



Australian Government
**Australian Pesticides and
Veterinary Medicines Authority**

Agricultural and Veterinary Chemicals Code Instrument No. 2 (Modular Assessment Fees) 2005

I, Roland Joseph Smith, Chief Executive Officer of the Australian Pesticides and Veterinary Medicines Authority, acting in accordance with my powers under subsection 32(1) of the *Agricultural and Veterinary Chemicals (Administration) Act 1992*, make this Instrument for the purposes of subsections 164(1A) and 165(1A) of the Agricultural and Veterinary Chemicals Code (the Agvet Code) scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*.

RJ Smith
Chief Executive Officer

Dated this Twenty-first day of June 2005

Part 1 Preliminary

1. Name of Instrument

This Instrument is the *Agricultural and Veterinary Chemicals Code Instrument No. 2 (Modular Assessment Fees) 2005*.

2. Commencement

This Instrument commences on 1 July 2005.

3. Object

The object of this Instrument is to set out criteria which, in circumstances when the modular assessment fee as provided by regulation 71 of the Agvet Regulations is to apply to a particular application made under the Agvet Code, describes which levels and types of modules, as set out in Schedule 7 of the Agvet Regulations, are to apply to the application.

4. Interpretation

(1) Unless the contrary intention appears, an expression used in the Agvet Code Act or the Agvet Regulations and in this Instrument has the same meaning in this Instrument as in the Agvet Code Act or the Agvet Regulations.

(2) In this Instrument, unless the contrary intention appears:

Acceptable Daily Intake (ADI) means the daily intake of a chemical which, during an entire lifetime, appears to be without appreciable risk to the health of the consumer on the basis of all the known facts at the time. The ADI is expressed in milligrams of the chemical per kilogram of body weight per day (mg/kg/day).

Acute Reference Dose (ARfD) means the estimate of the amount of a substance in food or drinking water, that can be ingested in one meal or during one day, without appreciable health risk to the consumer, on the basis of all known facts at the time. The ARfD is expressed in milligrams of the chemical per kilogram of body weight (mg/kg).

biological chemical product means an agricultural or veterinary chemical product where the active constituent comprises or is derived from a living organism (plant, animal, micro-organism, etc), with or without modification.

biotechnology chemical product is one that is developed by means of one of the following biotechnological processes

- (a) recombinant DNA technology;
- (b) controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes including transformed mammalian cells; or
- (c) hybridoma and monoclonal antibody methods.

Category, in relation to an application, means an item in Column 1 of Schedule 6 of the Agvet Regulations.

drug and poison scheduling in relation to a chemical substance means the determination by the National Drugs and Poisons Schedule Committee established by section 52B of the *Therapeutic Goods Act 1989* of the schedule to the Poisons Standard in which the name or description of the substance is included.

genetically-modified organisms (GMOs) are biotechnology chemical products.

immunobiological chemical product means a product which, when administered to the host, provides, induces or changes an immune response to a target chemical or biological entity. Immunobiological products include vaccines, antisera, antibodies and cytokines.

NDPSC means the National Drugs and Poisons Schedule Committee established by section 52B of the *Therapeutic Goods Act 1989*.

new active constituent means an active constituent that, at the time an application in respect of that active constituent is lodged with the APVMA, has not been approved in Australia.

new chemical product means a chemical product that, at the time an application in respect of that chemical product is lodged with the APVMA, has not been registered in Australia.

new source of active constituent means:

- (a) a new manufacturing source of an approved active constituent for an agricultural chemical product where, at the time an application in respect of that active constituent is lodged with the APVMA, that source has not been approved by the APVMA; or
- (b) a new manufacturing source of an approved active constituent for a veterinary chemical product that is an ectoparasiticide and for which there is no compendial standard, and where, at the time an application in respect of that active constituent is lodged with the APVMA, that source has not been approved by the APVMA.

reference product means reference chemical product as defined in section 3B of the Agvet Regulations.

Part 2 *Criteria for Working out which Application Module Applies*

5. Module 1 – Screening (Fee of \$460)

This module applies to all modular assessment fee applications (that is, categories 2, 10, 14, 23, 24 and 25) for:

- (a) approval of an active constituent for agricultural or veterinary chemical products;
- (b) registration of agricultural or veterinary chemical products;
- (c) approval of a label for containers for an agricultural or veterinary chemical product;
- (d) a variation to the particulars or conditions of approval of an active constituent for agricultural or veterinary chemical products;
- (e) a variation to the particulars or conditions of registration of agricultural or veterinary chemical products;
- (f) a variation to the particulars or conditions of approval of a label for containers for an agricultural or veterinary chemical product;
- (g) a permit in relation to agricultural or veterinary chemical products;
- (h) any other application requiring scientific or technical assessment by the APVMA.

6. Module 2 – Chemistry

(1) Module 2.1 – Level 1 Comprehensive Assessment (Fee of \$2,960)

- (a) A comprehensive chemistry assessment is required for applications for new agricultural or veterinary chemical products containing a new active constituent which meet any of the following criteria:
 - (i) an active constituent manufactured by chemical synthesis;
 - (ii) a highly purified and well-characterised active constituent derived from plants or animals;
 - (iii) a semi-synthetic active constituent manufactured by the chemical modification of a highly purified and well-characterised intermediate derived from plants or animals;
 - (iv) a semi-synthetic active constituent manufactured by the chemical modification of an intermediate produced by conventional fermentation;
 - (v) an active constituent produced by conventional fermentation or using recombinant DNA technology (excluding veterinary biologicals described in paragraph 6(2)(a) below);

- (vi) an active constituent produced by transgenic technology (excluding veterinary biologicals described in paragraph 6(2)(a) below);
- (vii) an active constituent that is a growth regulator, antibiotic or polypeptide; or
- (viii) some animal tissue extracts and some plant extracts/oils.

(2) Module 2.2 – Level 2 Reduced Assessment (Fee of \$2,025)

- (a) A reduced chemistry assessment is required for applications for agricultural or veterinary chemical products of the following type:
 - (i) new biological products containing a new active constituent except those included in subsection 6(1);
 - (ii) new agricultural chemical products containing a new active constituent which is used in household or industrial chemicals;
 - (iii) new agricultural chemical products containing a new source of existing active constituent;
 - (iv) new ectoparasiticide veterinary chemical products containing a new source of existing active constituent (for which there is no acceptable compendial standard);
 - (v) new veterinary immunobiological chemical products containing a new active constituent;
 - (vi) veterinary immunobiological chemical products with a major change to seed strains (including substitution of source or the addition of antigen);
 - (vii) new veterinary direct-fed microbial products containing a new active constituent;
 - (viii) new veterinary enzyme products containing a new active constituent;
 - (ix) new veterinary herbal products containing a new active constituent; or
 - (x) new agricultural or veterinary chemical products where the active constituent in the chemical product has been previously assessed in an application for a permit in relation to that chemical product
- (b) For the purposes of subparagraph 6(2)(a)(ii) an active constituent used in household and industrial chemicals includes certain solvents, surfactants and oils used to dilute or spread other agricultural chemicals, some disinfectants, and biocides used to control moulds and fungi in agriculture which are commonly-used household or industrial chemicals. If these chemicals are well known, in common use and have a history of safety in the context of use, they qualify for reduced chemistry assessment.

- (c) A reduced chemistry assessment is required for applications for a permit in relation to agricultural and veterinary chemical products containing a new active constituent.
 - (d) A reduced chemistry assessment is required for any other application for chemical products with a new active constituent which require a chemistry assessment that is not in subsection 6(1) above.
- (3) Module 2.3 – Level 3 Assessment (Fee of \$935)**
- (a) This chemistry assessment is required for applications for new agricultural or veterinary chemical products containing an existing active constituent requiring an assessment of chemistry and manufacture data for the product only.
- (4) Module 2.4 – Level 4 Limited Assessment (Fee of \$180)**
- (a) A limited chemistry assessment is required for applications for a variation to the particulars or conditions of registration of agricultural or veterinary chemical products including:
 - (i) minor formulation changes requiring technical assessment;
 - (ii) changes to product specifications with or without a change in manufacturing process; or
 - (iii) changes to non-active constituent specifications requiring technical assessment.
 - (b) A limited chemistry assessment is required for applications for a variation to the particulars or conditions of registration of agricultural or veterinary chemical products which meet any of the following criteria:
 - (i) extension of shelf life;
 - (ii) extension of in-use shelf life;
 - (iii) changes to storage temperature and/or conditions;
 - (iv) changes to packaging material (immediate container and/or closure system); or
 - (v) other applications where assessment of stability data may be required.
 - (c) A limited chemistry assessment is required for all applications for a variation to the particulars or conditions of registration of immunobiological chemical products.
 - (d) A limited chemistry assessment is required for applications for a permit in relation to a variation to the particulars or conditions of registration of agricultural or veterinary chemical products where chemistry assessment is required (for example, an extension of the shelf life of a batch of product).

- (e) A limited chemistry assessment is required for any other application for chemical products which require a chemistry assessment that is not in subsection 6(1) or 6(2) or paragraph 6(4) (a) to (d) above.

7. Module 3 – Toxicology (not requiring poison schedule classification)

(1) Module 3.1 – Level 1 Comprehensive Assessment (Fee of \$17,720)

- (a) A comprehensive toxicology assessment is required for applications of the following type:
 - (i) applications for:
 - (A) new agricultural or veterinary chemical products; or
 - (B) a permit in relation to agricultural or veterinary chemical products;containing a new active constituent and which are for food-producing use unless included in subsections 7(2) or 7(3) below.

(2) Module 3.2 – Level 2 Reduced Assessment (Fee of \$13,290)

- (a) A reduced toxicology assessment is required for applications of the following type:
 - (i) applications for:
 - (A) new agricultural or veterinary chemical products; or
 - (B) a permit in relation to agricultural or veterinary chemical products;containing a new active constituent and which are for non-food-producing use;
 - (ii) applications for:
 - (A) new agricultural or veterinary chemical products;
 - (B) a variation to the particulars or conditions of registration of agricultural or veterinary chemical products; or
 - (C) a permit in relation to agricultural or veterinary chemical products;containing an existing active constituent and which involve an extension of use from non-food-producing to food-producing use for the first time for any chemical product containing the active constituent which the chemical products contain (so that an ADI, with or without an ARfD, is required); or
 - (iii) applications for a research permit in relation to agricultural or veterinary chemical products which contain a new active constituent and are for food-producing use with restrictions including single season, single use, or specified research personnel.

(3) Module 3.3 – Level 3 Limited Assessment (Fee of \$2,635)

- (a) A limited toxicology assessment is required for applications of the following type:
- (i) applications for:
 - (A) new agricultural chemical products; or
 - (B) a permit in relation to agricultural or veterinary chemical products;
containing an existing active constituent and which involve a new formulation or a major change in formulation;
 - (ii) applications for new biological chemical products containing a new active constituent, adjuvant or excipient;
 - (iii) applications for:
 - (A) new agricultural or veterinary chemical products; or
 - (B) a variation to the particulars or conditions of registration of agricultural chemical products;
containing an existing active constituent and which involve an extension of use from commercial use to use by a householder in the home or home garden;
 - (iv) applications involving a change to one or more of the following:
 - (A) label safety directions (hazard statements);
 - (B) label first aid statements; or
 - (C) poison scheduling;
 - (v) applications for a research permit in relation to agricultural or veterinary chemical products containing a new active constituent and which are for non-food-producing use with restrictions including single season, single use, or specified research personnel
 - (vi) applications for:
 - (A) new agricultural or veterinary chemical products; or
 - (B) a permit in relation to agricultural or veterinary chemical products;
containing a new active constituent and where an acceptable overseas report or health assessment report has been supplied;
- (b) For the purposes of subparagraph 7(3)(a)(vi), an acceptable overseas report or health assessment report means a comprehensive toxicological assessment report on the active constituent which is of OECD-acceptable quality and dated 1 July 2005 or later. Summary reports would not be sufficient to qualify an application for a limited

toxicological assessment and a comprehensive or reduced assessment would be required.

- (c) A limited toxicology assessment is required for any other application for chemical products which require a toxicology assessment that is not in subsection 7(1) or (2) above.
 - (d) For the purposes of subparagraph 7(3)(a)(i), a major formulation change means a change to the formulation of an agricultural or veterinary chemical product, including new combinations of existing active constituents, such that safety to humans, the environment and/or target species may need separate assessment. For example, where:
 - (i) there has been a significant increase in the concentration of the active constituent which could affect the hazard potential, poison scheduling, safety directions or residues;
 - (ii) a major change in non-active constituent which significantly affects the performance, stability or other attributes of the product; or
 - (ii) the formulation has been changed significantly to accommodate a new application method or use-pattern (for example, changing from a wettable powder to an emulsifiable concentrate or changing from an oral drench to a topical pour-on dosage form).
- (4) Several types of applications for chemical products do not require toxicological assessment (Module 3 or 4) as they are not normally associated with any potential risks to human health. Where, however, there is any such risk, an appropriate toxicological assessment is required. The types of application for chemical products which do not normally require toxicological assessment are as follows:
- (a) applications for veterinary chemical products that are:
 - (i) mineral, vitamin and nutritional supplements for a single animal or a small number of animals and administered directly to the animal or administered daily in food or water;
 - (ii) animal bacterial and viral vaccines;
 - (iii) direct-fed microbial products where all the microbial active constituents are approved and have been previously considered by the National Drugs and Poisons Schedule Committee (NDPSC); or
 - (iv) enzyme products where all the active constituents are approved and have been previously considered by the NDPSC;
 - (b) applications for veterinary chemical products that are applications for an extension of use to non-food-producing animals; or
 - (c) applications for agricultural or veterinary chemical products that are applications for small scale trial permits authorized under APVMA permit 7250 (copy attached at Attachment A).

8. Module 4 – Toxicology (requiring poison schedule classification) (Fee of \$3,380)

This additional module applies to any modular assessment fee application (that is, category 2, 10, 14, 23, 24 or 25) for an agricultural or veterinary chemical product, where the application must be referred to the NDPSC for poisons scheduling, as required under Toxicology Modules 3.1, 3.2 or 3.3 (subsections 7(1), 7(2) and 7 (3) of this Instrument, respectively).

9. Module 5 – Residues

(1) Residues assessment includes the establishment of residue 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).

(2) Module 5.1 – Level 1 Comprehensive Assessment (Fee of \$5,085)

(a) A comprehensive residues assessment – comprising residues definition, MRLs, WHPs, and the assessment of trade implications – is required for applications of the following type:

(i) applications for:

- (A) new agricultural chemical products containing a new active constituent and which are for use on a food crop;
- (B) new agricultural chemical products containing an existing active constituent and which involve an extension of use from a non-food crop to a food crop;
- (C) a variation to the particulars or conditions of registration of agricultural chemical products containing an existing active constituent and which involve an extension of use from a non-food crop to a food crop; or
- (D) a permit in relation to agricultural chemical products containing a new active constituent and which are for use on a food crop;

(ii) applications for:

- (A) new veterinary chemical products containing a new active constituent and which are for use in/on food-producing animals;
- (B) new veterinary chemical products containing an existing active constituent and which involve an extension of use from companion animals to food-producing animals for the first time for any chemical product containing the active constituent which the veterinary chemical products contain;
- (C) a variation to the particulars or conditions of registration of veterinary chemical products containing an existing active constituent and which involve an extension of use

from companion animal to food-producing animals for the first time for any chemical product containing the active constituent which the veterinary chemical products contain;

- (D) new veterinary chemical products containing an existing active constituent and which have a new route of administration in food-producing animals; or
- (E) a permit in relation to veterinary chemical products containing a new active constituent and which are for use in/on food-producing animals.

(3) Module 5.2 – Level 2 Reduced Assessment – Product Registration only (Fee of \$4,330)

- (a) A reduced residues assessment – comprising MRLs, WHPs, and the assessment of trade implications – is required for applications of the following type:
 - (i) applications for:
 - (A) new agricultural chemical products; or
 - (B) a variation to the particulars or conditions of registration of agricultural chemical products;
containing an existing active constituent and which involve an extension of use to or use in a major food crop; or
 - (ii) applications for agricultural chemical products involving a major formulation change;
 - (iii) applications for:
 - (A) new veterinary chemical products; or
 - (B) a variation to the particulars or conditions of registration of veterinary chemical products;
containing an existing active constituent and which involve an extension of use to or use in/on new food-producing animals;
 - (iv) applications for:
 - (A) new veterinary chemical products; or
 - (B) a variation to the particulars or conditions of registration of veterinary chemical products;
containing an existing active constituent and which have an increased dose rate or frequency of application to food-producing animals and where a change to MRLs are required.
- (b) Applications for variation to the approval of a label of veterinary chemical products which have potential risks of residues and where a change to MRLs are required.

- (c) For the purposes of subparagraph 9(3)(a)(ii), a major formulation change has the same meaning as in paragraph 7(3)(d).
- (4) **Module 5.3 – Level 3 Reduced Assessment – Permit only (Fee of \$2,265)**
 - (a) A reduced residues assessment – comprising MRLs and WHPs – is required for applications for a permit in relation to agricultural and veterinary chemical products of the following type:
 - (i) applications for a permit in relation to agricultural chemical products containing an existing active constituent for use in a new food crop; or
 - (ii) applications for a permit in relation to veterinary chemical products containing an existing active constituent for use in/on new food-producing animals.
- (5) **Module 5.4 – Level 4 Limited Assessment – Product Registration only (Fee of \$2,025)**
 - (a) A limited residues assessment – comprising WHPs and, where necessary, MRLs and the assessment of trade implications – is required for applications for agricultural chemical products of the following type:
 - (i) applications for:
 - (A) new agricultural chemical products; or
 - (B) variations to the particulars or conditions of registration of agricultural chemical products;
containing an existing active constituent and which involve an extension of use to or use in a non-major food crop; or
 - (ii) applications for variation to the approval of a label of agricultural chemical products which have potential risks of residues.
 - (b) A limited residues assessment – comprising WHPs and, where necessary, assessment of trade implications – is required for applications for veterinary chemical products of the following type:
 - (i) applications for new veterinary chemical products containing an existing active constituent and which involve existing use patterns. Such applications are limited to non-aqueous injectables, pour-ons, intramammary dry cow infusions, implants and intraruminal devices only;
 - (ii) applications for veterinary chemical products – being non-aqueous injectables, pour-ons, intramammary dry cow infusions, implants and intraruminal devices only – involving a change in formulation;

- (iii) applications for variation to the approval of a label of veterinary chemical products which have potential risks of residues and where no change to MRLs are required; or
- (iv) applications for new veterinary chemical products containing an existing active constituent which are similar to a reference product except for a shorter WHP.
- (c) A limited residues assessment is required for any other application for chemical products which require a residues assessment that is not in subsections 9(2) or 9(3) or paragraphs 9(5)(a) or 9(5)(b) above.
- (6) Module 5.5 – Level 5 Limited Assessment – Permit only (Fee of \$1,070)**
 - (a) A limited residues assessment – comprising WHPs and, where necessary, MRLs – is required for applications for agricultural and veterinary chemical products of the following type:
 - (i) applications for a minor use, emergency use or a research permit in relation to agricultural chemical products containing an existing active constituent for use on a food crop; or
 - (ii) applications for a minor use, emergency use or a research permit in relation to veterinary chemical products containing an existing active constituent for use in/on food-producing animals.

10. Module 6 – Occupational Health and Safety (OH&S)

- (1) Module 6.1 – Level 1 Comprehensive Assessment (Fee of \$3,920)**
 - (a) A comprehensive OH&S assessment is required for applications for new agricultural chemical products containing new active constituents including biological chemical products.
- (2) Module 6.2 – Level 2 Reduced Assessment (Fee of \$2,635)**
 - (a) A reduced OH&S assessment is required for applications of the following type:
 - (i) applications for a research permit for use of agricultural chemical products containing a new active constituent and where the permit is for use by all persons;
 - (ii) applications for agricultural chemical products containing an existing active constituent and which involve a major formulation change;
 - (iii) applications for:
 - (A) new agricultural chemical products; or
 - (B) variations to the particulars or conditions of registration of agricultural chemical products;

containing an existing active constituent and which involve a new crop group or new situation and/or a new application method;

- (iv) applications for:
 - (A) new veterinary chemical products; or
 - (B) a permit in relation to veterinary chemical products containing a new active constituent and which are for use in/on food-producing animals (including biologicals);
- (v) applications for:
 - (A) new veterinary chemical products; or
 - (B) a permit in relation to veterinary chemical products containing a new active constituent and which are for use in/on non-food-producing animals (excluding biologicals).
- (b) For the purposes of subparagraph 10(2)(a)(ii), a major formulation change has the same meaning as in paragraph 7(3)(d).

(3) Module 6.3 – Level 3 Limited Assessment (Fee of \$1,305)

- (a) A limited OH&S assessment is required for applications of the following type:
 - (i) applications for a permit in relation to agricultural chemical products containing an existing active constituent and which involve a new application method or a new use situation and where the permit is for use by all persons;
 - (ii) applications for:
 - (A) new veterinary chemical products;
 - (B) a variation to the particulars or conditions of registration of veterinary chemical products; or
 - (C) a permit in relation to veterinary chemical products containing an existing active constituent and which involve a major formulation change and/or a change of use pattern; or
 - (iii) applications for a variation to the particulars or conditions of approval of a label for agricultural or veterinary chemical products which involve a change or reassessment of user safety directions and/or re-entry or re-handling statements.
- (b) A limited OH&S assessment is required for any other application for chemical products which require an OH&S assessment that is not in subsections 10(1) or 10(2) or paragraph 10(3)(a) above.

- (4) Several types of applications for chemical products do not require OH&S assessment as they are not normally associated with any potential risks to human health. Where, however, there is any such risk, an appropriate

toxicological assessment is required. The types of application for chemical products which do not normally require OH&S assessment are as follows:

- (a) applications for veterinary chemical products that are:
 - (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 (TGA) 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 single animal or a small number of animals and 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 companion animals;
 - (vi) stock feed 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;
 - (vii) animal bacterial and viral vaccines;
 - (viii) extension of use applications to non-food animals; or
 - (ix) a research permit in relation to veterinary chemical products.
- (b) applications for agricultural chemical products that are:
 - (i) products to be used by the householder in the home and home garden; or
 - (ii) a research permit in relation to agricultural chemical products, excluding new application method or new use situation (existing active constituents) for use by all persons.
- (c) applications for agricultural and veterinary chemical products that are microbial products where all the microbial active constituents are approved active constituents.

11. Module 7 – Environment

(1) Phase I Environmental impact assessment for veterinary medicinal products

Phase I environmental impact assessment applies to veterinary chemical products other than biological products. It is assumed that veterinary chemical products with limited use and limited environmental exposure will have

limited environmental effects and thus stop in Phase I, meaning that no further environmental assessment is required.

If a veterinary chemical product meets any of the following criteria it stops in Phase I:

- (a) it is exempt from the need for environmental assessment by legislation and/or regulation;
- (b) it is a natural substance, the use of which will not alter the concentration or distribution of the substance in the environment;
- (c) it will be used only in non-food-producing animals;
- (d) it is intended for use in a minor species that is reared and treated similarly to a major species for which an environmental impact assessment already exists;
- (e) it will be used to treat a small number of animals in a flock or herd (for example: intramammary products, surgical anaesthetics, and hormonal reproductive aids for individual animals);
- (f) it is extensively metabolised in the treated animal;
- (g) it is for use in terrestrial species and entry to the terrestrial environment is prevented through disposal of the terrestrial waste matrix;
- (h) it is for use in terrestrial species, it is neither an ectoparasiticide nor an endoparasiticide, and the predicted environmental concentration of the chemical product in the soil (PEC_{soil}) is less than 100 $\mu\text{g}/\text{kg}$; or
- (i) it is for use in aquatic species reared in a confined facility, it is neither an ectoparasiticide nor an endoparasiticide, and the environmental introduction concentration ($EIC_{aquatic}$) of the chemical product released from aquaculture facilities is less than 1 $\mu\text{g}/\text{L}$.

Some veterinary chemical products which might otherwise stop in Phase I may nevertheless require additional environmental information for assessment to address particular concerns associated with their activity and use. For example, exceptional cases will require environmental assessment where the proposed product/use could have a potentially significant impact on a threatened or endangered species, wetland, floodplain, cultural or historical resource, or other environmentally significant resource.

Veterinary chemical products which progress to Phase II will require assessment of environmental aspects under Modules 7.1 or 7.2 or 7.3 as described below.

(2) Module 7.1 – Level 1 Comprehensive Assessment (Fee of \$11,460)

- (a) A comprehensive environment assessment is required for applications of the following type:
 - (i) applications for new agricultural or veterinary chemical products containing a new active constituent (unless included in subsections 11(1), 11(3) or 11(4)); or

- (ii) applications for new agricultural chemical products containing a new combination of approved active constituents and where the new product involves an extension of use to a new crop or a new situation.

(3) Module 7.2 – Level 2 Reduced Assessment (Fee of \$2,960)

- (a) A reduced environment assessment is required for applications of the following type:
 - (i) applications for:
 - (A) new agricultural or veterinary chemical products; or
 - (B) a variation to the particulars or conditions of registration of agricultural or veterinary chemical products;
containing existing active constituents and where the new product or variation involves an extension of use to a new crop, a new situation or a new herd animal;
 - (ii) applications for:
 - (A) new agricultural or veterinary chemical products; or
 - (B) a variation to the particulars or conditions of registration of agricultural or veterinary chemical products;
which involve a major formulation change or an increased dose rate or frequency of application;
 - (iii) applications for a variation to the particulars or conditions of registration of agricultural chemical products involving an extension to aerial use; or
 - (iv) applications for a permit in relation to agricultural or veterinary chemical products containing a new active constituent.
- (b) For the purposes of subparagraph 11(3)(a)(ii), a major formulation change has the same meaning as in paragraph 7(3)(d).

(4) Module 7.3 – Level 3 Limited Assessment (Fee of \$565)

- (a) A limited environment assessment is required for applications of the following type:
 - (i) applications for:
 - (A) new agricultural chemical products (other than a vertebrate poison); or
 - (B) a variation to the particulars or conditions of registration of agricultural chemical products (other than a vertebrate poison);
containing new or existing active constituents and where the product is for use:
 - (A) by the householder in the home or home garden;

- (B) by the householder in a swimming pool or spa;
- (C) in buildings not used in animal production (for example, warehouses, offices, or glasshouses);
- (D) as a treatment for stored produce or goods; or
- (E) as a post-harvest application to any crop;
- (ii) applications for a variation to the approval of a label of agricultural or veterinary chemical products involving environmental instructions or warnings; or
- (iv) applications for a permit in relation to agricultural or veterinary chemical products containing existing active constituents.
- (b) A limited environment assessment is required for any other application for chemical products which require an environment assessment that is not in subsections 11(2) or 11(3) or paragraph 11(4)(a) above.
- (5) Several types of applications for veterinary chemical products do not require environmental assessment as they are not normally associated with any potential risks to the environment. Where, however, there is any such risk, an appropriate environmental assessment is required. The types of veterinary applications which do not normally require environmental assessment are:
 - (a) animal therapeutics and mineral and nutritional supplements in single, capsule, slow release bolus or skin implant form other than parasiticides;
 - (b) animal immunobiological products (except those containing GMOs);
 - (c) animal therapeutics given by injection for use under prescription in individual animals;
 - (d) applications for extension of use of a registered product in/on non-food animals; or
 - (e) animal therapeutics which are included in the Phase I Environmental Impact Assessment for Veterinary Medicinal Products as described in paragraph 11(1) above.

12. Module 8 – Efficacy and Safety

- (1) Assessment of efficacy and safety refers to assessment of efficacy and host crop or animal safety and includes (as relevant to either agricultural or veterinary chemical products as the case may be):
 - (a) assessment of the results of experimental trials for efficacy and safety;
 - (b) effect on following crops or non-target crops;
 - (c) organoleptic tests;
 - (d) effects of residues on subsequent processing of crops;
 - (e) safety to non-target crops;

- (f) pharmacologic studies; or
 - (g) compatibility studies.
- (2) In this module the term “food-producing animal” includes fibre-producing species of animals such as sheep, goats, llamas and alpacas.
- (3) **Module 8.1 – Level 1 Comprehensive Assessment (Fee of \$1,695)**
- (a) A comprehensive efficacy and safety assessment is required for applications of the following type:
 - (i) applications for new agricultural chemical products containing:
 - (A) a new active constituent;
 - (B) a new combination of existing active constituents; or
 - (C) a significant new formulation not included in module 8.2 below;
 - (ii) applications for new or existing agricultural chemical products containing an existing active constituent and which are for use in a new crop group or new situation and/or for the control of new pests;
 - (iii) applications for new veterinary chemical products containing a new active constituent or a new combination of existing active constituents and which involve use in/on a food-producing animal; or
 - (iv) applications for new or existing veterinary chemical products containing an existing active constituent and which involve use in/on a new food-producing animal.
- (4) **Module 8.2 – Level 2 Reduced Assessment (Fee of \$680)**
- (a) A reduced efficacy and safety assessment is required for applications of the following type:
 - (i) applications for existing agricultural chemical products which involve an extension of use to a new host or a new pest within the same crop group or situation and with the same general use pattern;
 - (ii) applications for new or existing agricultural chemical products containing an existing active constituent and which involve:
 - (A) new household or home garden use;
 - (B) an extension of use involving a new minor use for new pests where the use and the pests are closely similar to an existing use pattern; or
 - (C) a significant new formulation requiring reduced assessment of both efficacy and safety;

- (iii) applications for new veterinary chemical products for use in/on companion animals;
 - (iv) applications for new or existing veterinary chemical products involving an extension of use to a new companion animal species;
 - (v) applications for new or existing veterinary chemical products involving an extension of use to a new pest or disease or for a new purpose in/on the same food-producing animal;
 - (vi) applications for new or existing veterinary chemical products involving a change to the dosage or administration instructions – including treatment number, frequency, duration, dose, and route of administration – in/on the same food-producing animal; or
 - (vii) applications for new or existing veterinary chemical products for use in/on a food-producing animal with a new formulation which is not the same, nor closely similar, nor similar to a reference product.
- (b) For the purposes of subparagraphs 12(4)(a)(iii) or (iv), a companion animal means a dog, cat or horse.

(5) Module 8.3 – Level 3 Limited Assessment (Fee of \$455)

- (a) A limited efficacy and safety assessment is required for applications of the following type:
- (i) applications for new agricultural chemical products where efficacy and safety data are required to demonstrate similarity to an existing registered product;
 - (ii) applications for variation to:
 - (A) the particulars or conditions of registration of existing agricultural chemical products involving a formulation change; or
 - (B) the approval of a label of existing agricultural chemical products;
 which are expected to have a minor impact on efficacy or crop safety;
 - (iii) applications for variation to the particulars or conditions of registration of agricultural chemical products which involve an extension of use to a minor use within the same crop group or situation and which involve an existing pest and application rate;
 - (iv) applications for a permit in relation to agricultural chemical products which involve a minor use on a new crop or situation;

- (v) applications for new veterinary chemical products where efficacy and safety data are required to demonstrate similarity to an existing registered product;
 - (vi) applications for new veterinary chemical products for use in/on a non-food producing animal other than a dog, cat or horse;
 - (vii) applications for existing veterinary chemical products which involve an extension of use to a new non-food producing animal other than a dog, cat or horse;
 - (viii) applications for variation to:
 - (A) the particulars or conditions of registration of existing veterinary products involving a formulation change; or
 - (B) the approval of a label of existing veterinary products; which are expected to have a minor impact on efficacy or host animal safety;
 - (ix) applications for a permit in relation to veterinary chemical products which involve a minor use in/on a new animal species;
 - (x) applications for veterinary chemical products which involve demonstration of pharmaceutical equivalence with a registered product; or
 - (xi) any other application for chemical products which require an efficacy and/or safety assessment of a type that is not included in subsections 12(3), 12(4) or 12(5) above.
- (6) For the purposes of section 12, a major formulation change means a change to the formulation of an agricultural or veterinary chemical product, including new combinations of existing active constituents, such that efficacy and/or safety to the host crop/animal requires assessment. For example, where:
- (a) there has been a significant change in the concentration of active constituent and where the application/dose rate to the crop/animal is changed;
 - (b) a major change in non-active constituent significantly affects the performance, stability or other attributes of the product;
 - (c) there has been a significant change in product specifications;
 - (d) the formulation has been changed significantly to accommodate a new application method or use-pattern (for example, changing from a wettable powder to an emulsifiable concentrate or changing from an oral drench to a topical pour-on dosage form); or
 - (e) the new formulation is not identical, nor closely similar, nor similar to a registered reference product.

- (7) Applications for major changes in formulation require assessment under Module 8.1. However, applicants may provide valid scientific argument regarding submission of relevant efficacy/safety data to justify a different level of assessment. For example:
- (a) if the change in formulation is likely to affect only efficacy **or** safety, then assessment under Module 8.3 would be appropriate; or
 - (b) data to demonstrate comparable efficacy/bioequivalence with the previous formulation would be assessed under Module 8.3.
- (8) For the purposes of subparagraphs 12(3)(a)(iii), 12(3)(a)(iv), 12(4)(a)(v), 12(4)(a)(vi), and 12(4)(a)(vii), a food-producing animal is any animal used to produce food for human consumption, or which is used as food for human beings, and includes any buffalo, cattle, deer, fish (other than ornamental fish), goat, kangaroo, pig, poultry, rabbit, sheep, bee, crustacean or mollusc. For the purposes of efficacy and safety this includes fibre-producing animal species, which is any animal used to produce fibre (including wool and mohair) for human use.

New products for use in/on food or fibre-producing animal species – other than cattle, sheep, pigs and chickens – qualify for a reduced (Level 2) efficacy and safety assessment (for example: goats, llamas, alpacas, and emus).

13. Module 9 – Non-food trade (Fee of \$1,070)

- (1) This module applies to applications for agricultural and veterinary chemical products (as the case may be) involving trade risks not related to food residues, including :
- (a) residues in wool and fibre;
 - (b) the presence of disease or seropositive testing to exotic or notifiable agents;
 - (c) hormonal growth promotants and other endocrine substances; or
 - (d) genetically-modified produce.

14. Module 10 – Special Data

- (1) All modular assessment fee applications (that is, for categories 2, 10, 14, 23, 24 or 25) for the registration of chemical products which contain active constituents that are new antibiotic substances or which contain genetically-modified organisms (GMOs) require the submission of Special data.
- (2) **Module 10.1 – Level 1 Comprehensive Assessment (nil fee)**
- (a) A comprehensive Special Data assessment is required for applications of the following type:
 - (i) applications for new veterinary chemical products containing a new antibiotic active constituent; or

- (ii) applications for a permit in relation to veterinary chemical products containing a new antibiotic active constituent (other than for small-scale research).
- (3) Module 10.2 – Level 2 Reduced Assessment (nil fee)**
 - (a) A reduced Special Data assessment is required for applications of the following type:
 - (i) applications for:
 - (A) new veterinary chemical products; or
 - (B) a variation to the particulars or conditions of registration of veterinary chemical products;

containing an existing antibiotic active constituent and which is expected to result in significantly increased volume of use or an increased risk to public health including:

 - (A) an extension of use to a new food-producing species, or a dog or a cat;
 - (A) an extension of use to another major group within the same food-producing species (for example: broiler chickens to layers; beef cattle to dairy cattle); or
 - (B) a change in dosage form or use pattern (for example: from use in individual animals to mass medication).
 - (ii) applications for a permit in relation to veterinary chemical products containing an existing antibiotic active constituent and which are for use in/on a new animal species.
- (4) Module 10.3 – Level 3 Limited Assessment (nil fee)**
 - (a) A limited Special Data assessment is required for any application not included in Modules 10.1 or 10.2 which requires an assessment of Special Data including an assessment of agricultural or veterinary chemical products containing GMOs.

15. Module 11 – Finalisation

- (1)** This module encompasses administrative and technical steps in public consultation on and the finalisation of applications.
- (2) Module 11.1 – Type 1 (Fee of \$2,025)**
 - (a) This module applies to applications for:
 - (i) the registration of agricultural or veterinary chemical products;
 - (ii) a variation to the particulars or conditions of registration of agricultural or veterinary chemical products; or
 - (iii) a permit in relation to agricultural or veterinary chemical products;

which require three or more modular assessments from amongst the modules 2.1 through to 10.3, but excluding 2.4.

(3) Module 11.2 – Type 2 (Fee of \$1,070)

(a) This module applies to applications for:

- (i) the registration of agricultural or veterinary chemical products;
or
- (ii) a variation to the particulars or conditions of registration of agricultural or veterinary chemical products;

which require one or two modular assessments only from amongst the modules 2.1 through to 10.3.

(4) Module 11.3 – Type 3 (Fee of \$565)

(a) This module applies to applications for a permit in relation to agricultural and veterinary chemical products which require one or two modular assessments only from amongst the modules 2.1 through to 10.3.

(5) Module 11.4 – Type 4 (Fee of \$145)

(a) This module applies to any application involving

- (i) no technical assessment; or
- (ii) assessment under module 2.4 only.

16. Module 12 – Data Protection (Fee of \$155)

This module applies to any application which attracts the data protection provisions of Part 7B of the *Agricultural and Veterinary Chemicals (Administration) Act 1994*; or Division 4A of Part 2; or Part 3 of the *Agricultural and Veterinary Chemicals Code* scheduled to the *Agricultural and Veterinary Chemicals Code Act 1994*.

Part 3 Fees and Assessment Periods

17. Modular Assessment Fees

If, as a result of this Instrument, a module, level or type of assessment is appropriate for a particular application then the fee payable in respect of that module, level or type is the fee set out in column 4 of Schedule 7.

Note 1 For reference, the fee payable in respect of a module, level or type of assessment is set out (in brackets) in this Instrument beside that module, level or type.

Note 2 The method of working out the total modular assessment fee payable in respect of any particular application assessed by modular assessment is set out in regulation 71 of the Agvet Code Regulations.

18. Modular Assessment Periods

If, as a result of this Instrument, a module, level or type of assessment is appropriate for a particular application then the period within which the APVMA must complete that particular modular, level or type is the period set out in column 3 of Schedule 7.

Note 1 The method of working out the total modular assessment period within which the APVMA's assessment of any particular application, which is assessed by modular assessment, must be completed is set out in regulation 77 of the Agvet Code Regulations.



**Australian Pesticides &
Veterinary Medicines Authority**

PERMIT TO ALLOW THE CONDUCT OF SMALL-SCALE TRIALS WITH AGVET CHEMICALS

Permit Number – PER 7250

This permit, is issued under section 114 of the Agvet Codes, to allow those persons stipulated below to conduct small-scale trials in any jurisdiction, as defined in the conditions of use, with agricultural or veterinary chemical active constituents or products, whether such active constituents or products are approved or registered or not. The permit also allows those persons stipulated below to possess any active constituent or chemical product described below for the purposes described under this permit.

CONDITIONS OF USE

1. ***Persons who can conduct trials under this permit:***
All persons who are trained or experienced in the handling and use of agricultural or veterinary chemicals and who handle and use agricultural or veterinary chemicals as part of their normal duties in their employment for an organisation for which they are conducting a trial;
2. ***Jurisdictions in which this permit applies***
All jurisdictions.
3. ***Products/Actives that can be used under this permit***
Any active constituent or chemical product, except:
 - one which is or contains a genetically modified organism; or
 - veterinary biologicals used outside the confines of a research facility; or
 - any active constituent or chemical product used in a trial where the trial is conducted in a jurisdiction where that active constituent or chemical product is proscribed by legislation or
 - any active constituent or chemical product whose use has been prohibited under the Agricultural and Veterinary Chemicals (Administration) Regulations 2004.

4. Purpose/Situation

For the conduct of ‘Small-Scale Trials’ that, for the purposes of this permit, are defined as:

- (i) screening tests, laboratory assessment and other research conducted within the confines of a research facility. (A research facility includes research station, research laboratory, research glasshouse, veterinary surgery or hospital, university or similar institution); or
- (ii) trials conducted to generate data relating to efficacy, residues, crop or animal safety or other scientific information outside the confines of a research facility where the size of the trial annually does not exceed the following:
 - a. a total of 5 hectares nationally , with a maximum of 1 hectare in any one jurisdiction in the case of any food and/or fibre field crop or
 - b. a total of 500 plants nationally with a maximum of 100 plants in any one jurisdiction for plants other than those in a food and/or fibre field crop; or
 - c. a total of 100 cattle, pigs, or deer; 1000 sheep or goats; or 2000 poultry; or 100 non-food animal species; or
 - d. patch trials of antifouling paint products where the area treated on each vessel does not exceed 10 square metres and no more than 2 vessels in any one jurisdiction or a total of 10 vessels nationally are treated; or
 - e. raft panel trials using antifouling paints where the total national area of treated panel does not exceed 100 square metres with a maximum of 10 square metres treated at any one site; or
 - f. 5 cubic metres of timber or timber products in any one jurisdiction, or a total of 25 cubic metres nationally; or
 - g. any other situation where the total area treated nationally is not greater than 10 sq metres; or
 - h. fumigation trials conducted under the Australian Standard for General Fumigation Procedures (AS 2476-1981) where the total national area treated does not exceed 400 cubic metres with a maximum of 160 cubic metres to be treated per jurisdiction and no individual treatment site exceeds 40 cubic metres.

ADDITIONAL CONDITIONS

- 5. Do not dispose of any produce from plants or animals treated during a trial that can result in direct or indirect consumption of this produce by humans for a period of 12 months from application of the agricultural or veterinary chemical.
- 6. Do not dispose of or allow the use of any treated commodity or item that will result in direct or indirect exposure of humans to the agricultural or veterinary chemical used in the trial.
- 7. Persons handling/applying the agricultural or veterinary chemical for the purposes of conducting the trial must wear appropriate personal protective equipment to minimise their exposure to the agricultural or veterinary chemical via the eyes, skin, nose or mouth.

8. All trials involving animals must comply with conditions laid down in animal welfare legislation or guidelines, which are applicable in the jurisdiction where trials are conducted.
9. The organisation or individual for which the trial is being conducted must maintain detailed records listing:
 - a. the date the trial is conducted;
 - b. for trials conducted within the confines of a research facility, the name and address of the research facility; for trials conducted outside the confines of a research facility, the jurisdiction and specific location within each jurisdiction that the trials are conducted;
 - c. the trial details, including plants, animals or items treated, the pest controlled or reason for treating, the rates and frequency of application;
 - d. the active constituents or chemical products used plus the total amounts used;
 - e. the method of disposal of produce from treated plants or animals; and
 - f. the names of the persons conducting or controlling the trials.
10. The organisation or individual for which the trial is being conducted must maintain the records described in 9 a.- f. above for each trial for a period of not less than 2 years from the date of commencing each trial and such records must be made available to the APVMA upon their request.

This permit remains in force until it is cancelled.

DATED: 7 June 2004

Eva Bennet - Serlains

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(signature of delegate)