes, pathways and use patterns of a chemical, with the aim of quantifying its emissions (or releases) into water, air, soil and/or solid waste. There are a range of ESDs prepared by the OECD for various situations, which may provide useful guidance to applicants in preparing risk assessments for some agricultural product situations. These documents may be located on, and downloaded from, the OECD web site.

Many of the ESDs listed on the OECD website relate more to industrial than agricultural or veterinary chemicals, but those currently available that may be useful for products considered to be agricultural products include:

The list of ESDs is continually growing, so you should check from time to time for updates. OECD scenarios are likely to be worst-case, and will be adapted by the APVMA as appropriate for local situation.

11. Format for submission of Part 7 environment data

11.1. OECD format

The APVMA accepts as a suitable data format all data submissions made in accordance with the OECD common format for pesticide registrations, as depicted in Figure 1, p13 of the Main document OECD Guidance for Industry Data Submissions on Plant Protection Products and their Active Substances available on the OECD website. As the OECD states:

‘Pesticide producers, who are responsible for testing any pesticide they want to register, usually have to present registration submissions in different formats for different OECD countries. The OECD common format should therefore reduce redundancies in the preparation of submissions by industry.’

You are encouraged to follow the comprehensive guidance documents and forms located on the OECD website, when preparing submissions. The APVMA also encourages use of the OECD dossier numbering system. A template version of this for active constituents is also included in Chapter 3 of the RAM (EPHC, 2009).

12. More information

Applicants seeking further information about relevant environmental data for specific uses may wish to apply for pre-application assistance or make an application for a technical assessment.

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- the dry film thickness
- the specified lifetime for that dry film thickness
- the weight fraction of the active ingredient in the biocide
- the concentration of the biocide in the wet paint
- the solid volume ratio (volume of dry paint versus the volume of wet paint in per cent)
- the specific gravity of the wet paint.
  - Series No. 2: Wood preservatives (OECD, 2013)
  - Series No. 4: Water treatment chemicals
  - Series No. 13: Antifouling products (main document and annex) (OECD 2005)
  - Series No. 14: Insecticides for stables and manure storage systems
  - Series No. 18: Insecticides, acaricides and products to control other arthropods for household and professional uses.

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1	1 July 2014	First version

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is the Australian Government regulator of agricultural and veterinary (agvet) chemical products.

We acknowledge the traditional owners and custodians of country throughout Australia and acknowledge their continuing connection to land, sea and community. We pay our respects to the people, the cultures and the elders past, present and emerging.