Australian Government

Australian Pesticides and Veterinary Medicines Authority

Risk assessment module descriptions

August 2022

Comments and enquiries regarding copyright:

Assistant Director, Communications
Australian Pesticides and Veterinary Medicines Authority
GPO Box 3262
Sydney NSW 2001 Australia

Telephone: +61 2 6770 2300

Email: communications@apvma.gov.au.

This publication is available from the APVMA website.

Contents

List of tables

Executive Summary

The module structure for technical assessment of applications has not been significantly changed for a number of years. As part of the 2022 Cost Recovery Implementation Statement (CRIS), the Australian Pesticides and Veterinary Medicines Authority (APVMA) is proposing revised modular descriptors including proposing new (shorter) modules for certain categories of assessment, as well as formalising timeframe and fee savings resulting from the provision of a suitable international assessment.

Module descriptors

Consideration has been given to the module descriptors, the timeframes and the relevant fees. Following this, a proposal has been developed for changes to the module descriptors, as well as introduction of new modules to capture assessment types where a reduced timeframe is considered appropriate. An additional key area of change is to consolidate the modules relating to toxicology and to occupational health and safety into a number of 'health' modules. This reflects the current assessment processes within the APVMA. The detailed changes to the module descriptors are set out below, along with proposed timeframes for each of these module types.

No changes are proposed to the module descriptors for efficacy (modules 8.1, 8.2 and 8.3) and for the Poisons Scheduling module.

International assessments

The APVMA has had a long-standing policy of utilising international assessments to facilitate the approval of new active constituents and registration of products based on the submission of an acceptable international assessment along with the underlying data.

While the APVMA has been gaining experience in the efficient use of international assessments, we have been utilising project plans developed on a case-by-case basis. These plans are constructed at pre-application assistance in a similar manner to the project plans developed for timeshift applications, and usually result in time saving for the application, to a greater or lesser extent.

The project plan process has enabled time savings to be realised by applicants. It is now proposed to recognise this formally and offer reductions in fees to reflect the reduced assessment effort. The details are set out below.

Module descriptors

Table 1: Module descriptor – agricultural

New module items	New Module Description - agriculture	Proposed timeframe	Proposed fee ($)
Chemistry (previously modules 2.1, 2.2 and 2.3)			
Chemistry 1	A new product requiring registration, containing a new active constituent requiring approval (other than those mentioned in Chemistry 2). Approval of a new active constituent (other than those mentioned in Chemistry 2).	13 months	11 074
Chemistry 2	A new product requiring registration, containing a new active constituent requiring approval, which is one or more of: • biological • already used in domestic or industrial formulations • an adjuvant used with agricultural products. Apply for a permit containing a new active constituent requiring a chemistry assessment. A new active constituent requiring approval, which is one or more of: • biological • already used in domestic or industrial formulations • an adjuvant for use with agricultural products.	9 months	3 075
Chemistry 3	A new manufacturing source of an approved active constituent (other than those mentioned in Chemistry 4 or Chemistry 5). Register a new product that contains an approved active constituent. Vary the registered particulars of a product including registration, label approval and/or active constituent approval, to make a formulation change. Apply for a permit for a product containing an approved active constituent requiring a chemistry assessment.	6 months	1 954
Chemistry 4	Vary the following registered particulars of a product: • Extension of shelf life • Extension of in-use shelf life • Storage conditions • Pack size and/or packaging, requiring a chemistry assessment Vary an approved source of an active constituent to add a manufacturing site of a non-pharmacopeia active, with no changes to current specifications/DoC, or manufacturing process.	3 months	970

New module items	New Module Description - agriculture	Proposed timeframe	Proposed fee ($)
	Apply for a permit involving changes to the registered particulars or conditions of a product (e.g. extension of shelf-life)		
Chemistry 5	A new source of an approved active constituent, where the active constituent is manufactured to the standard of an APVMA-recognised pharmacopoeia monograph. 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.	2 months	480
Health (Previously modules 3.1, 3.2 and 3.3 as well as 6.1, 6.2 and 6.3)			
Health 1	A new product requiring registration, containing a new active constituent requiring approval, including a toxicology and worker exposure assessment. A permit for a product containing a new active constituent with food crop uses (other than described in Health 2 or Health 3).	13 months	36 740
Health 2	A new active constituent proposed for food crop uses requiring approval not mentioned in *Health 3,* where no worker exposure assessment is required.	11 months	27 920
Health 3	A new active constituent with non-food uses requiring approval. A new product requiring registration, or a permit, containing a new active constituent requiring approval, with non-food uses. A new product requiring registration, or a permit, containing an approved active constituent with first food uses. Vary the registered particulars of a product, or label approval of a product, containing an approved active constituent with first food uses. A permit for a product containing a new active constituent with food uses, not requiring a full health assessment.	9 months	18 980
Health 4	A new biological active requiring approval. A new product requiring registration, containing a new biological active constituent requiring approval. A new product requiring registration, a variation to a registered product, or a permit for a product containing an approved active constituent, which results in one or more of: • changes to the Poisons Standard • establishment of first aid hazard statements where exposure modelling for occupational exposure is also required • a new combination of approved actives • a major formulation change.	5 months	7 963

New module items	New Module Description - agriculture	Proposed timeframe	Proposed fee ($)
	A permit for a product containing a new active constituent with non-food uses, not requiring a full Health assessment. A permit for a product containing an approved active constituent in a new formulation, requiring Health consideration.		
Health 5	Vary the registered particulars of a product, or registration of a new product containing an approved active constituent requiring the establishment of hazard-based safety directions, where applicator exposure does not exceed currently registered products. Vary the registered particulars of a product to add uses requiring exposure modelling for occupational exposure, providing the product formulation is not changed.	4 months	4 000
Health 6	A new source of an approved active constituent, requiring *Health* consideration of novel impurities.	2 months	2 000
Residues (previously module 5.1, 5.2, 5.3, 5.4 and 5.5)			
Residues 1	A new product requiring registration, containing a new active constituent requiring approval, to be used on a food crop, other than mentioned in Residues 4. A new product requiring registration, containing an approved active constituent, to be first used on a food crop, other than mentioned in Residues 4. Vary the registered particulars of a product containing an approved active constituent, to include first use on food crop, other than mentioned in Residues 4. 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.	13 months	25 650
Residues 2	A new product requiring registration, vary the registered particulars of a product containing an approved active constituent, or a permit for use on: • 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	A new product requiring registration, vary the registered particulars of a product, or a permit for use on: • 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

New module items	New Module Description - agriculture	Proposed timeframe	Proposed fee ($)
Residues 4	A new product requiring registration, vary the registered particulars of a product, or a permit for use in 1 to 3 crops or crop groups. A new product requiring registration, containing a new or approved active constituent, to be first used on a food crop, or a permit, where a Table 5 entry is likely to be appropriate.	4 months	7 465
Residues 5	A new product requiring registration, to vary the registered particulars of a product or apply for a permit for where the active constituent is already listed in Table 5, to add a new use. Vary the residues and trade text of an approved label with no additional residues data, no changes to Maximum Residue Limits, and no requirement for trade consultation. A new product requiring registration, a permit, or variation of the registered particulars of a product to add a new use on one crop which is not a major export commodity and does not produce animal feed.	3 months	2 000
Environment (previously 7.1, 7.2 and 7.3)			
Environment 1	A new product requiring registration, containing a new active constituent requiring approval, not mentioned in *Environment 3*. A product containing an approved active constituent with first use as an agricultural product not mentioned in *Environment 2* or *Environment 3*.	13 months	26 390
Environment 2	A new product requiring registration containing a new, biological active constituent requiring approval. A new adjuvant or surfactant product requiring registration containing a new active constituent requiring approval. A new product requiring registration containing an approved active constituent which is: • 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 *Environment* 3), 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. Vary a product to: • add uses on new crops or crop groups, or a new situation • increase the application rate or frequency for an existing use pattern. A permit for a product containing a new active constituent.	7 months	7 659

New module items	New Module Description - agriculture	Proposed timeframe	Proposed fee ($)
Environment 3	A new product requiring registration, containing a new or approved active constituent, where the product is not a vertebrate poison and: • 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. A new product functioning as an adjuvant or surfactant, containing and approved active constituent unless another registered product exists 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. Vary the registered particulars of a product, label approval, or active constituent approval to: • 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) • undertake a spray-drift assessment that does not involve an increase in rate, or new exposure scenarios for non-target species • change a formulation resulting in altered environment risk. A permit for a product containing an approved active constituent, which requires an environmental assessment due to a varied exposure scenario.	4 months	2 979
Environment 4	A new product requiring registration, containing an approved active constituent, requiring assessment of only new spray-drift reduction technology, and/or deposition curve. Vary product registration, label approval, and/or active constituent approval requiring assessment of only new spray-drift reduction technology, and/or deposition curve. A permit for a product containing an approved active constituent, requiring assessment of only new spray-drift reduction technology, and/or deposition curve.	3 months	1 490

Table 2: Module descriptor – veterinary

New module items	New module description - veterinary	Proposed timeframe	Proposed fee ($)
Chemistry (previously modules 2.1, 2.2 and 2.3)			
Chemistry 1	New active constituent requiring approval, with or without a new product requiring registration, including: • an active constituent manufactured via chemical synthesis • a highly purified, and well characterised active constituent derived from plants or animals • a semi-synthetic active constituent, manufactured via chemical modification of a highly purified, and well characterised intermediate, derived from plants or animals • a semi-synthetic active constituent manufactured by the chemical modification of an intermediate produced by conventional fermentation • an active constituent produced via conventional fermentation, or using recombinant DNA technology (excluding products described in *Chemistry* 2) • an active constituent produced by transgenic technology (excluding products described in *Chemistry* 2) • an active constituent that functions as a growth regulator, antibiotic, or polypeptide • some animal tissue extracts, and some plant extracts or oils.	13 months	11 074
Chemistry 2	A new product requiring registration, and/or a new active constituent requiring approval not mentioned in *Chemistry 1 or 5*, including: • new biological products • new immunobiological • 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 • new direct fed microbial products • new enzyme products • new herbal products. A permit for a product containing a new active constituent.	9 months	3 075
Chemistry 3	A variation to add a new source to an approved active constituent (unless mentioned in *Chemistry 4 or Chemistry 5*). A new product requiring registration containing an approved active constituent. Vary the registered particulars of a product, approved label, and/or active constituent approval to change the formulation. A permit for a product containing an approved active constituent requiring a chemistry assessment.	6 months	1 954

New module items	New module description - veterinary	Proposed timeframe	Proposed fee ($)
Chemistry 4	Vary the registered particulars of a product or permit to: • extend shelf-life • extend in-use shelf-life • change storage conditions • change pack size or packaging, requiring a chemistry assessment. Vary the particulars of an approved active constituent to approve an additional manufacturing site of a non-pharmacopoeia active constituent, with no changes to current specifications/DoC, or the manufacturing process.	3 months	970
Chemistry 5	Approve a new source of an existing 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) Vary the particulars 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) Approval of a new product or permit which is an autogenous vaccine using previously known adjuvants/excipients	2 months	480
Health (Previously modules 3.1, 3.2 and 3.3 as well as 6.1, 6.2 and 6.3)			
Health 1	A new product for food species requiring registration, containing a new active constituent requiring approval, including a toxicology and worker exposure assessment, other than described in Health 3. A permit for a product containing a new active constituent for use in a food species (other than described in Health 3 or Health 4).	13 months	36 740
Health 2	A new active constituent with food species uses requiring approval not mentioned in *Health 3,* where no worker exposure assessment is required.	11 months	27 920
Health 3	A new product requiring registration, or a permit, with a new active constituent requiring approval for use in a non-food species. A new product requiring registration, a permit for a product, or to vary the registered particulars of a product containing an approved active constituent for first use in food species, requiring the establishment of an ADI and/or ARfD. A new active constituent requiring approval for use in a non-food species. 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 *Health 4*.	9 months	18 980

New module items	New module description - veterinary	Proposed timeframe	Proposed fee ($)
Health 4	A new product requiring registration, or permit containing a new biological active constituent requiring approval. A new product requiring registration, vary the registered particulars of a product or a permit for a product containing an approved active constituent, which results in one or more of: • changes to the Poisons Standard • establishment of first aid hazard statements where exposure modelling for occupational exposure is also required • a new combination of approved actives • a major formulation change. A permit for a product containing a new active constituent for use on non-food species, not requiring a full Health assessment.	5 months	7 963
Health 5	Vary the registered particulars of a product, or registration of a new product containing an approved active constituent, or approval or a new permit requiring the establishment of hazard-based safety directions, where applicator exposure does not exceed currently registered products. Vary the registered particulars of a product or a permit to add uses in new species and no changes are made to the product formulation and occupational exposure modelling is required	4 months	4 000
Health 6	A new source of an approved active constituent, requiring *Health* consideration of novel impurities.	2 months	2 000
Residues (previously module 5.1, 5.2, 5.3, 5.4 and 5.5)			
Residues 1	A new product requiring registration, containing a new active constituent requiring approval or an approved active constituent, with first uses in a food species, other than mentioned in Residues 4. Vary the registered particulars of a product containing an approved active constituent, to include first use on food species, other than mentioned in Residues 4. 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 Residues 4.	13 months	25 650
Residues 2	A new product requiring registration, or 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. Vary the registered particulars of a product, label approval, and/or the particulars for an active constituent for: • use in a new food species, 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

New module items	New module description - veterinary	Proposed timeframe	Proposed fee ($)
Residues 3	A new product requiring registration, vary the registered particulars of a product, or a permit for use necessitating the establishment of Maximum Residue Limits for a minor species, which does not produce a major export commodity.	6 months	9 000
Residues 4	A new product requiring registration, vary the registered particulars of a product, or 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 A new product requiring registration, or a permit, containing a new active constituent requiring approval for use on food species, resulting in consideration of a Table 5 entry for the first time.	4 months	7 465
Residues 5	A new product requiring registration, to vary the registered particulars of a product or apply for a permit for where the active constituent is already listed in Table 5, to add a new use. Vary the residues and trade text of an approved label with no additional residues data, no changes to Maximum Residue Limits, and no requirement for trade consultation.	3 months	2 000
Environment (previously 7.1, 7.2 and 7.3)			
Environment 1	A new product requiring registration, containing a new active constituent requiring approval, requiring a VICH Phase II assessment. A new product requiring registration, or to vary the registered particulars 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. Vary the registered particulars of a product, label approval and/or active constituent requiring a VICH Phase II assessment, where the product, of the active constituent of the product has only been subject to a VICH Phase I assessment..	13 months	26 390
Environment 2	A new product requiring registration, containing an approved active constituent with an existing VICH Phase II assessment, 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. Vary a label approval, the particulars of a constituent, or the registered particulars of a product previously subject to a VICH Phase II assessment to: Add a new herd animal or situation Change the application method Increase the application rate, dose, or frequency of an existing use. A permit for a product containing a new active constituent unless mentioned in *Environment 3*.	7 months	7 659

11 Risk assessment module descriptions

New module items	New module description - veterinary	Proposed timeframe	Proposed fee ($)
Environment 3	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	A new product requiring registration containing a new active constituent requiring a VICH Phase I assessment. A new product requiring registration 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. A permit for a product containing a new active constituent subject to a VICH Phase I assessment.	3 months	1 490

International assessments

The APVMA has had a long-standing policy of using overseas or international assessments to facilitate the approval of new active constituents and the registration of products based on the submission of an acceptable assessment from a trusted overseas regulator or international scientific body, along with the provision of the underlying data.

Information on this process is set out on our website, which covers the data generated for overseas regulators which we will accept as support for an Australian assessment, international standards we will use in our assessments, and countries and bodies we accept assessments from. The page also sets out our criteria for accepting an international assessment, how to submit an international assessment, and how we use the data, as well as the CEO expectations on use of international data standards.

To ensure the assessments and full underlying data are auditable for the APVMA's evaluation, we work with applicant to develop project plans on a case-by-case basis. These plans are constructed at pre-application assistance in a similar manner to the project plans developed for timeshift applications, and usually result in time saving for the application.

This process has enabled time savings to be realised by applicants and reduced the assessment effort for the APVMA. It is now proposed to recognise this formally and offer reductions in fees to reflect the reduced assessment effort.

The criteria for accepting an international assessment remain unchanged. The 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. Further criteria of overseas/international assessments to be acceptable are available on the APVMA website.

Where component assessments influenced by the use pattern cannot be extrapolated to Australian use, additional data may be required.

As part of the pre-application assistance process, the APVMA will provide applicants with guidance on whether components of existing overseas/international assessments could be used to support an application for approval, registration or variation of an active constituent or agvet chemical product in Australia.

Where overseas/international assessments are submitted, the APVMA will use these as much as possible, undertaking the appropriate peer review but not commissioning or undertaking detailed analysis of the supporting data unless there is a justifiable reason to do so.

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

In using overseas or international assessment reports, a significant timesaving is anticipated in relevant modules: this may include the chemistry, health, environment, residues and efficacy modules, noting that there may be a need for Australian data in some areas. 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.

The proposed time and fee savings are presented below in Table 3. The application of these savings will require the development of a project plan as a component of pre-application assessment and will be based on the submission of a suitable international assessment along with the underlying data.

Table 3: International assessment – time and fee saving

Area	Module without international assessment	Module with relevant international assessment (new module structure)
Chemistry	Chemistry 1	Chemistry 3
	Chemistry 2	Chemistry 3
Efficacy and Safety	Case by case for discussion at pre-application assessment. Use elements of international assessment to the fullest extent possible and apply relevant cost/time savings as appropriate.	
Environment	Environment 1	Environment 2
	Environment 2	Environment 3
Health	Health 1	Health 3
Residues	Residues 1	Residues 2
	Residues 2	Residues 4