



Australian Government

**Australian Pesticides and
Veterinary Medicines Authority**



Risk assessment module descriptors

February 2023

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What are the module descriptors?

The Australian Pesticides and Veterinary Medicines Authority (APVMA) organises the assessments that may need to be done as part of evaluating an application into modules. The module descriptors explain what types of applications need which modules.

The module descriptors are designed to inform APVMA applicants and assist APVMA decision-makers in determining which modules to apply for different types of applications. Application fees and assessment periods are based on the modules and module levels detailed in this document.

There are 2 different tables of module descriptors in this document: one for agricultural chemicals (including insecticides and pool chemicals) and a separate table for veterinary medicines. While the modules have the same names, timeframes and fees, the criteria are different for the 2 tables. Please ensure you use the right table for your product.

The module descriptors are designed to be read top down. Once your application meets a module level descriptor your application should be submitted with that module and level. If no module level has been described for the application type by the end of the descriptors for a module it is likely that module is not necessary. However, all applicants are encouraged to get pre-application assistance (PAA) to ensure they have the right modules for their application.

Please note that the module descriptors are not law. From time to time, it may be necessary to depart from these descriptions when working out which modules are necessary for a particular application. If you are not sure, or you do not think a particular recommended module or level is relevant to your application, please apply for PAA. If an applicant proceeds to lodge their application without the recommended modules it may be delayed through re-categorisation or rejection.

February 2023 changes

There have been changes to the module descriptors effective from 1 February 2023. These changes were consulted on as part of the 2022 Cost Recovery Implementation Statement. These include:

- Toxicology and Work and Health Safety modules being combined and relabelled 'Health'.
- Additional modules in Chemistry and Environment where a reduced timeframe and fee was deemed appropriate.
- Changes to the Residues modules to remove permit specific modules and redistribute work across all 5 modules.
- Relabelling the modules from numbers to more meaningful names.

The other change is to provide timeframe and fee reductions for applications where appropriate overseas assessments are submitted, along with the supporting data. PAA and a project plan are required to use this pathway.

Relevant data for all modules

The [data guidelines](#) on our website set out the data that may be relevant to particular assessment modules.

These documents provide applicants with guidance on the data and information to provide to support their application. For the APVMA to grant an approval or registration, the APVMA must be satisfied that the safety, trade and efficacy criteria relevant to the particular product or active constituent are met. The data guidelines are not intended to be prescriptive and should not be perceived as APVMA requirements.

Module descriptors – agricultural chemicals

The following module descriptors apply for all products defined as agricultural chemicals, and for active constituents for use in agricultural products. Veterinary medicines have slightly different module descriptors, please refer to the veterinary medicines module descriptors beginning on page 13.

Table 1: Module descriptors for agricultural chemicals

Module item	Module description – agricultural chemicals	Timeframe	Fee (\$)
Preliminary assessment			
Preliminary assessment is an administrative assessment to determine that your application is complete and meets the application requirements.			
Preliminary assessment	Applies to all modular applications		902
Chemistry			
Chemistry data is required for most registrations and approvals. Chemistry and manufacture assessments include consideration of both the active constituent and the formulated agricultural chemical product. Data evaluated as part of a chemistry assessment includes manufacturing processes; quality control; specifications for the product/active constituents, product constituents and containers; physicochemical properties; batch analyses; storage stability; analytical methods; and packaging and labelling.			
Chemistry 1	Approval of a new active constituent with or without registration of a new product and requiring a full chemistry assessment. <i>Chemistry 1</i> generally applies to well characterised active constituents and typically includes active constituents manufactured wholly by chemical synthesis, by chemical modification of plant or animal extracts or fermentation products, or directly by fermentation (with or without transgenic or recombinant DNA technology).	13 months	11 074
Chemistry 2	Approval of a new active constituent with or without registration of a new product. <i>Chemistry 2</i> generally applies to active constituents without a full data set generated specifically for the new active constituent and typically includes: <ul style="list-style-type: none"> • some new biological active constituents, including essential oils, herbal extracts and other less well characterised entities • active constituents already used in domestic or industrial formulations • active constituents used as adjuvants for tank mixing with other agricultural products. Approval of a permit for an unregistered product containing a new active constituent.	9 months	3 075

Module item	Module description – agricultural chemicals	Timeframe	Fee (\$)
Chemistry 3	<p>Registration of a new product containing an approved active constituent. [3(a)]</p> <p>Approval of a permit for an unregistered product containing an approved active constituent. [3(b)]</p> <p>Approval of a new manufacturing source of an approved active constituent (other than those mentioned in <i>Chemistry 4</i> or <i>Chemistry 5</i>). [3(c)]</p> <p>Variation of an approval of an active constituent (other than those mentioned in <i>Chemistry 4</i> or <i>Chemistry 5</i>). [3(d)]</p> <p>Variation of a product to make a formulation change. [3(e)]</p>	6 months	1 954
Chemistry 4	<p>Variation of a product or approval of a permit where a chemistry assessment is required to [4(a)]:</p> <ul style="list-style-type: none"> • extend shelf-life • extend in-use shelf-life • change storage conditions • change net contents, requiring a chemistry assessment. <p>Variation of an approved active constituent to approve an additional manufacturing site of a non-pharmacopoeia active constituent, with no changes to current specifications/ Declaration of Composition (DoC), or the manufacturing process. [4(b)]</p>	3 months	970
Chemistry 5	<p>Approval of a new source of an approved active constituent, where the active constituent is manufactured to the standard of an APVMA-recognised pharmacopoeia monograph (BP, Ph Eur, USP).</p> <p>Variation of an approved source of an approved active constituent, where the active constituent is manufactured to the standard of an APVMA-recognised pharmacopoeia monograph (BP, Ph Eur, USP).</p>	2 months	480

5 Risk assessment module descriptors

Module item	Module description – agricultural chemicals	Timeframe	Fee (\$)
Health			
<p>The Health modules replace the Toxicology and Work Health and Safety modules from 1 February 2023. These modules assess the potential human health hazards arising from proposed uses of agricultural chemical products. This information is important in establishing relevant health recommendations for safe use of agricultural chemical products, including acceptable daily intakes; acute reference doses; poison scheduling; first aid instructions; safety directions; warning statements; re-entry/re-handling statements; and other limitations on use (for example, restraints, restrictions).</p> <p>Several types of applications for registration of a new product do not require exposure assessment as the product is not normally associated with any potential risks to human health. Where, however, there is any such risk, an appropriate exposure assessment is required. The types of applications which do not normally require exposure assessment are variations for products to be used domestically in the home and home garden, and microbial products where all the microbial active constituents are approved active constituents.</p>			
Health 1	<p>Registration of a new product containing a new active constituent requiring approval, including a toxicology and exposure assessment.</p> <p>Approval of a permit for an unregistered product containing a new active constituent with food crop uses (other than described in <i>Health 2</i> or <i>Health 3</i>).</p>	13 months	36 740
Health 2	Approval of a new active constituent proposed for food crop uses not mentioned in <i>Health 3</i> , where no exposure assessment is required.	11 months	27 920
Health 3	<p>Registration of a new product, or approval of a permit for a product, containing a new active constituent requiring approval, with non-food uses [3(a)]</p> <p>Approval of a new active constituent with non-food uses [3(b)]</p> <p>Approval of a permit for an unregistered product containing a new active constituent with food uses, not requiring a full health assessment [3(c)]</p> <p>Registration of a new product, or approval of a permit for a product, containing an approved active constituent requiring approval first time for food uses, requiring the establishment of an ADI and/or ARfD [3(d)]</p> <p>Variation of a product containing an approved active constituent with first food uses, requiring the establishment of an ADI and/or ARfD [3(e)]</p>	9 months	18 980

Module item	Module description – agricultural chemicals	Timeframe	Fee (\$)
Health 4	<p>Registration of a new product, a variation to a registered product, or approval of a permit for a product containing an approved active constituent, which results in one or more of [4(a)]:</p> <ul style="list-style-type: none"> • changes to the Poisons Standard/Health Based Guidance Value (ADI/ARfD) [4(a)1] • establishment of first aid instructions and hazard statements where exposure modelling is also required • a new combination of approved actives • a major formulation change compared to previously assessed formulations. <p>Approval of a new biological active constituent. [4(b)]</p> <p>Registration of a new product containing a new biological active constituent requiring approval. [4(c)]</p> <p>Approval of a permit for a product containing a new active constituent with non-food uses, not requiring a full Health assessment. [4(d)]</p> <p>Approval of a permit for an unregistered product containing an approved active constituent in a new formulation, requiring Health consideration. [4(e)]</p>	5 months	7 963
Health 5	<p>Variation of a product, or approval of a permit for a product, requiring the establishment of hazard-based safety directions, where exposure does not exceed currently registered products. [5(a)]</p> <p>Variation of a product, or approval of a permit for a registered product, to add uses requiring exposure modelling, providing the product formulation is not changed. [5(b)]</p>	4 months	4 000
Health 6	Approval of a new source of an approved active constituent, requiring Health consideration of novel impurities.	2 months	2 000
Poisons scheduling			
This is an additional module that applies to any application for either an agricultural or veterinary chemical, where the application must be referred to Therapeutic Goods Administration (TGA) for poisons scheduling.			
Poisons scheduling	Applications that are referred to the Secretary of the Department of Health for poisons scheduling, in addition to a Health assessment.	13 months	2 435
Residues			
Residues assessment includes the establishment of residues definition, maximum residue limits (MRLs), and withholding periods (WHPs), and the assessment of the trade implications of an application including the establishment of any export intervals (EIs).			

7 Risk assessment module descriptors

Module item	Module description – agricultural chemicals	Timeframe	Fee (\$)
Residues 1	<p>Registration of a new product containing a new active constituent requiring approval, to be used on a food crop, other than mentioned in Residues 4.</p> <p>Registration of a new product containing an approved active constituent, to be first used on a food crop, other than mentioned in Residues 4.</p> <p>Approval of a permit for a product containing a new or approved active constituent to be used on a food crop for the first time, other than mentioned in Residues 4.</p> <p>Variation of a product containing an approved active constituent, to include first use on food crop, other than mentioned in Residues 4.</p>	13 months	25 650
Residues 2	<p>Registration of a new product, variation of a product containing an approved active constituent, or approval of a permit for a product for use on:</p> <ul style="list-style-type: none"> • a food crop that produces a major export commodity, where finite residues are expected, and consideration of Maximum Residue Limits, Withholding Periods, and/or trade implications is required. • more than 6 food crops or crop groups. 	8 months	11 149
Residues 3	<p>Registration of a new product, variation of a product, or approval of a permit for a product for use on:</p> <ul style="list-style-type: none"> • a food crop that produces a major export commodity, where finite residues are not expected, or where no changes to Maximum Residue Limits are required. • 4 to 6 crops or crop groups. 	6 months	9 000
Residues 4	<p>Registration of a new product, variation of a product, or approval of a permit for a product for use in one to 3 crops or crop groups.</p> <p>Registration of a new product containing a new or approved active constituent, to be first used on a food crop, or approval of a permit, where a Table 5 entry in the Agricultural and Veterinary Chemicals Code (MRL Standard) Instrument 2019 is likely to be appropriate.</p>	4 months	7 465
Residues 5	<p>Registration of a new product, variation of a product, or approval of a permit for a product where the active constituent is already listed in Table 5 in the Agricultural and Veterinary Chemicals Code (MRL Standard) Instrument 2019 to add a new use. [5(a)]</p> <p>Registration of a new product, variation of a product, or approval of a permit for a product to add a new use on one crop which is not a major export commodity and does not produce animal feed. [5(b)]</p> <p>A variation of the residues and trade text of an approved label for a registered product with no additional residues data, no changes to Maximum Residue Limits, and no requirement for trade consultation. [5(c)]</p>	3 months	2 000

Module item	Module description – agricultural chemicals	Timeframe	Fee (\$)
Environment			
Where there is any potential risk to the environment, an appropriate environmental assessment is required.			
Environment 1	<p>Registration of a new product containing a new active constituent requiring approval, not mentioned in <i>Environment 3</i> [1(a)]</p> <p>Registration of a product containing an approved active constituent with first use as an agricultural product not mentioned in <i>Environment 2</i> or <i>Environment 3</i> [1(b)]</p>	13 months	26 390
Environment 2	<p>Registration of a new product containing a new biological active constituent requiring approval [2(a)].</p> <p>Registration of a new adjuvant or surfactant product containing a new active constituent requiring approval [2(b)]</p> <p>Registration of a new product containing an approved active constituent which is [2(c)]:</p> <ul style="list-style-type: none"> • a new combination of approved active constituents • a vertebrate poison • a major formulation change • for use in any crop (or situation other than those mentioned in <i>Environment 3</i>), except where a registered product exists with the same uses, actives, similar formulation type at an equivalent or higher dose, frequency or rate of application, and no new consideration of environmental exposure is required. <p>Approval of a permit for an unregistered product containing a new active constituent [2(d)]</p> <p>A variation of a product to [2(e)]:</p> <ul style="list-style-type: none"> • add uses on new crops or crop groups, or a new situation • increase the application rate or frequency for an existing use pattern. 	7 months	7 659
Environment 3	<p>Registration of a new product containing a new or approved active constituent, where the product is not a vertebrate poison and [3(a)]:</p> <ul style="list-style-type: none"> • is for use in the home, home garden, swimming pool, or spa; or • is for use in buildings not used in animal production (e.g., warehouses, glasshouses, offices); and • the product is not comparable to a registered product with the same active constituent and use, applied at equivalent or high dose, rate or frequency, and no new consideration of environment exposure is required. <p>Registration of a new product functioning as an adjuvant or surfactant, or a new biological product containing an approved active constituent unless another registered product exists with the same active constituent and use,</p>	4 months	2 979

Module item	Module description – agricultural chemicals	Timeframe	Fee (\$)
	<p>applied at equivalent or high dose, rate or frequency, and no new consideration of environment exposure is required [3(b)]</p> <p>Approval of a permit for a product containing an approved active constituent, which requires an environmental assessment due to a varied exposure scenario when compared to existing registered uses [3(c)].</p> <p>Variation of a product to [3(d)]:</p> <ul style="list-style-type: none"> • add a new crop to an existing crop group • add a use in the home, home garden, swimming pool, or spa • add a use in buildings not used in animal production (e.g., warehouses, glasshouses, offices) • change a formulation resulting in altered environment risk. 		
Environment 4	<p>Registration of a new product containing an approved active constituent, requiring assessment of only new spray-drift reduction technology, and/or deposition curve [4(a)]</p> <p>Approval of a permit for a product containing an approved active constituent, requiring assessment of only new spray-drift reduction technology, and/or deposition curve [4(b)]</p> <p>Variation of a product that requires [4(c)]:</p> <ul style="list-style-type: none"> • a spray-drift assessment that does not involve an increase in rate, or new exposure scenarios for non-target species • an assessment of new spray-drift reduction technology, and/or deposition curve. 	3 months	1 490

Efficacy and safety

Assessment of efficacy and safety refers to assessment of efficacy and host crop safety and includes assessment of the results of experimental trials for efficacy and safety; effect on following crops or non-target crops; organoleptic tests; effects of residues on subsequent processing of crops, and safety to non-target crops.

Applications for variation that involve a major formulation change will be considered under the module level that would apply if they were a new product registration.

- If the change in formulation is likely to affect only safety, then assessment under *Efficacy and Safety 3* may be appropriate.
- Data to demonstrate comparable efficacy with the previous formulation may be assessed under *Efficacy and Safety 3*.
- Data to demonstrate comparable bioequivalence with the previous formulation may be assessed under *Efficacy and Safety 3*.

Module item	Module description – agricultural chemicals	Timeframe	Fee (\$)
Efficacy and Safety 1	<p>Registration of a product containing a new active constituent [1(a)].</p> <p>Registration of a product containing an approved active constituent which involves [1(b)]:</p> <ul style="list-style-type: none"> • use in a new crop which is in a new crop group or new situation; or • a new formulation type; or • a new combination of approved active constituents. <p>A variation of a product which involves a new crop in a new crop group or new situation [1(c)].</p>	6 months	4 740
Efficacy and Safety 2	<p>Registration of a product containing an approved active constituent which involves [2(a)]:</p> <ul style="list-style-type: none"> • a new domestic or home garden use; • a new minor use with the same general use pattern as an existing registered product; • a new pest or new crop within the same crop group or situation with the same general use pattern as an existing registered product; or • a formulation not considered similar to an existing registered product, not covered by <i>Efficacy and Safety 1</i> or <i>Efficacy and Safety 3</i> and where efficacy and crop safety data is required. <p>A variation of a product which involves [2(b)]:</p> <ul style="list-style-type: none"> • a new pest or new crop within the same crop group or situation with the same general use pattern as an existing registered product; • a new minor use with the same general use pattern as an existing registered product; • new domestic or home garden use; • an increase in application rate or frequency for an existing use pattern; or • a new application method or equipment. 	4 months	1 950

Module item	Module description – agricultural chemicals	Timeframe	Fee (\$)
Efficacy and Safety 3	<p>Registration of a product where only bioequivalence (including scientific argument) is required to demonstrate the efficacy and crop safety compared to a currently registered product where the product is defined as similar to an existing registered product [3(a)].</p> <p>Approval of a permit for minor or emergency use of a product, and/or where consultation with states and territories is required [3(b)].</p> <p>A variation of a product which involves [3(c)]:</p> <ul style="list-style-type: none"> • a formulation change; or • where only bioequivalence (including scientific argument) is required to demonstrate the efficacy and crop safety compared to a currently registered product where the product is defined as similar to an existing registered product; or • a variation that is not referred to above and that is not an item 12 variation. 	3 months	1 160
Non-food trade			
This module examines trade implications which may occur in non-food materials or organisms.			
Non-food trade	<p>Registration of a product or a variation of a product involving trade risks not related to food residues, including:</p> <ul style="list-style-type: none"> • residues in fibre, or • genetically modified produce. 	6 months	1 175
Special data			
<p>This module applies to all applications for registration of a new chemical product or variation of a product, which contain active constituents that are new antibiotic substances, or which contain genetically modified organisms (GMOs).</p> <p>This module is also used to confirm regulatory acceptable levels (RALs) for spray drift risk assessment.</p>			
Special data 1	Approval of an active constituent containing a GMO.	13 months	Nil
Special data 2	Confirmation of RALs for spray drift risk assessment (where this has not already been confirmed through PAA).	7 months	Nil
Special data 3	<p>Registration of a new product containing GMOs.</p> <p>A variation to a product including an assessment of products containing GMOs, requiring a special data assessment.</p>	7 months	Nil
Finalisation			
This module encompasses administrative steps relating to the finalisation of the application which can include public consultation, entering the required information into the relevant record or register and the completion of the technical evaluation and risk assessment report outlining the evaluation of the application.			

Module item	Module description – agricultural chemicals	Timeframe	Fee (\$)
Finalisation 1	<p>Registration of a new product where:</p> <ul style="list-style-type: none"> • 3 or more technical assessment modules apply; or • the consideration of 3 or more assessment reports from technical assessment modules conducted under previous applications is required. <p>Approval of a new active constituent.</p> <p>Approval of a permit where 3 or more technical assessment modules apply.</p> <p>A variation where:</p> <ul style="list-style-type: none"> • 3 or more technical assessment modules apply; or • the consideration of 3 or more assessment reports from technical assessment modules conducted under previous applications is required. 	3 months	8 110
Finalisation 2	<p>Registration of a new product where:</p> <ul style="list-style-type: none"> • fewer than 3 technical assessment modules apply; or • the consideration of fewer than 3 assessment reports from technical assessment modules conducted under previous applications is required. <p>Approval of a permit where fewer than 3 technical assessment modules apply.</p> <p>A variation where:</p> <ul style="list-style-type: none"> • fewer than 3 technical assessment modules apply; or • the consideration of fewer than 3 assessment reports from technical assessment modules conducted under previous applications is required. 	2 months	3 090
Finalisation 3	<p>Minor applications requiring no or minimal assessment.</p> <p>Variations requiring no or minimal assessment.</p> <p>Approval or variation of an approval for an existing active constituent.</p>	2 months	1 730
Limits on use of information			
<p>This module relates to the protection, handling and use of information provided to the APVMA. In general, the APVMA must not use information given to it in connection with one application to assess or make a decision on another application, except in specific circumstances. These circumstances include, but are not limited to, where the applicant has given consent for the information to be shared or in an emergency situation; see CCI Practice Statement. This 'limited use data' includes information such as reports, studies and scientific arguments that may or may not include confidential commercial information. The applicant can request the module at the time an application is lodged, but the APVMA may also include it once an assessment of the application is undertaken.</p>			
Limits on use of information			460

Module descriptors – veterinary medicines

The following module descriptors apply for all products defined as veterinary medicines, and active constituents for use in veterinary medicines.

Table 2: Module descriptors for veterinary medicines

Module item	Module description – veterinary medicines	Timeframe	Fee (\$)
Preliminary assessment			
Preliminary assessment is an administrative assessment to determine that your application is complete and meets the application requirements.			
Preliminary assessment	Applies to all modular applications		902
Chemistry			
Chemistry data is required for most registrations and approvals. Chemistry and manufacture assessments include consideration of both the active constituent and the formulated veterinary chemical product; the manufacturing process; quality control; specifications for the product/active constituents, product constituents and containers; batch analyses; storage stability; analytical methods; and packaging and labelling.			
Chemistry 1	Approval of a new active constituent, with or without registration of a new product, and requiring a full chemistry assessment. <i>Chemistry 1</i> generally applies to well characterised active constituents and includes for example, active constituents manufactured wholly by chemical synthesis, by chemical modification of plant or animal extracts or fermentation products, or directly by fermentation (with or without transgenic or recombinant DNA technology).	13 months	11 074
Chemistry 2	Registration of a new product containing a new active constituent requiring approval or approval of a new active constituent alone and not mentioned in <i>Chemistry 1</i> . <i>Chemistry 2</i> includes for example: <ul style="list-style-type: none"> • new biological active constituents not mentioned below or in <i>Chemistry 1</i> [[2(a)1] • new immunobiologicals [2(a)2] • immunobiological products with a major change to seed strains (including substitution of source or the addition of antigen) such that it is considered a new product [2(a)3] • new direct fed microbial products [2(a)4] • new enzyme products [2(a)5] • new herbal products [2(a)6] Approval of a permit for an unregistered product containing a new active constituent. [2(b)]	9 months	3 075

Module item	Module description – veterinary medicines	Timeframe	Fee (\$)
Chemistry 3	<p>Registration of a new product containing an approved active constituent. [3(a)]</p> <p>Approval of a permit for an unregistered product containing an approved active constituent. [3(b)]</p> <p>Approval of a new manufacturing source of an approved active constituent (other than those mentioned in <i>Chemistry 4</i> or <i>Chemistry 5</i>). [3(c)]</p> <p>Variation of an approval of an active constituent (other than those mentioned in <i>Chemistry 4</i> or <i>Chemistry 5</i>). [3(d)]</p> <p>A variation to a product to make a formulation change. [3(e)]</p>	6 months	1 954
Chemistry 4	<p>Variation of a product or approval of a permit where a chemistry assessment is required to [4(a)]:</p> <ul style="list-style-type: none"> • extend shelf-life • extend in-use shelf-life • change storage conditions • change net contents, requiring a chemistry assessment. <p>A variation of an approved active constituent to add a manufacturing site of a non-pharmacopoeia active constituent, with no changes to current specifications/Declaration of Composition (DoC), or the manufacturing process. [4(b)]</p>	3 months	970
Chemistry 5	<p>Registration of a new product or approval of a permit for a product which is an autogenous vaccine using previously known adjuvants/excipients. [5(a)].</p> <p>Approve a new source of an existing active constituent, or variation of an approved source of active constituent, to approve an additional manufacturing site of the active constituent manufactured to the standard of a monograph of an APVMA-recognised pharmacopoeia (BP, Ph Eur, USP). [5(b)]</p>	2 months	480

Module item	Module description – veterinary medicines	Timeframe	Fee (\$)
Health			
<p>The Health modules replace the Toxicology and Work Health and Safety modules from 1 February 2023. These modules assess the potential human health hazards arising from proposed uses of agricultural chemical products. This information is important in establishing relevant health recommendations for safe use of veterinary medicines, including acceptable daily intakes; acute reference doses; poison scheduling; first aid instructions; safety directions; warning statements; re-entry/re-handling statements; and other limitations on use.</p> <p>For the purposes of determining the appropriate module, the following products do not normally require toxicological assessment:</p> <ol style="list-style-type: none"> a. Mineral, vitamin or nutritional supplements for a single animal or a small number of animals that are administered directly to the animal or are administered daily in food or water. b. Animal bacterial and viral vaccines. <p>Several types of applications for registration of a new product do not generally require exposure assessment as the product is not normally associated with any potential risks to human health. Where there is any such risk, an appropriate assessment is required. The types of application for products which do not normally require exposure assessment are as follows:</p> <ol style="list-style-type: none"> a. Applications for a permit for a product, registration of a new product or variation a product that are: <ol style="list-style-type: none"> i. animal therapeutics and mineral and nutritional supplements in tablet, capsule, slow-release bolus or skin implant form; ii. animal therapeutics which have Therapeutic Goods Administration approval for direct administration to humans and the use pattern indicates low worker exposure potential (that is, not mob or flock treatments with a drench or a pour on, or as a feed additive, or other equivalent use pattern, as these have high worker exposure potential); iii. mineral, vitamin and nutritional supplements for a single animal or a small number of animals and are administered directly to the animal or into daily food or water; iv. vitamins; digestive enzyme supplements; electrolytes; iron and haematopoietic agents; tonics and stimulants; or preservatives; v. micro-organism and enzyme products for use in non-food species; vi. stockfood additives and nutrition or metabolism products (other than those listed in this paragraph) with established safety directions, which are directly applicable to the concentration of the additive and the form in which it is to be used; and vii. animal bacterial and viral vaccines. 			
Health 1	<p>Registration of a new product for food species, containing a new active constituent requiring approval, including a toxicology and exposure assessment, other than described in <i>Health 3</i>.</p> <p>Approval of a permit for an unregistered product containing a new active constituent for use in a food species (other than described in <i>Health 3</i> or <i>Health 4</i>).</p>	13 months	36 740
Health 2	Approval of new active constituent with food species uses requiring approval not mentioned in <i>Health 3</i> , where no exposure assessment is required.	11 months	27 920

Module item	Module description – veterinary medicines	Timeframe	Fee (\$)
Health 3	<p>Registration of a new product, or approval of a permit for a product, with a new active constituent requiring approval for use in a non-food species. [3(a)]</p> <p>Approval of a new active constituent for use in a non-food species. [3(b)]</p> <p>Registration of a new product, approval of a permit for a product, or a variation of a product containing an approved active constituent for first use in food species, requiring the establishment of an ADI and/or ARfD. [3(c)]</p> <p>Approval of a permit for a product containing a new active constituent for use in a food species where a full Health assessment is not required, other than where mentioned in <i>Health 4</i> [3(d)].</p>	9 months	18 980
Health 4	<p>Registration of a new product, or approval of a permit for a product containing a new biological active constituent requiring approval [4(a)]</p> <p>Registration of a new product, variation of a product, or approval of a permit for a product containing an approved active constituent, which results in one or more of [4(b)]:</p> <ul style="list-style-type: none"> • changes to the Poisons Standard [4(b)1] • establishment of first aid instructions and hazard statements where exposure modelling is also required • a new combination of approved actives • a major formulation change. <p>Approval of a permit for a product containing a new active constituent for use on non-food species, not requiring a full Health assessment. [4(c)]</p>	5 months	7 963
Health 5	<p>Registration of a new product containing an approved active constituent requiring the establishment of hazard-based safety directions, where exposure does not exceed currently registered products [5(a)]</p> <p>Variation of a product, or approval of a permit for a product containing an approved active constituent, requiring the establishment of hazard-based safety directions, where exposure does not exceed currently registered products. [5(b)]</p> <p>Variation of a product, or approval of a permit for a registered product to add uses in new species, or to vary the rate, frequency or application method and no changes are made to the product formulation, but where exposure modelling is required. [5(c)]</p>	4 months	4 000
Health 6	Approval of a new source of an approved active constituent, requiring Health consideration of novel impurities.	2 months	2 000

Module item	Module description – veterinary medicines	Timeframe	Fee (\$)
Poisons scheduling			
This is an additional module that applies to any application for either an agricultural or veterinary chemical, where the application must be referred to Therapeutic Goods Administration (TGA) for poisons scheduling.			
Poisons scheduling	Applications where poison scheduling is required. This will include all new active ingredients or where changes are required to an established schedule for an existing active constituent (excluding vaccines).	13 months	2 435
Residues			
Residues assessment includes the establishment of residues definition, maximum residue limits (MRLs), and withholding periods (WHPs), and the assessment of the trade implications of an application including the establishment of any export intervals (EIs).			
Residues 1	<p>Registration of a new product containing a new active constituent requiring approval or an approved active constituent, with first uses in a food species, other than mentioned in <i>Residues 4</i>.</p> <p>Approval of a permit for a product containing a new or approved active constituent to be used in food species for the first time, other than mentioned in <i>Residues 4</i>.</p> <p>Variation of a product containing an approved active constituent, to include first use on food species, other than mentioned in <i>Residues 4</i>.</p>	13 months	25 650
Residues 2	<p>Registration of a new product, or approval of a permit for a product, containing an approved active constituent approved for use on certain food species to include new food species, which produce a major export commodity, where finite residues are expected and consideration of Maximum Residue Limits, Withholding Periods, and/or trade implications is required.</p> <p>Variation of a product for:</p> <ul style="list-style-type: none"> • use in a new food species, which produces a major export commodity, where finite residues are expected and consideration of Maximum Residue Limits, Withholding Periods, and/or trade implications is required, or • a change to the dose rate or frequency of application to food species requiring a change to, or establishment of, Maximum Residue Limits. 	8 months	11 149
Residues 3	Registration of a new product, variation of a product, or approval of a permit for use requiring the establishment of Maximum Residue Limits for a minor species, which does not produce a major export commodity.	6 months	9 000

Module item	Module description – veterinary medicines	Timeframe	Fee (\$)
Residues 4	<p>Registration of a new product, variation of a product, or approval of a permit for use on food species, which produce major export commodities where finite residues are not expected, or no changes to Maximum Residue Limits are required.</p> <p>Registration of a new product, or approval of a permit, containing a new active constituent requiring approval for use on food species where a Table 5 entry in the Agricultural and Veterinary Chemicals Code (MRL Standard) Instrument 2019 is likely to be appropriate.</p>	4 months	7 465
Residues 5	<p>Registration of a new product, variation of a product, or approval of a permit for a product where the active constituent is already listed in Table 5 in the Agricultural and Veterinary Chemicals Code (MRL Standard) Instrument 2019 to add a new use.</p> <p>A variation of the residues and trade text of an approved label for a registered product with no additional residues data, no changes to Maximum Residue Limits, and no requirement for trade consultation.</p>	3 months	2 000

Environment

Where there is any potential risk to the environment, an appropriate environmental assessment is required. However, some types of applications for registration of a new product containing an approved active constituent do not require environmental assessment as they are not normally associated with any potential risks to the environment. The types of products which do not normally require environmental assessment are:

- animal therapeutics and mineral and nutritional supplements in single, capsule, slow-release bolus or skin implant form other than parasiticides
- animal immunobiological products (except those containing GMOs)
- animal therapeutics given by injection for use under prescription in individual animals.

The [VICH website](#) has guidance on both phase I and phase II assessments.

Environment 1	<p>Registration of a new product containing a new active constituent requiring approval, requiring a VICH Phase II assessment [1(a)].</p> <p>Registration of a new product, or variation of a product, containing an approved active constituent requiring a VICH Phase II assessment, where the reference product has only been subject to a VICH Phase I assessment [1(b)].</p> <p>Variation of a product, label approval and/or active constituent requiring a VICH Phase II assessment, where the product, or the active constituent of the product has only been subject to a VICH Phase I assessment [1(c)].</p>	13 months	26 390
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Module item	Module description – veterinary medicines	Timeframe	Fee (\$)
Environment 2	<p>Registration of a new product containing an approved active constituent, not mentioned in <i>Environment 1</i> or <i>Environment 4</i>, unless there is a registered reference product with the same active constituent, for use in the same situation or herd animal, at an equivalent or higher dose, and does not require environmental exposure consideration [2(a)].</p> <p>Approval of a permit for a product containing a new active constituent unless mentioned in <i>Environment 3</i> [2(b)].</p> <p>Variation of a product previously subject to a VICH Phase II assessment to:</p> <ul style="list-style-type: none"> • add a new herd animal or situation [2(c)1]: • change the application method [2(c)2]: • increase the application rate, dose, or frequency of an existing use [2(c)3]. 	7 months	7 659
Environment 3	Approval of a permit for a product containing an approved active constituent requiring a VICH Phase II assessment, where the product has only been subject to a VICH Phase I assessment.	4 months	2 979
Environment 4	<p>Registration of a new product containing a new active constituent requiring a VICH Phase I assessment [4(a)].</p> <p>Registration of a new product containing an approved active constituent or a variation to a registered product requiring a VICH Phase I assessment, except where the reference product is a registered product with the same active constituent, for use in the same situation or herd animal, at an equivalent or higher dose, not requiring consideration of environmental exposure [4(b)].</p> <p>Approval of a permit for an unregistered product containing a new active constituent subject to a VICH Phase I assessment [4(c)].</p>	3 months	1 490

Efficacy and safety

Assessment of efficacy and safety refers to assessment of efficacy and animal safety and includes (as relevant): assessment of the results of experimental trials for efficacy and safety; organoleptic tests; safety to target animals, and pharmacologic studies.

Applications for variation that involve a major formulation change will be considered under the module level that would apply if they were a new product registration.

- If the change in formulation is likely to affect only safety, then assessment under *Efficacy and Safety 3* may be appropriate.
- Data to demonstrate comparable efficacy with the previous formulation may be assessed under *Efficacy and Safety 3*.
- Data to demonstrate comparable bioequivalence with the previous formulation may be assessed under *Efficacy and Safety 3*.

Module item	Module description – veterinary medicines	Timeframe	Fee (\$)
Efficacy and Safety 1	<p>Registration of a new product containing a new active constituent for use in major food-producing species (cattle, sheep, pigs and chickens) or companion animals (dog, cat horse). [1(a)]</p> <p>Registration of a new product containing an approved active constituent which involves: [1(b)]</p> <ul style="list-style-type: none"> • use in/on a food species or dog, cat, or horse for the first time [1(b)1]; or • a new formulation type [1(b)2]; or • a new combination of approved active constituents [1(b)3]. <p>Variation of a product which involves use in a new food species or dog, cat, or horse. [1(c)]</p>	6 months	4 740
Efficacy and Safety 2	<p>Registration of a new product containing a new active constituent for use in food or fibre species other than cattle, sheep, pigs and chickens. [2(a)]</p> <p>Registration of a new product that contains an approved active constituent which involves [2(b)]:</p> <ul style="list-style-type: none"> • a new pest or disease or for a new purpose in/on a food species or dog, cat, or horse[2(b)1]; or • new dosage or administration instructions in/on the species. This includes having consideration of dose, frequency, duration, and route of administration [2(b)2]; or • a product that is not the same, nor closely similar, nor similar to an existing registered reference product [2(b)3]. <p>Variation of a product which involves [2(c)]:</p> <ul style="list-style-type: none"> • use on a new pest or disease or for a new purpose in the same food species or companion animal [2(c)1]; or • a change to the dosage or administration instructions – including treatment number, frequency, duration, dose, and route of administration – in the same food species or companion animal [2(c)2]. 	4 months	1 950

Module item	Module description – veterinary medicines	Timeframe	Fee (\$)
Efficacy and Safety 3	<p>Registration of a new product containing a new active constituent for use in non-food species other than companion animals (i.e. dog, cat or horse). [3(a)]</p> <p>Register a new product that contains an approved active constituent which involves: [3(b)]</p> <ul style="list-style-type: none"> • use in or on a non-food species (other than a dog, cat or horse) [3(b)1]; or • a product which is similar to a registered reference product : [3(b)2]. <p>Approval of a permit for minor or emergency use of a product, and/or where consultation with states and territories is required. [3(c)]</p> <p>Variation of a product registration which involves: [3(d)]</p> <ul style="list-style-type: none"> • a formulation change [3(d)1]; or • use in a non-food species (other than a dog, cat or horse) [3(d)2]; or • where only bioequivalence or pharmaceutical equivalence is required to demonstrate the efficacy and safety [3(d)3]. 	3 months	1 160
Non-food trade			
This module examines trade implications which may occur in non-food materials or organisms.			
Non-food trade	<p>Register a new product or a variation involving trade risks not related to food residues, including:</p> <ul style="list-style-type: none"> • residues in wool and fibre; • genetically modified produce; • the presence of disease or seropositive testing to exotic or notifiable agents; • hormonal growth promotants and other endocrine substances. 	6 months	1 175
Special data			
This module applies to all applications for registration of a new product, or variation of product, which contains active constituents that are new antibiotic substances, or which contain genetically modified organisms (GMOs) require a special data assessment.			
Special data 1	<p>Registration of a new product or approval of a permit for a product containing a new antibiotic active constituent.</p> <p>Assessment of an active constituent containing a genetically modified organism (GMO).</p>	13 months	Nil

Module item	Module description – veterinary medicines	Timeframe	Fee (\$)
Special data 2	<p>Registration of a product containing an approved antibiotic active constituent and which is expected to result in significantly increased volume of use of the approved antibiotic active constituent or an increased risk to public health including:</p> <ul style="list-style-type: none"> • a variation of use in a new food species, or a dog or a cat; • a variation of use to another major group within the same food species (for example: broiler chickens to layers; beef cattle to dairy cattle); or • a change in dosage form or use pattern (for example: from use in individual animals to mass medication). <p>Approval of a permit for a product containing an approved antibiotic active constituent and which are for use in a new species.</p>	7 months	Nil
Special data 3	<p>Registration of a new product containing GMOs.</p> <p>Variation to a product including a product containing GMOs requiring a special data assessment that is not included in the Special Data 1 or Special Data 2 modules.</p>	7 months	Nil
Finalisation			
<p>This module encompasses administrative steps relating to the finalisation of the application which can include public consultation, entering the required information into the relevant record or register and the completion of the technical evaluation and risk assessment report outlining the evaluation of the application.</p>			
Finalisation 1	<p>Registration of a new product where:</p> <ul style="list-style-type: none"> • 3 or more technical assessment modules apply; or • the consideration of 3 or more assessment reports from technical assessment modules conducted under previous applications is required. <p>Approval of a new active constituent.</p> <p>Approval of a permit where three or more technical assessment modules apply.</p> <p>A variation where:</p> <ul style="list-style-type: none"> • 3 or more technical assessment modules apply; or • the consideration of 3 or more assessment reports from technical assessment modules conducted under previous applications is required. 	3 months	8 110

Module item	Module description – veterinary medicines	Timeframe	Fee (\$)
Finalisation 2	<p>Registration of a new product where:</p> <ul style="list-style-type: none"> • fewer than 3 technical assessment modules apply; or • the consideration of fewer than 3 assessment reports from technical assessment modules conducted under previous applications is required. <p>Approval of a permit where fewer than 3 technical assessment modules apply.</p> <p>A variation where:</p> <ul style="list-style-type: none"> • fewer than 3 technical assessment modules apply; or • the consideration of fewer than 3 assessment reports from technical assessment modules conducted under previous applications is required. 	2 months	3 090
Finalisation 3	<p>Minor applications requiring no or minimal assessment.</p> <p>Variations requiring no or minimal assessment.</p> <p>Approval or variation of an existing active constituent.</p>	2 months	1 730
Limits on use of information			
<p>This module relates to the protection, handling and use of information provided to the APVMA. In general, the APVMA must not use information given to it in connection with one application to assess or make a decision on another application, except in specific circumstances. These circumstances include, but are not limited to, where the applicant has given consent for the information to be shared or in an emergency situation; see CCI Practice Statement. This 'limited use data' includes information such as reports, studies and scientific arguments that may or may not include confidential commercial information. The applicant can request the module at the time an application is lodged, but the APVMA may also include it once an assessment of the application is undertaken.</p>			
Limits on use of information			460

International and overseas assessments

The APVMA can use overseas or international assessments to facilitate the approval of active constituents and the registration of products, based on the submission of an acceptable assessment from a trusted overseas regulator or international scientific body. The overseas or international assessment must consider the same active constituent or product intended for approval or registration in Australia. The full supporting underlying data must also be submitted.

Information [on this process](#) is set out on our website, which covers:

- a) the data generated for overseas regulators which we will accept as support for an Australian assessment
- b) international standards we will use in our assessments
- c) countries and bodies we accept assessments from
- d) our criteria for accepting an international assessment
- e) how to submit an overseas or international assessment
- f) how we use the data.

When suitable overseas/international assessments are available, the APVMA can offer reduced timeframes and fees to reflect the reduced regulatory effort. To take advantage of this process, applicants must seek pre-application assistance.

As part of the PAA the APVMA will work with an applicant to develop a project plan and agree on which overseas assessments are likely to result in lower fees and timeframes. Where component assessments influenced by the use pattern cannot be extrapolated to Australian use, additional data may be required.

The APVMA's decisions are based on Australian legislative requirements, however the assessment reports will outline considerations against Australian legislative requirements, drawing on or referring to the overseas or international assessment report as needed.

The poisons scheduling module is contingent on consideration by the Therapeutic Goods Administration and is not influenced by the overseas or international assessment; however, the APVMA will utilise the timesaving provided by the international assessment in the health module to expedite submission to the scheduling process.

Table 3: International assessment – proposed lower module levels

Area	Module without overseas assessment	Module when relevant overseas assessment is submitted
Chemistry	Chemistry 1	Chemistry 3
	Chemistry 2	Chemistry 3
Health	Health 1	Health 3
Residues	Residues 1	Residues 2
	Residues 2	Residues 4
Environment	Environment 1	Environment 2
	Environment 2	Environment 3
Efficacy and Safety	Case-by-case for discussion at pre-application assessment. The APVMA aims to use overseas assessment to the fullest extent possible and apply cost/time savings as appropriate.	

Table 4: Document change record

Date	Change
19 January 2023	Minor reordering of application types within the Health modules. Addition of numbering and lettering to align with the data required for modules documents.