Agricultural and Veterinary Chemicals Code Regulations 1995

Statutory Rules 1995 No. 27 as amended

made under the

Agricultural and Veterinary Chemicals Code Act 1994

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Attorney-General’s Department, Canberra
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Part 1 Preliminary

1 Name of Regulations [see Note 1]

These Regulations are the Agricultural and Veterinary Chemicals Code Regulations 1995.

2 Commencement [see Note 1]

These Regulations commence on the same day as the Agricultural and Veterinary Chemicals Code Act 1994.

3 Interpretation

(1) In these Regulations, unless the contrary intention appears:


active constituent number, for an active constituent for a proposed or existing chemical product for which approval is sought in an application mentioned in section 11B of the Code, means the number that the APVMA gives to the active constituent after the application is lodged.

application number, for an application mentioned in section 11B, 28B or 34G of the Code, means the number that the APVMA gives to the application after the application is lodged.

approved active constituent means an active constituent approved under Part 2 of the Code.

biological pesticide means an agricultural chemical product containing, or derived from, a living organism, whether or not the organism is genetically modified.

block or lick means a blend or mixture of one or more stockfood ingredients compressed or poured into a solid block form for voluntary consumption by livestock.

British Pharmacopoeia means the book of that name published for the British Pharmacopoeia Commission.
Regulation 3

British Pharmacopoeia (Veterinary) means the book of that name published on the recommendation of the Medicines Commission of the United Kingdom.

chemical product number, for a chemical product for which registration is sought in an application mentioned in section 11B of the Code, means the number that the APVMA gives to the chemical product after the application is lodged.

Code means the Agvet Code of this jurisdiction.

CSIRO means the Commonwealth Scientific and Industrial Research Organization established by the Science and Industry Research Act 1949.

direct-fed microbial product means a chemical product that:
(a) contains viable micro-organisms; and
(b) is intended for oral administration to animals.

emergency use, in relation to a chemical product or an active constituent, means a use of the product or constituent arising from an emergency in which there is a genuinely believed need for the use of the product or constituent.

European Pharmacopoeia means the book of that name published for the European Pharmacopoeia Commission.

FAO Specifications for Plant Protection Products means the publications of that name published by the Food and Agriculture Organization of the United Nations.

formulation change, in relation to a chemical product, means:
(a) a change in the source of any active constituent of the product; or
(b) a variation in the amount or concentration of one or more of the active constituents, or other constituents, of the product; or
(c) the addition to the product, or removal from the product of one or more of the active constituents, or other constituents, of the product.

hormonal growth promotant means a veterinary chemical product containing a substance that is, or a mixture of substances that are, responsible for oestrogenic, androgenic or gestagenic activity to enhance growth or production in bovines or bubalines.
immunobiological product means a chemical product which, when administered to a vertebrate or invertebrate living creature, provides, induces or changes an immune response to a particular chemical or biological entity in that creature.

legal practitioner means a person who is admitted, and entitled to practise, as a barrister or solicitor in a State or Territory.

medical practitioner means a person registered or licensed as a medical practitioner under a law of a State or Territory.

medicated block or lick means a block or lick incorporating a veterinary chemical product.

medicated premix means a premix that incorporates one or more veterinary chemical products for the purpose of:
(a) preventing or treating disease; or
(b) enhancing growth, production, work or performance; or
(c) altering reproductive physiology.

medicated stockfood means a ready-to-use stockfood that incorporates one or more veterinary chemical products for the purpose of:
(a) preventing or treating disease; or
(b) enhancing growth, production, work or performance; or
(c) altering reproductive physiology.

minor use, in relation to a chemical product or an active constituent, means a use of the product or constituent that would not produce sufficient economic return to an applicant for registration of the product to meet the cost of registration of the product, or the cost of registration of the product for that use, as the case requires (including, in particular, the cost of providing the data required for that purpose).

modular assessment fee has the meaning given in regulation 71.

modular assessment period has the meaning given in regulation 77.

NATA means the National Association of Testing Authorities, Australia, a company having the Australian Company Number 004379748.

notification number, means a notification number assigned to a person under regulation 47.
**nutritional ingredient** includes, but is not limited to, the following:

(a) protein meals (as a protein source);
(b) fermentation products from human foods, (including brewer’s grains, yeasts and yeast extracts);
(c) hay, including lucerne hay and peanut hay;
(d) chaff;
(e) straw;
(f) grains, other similar seeds and the products of those grains or seeds;
(g) vitamins, minerals and amino acids at normal nutritional levels;
(h) salt, limestone and inorganic phosphorus sources;
(i) fats and oils;
(j) milk by-products;
(k) non-protein nitrogen sources;
(l) molasses.

**poison schedule classification**, in relation to a chemical product, means classification of the product or any of its constituents in the Standard for the Uniform Scheduling of Drugs and Poisons.

**pool or spa hypochlorite** means a chemical product that:

(a) is for use in a swimming pool or spa that is for use by human beings; and

(b) is a formulation of calcium hypochlorite, lithium hypochlorite or sodium hypochlorite that complies with the standard (if any) last published for that formulation by the National Registration Authority for Agricultural and Veterinary Products in the **Gazette** and in force on 31 October 1999.

*Note* The National Registration Authority for Agricultural and Veterinary Products is the former name of APVMA.

**premix** means a mixture that:

(a) contains vitamins, minerals, amino acids or other substances; and

(b) is intended to be added to stockfood to form a finished feed for feeding to a group of animals.
** Regulation 3 **

**purchaser declaration number** means a distinguishing number issued in respect of premises by a State or Territory or by an authority of a State or Territory, for the purpose of identifying those premises as premises where animals to be treated with a hormonal growth promotant are, or are to be, kept.

**reference active constituent** has the meaning given by regulation 3A.

**reference chemical product** has the meaning given by regulation 3B.

**Standard for the Uniform Scheduling of Drugs and Poisons** means the publication of that name published by the Department of Human Services and Health.

**stockfood** means a basic food or food mixture that:

(a) contains one or more nutritional ingredients; and

(b) is intended to be fed to animals for the maintenance of life, normal growth, production, work, reproduction or performance.

**stockfood non-active constituent** means any organic acid, antioxidant, pellet binding product, mould inhibitor, preservative, feed handling improver, colouring agent, anticaking agent, deodorising agent or other substance or mixture of substances intended to be added to stockfood for continuous, long-term administration to animals for a purpose other than:

(a) preventing or treating disease; or

(b) enhancing growth, production, work or performance; or

(c) altering reproductive physiology.

**stockfood supplement** means any substance or mixture of substances in the form of tablets, sachets or measures added to stockfood for administration to animals individually in order to supplement or balance that stockfood, but does not include a substance or mixture of substances in an injectable dose form, an intraruminal bolus, a block or a lick.

**supply**, in relation to any product or thing, includes cause or permit the supply of the product or thing.

Note  Section 3 of the Code provides that supply includes do, or cause or permit the doing of, any of the following:

(a) sell;
Regulation 3A

(b) expose for sale;
(c) send or deliver for sale or on sale;
(d) dispose of under a hire purchase agreement;
(e) exchange;
(f) give;
(g) offer to do an act that would be a supply (including an act referred to in any of the above paragraphs).

total leviable value has the same meaning as in the Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994.


(1A) Unless the contrary intention appears, an expression used in both these Regulations and the Code has the same meaning in these Regulations as in the Code.

(2) Unless the contrary intention appears, a reference in these Regulations to a book or other publication is a reference to the latest edition of that book or publication as modified or amended from time to time, and includes any addendum or other addition to the book or publication.

3A Meaning of reference active constituent

For these Regulations, reference active constituent, for an application mentioned in section 11B or 28B of the Code (the primary application), means an active constituent that:

(a) is the subject of another application, being an application under section 10 or 27 of the Code that was lodged before the primary application; and

(b) is referred to in the primary application because information that is relevant to the active constituent is also relevant to the primary application.
3B **Meaning of reference chemical product**

For these Regulations, *reference chemical product*, for an application mentioned in section 11B or 28B of the Code (the primary application), means a chemical product that:

(a) is the subject of another application, being an application under section 10 or 27 of the Code that was lodged before the primary application; and

(b) is referred to in the primary application because information that is relevant to the chemical product is also relevant to the primary application.

4 **Definition of date-controlled chemical product — section 3 of the Code**

For the purposes of the definition of *date-controlled chemical product* in section 3 of the Code, the following are declared to be date-controlled chemical products:

(a) each veterinary chemical product;

(b) an agricultural chemical product specified in Schedule 1.

5 **Definition of excluded organism — section 3 of the Code**

For the purposes of the definition of *excluded organism* in section 3 of the Code, a vertebrate animal is an excluded organism.

6 **Definition of protection period — section 3 of the Code**

(1) Subject to this regulation, the period, in years, in relation to protected registration information of a kind specified in columns 2 and 3 of an item in Schedule 2 is the period worked out in accordance with the formula:

\[ 2 + 5 \frac{A}{B} \]
where:

A is the number, or the total number, as the case requires, of points allocated to that item in column 4 of Schedule 2; and

B is 600.

(2) If the period worked out in accordance with subregulation (1) in relation to an item is not a whole number, it is to be rounded to the nearest whole number.

(3) If the period worked out in accordance with subregulations (1) and (2) in relation to an item is more than 7 years, the period is taken to be 7 years.

7 Definition of agricultural chemical product — section 4 of the Code

(1) For the purposes of subsection 4 (3) of the Code, a substance or mixture of substances included in any of the following classes of substances or mixtures of substances is declared to be an agricultural chemical product:

(a) dairy cleansers for on-farm use;

(b) any substance used in conjunction with an agricultural chemical product to identify areas treated with that product;

(c) insect repellents for use on human beings.

(2) For the purposes of paragraph 4 (4) (b) of the Code, a substance or mixture of substances included in a class of substances or mixtures of substances specified in Column 2 of an item in Schedule 3 is declared not to be an agricultural chemical product.

8 Definition of veterinary chemical product — section 5 of the Code

(1) For the purposes of paragraph 5 (3) (b) of the Code, a substance or mixture of substances included in any of the following classes of substances or mixtures of substances is declared to be a veterinary chemical product:
Regulation 8

(a) allergenic substances supplied or used for administration to an animal by any means, or for consumption by an animal;
(b) medicated blocks or licks;
(c) enzymes supplied or used for administration to an animal by any means, or for consumption by an animal;
(d) stockfood non-active constituents except stockfood non-active constituents excluded from this class by an order under section 7 of the Act;
(e) direct-fed microbial products;
(f) sheep branding substances.

(2) Section 7 of the Act (which deals with the power to make orders) applies to the prescription of stockfood non-active constituents excluded from the class described in paragraph (1) (d).

(3) For the purposes of paragraph 5 (4) (b) of the Code, a substance or mixture of substances included in any of the following classes of substances or mixtures of substances is declared not to be a veterinary chemical product:
(a) stockfoods;
(b) medicated stockfoods to which subregulation (4) applies;
(c) medicated premixes to which subregulation (4) applies;
(d) blocks and licks (other than medicated blocks or licks) to which subregulation (5) applies;
(e) premixes to which subregulation (5) applies;
(f) stockfood supplements to which subregulation (5) applies;
(g) colour intensifiers for aviary birds.

(4) This subregulation applies to a medicated stockfood or medicated premix if:
(a) any veterinary chemical product that is incorporated in the medicated stockfood or medicated premix:
   (i) is a registered chemical product; and
   (ii) is incorporated at a rate of use in accordance with the approved label for containers for that registered chemical product; and
(b) the container for the medicated stockfood or medicated premix is labelled in accordance with the instructions on the approved label for that registered chemical product.

(5) This subregulation applies to a block, lick, premix or stockfood supplement:

(a) for which the only claim on the label consists of the words ‘to supplement diets where levels may be low’, or words to that effect; and

(b) that incorporates, in respect of any vitamin, mineral or amino acid listed on the label, not less than 25% of the daily requirement of that vitamin, mineral or amino acid for the species for which the premix or stockfood supplement is intended.

(6) For the purposes of paragraph (5) (b), the daily requirement of a vitamin, mineral or amino acid is the amount of the vitamin, mineral or amino acid specified as the daily requirement by:

(a) if the species is a dog, cat or horse — the US National Research Council of the US National Academy of Sciences; or

(b) if the species is a ruminant, a pig or poultry — the relevant feeding standard.

(7) In paragraph (6) (b), the relevant feeding standard means:

(a) in the case of a ruminant — the standard ‘Feeding Standards for Australian Livestock: Ruminants Standing Committee on Agriculture, Ruminants Subcommittee East Melbourne 1990’, published by CSIRO; or

(b) in the case of a pig — the standard ‘Feeding Standards for Australian Livestock: Pigs Standing Committee on Agriculture, Pig Subcommittee East Melbourne c1987’, published by CSIRO; or

(c) in the case of poultry — the standard ‘Feeding Standards for Australian Livestock: Poultry Standing Committee on Agriculture, Poultry Subcommittee East Melbourne c1987’, published by CSIRO.
Part 2 Approvals and registration

8A Summaries of applications for active constituents for companion animal products

For subsection 11B (2) of the Code, the details that must be included in the summary of the application if the application is for approval of an active constituent for a proposed or existing chemical product that is a companion animal product are:

(a) the name of the applicant; and
(b) the application number; and
(c) the name of the active constituent; and
(d) the active constituent number; and
(e) a short description of the application and its purpose, including the way in which the active constituent is intended to be used.

8B Summaries of applications for active constituents other than for companion animal products

(1) For subsection 11B (2) of the Code, this regulation sets out the details that must be included in the summary of the application if the application is for approval of an active constituent for a proposed or existing chemical product other than a companion animal product.

(2) The details are:

(a) the name of the applicant; and
(b) the application number; and
(c) the name of the active constituent; and
(d) the active constituent number; and
(e) a short description of the application and its purpose, including the way in which the active constituent is intended to be used; and
(f) for any reference active constituent mentioned in the application:
(i) the name of the reference active constituent; and
(ii) if the active constituent is an approved active constituent — the distinguishing number that the APVMA gave to the active constituent when the approval was granted; and
(g) a short description of each item of information contained in, or accompanying, the application in compliance with paragraph 11 (1) (b) of the Code, including the details set out in subregulation (3); and
(h) any other information that the APVMA considers to be relevant to its decision on the application.

(3) For paragraph (2) (g), the details for each item of information are:
(a) the title shown on the item of information; and
(b) the name of the author, or of each of the authors, of the information; and
(c) the date shown on the item of information (if any); and
(d) if no date is shown on the item of information — the date when the preparation of the information was completed; and
(e) if the information was published:
   (i) the date when it was published; and
   (ii) the name of the publication in which it was published; and
(f) the reference number shown on the item of information; and
(g) the name and address of the authorising party for the information.

8C Summaries of applications for companion animal products

(1) For subsection 11B (2) of the Code, subregulation (2) sets out the details that must be included in the summary of the application if the application is for:
(a) registration of a chemical product that is a companion animal product; or
(b) approval of a label for a container for a chemical product that is a companion animal product.

(2) The details are:
(a) the name of the applicant; and
(b) the application number; and
(c) the chemical product number; and
(d) the name of each of the active constituents of the chemical product; and
(e) a short description of the application and its purpose, including the way in which the chemical product is intended to be used.

8D Summaries of applications for chemical products other than companion animal products or repacks

(1) For subsection 11B (2) of the Code, this regulation sets out the details that must be included in the summary of the application if the application is for:
(a) registration of a chemical product other than:
   (i) a companion animal product; or
   (ii) a chemical product mentioned in paragraph 8E (1) (a); or
(b) approval of a label for a container for such a chemical product.

(2) The details are:
(a) the name of the applicant; and
(b) the application number; and
(c) the name of the chemical product; and
(d) the chemical product number; and
(e) the name of each of the active constituents of the chemical product; and
(f) a short description of the application and its purpose, including the way in which the chemical product is intended to be used; and
(g) for any reference active constituent mentioned in the application:
Regulation 8D

(i) the name of the reference active constituent; and
(ii) if the active constituent is an approved active constituent — the distinguishing number that the APVMA gave to the active constituent when the approval was granted; and

(h) for any reference chemical product mentioned in the application:
   (i) the name of the reference chemical product; and
   (ii) if the chemical product has been registered — the distinguishing number that the APVMA gave to the chemical product when the APVMA decided to register the product; and

(i) a short description of each item of information contained in, or accompanying, the application in compliance with paragraph 11 (1) (b) of the Code, including the details set out in subregulation (3); and

(j) any other information that the APVMA considers to be relevant to its decision on the application.

(3) For paragraph (2) (i), the details for each item of information are:
   (a) the title shown on the item of information; and
   (b) the name of the author, or of each of the authors, of the information; and
   (c) the date shown on the item of information (if any); and
   (d) if no date is shown on the item of information — the date when the preparation of the information was completed; and
   (e) if the information was published:
      (i) the date when it was published; and
      (ii) the name of the publication in which it was published; and
   (f) the reference number shown on the item of information; and
   (g) the name and address of the authorising party for the information.
8E  **Summaries of applications for registration of registered chemical products with new brand name**

(1) For subsection 11B (2) of the Code, subregulation (2) sets out the details that must be included in the summary of the application if the application is for:

(a) registration of a chemical product (whether it is a companion animal product or another kind of chemical product) that:
   (i) is the same as a registered chemical product; but
   (ii) is intended to be marketed under a brand name that is different from the brand name used for the registered chemical product; or

(b) approval of a label for a container for such a chemical product.

(2) The details are:
   (a) the name of the applicant; and
   (b) the application number; and
   (c) the chemical product number; and
   (d) the name of each of the active constituents of the chemical product; and
   (e) a short description of the application and its purpose, including the way in which the chemical product is intended to be used.

9  **Certain agricultural products must contain dye or pigment**

(1) For the purposes of paragraphs 14 (3) (d) and 29 (1) (d) of the Code, an agricultural chemical product of a kind specified in subregulation (2), (3) or (4) must comply with the requirements prescribed by this regulation in relation to that product.

(2) A molluscicide in the form of a bait and of which the active constituent is metaldehyde:
   (a) must contain sufficient green pigment or dye to colour the bait a distinctive green colour; and
   (b) must not contain, in the bait, any bone meal or other product of animal origin.
Part 2 Approvals and registration

Regulation 11

(3) A molluscicide in the form of a bait and of which the active constituent is methiocarb:
   (a) must contain sufficient blue pigment or dye to colour the bait a distinctive blue colour; and
   (b) must not contain, in the bait, any bone meal or other product of animal origin.

(4) An agricultural chemical product that is to be applied to seeds that are to be stored before planting or sowing must contain sufficient pigment or dye to colour the seed to which the product is applied so as to enable that seed to be readily distinguished from seed to which the product has not been applied.

11 Labels to contain certain information

(1) For the purposes of paragraphs 14 (3) (d) and 29 (1) (d) and subsection 34A (1) of the Code, a label for containers for a chemical product must comply with the requirements of subregulation (2).

(2) A label must contain the following information:
   (a) the appropriate signal heading in accordance with the Standard for the Uniform Scheduling of Drugs and Poisons;
   (b) the name of the chemical product;
   (c) the name of each active constituent of the product;
   (d) the proportion of each active constituent of the product;
   (e) the name of each other constituent classified as a poison in the Standard for the Uniform Scheduling of Drugs and Poisons;
   (f) the proportion of any other constituent referred to in paragraph (e);
   (g) provision for a batch number;
   (h) provision for an expiry date, if applicable;
   (i) provision for a date of manufacture, if applicable;
   (k) the name and address of the person who is primarily responsible for marketing the product;
   (l) the net contents of the product;
(m) the distinguishing number of the label (including any distinguishing number given to the label under paragraph 178 (2) (a) of the Code);

(n) any other particulars of the product that the APVMA thinks appropriate.

11A Orders about labels for containers for pool or spa hypochlorites

For paragraph 7 (1) (b) of the Act, section 7 of the Act applies to requirements for paragraphs 14 (3) (d) and 29 (1) (d) and subsection 34A (1) of the Code in relation to a label for containers for pool or spa hypochlorites.

12 Labels to contain additional instructions

For the purposes of subparagraph 14 (3) (g) (x), subsection 34A (1) and subparagraph 56E (1) (f) (x) of the Code, a label must contain adequate instructions relating to the following:

(a) if the chemical product is a veterinary chemical product — the duration of any treatment using the product;

(b) any matter, other than a matter referred to in subparagraph 14 (3) (g) (ix) or 56E (1) (f) (ix) of the Code, that, in the opinion of the APVMA, requires additional instructions.

13 Assessment of use of an active constituent as an undue hazard

For the purposes of paragraph 14 (4) (e) of the Code (which deals with the grant or refusal of applications), the APVMA must have regard to the method of analysis (if any) of the chemical composition of the active constituent concerned.

14 Assessment of use of a chemical product as an undue hazard

For the purposes of paragraphs 14 (5) (i) and 56E (2) (i) of the Code, the APVMA must have regard to the method of analysis (if any) of the chemical composition and form of the constituents of the chemical product concerned.
Part 2 Approvals and registration

Regulation 15

15  Particulars of approved active constituents to be recorded

(1) Subject to subregulation (2), for the purposes of subsection 19 (2) of the Code, the following particulars must be entered in the Record of Approved Active Constituents in relation to the approval of an active constituent:

(a) if a name is given to the active constituent by the International Union of Pure and Applied Chemistry — that name;

(b) if no name is given to the active constituent by the International Union of Pure and Applied Chemistry — the name given to the active constituent in an order, publication or approval referred to in regulation 42 that specifies the standard for the active constituent for the purposes of that regulation;

(c) the common name for the active constituent proposed by the applicant and accepted by the APVMA;

(d) the composition and purity of the active constituent;

(e) the name of the manufacturer of the active constituent;

(f) the address of each site at which the active constituent is manufactured by the manufacturer;

(g) the name and business address of the applicant;

(h) the date of entry of these particulars in the Record of Approved Active Constituents;

(i) the date (if any) on which the approval ends.

(2) In relation to an active constituent approved in accordance with section 14A of the Code, the particulars mentioned in paragraphs (1) (c) to (j) need be entered in the Record of Approved Active Constituents only if those particulars are readily available to the APVMA.

16  Particulars of registered chemical products to be recorded

For the purposes of subsection 20 (2) of the Code (which deals with registration of a chemical product), the following particulars must be entered in the Register of Chemical Products in relation to the registration of a chemical product:
(a) the distinguishing name of the chemical product proposed by the applicant and accepted by the APVMA;
(b) the constituents of the chemical product;
(c) the concentration of each constituent of the chemical product;
(d) if possible, the composition and purity of each active constituent of the chemical product;
(e) the name and business address of the applicant;
(f) the name of each State or Territory in respect of which the chemical product is registered;
(g) the name of each manufacturer of the chemical product;
(h) the address of each site at which the chemical product is manufactured by the manufacturer;
(j) the date of entry of these particulars in the Register of Chemical Products;
(k) the date on which the registration ends.

18 Containers for the supply of registered chemical products

(1) For the purposes of paragraph 23 (2) (a) of the Code (which deals with additional conditions of registration relating to containers), a container for a chemical product must:

(a) be impervious to, and incapable of chemical reaction with, its contents when under conditions of temperature and pressure that are likely to be encountered in normal service; and

(b) have sufficient strength and impermeability to prevent leakage of its contents during handling, transport and storage under normal handling conditions; and

(c) if it is intended to be opened more than once — be able to be securely and readily closed and reclosed; and

(d) have sufficient excess capacity to prevent it from breaking if its contents expand during handling, transport or storage; and

(e) enable all or any part of its contents to be removed or discharged in such a way that, with the exercise of no more than reasonable care, the contents cannot:
Regulation 19

(i) harm any person; or
(ii) have an unintended effect that is harmful to the environment.

(2) Nothing in subregulation (1) is intended to affect the operation of any other law that applies in relation to containers for chemical products.

19 Information to be given in notice to approved person

(1) For the purposes of subsection 24 (2) of the Code, the following information must be contained in a notice to the approved person of the approval of an active constituent:
   (a) the particulars of the active constituent entered in the Record of Approved Active Constituents;
   (b) the date (if any) on which the approval ends;
   (c) any conditions of the approval under section 23 of the Code, other than a condition specifying the date on which the approval ends;
   (d) particulars of the notice of the approval to be published under subsection 52 (1) of the Code;
   (e) the date on which the notice to the approved person is issued.

(2) For the purposes of subsection 24 (2) of the Code, the following information must be contained in a notice to the approved person of the registration of a chemical product:
   (a) a copy or sample of an approved label for containers for the chemical product;
   (b) the date of its registration under section 22 of the Code;
   (c) the date on which the registration ends;
   (d) any conditions of the registration under section 23 of the Code, other than a condition specifying the date on which the registration ends;
   (e) particulars of any notice of the registration to be published under subsection 52 (2) of the Code;
   (f) any other details, entered in the Register of Chemical Products, about the chemical product that the APVMA thinks appropriate.
(3) For the purposes of subsection 24 (2) of the Code, the following information must be contained in a notice to the approved person of the approval of a label for containers for a chemical product:

(a) the name of the chemical product;

(b) a copy or sample of the approved label, including the distinguishing number given to the label under subsection 21 (2) of the Code;

(c) the date of the label’s approval under section 22 of the Code;

(d) any conditions of the approval under section 23 of the Code.

19AA Summaries of applications for variation of approvals for active constituents for companion animal products

For subsection 28B (2) of the Code, the details that must be included in the summary of the application if the application is for variation of the relevant particulars or conditions of the approval of an active constituent for a proposed or existing chemical product that is a companion animal product are:

(a) the name of the applicant; and

(b) the application number; and

(c) the name of the active constituent; and

(d) the distinguishing number that the APVMA gave to the active constituent when the approval was granted; and

(e) a short description of the application and its purpose, including the way in which the active constituent is intended to be used.
Regulation 19AB

19AB Summaries of applications for variation for active constituents other than for companion animal products

(1) For subsection 28B (2) of the Code, this regulation sets out the details that must be included in the summary of the application if the application is for variation of the relevant particulars or conditions of the approval of an active constituent other than an active constituent for a chemical product that is a companion animal product.

(2) The details are:

(a) the name of the applicant; and
(b) the application number; and
(c) the name of the active constituent; and
(d) the distinguishing number that the APVMA gave to the active constituent when the approval was granted; and
(e) a short description of the application and its purpose, including the way in which the active constituent is intended to be used; and
(f) for any reference active constituent mentioned in the application:
   (i) the name of the reference active constituent; and
   (ii) if the active constituent is an approved active constituent — the distinguishing number that the APVMA gave to the active constituent when the approval was granted; and
(g) for any reference chemical product mentioned in the application:
   (i) the name of the reference chemical product; and
   (ii) if the chemical product has been registered — the distinguishing number that the APVMA gave to the chemical product when the APVMA decided to register the product; and
(h) a short description of each item of information contained in, or accompanying, the application in compliance with paragraph 11 (1) (b) of the Code, including the details set out in subregulation (3); and
(i) any other information that the APVMA considers to be relevant to its decision on the application.

(3) For paragraph (2) (h), the details for each item of information are:
(a) the title shown on the item of information; and
(b) the name of the author, or of each of the authors, of the information; and
(c) the date shown on the item of information (if any); and
(d) if no date is shown on the item of information — the date when the preparation of the information was completed; and
(e) if the information was published:
   (i) the date when it was published; and
   (ii) the name of the publication in which it was published; and
(f) the reference number shown on the item of information; and
(g) the name and address of the authorising party for the information.

19AC  Summaries of applications for variation for companion animal products

(1) For subsection 28B (2) of the Code, subregulation (2) sets out the details that must be included in the summary of the application if the application is for variation of the relevant particulars or conditions of:
(a) the registration of a chemical product that is a companion animal product; or
(b) the approval of a label for a container for a chemical product that is a companion animal product.

(2) The details are:
(a) the name of the applicant; and
(b) the application number; and
(c) the name of the chemical product; and
(d) if the application is in relation to the registration of a chemical product — the distinguishing number that the
APVMA gave to the product when it decided to register the product; and
(e) the name of each of the active constituents of the chemical product; and
(f) a short description of the application and its purpose, including the way in which the chemical product is intended to be used.

19AD Summaries of applications for variation for chemical products other than companion animal products

(1) For subsection 28B (2) of the Code, this regulation sets out the details that must be included in the summary of the application if the application is for variation of the relevant particulars or conditions of:
(a) the registration of a chemical product other than a companion animal product; or
(b) the approval of a label for a container for a chemical product other than a companion animal product.

(2) The details are:
(a) the name of the applicant; and
(b) the application number; and
(c) the name of the chemical product; and
(d) if the application is in relation to the registration of a chemical product — the distinguishing number that the APVMA gave to the product when it decided to register the product; and
(e) the name of each of the active constituents of the chemical product; and
(f) a short description of the application and its purpose, including the way in which the chemical product is intended to be used; and
(g) for any reference active constituent mentioned in the application:
   (i) the name of the reference active constituent; and
   (ii) if the active constituent is an approved active constituent — the distinguishing number that the
APVMA gave to the active constituent when the approval was granted; and

(h) for any reference chemical product mentioned in the application:
   (i) the name of the reference chemical product; and
   (ii) if the chemical product has been registered — the distinguishing number that the APVMA gave to the chemical product when the APVMA decided to register the product; and

(i) a short description of each item of information contained in, or accompanying, the application in compliance with paragraph 11 (1) (b) of the Code, including the details set out in subregulation (3); and

(j) any other information that the APVMA considers to be relevant to its decision on the application.

(3) For paragraph (2) (i), the details for each item of information are:

(a) the title shown on the item of information; and

(b) the name of the author, or of each of the authors, of the information; and

(c) the date shown on the item of information (if any); and

(d) if no date is shown on the item of information — the date when the preparation of the information was completed; and

(e) if the information was published:
   (i) the date when it was published; and
   (ii) the name of the publication in which it was published; and

(f) the reference number shown on the item of information; and

(g) the name and address of the authorising party for the information.
**Regulation 19A**

19A Variation of relevant particulars or conditions of approval or registration

For the purposes of paragraph 29 (1) (d) of the Code, regulations 9, 10, 11 and 11A apply to an application for variation of the relevant particulars or of the conditions of approval or registration as they apply to an application for approval or registration.

20 Continued approval of an active constituent

For the purposes of paragraph 32 (1) (aa) and subsection 34 (5) of the Code, the requirement for continued approval of an active constituent is that the continued use of, or any other dealing with, the constituent in accordance with the instructions for its use or for such a dealing that the APVMA has approved:

(a) would not be an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues; and

(b) would not be likely to have an effect that is harmful to human beings; and

(c) would not be likely to have an unintended effect that is harmful to animals, plants or things or to the environment; and

(d) would not unduly prejudice trade or commerce between Australia and places outside Australia.

21 Continued registration of a chemical product

For the purposes of paragraph 32 (1) (aa) and subsection 34 (5) of the Code, the requirements for continued registration of a chemical product are:

(a) that the continued use of, or any other dealing with, the product in accordance with the instructions for its use or for such a dealing that the APVMA has approved:

   (i) would not be an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues; and
(ii) would not be likely to have an effect that is harmful to human beings; and
(iii) would not be likely to have an unintended effect that is harmful to animals, plants or things or to the environment; and
(iv) would not unduly prejudice trade or commerce between Australia and places outside Australia; and
(b) that the continued use of the product in accordance with the instructions for its use that the APVMA has approved would be effective according to criteria determined by the APVMA for the product; and
(c) if regulation 9 or 10 applies to the product — that the product complies with that regulation.

22 Continued approval of a label
For the purposes of paragraph 32 (1) (aa) and subsection 34 (5) of the Code, the requirements of continued approval of a label for containers for a chemical product are that:
(a) the label contains adequate instructions about such of the matters set out in paragraph 14 (3) (g) of the Code (including matters prescribed in regulation 12 for the purposes of subparagraph 14 (3) (g) (x) of the Code), as the APVMA thinks appropriate; and
(b) the label complies with regulation 11 and any orders made for the purposes of regulation 11A; and
(c) if necessary, the approval is subject to appropriate conditions under section 23 of the Code.

22A Prescribed uses (Code, s 34F (5))
(1) For subsection 34F (5) of the Code, a use is prescribed if:
(a) the use is:
   (i) a non-major crop use (that is, a use for a food crop listed in Column 4 (‘Non-major uses’) of Part 1 of Schedule 3A, or a non-food crop or situation use listed in Column 4 (‘Non-major uses’) of Part 3 of that Schedule); or
Regulation 22B

(ii) a non-major animal use (that is, a use for an animal listed in Column 4 (‘Non-major uses’) of Part 2 of Schedule 3A); and

(b) an application has been made to the APVMA, data has been submitted to the APVMA for the purposes of the application, and the data is directly and specifically relevant to the use; and

(c) the data was required, and relied on, by the APVMA to grant the application; and

(d) the use is specified on a label.

(2) For paragraph (1) (d), a non-major crop use is taken to be specified on a label if, on the label, there is specified a crop group listed in Column 2 (‘Crop/situation group’) of:

(a) the item that, in Part 1 of Schedule 3A, mentions the relevant non-major food crop; or

(b) the item that, in Part 3 of that Schedule, mentions the relevant non-food crop or situation.

22B Summaries of advice on applications for active constituents

(1) For paragraph 34G (3) (b) of the Code, this regulation sets out the matters that must be included in the summary of the advice if the advice was for an application for:

(a) approval of an active constituent for a proposed or existing chemical product; or

(b) variation of the relevant particulars or conditions of the approval of an active constituent for a proposed or existing chemical product.

(2) The matters are:

(a) the name of the applicant; and

(b) the application number; and

(c) the name of the active constituent; and

(d) the distinguishing number that the APVMA gave to the active constituent when the approval was granted; and
(e) a short description of the application and its purpose, including the way in which the active constituent is intended to be used; and

(f) brief details about the APVMA’s decision to grant the approval; and

(g) a summary of the advice given by the person, body or Government that the APVMA consulted, including:
   (i) the kind of information given to the APVMA with the advice; and
   (ii) any advice given in relation to any trials or related matters mentioned in the application; and
   (iii) a summary of the results from any trials mentioned in the advice as relevant; and
   (iv) the conclusions included in the advice; and

(h) a list of the items of information that the person, body or Government considered relevant to giving the advice, including the details set out in subregulation (3); and

(i) any other information given with the advice that the APVMA considers was relevant to its decision on the application.

(3) For paragraph (2) (h), the details for each item of information are:
   (a) the data number given to the information by the APVMA; and
   (b) the title shown on the item of information; and
   (c) the name of the author, or of each of the authors, of the information; and
   (d) if a date is shown on the item of information — the date shown; and
   (e) if no date is shown on the item of information — the date when the preparation of the information was completed; and
   (f) if the information was published:
      (i) the date when it was published; and
      (ii) the name of the publication in which it was published; and
(g) the reference number shown on the item of information; and
(h) the name and address of the authorising party for the information.

22C Summaries of advice on applications for chemical products

(1) For paragraph 34G (3) (b) of the Code, this regulation sets out the matters that must be included in the summary of the advice if the advice was for an application for:
(a) registration of a chemical product; or
(b) variation of the relevant particulars or conditions of:
   (i) the registration of a chemical product; or
   (ii) the approval of a label for a container for a chemical product.

(2) The matters are:
(a) the name of the applicant; and
(b) the application number; and
(c) the name of the chemical product; and
(d) if the application was for registration of a chemical product — the distinguishing number that the APVMA gave to the product when it decided to register the product; and
(e) the name of the active constituents of the chemical product; and
(f) a short description of the application and its purpose, including the way in which the chemical product is intended to be used; and
(g) brief details about the APVMA’s decision to grant the application; and
(h) a summary of the advice given by the person, body or Government that the APVMA consulted, including:
   (i) the kind of information given; and
   (ii) any advice given in relation to any trials or related matters mentioned in the application; and
(iii) a summary of the results from any trials mentioned in the advice as relevant; and
(iv) the conclusions included in the advice; and
(i) a list of the items of information that the person, body or Government considered relevant to giving the advice, including the details set out in subregulation (3); and
(j) any other information given with the advice that the APVMA considers was relevant to its decision on the application.

(3) For paragraph (2) (i), the details for each item of information are:
(a) the data number given to the information by the APVMA; and
(b) the title shown on the item of information; and
(c) the name of the author, or of each of the authors, of the information; and
(d) if a date is shown on the item of information — the date shown; and
(e) if no date is shown on the item of information — the date when the preparation of the information was completed; and
(f) if the information was published:
   (i) the date when it was published; and
   (ii) the name of the publication in which it was published; and
(g) the reference number shown on the item of information; and
(h) the name and address of the authorising party for the information.

23 Late applications for renewal of registration of chemical product

(1) For the purposes of subsection 48 (3) of the Code, the APVMA may accept a late application for the renewal of the registration of a chemical product:
(a) if:
Part 2 Approvals and registration

Regulation 23

(i) before the end of the period for making an application referred to in subsection 48 (2) of the Code, the applicant requests in writing that the APVMA accept a late application; and

(ii) the APVMA agrees to that request; or

(b) in any other case — if the APVMA thinks it would be unreasonable not to accept the late application.

(2) The fee payable for acceptance of a late application for the renewal of the registration of a chemical product (other than an application to which paragraph (1) (a) applies) is $50.
Part 2A  Listable chemical products

23A  Listing Schedule

For subsection 56C (1) of the Code, Part 2 of Schedule 3B lists chemical products or classes of chemical products that can be granted listed registration under Part 2A of the Code.

Note 1  Schedule 3B sets out products that are listable chemical products.

Note 2  Division 4 of Part 2A of the Code provides how applications for listed registration of a listable chemical product for which there is an established standard are to be dealt with.

23B  Particulars of registered listed chemical products to be recorded

(1) For the purposes of paragraph 56M (2) (a) of the Code, the following particulars must be entered in the Register of Chemical Products in relation to the listed registration of a chemical product:

(a) the distinguishing name of the product proposed by the applicant and accepted by the APVMA;
(b) the constituents of the product;
(c) the concentration of each constituent of the product;
(d) if possible, the composition and purity of each active constituent of the product;
(e) the name and business address of the applicant;
(f) the name of each State or Territory in respect of which the product is registered;
(g) the name of each manufacturer of the product;
(h) the address of each site at which the product is manufactured by the manufacturer;
(i) the date of entry of these particulars in the Register of Chemical Products;
(j) the date on which the registration ends.
Regulation 23C

(2) Subregulation (1) does not apply in relation to particulars that are contained in the established standard for the registered listed chemical product.

23C Containers for the supply of registered listed chemical products

(1) Subject to subregulation (2), for the purposes of paragraph 56O (2) (a) of the Code, a container for a registered listed chemical product must:

(a) be impervious to, and incapable of chemical reaction with, its contents when under conditions of temperature and pressure that are likely to be encountered in normal service; and

(b) have sufficient strength and impermeability to prevent leakage of its contents during handling, transport and storage under normal handling conditions; and

(c) if it is intended to be opened more than once — be able to be securely and readily closed and reclosed; and

(d) have sufficient excess capacity to prevent it from breaking if its contents expand during handling, transport or storage; and

(e) enable all or any part of its contents to be removed or discharged in such a way that, with the exercise of no more than reasonable care, the contents cannot:

(i) harm any person; or

(ii) have an unintended effect that is harmful to the environment.

(2) Subregulation (1) does not apply if the established standard for the registered listed chemical product requires the product to be kept in containers that comply with requirements specified in the standard.

(3) Nothing in subregulations (1) and (2) is intended to affect the operation of any other law that applies in relation to containers for chemical products.
23D  **Information to be given in notice to approved person**

For the purposes of subsection 56P (2) of the Code, the following information must be contained in a notice to the approved person of the listed registration of a chemical product:

(a) if the established standard that applies to the registered listed chemical product has been published in the *Gazette* — the date of its publication;

(b) if the established standard that applies to the registered listed chemical product has not been published in the *Gazette* — a copy of the established standard;

(c) a copy or sample of any label for the container for the registered listed chemical product, being a label that is contained in, or required by, the established standard that applies to the product;

(d) the date of its registration under section 56N of the Code;

(e) the date on which the registration ends;

(f) any conditions of the registration under section 56O of the Code, other than a condition specifying the date on which the registration ends;

(g) particulars of any notice of listed registration to be published under subsection 56ZO (1) of the Code;

(h) any other details, entered in the Register of Chemical Products, about the registered listed chemical product that the APVMA thinks appropriate.

23E  **Continued listed registration of chemical product**

For the purposes of paragraph 56X (1) (b) of the Code, the requirements for continued listed registration of a chemical product are:

(a) that the continued use of, or any other dealing with, the product in accordance with the instructions for its use or for such a dealing that the APVMA has approved:

   (i) would not be an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues; and
Regulation 23F

(ii) would not be likely to have an effect that is harmful to human beings; and
(iii) would not be likely to have an unintended effect that is harmful to animals, plants or things or to the environment; and
(iv) would not unduly prejudice trade or commerce between Australia and places outside Australia; and

(b) that the continued use of the product in accordance with the instructions for its use that the APVMA has approved would be effective according to criteria determined by the APVMA for the product.

23F Late applications for renewal of listed registration of chemical product

(1) For the purposes of subsection 56ZL (3) of the Code, the APVMA may accept a late application for the renewal of the listed registration of a chemical product:

(a) if:

(i) before the end of the period for making an application referred to in subsection 56ZL (2) of the Code, the applicant requests in writing that the APVMA accept a late application; and

(ii) the APVMA agrees to that request; or

(b) in any other case — if the APVMA thinks it would be unreasonable not to accept the late application.

(2) The fee payable for acceptance of a late application for the renewal of the listed registration of a chemical product (other than an application to which paragraph (1) (a) applies) is $30.
Part 2B  Reserved chemical products

23G  Reserved Schedule

For subsection 56ZU (1) of the Code, Part 2 of Schedule 3C specifies chemical products or classes of chemical products that are reserved chemical products for the purposes of the Code.

23H  Conditions for dealing with reserved chemical product — containers for supply

(1) For subsection 56ZU (3) of the Code, a container used for the supply of a chemical product mentioned in Part 2 of Schedule 3C must:

(a) be impervious to, and incapable of chemical reaction with, its contents when under conditions of temperature and pressure that are likely to be encountered in normal service; and

(b) have sufficient strength and impermeability to prevent leakage of its contents during handling, transport and storage under normal handling conditions; and

(c) if it is intended to be opened more than once — be able to be securely and readily closed and reclosed; and

(d) have sufficient excess capacity to prevent it from breaking if its contents expand during handling, transport or storage; and

(e) enable all or any part of its contents to be removed or discharged in such a way that, with the exercise of no more than reasonable care, the contents cannot:

(i) harm a person; or

(ii) have an unintended effect that is harmful to the environment.

(2) Nothing in subregulation (1) affects the operation of any other law that applies in relation to containers for chemical products.
Conditions for dealing with reserved chemical product — labels

(1) For subsection 56ZU (3) of the Code, a label for a chemical product mentioned in Part 2 of Schedule 3C must not contain a claim about the product and its active constituents that is inconsistent with:

(a) the definition of disinfectant in section 1 of Part 1 of Schedule 3C; and

(b) the particulars of the product, and active constituents of the product, set out in Schedule 3C.

(2) For subsection 56ZU (3) of the Code, a label for a chemical product of the kind mentioned in Part 2 of Schedule 3C must include any first aid instructions and safety directions that apply to the product, based on its type and formulation, in accordance with the document entitled Handbook of First Aid Instructions, Safety Directions, Warning Statements and General Safety Precautions for Agricultural and Veterinary Chemicals, published by the Office of Chemical Safety in the Therapeutic Goods Administration of the Department of Health and Ageing, as in force from time to time.

Note The Handbook of First Aid Instructions, Safety Directions, Warning Statements and General Safety Precautions for Agricultural and Veterinary Chemicals can be found on the Therapeutic Goods Administration website at http://www.tga.gov.au.
Part 3 Compensation for provider of certain information in respect of continued registration of certain chemical products

Division 1 Notices

24 Protected registered information — notice to primary applicant

For the purposes of subparagraph 60 (3) (a) (i) of the Code, a notice to a primary applicant must contain the following information about the secondary applicant and the secondary chemical product:

(a) if the secondary chemical product is a registered chemical product:
   (i) the name and business address of the secondary applicant entered in the Register of Chemical Products; and
   (ii) the particulars of the secondary chemical product entered in the Register of Chemical Products or, if the primary applicant so requests, the particulars of the approved active constituent entered in the Record of Approved Active Constituents; and
   (iii) a copy of the approved label for a container for the secondary chemical product;

(b) if the secondary chemical product is not a registered chemical product — the name and business address of the secondary applicant contained in the application for registration of the secondary chemical product.

25 Protected registered information — notice to secondary applicant

For the purposes of subparagraph 60 (3) (a) (ii) of the Code, the information about each primary applicant and primary chemical product that must be contained in a notice to the secondary applicant is:
(a) the name and business address of each primary applicant; and
(b) the particulars of each primary chemical product, entered in the Register of Chemical Products or, if the secondary applicant so requests, the particulars of each approved active constituent, entered in the Record of Approved Active Constituents; and
(c) a copy of the approved label for a container for each primary chemical product.

Division 2 Conduct of arbitration

26 Rules governing the conduct of an arbitration

(1) For the purposes of section 71 of the Code (which deals with the conduct of an arbitration), regulations 27 to 39 apply to an arbitration under Division 3 of Part 3 of the Code.

(2) A law that relates to the conduct of commercial arbitration, to the extent that it is inconsistent with any regulation mentioned in subregulation (1), does not apply to an arbitration under Division 3 of Part 3 of the Code.

27 Notice of appointment of arbitrator

(1) When an arbitrator is appointed for a purpose of the Code, the APVMA must give notice in writing of the appointment, stating the arbitrator’s name and address, to:
   (a) each primary applicant in the matter to be arbitrated; and
   (b) the secondary applicant in the matter; and
   (c) the mediator in the matter.

(2) The notice must be given within a reasonable period after the appointment.
28 Parties to give information to arbitrator
As soon as practicable after being notified of the arbitrator’s appointment, an applicant must tell the arbitrator in writing about any proposal as to the terms of compensation that was made by the applicant in the course of negotiations.

29 Mediator to submit report
As soon as practicable after being notified of the arbitrator’s appointment, the mediator must give a written report to the arbitrator:
(a) setting out the proposals and counter proposals (if any) made by the applicants during the mediation; and
(b) summarising the issues raised during the mediation.

30 Arbitrator to conduct a hearing
Before determining the terms of compensation (if any), the arbitrator must conduct a hearing.

31 Arbitrator to give the applicants notice of the hearing
(1) The arbitrator must give written notice of a hearing to each party to the arbitration, at least 14 days before the hearing.
(2) The notice must specify the date, time and place of the hearing.

32 Arbitrator’s powers if applicant does not attend the hearing
If the arbitrator has given a party to the arbitration notice of a hearing in accordance with regulation 31, the arbitrator may determine terms of compensation in accordance with Division 3 of Part 3 of the Code even if the applicant does not attend the hearing.

33 Procedure at the hearing
The arbitrator may determine the procedure to be observed at a hearing.
34 Representation at the hearing

(1) Subject to subregulation (2), a party to an arbitration must not be represented by a legal practitioner at the hearing.

(2) Subject to subregulation (3), the arbitrator may permit a party to be represented by a legal practitioner if, in the opinion of the arbitrator:
   (a) legal representation is likely to shorten the proceedings or reduce costs; or
   (b) the party would be unfairly disadvantaged if the party were not represented.

(3) The arbitrator must not permit an applicant to be represented by a legal practitioner if, in the opinion of the arbitrator, another party would be unfairly disadvantaged as a result.

35 Arbitrator may require information etc

(1) If the arbitrator reasonably believes that a person is able to give information or produce a document that may be used for the purpose of determining:
   (a) an amount referred to in subparagraph 69 (1) (b) (i) or (ii) of the Code (each of which deals with the amount of the cost of obtaining protected registration information); or
   (b) what, for the purposes of paragraph 69 (1) (b) of the Code, is a fair proportion of that amount; or
   (c) any other matter relevant to the determination of what is a reasonable proposal as to the terms of compensation;

the arbitrator may give notice in writing to the person in accordance with subregulation (2).

(2) A notice under subregulation (1) may require the person:
   (a) to give the information to the arbitrator within the time and in the manner specified in the notice; or
   (b) to attend before the arbitrator at a specified time and place and answer any question; or
   (c) to produce the document to the arbitrator in accordance with the notice.
(3) A person must not fail to comply with a notice given to the person under subregulation (1).

Penalty: 5 penalty units.

(3A) It is a defence to a prosecution under subregulation (3) if the defendant has a reasonable excuse.

Note A defendant bears an evidential burden in relation to the matter mentioned in this subregulation — see section 13.3 of the Criminal Code.

(3B) An offence under subregulation (3) is an offence of strict liability.

Note For strict liability, see section 6.1 of the Criminal Code.

(4) An arbitrator may require evidence to be given on oath or affirmation, and for that purpose, the arbitrator may administer an oath or affirmation.

36 Fair proportion of cost of providing protected registration information

For the purposes of subsection 69 (2) of the Code, the matters to which the arbitrator must have regard in determining what is a fair proportion of an amount of the cost incurred by a primary applicant are as follows:

(a) the time that has elapsed since the protected registered information was obtained by the primary applicant;
(b) the value of sales of the primary chemical product concerned since the registration of the product;
(c) whether the primary applicant has already received compensation for the use of the protected registered information by the APVMA;
(d) the cost of obtaining the protected registered information if it were to be compiled at the time of the arbitration.

37 Arbitrator’s costs

(1) The parties to an arbitration are jointly and severally liable to pay any costs reasonably incurred by the arbitrator in relation to the arbitration.
Part 3  Compensation for provider of certain information in respect of continued registration of certain chemical products
Division 2  Conduct of arbitration

Regulation 38

(2) The APVMA may elect to pay the arbitrator’s costs mentioned in subregulation (1).

(3) If the APVMA pays the arbitrator’s costs, the APVMA may recover the costs from all or any of the applicants as a civil debt in a court of competent jurisdiction.

38 Applicants’ costs of arbitration

Each party to an arbitration must bear the party’s own costs relating to the arbitration.

39 Arbitrator exonerated from liability

No action lies against an arbitrator for anything done in the course of an arbitration, if it is done in accordance with the Code and these Regulations.
Part 4 Control of chemical products

Division 1 General

40A Exemption of existing use active constituents

(1) Subsection 74 (1) of the Code (which deals with the possession of substances for supply) does not apply to a person in relation to the person’s possession or custody of a substance to which that subsection applies, if the substance is an existing use active constituent.

(2) Subsection 76 (1) of the Code (which deals with the supply of active constituents) does not apply to a person in relation to the supply by the person of an active constituent to which that subsection applies, if the substance is an existing use active constituent.

(3) In this regulation, existing use active constituent means an active constituent for a chemical product that is taken by section 172 or 174 or subsection 176 (1) of the Code to have been registered under the Code.

(4) Subregulations (1) and (2) have effect from the commencement of the Code until the end of 12 months after that commencement.

40 Supply of substances for research etc for chemical products

(1) Subsections 74 (1) and 75 (1) of the Code (which deal with the possession of chemical products and active constituents for supply) do not apply to a person in relation to an amount of:
   (a) a substance that is likely to be used as an active constituent for a chemical product; or
   (b) an active constituent for a chemical product; or
   (c) a chemical product;
   to which subregulation (2) applies.
(2) This subregulation applies to a substance, constituent or chemical product in the possession or custody of a person if:
   (a) the substance, constituent or product is to be used only for the purposes of research in connection with a chemical product; and
   (b) the amount of the substance, constituent or product does not exceed the amount specified in subregulation (5); and
   (c) the person complies with subregulations (6) and (8) in respect of the substance, constituent or product.

(3) Subsections 76 (1), 77 (1), 78 (1) and 79 (1) of the Code (which deal with the supply of chemical products and active constituents) do not apply to a person in relation to an amount of:
   (a) a substance that is likely to be used as an active constituent for a chemical product; or
   (b) an active constituent for a chemical product; or
   (c) a chemical product; to which subregulation (4) applies.

(4) This subregulation applies to a substance, constituent or chemical product supplied by a person if:
   (a) the substance, constituent or product is to be used only for the purposes of research in connection with a chemical product; and
   (b) the amount of the substance, constituent or product supplied in any 12 month period does not exceed the amount specified in subregulation (5); and
   (c) the person complies with subregulations (7) and (8) in respect of the substance, constituent or product.

(5) For the purposes of subregulations (2) and (4), the amount of the substance, constituent or chemical product is:
   (a) in the case of a substance or constituent — 3 kilograms; or
   (b) in the case of a chemical product — 6 kilograms.

(6) A person referred to in subregulation (2) must make a record stating the amount of the substance, constituent or chemical product in the person’s possession or custody at any time.
(7) A person referred to in subregulation (4) must make a record that shows, at any time, the amount of the substance, constituent or chemical product supplied by the person in the preceding 12 month period.

(8) A record made under subregulation (6) or (7):
   (a) must be in a form that is readily accessible for the purposes of Part 9 of the Code (which deals with enforcement); and
   (b) must be kept at the business premises of the person who made it for at least 2 years after it is made.

41 Supply etc of substances with constituents differing from registered particulars

(1) This regulation has effect for the purposes of sections 83, 83A, 99 and 102 of the Code.

(2) For the purposes of paragraphs 83 (1) (a), 83A (1) (a), 99 (2) (a) and 102 (1) (b) and (ba) of the Code, the prescribed extent, in the case of an active constituent of a registered chemical product or registered listed chemical product, is nil.

(3) For the purposes of paragraphs 83 (1) (b), 83A (1) (b), 99 (2) (b) and 102 (1) (c) and (ca) of the Code, the prescribed extent, for a constituent of a registered chemical product or registered listed chemical product:
   (a) that is an active constituent; and
   (b) in respect of which a standard is prescribed under section 87 of the Code;
   is the extent (if any) of variation of concentration permitted by that standard.

42 Prescribed standards for chemical products

(1) For the purposes of section 87 of the Code (which deals with standards for chemical products), all chemical products are prescribed.
Part 4 Control of chemical products
Division 1 General

Regulation 42

(2) Section 7 of the Act (which deals with the power to make orders) applies to the specification of standards in respect of:
(a) a chemical product; and
(b) a constituent contained in a chemical product.

(3) The standard for a chemical product, or a constituent contained in a chemical product, is:
(a) the standard specified in respect of the chemical product or the constituent in an order under section 7 of the Act; or
(b) in the case of a constituent (not being a constituent referred to in paragraph (a)) in respect of which a standard is specified in Appendix L of the Standard for the Uniform Scheduling of Drugs and Poisons — that standard; or
(c) in the case of a veterinary chemical product or of a constituent (not being a chemical product or constituent referred to in paragraph (a) or (b)), in respect of which a standard is specified in:
   (i) the British Pharmacopoeia; or
   (ii) the British Pharmacopoeia (Veterinary); or
   (iii) the European Pharmacopoeia; or
   (iv) the United States Pharmacopoeia;
   the standard specified in the first of those publications, in the order set out in this paragraph, that applies to the product or constituent; or
(d) in the case of a chemical product or constituent (not being a product or constituent referred to in paragraph (a), (b) or (c)), in respect of which a standard is specified in any of the FAO Specifications for Plant Protection Products — that standard; or
(e) in the case of a chemical product or constituent (not being a product or constituent referred to in paragraph (a), (b), (c) or (d)) — the standard (if any) approved by the APVMA in respect of the product or constituent.

(4) If no standard is prescribed under subregulation (3) in respect of the concentration of an active constituent of a particular chemical product, the standard in respect of the concentration of that active constituent is the standard set out in the following table:
<table>
<thead>
<tr>
<th>Concentration of each active constituent as specified on the product label (g/kg or g/L at 20°C)</th>
<th>Standard (allowable variation)</th>
</tr>
</thead>
<tbody>
<tr>
<td>500 or more</td>
<td>± 25 g/kg or g/L of the active constituent</td>
</tr>
<tr>
<td>From 250 up to but not including 500</td>
<td>± 5% of the content of the active constituent</td>
</tr>
<tr>
<td>From 100 up to but not including 250</td>
<td>± 6% of the content of the active constituent</td>
</tr>
<tr>
<td>Less than 100</td>
<td>± 10% of the content of the active constituent</td>
</tr>
</tbody>
</table>

43 When statements about chemical products can be made or reported

(1) For the purposes of subsection 89 (3) of the Code, a person is not prevented from making or reporting a statement about a chemical product if the statement is not made for the purpose of promoting the product and is one of the following kinds of statement:

(a) a statement made:
   (i) in a scientific paper or other scientific literature, or in a scientific report or presentation; or
   (ii) at a conference or seminar, or in an address, meeting or discussion, concerning chemical products;
   being a statement based on data published in a reputable, refereed scientific journal or of a standard publishable in such a journal;

(b) a statement made on radio or television or in a newspaper, journal or newsletter, as fair comment on any material:
   (i) published for the purposes of a conference or seminar; and
   (ii) based on data referred to in paragraph (a).

(2) Nothing in subregulation (1) is taken to permit a statement that would, apart from that subregulation, contravene section 84 of the Code.
44 Record of manufacture or import of date-controlled chemical product

(1) For the purposes of paragraph 90 (a) of the Code, a record in relation to a date-controlled chemical product:
   (a) must be made:
      (i) in written or electronic form; and
      (ii) in such a way as to ensure that the record is readily accessible for the purposes of Part 9 of the Code (which deals with enforcement); and
   (b) must include the following particulars:
      (i) the name and business address of the manufacturer;
      (ii) if the product is imported — the name and business address of the importer;
      (iii) the distinguishing name of the product;
      (iv) if the product is a registered chemical product — the distinguishing number given to the product under section 20 of the Code;
      (v) the volume or quantity manufactured or imported;
      (vi) the batch number.

(2) For the purposes of paragraph 90 (b) of the Code, the period for keeping a record of a date-controlled chemical product is the period that begins when the record is made and ends 12 months after the expiry date of the product to which it relates.

45 Restricted chemical products

For the purposes of subsection 93 (1) of the Code (which deals with restricted chemical products), a chemical product specified in Column 2 of Schedule 4 is declared to be a restricted chemical product, the APVMA having certified in writing, in respect of the product, under subsection 93 (2) of the Code, that it is in the public interest for the product to be so declared.
46 Supply of chemical product — batch number or record of supply

(1) A person may supply a chemical product only if:
   (a) the container for the product has attached to it a label containing a batch number, in a form approved by the APVMA, that enables the APVMA to identify the batch of that chemical product from which the contents of the container were taken; or
   (b) the person makes a record, in respect of the supply, in accordance with subregulation (2).

Penalty: 10 penalty units.

(1A) Subregulation (1) does not apply to a chemical product in relation to which, or in relation to containers for which, registration or approval of a label by the previous registering authority was in force immediately before the commencement of the Code, if:
   (a) the chemical product was manufactured before 1 October 1996; and
   (b) the label as registered or approved does not contain provision for a batch number; and
   (c) under paragraph 174 (1) (c) or 176 (1) (d) or subsection 176 (2) of the Code, the label is taken to have been approved in relation to the chemical product; and
   (d) when the chemical product is supplied — a label in the form taken to be approved under the Code is attached to it.

(1B) Subregulation (1) does not apply to a chemical product that:
   (a) was manufactured before 1 October 1996; and
   (b) is required to be registered under the Code; and
   (c) immediately before the commencement of the Code, was not required to be registered or approved under a corresponding previous law.

(1C) Subregulations (1A) and (1B) cease to have effect on 30 April 1998.
(2) For the purposes of paragraph (1) (b), a person who supplies a chemical product must make, as soon as practicable, a record:
   
   (a) in a form approved by the APVMA; and

   (b) in such a way as to ensure that the record is readily accessible for the purposes of Part 9 of the Code (which deals with enforcement); and

   (c) including the following particulars:

      (i) the name and address of the person who supplied the product;

      (ii) the name and address of the person to whom the product was supplied;

      (iii) the date of supply;

      (iv) the quantity of the product supplied or, if the product is supplied as part of a mixture of chemical products, the quantity of the mixture of products supplied;

      (v) the identification number of the container in which the product was transported or stored for the purpose of supply or, if the container is a bulk tank, the location of the container;

      (vi) the distinguishing name of the product supplied or, if the product is supplied as part of a mixture of chemical products, the distinguishing name of each of those products;

      (vii) if the batch number of the product supplied or, if the product is supplied as part of a mixture of chemical products, the batch number of each of those products supplied, is known to the person who supplied the product — that batch number, or as the case requires, those batch numbers;

      (viii) if the product is supplied in a refillable container — the date on which the product was placed in the container.

(3) A person who makes a record under subregulation (2) must keep the record for 3 years after it is made.

Penalty: 10 penalty units.
(4) It is a defence to a prosecution under subregulation (1) or (3) if the defendant has a reasonable excuse.

Note A defendant bears an evidential burden in relation to the matter mentioned in this subregulation — see section 13.3 of the Criminal Code.

(5) An offence under subregulation (1) or (3) is an offence of strict liability.

Note For strict liability, see section 6.1 of the Criminal Code.

Division 2 Supply of hormonal growth promotants

47 Notice of intention to supply hormonal growth promotant

(1) If a person gives notice in writing to the APVMA:
   (a) declaring the person’s intention to supply a hormonal growth promotant; and
   (b) specifying each premises from which the person intends to supply the promotant;
   the APVMA must assign, on payment of the prescribed application fee, a unique notification number to the person for each of those premises.

(2) The prescribed application fee is $275 for each premises specified in the notice.

47A Notification number may be replaced or withdrawn

(1) The APVMA may, at any time, by notice in writing to the assignee of a notification number for particular premises:
   (a) without payment of a fee, assign a notification number for the premises in place of a notification number previously assigned; or
   (b) if it appears to the APVMA that the premises are no longer used for the supply of hormonal growth promotant — inform the assignee that it intends, after a specified period, to withdraw the assigned notification number.
(2) If, within the specified period, the assignee does not satisfy the APVMA that the premises are still used for the supply of hormonal growth promotant, the APVMA may withdraw the assigned notification number.

47AB Review of decision withdrawing assigned notification number

Application may be made under the Administrative Appeals Tribunal Act 1975 to the Administrative Appeals Tribunal for review of a decision of the APVMA under paragraph 47A (b) withdrawing an assigned notification number.

47B Notification number to be renewed annually

(1) Assignment of a notification number:
   (a) begins to have effect on the day of the assignment; and
   (b) unless continued under subregulation (2) — ceases to have effect at the end of 1 year after that day.

(2) A person to whom a notification number has been assigned for premises may continue the assignment of that number for those premises by giving notice in accordance with subregulation 47 (1), and paying the prescribed fee under subregulation 47 (2), on or before the day on which the assignment ceases to have effect.

47C Hormonal growth promotant not to be supplied etc

(1) A person may supply a hormonal growth promotant only if:
   (a) a notification number has been assigned to the person for the premises from which the supply occurs; and
   (b) the notification number has not been withdrawn; and
   (c) the assignment of the notification number has not ceased to have effect.

Penalty: 10 penalty units.
(1A) It is a defence to a prosecution under subregulation (1) if the defendant has a reasonable excuse.

Note: A defendant bears an evidential burden in relation to the matter mentioned in this subregulation — see section 13.3 of the *Criminal Code*.

(1B) An offence under subregulation (1) is an offence of strict liability.

Note: For strict liability, see section 6.1 of the *Criminal Code*.

(2) For the purposes of subregulation (1), premises from which supply occurs are premises from which the promotant is first taken:
(a) in response to a particular request for supply; and
(b) in the form and container in which it is supplied.

### 48 Supply of hormonal growth promotant — purchaser’s declaration

(1) A person may supply a hormonal growth promotant only if:
(a) the recipient gives to the supplier, at the time of acquisition, a declaration that:
   (i) is in a form approved by the APVMA; and
   (ii) states:
      (A) the total quantity and type of the promotant acquired; and
      (B) the batch number of the promotant; and
      (C) the purchaser declaration number for the premises where animals proposed to be treated with the promotant are to be kept; and
   (iii) acknowledges that the recipient is aware that an animal treated with a hormonal growth promotant must be marked as an animal so treated, as required by the law of this jurisdiction (that is, by making in its ear an equilateral triangular hole 20 millimetres on each side); or
(b) the recipient has been assigned a notification number that has not ceased to have effect and has not been withdrawn.

Penalty: 10 penalty units.
Regulation 49

(2) It is a defence to a prosecution under subregulation (1) if the defendant has a reasonable excuse.

Note A defendant bears an evidential burden in relation to the matter mentioned in this subregulation — see section 13.3 of the Criminal Code.

(3) An offence under subregulation (1) is an offence of strict liability.

Note For strict liability, see section 6.1 of the Criminal Code.

49 Record of supply of hormonal growth promotant — manufacturer and supplier

(1) A person who manufactures and supplies a hormonal growth promotant must make, on each occasion on which the promotant is supplied to another person (in this regulation called the recipient), a record containing the following particulars:

(a) the distinguishing name of the promotant entered in the Register of Chemical Products;

(b) the name and address of the manufacturer;

(c) the notification number assigned to the premises from which the promotant was supplied to the recipient;

(d) the quantity of the promotant supplied;

(e) the date of manufacture of the promotant;

(f) the batch number of the promotant;

(g) the quantity of promotant manufactured in that batch;

(h) the date of supply of the promotant;

(i) the name and address of the recipient;

(j) if 1 or more notification numbers have been allotted to the recipient:

   (i) the notification number, and address, of each premises to which the promotant is supplied; and

   (ii) the quantity of the promotant supplied to each of those premises;
(k) if no notification number has been allotted to the recipient — the purchaser declaration number for the premises where animals treated with the promotant are to be kept.

Penalty: 10 penalty units.

Note Regulation 52 sets out further requirements regarding the form of the record.

(2) It is a defence to a prosecution under subregulation (1) if the defendant has a reasonable excuse.

Note A defendant bears an evidential burden in relation to the matter mentioned in this subregulation — see section 13.3 of the Criminal Code.

(3) An offence under subregulation (1) is an offence of strict liability.

Note For strict liability, see section 6.1 of the Criminal Code.

50 Record of supply of hormonal growth promotant — importer and supplier

(1) A person who imports and supplies a hormonal growth promotant must make, on each occasion on which the promotant is supplied to another person (in this regulation called the recipient), a record containing the following particulars:

(a) the distinguishing name of the promotant entered in the Register of Chemical Products;
(b) the name and address of the importer;
(c) the notification number assigned to the premises from which the promotant was supplied to the recipient;
(d) the quantity of the promotant supplied;
(e) the date of importation of the promotant;
(f) the batch number of the promotant;
(g) the quantity of promotant imported from that batch;
(h) the date of supply of the promotant;
(i) the name and address of the recipient;
Regulation 51

(j) if 1 or more notification numbers have been allotted to the recipient:
   (i) the notification number, and address, of each premises to which the promotant is supplied; and
   (ii) the quantity of the promotant supplied to each of those premises;

(k) if no notification number has been allotted to the recipient — the purchaser declaration number for the premises where animals treated with the promotant are to be kept.

Penalty: 10 penalty units.

Note Regulation 52 sets out further requirements regarding the form of the record.

(2) An offence under subregulation (1) is an offence of strict liability.

Note For strict liability, see section 6.1 of the Criminal Code.

51 Record of supply of hormonal growth promotant — other suppliers

(1) This regulation applies to a person (in this regulation called the supplier) who:
   (a) receives a hormonal growth promotant from another supplier (in this regulation called the previous supplier); and
   (b) supplies the promotant to another person (in this regulation called the recipient).

(2) When the promotant is supplied, the supplier must make a record containing the following particulars:
   (a) the distinguishing name of the promotant entered in the Register of Chemical Products;
   (b) the name and address of the supplier;
   (c) the notification number assigned to the premises from which the promotant was supplied to the recipient;
   (d) the batch number of the promotant;
   (e) the name and address of the recipient;
(f) the date of supply of the promotant to the recipient;
(g) the quantity of the promotant supplied to the recipient;
(h) the total quantity of the promotant remaining in the supplier’s possession after supply;
(i) the name and address of the previous supplier;
(j) the notification number (if any) assigned under this Division to the previous supplier for the premises from which the promotant was supplied by the previous supplier;
(k) the date of supply of the promotant by the previous supplier;
(l) the total quantity of the promotant supplied by the previous supplier;
(m) if 1 or more notification numbers have been allotted to the recipient:
   (i) the notification number, and address, of each premises to which the promotant is supplied; and
   (ii) the quantity of the promotant supplied to each of those premises;
(n) if no notification number has been allotted to the recipient — the purchaser declaration number for the premises where animals treated with the promotant are to be kept.

Penalty: 10 penalty units.

Note Regulation 52 sets out further requirements regarding the form of the record.

(3) It is a defence to a prosecution under subregulation (2) if the defendant has a reasonable excuse.

Note A defendant bears an evidential burden in relation to the matter mentioned in this subregulation — see section 13.3 of the Criminal Code.

(4) An offence under subregulation (2) is an offence of strict liability.

Note For strict liability, see section 6.1 of the Criminal Code.
52 Record of supply of hormonal growth promotant — general requirements

For the purposes of regulations 49, 50 and 51, a record must be made:
(a) in written or electronic form; and
(b) in such a way as to be readily accessible for the purposes of Part 9 of the Code (which deals with enforcement).

53 Copy of records to be given to APVMA

(1) A person who makes a record under regulation 49, 50 or 51 must give a copy of the record to the APVMA within 14 days after the end of the month in which it was made.

(2) A person must not fail to comply with subregulation (1).

Penalty: 10 penalty units.

(3) It is a defence to a prosecution under subregulation (1) if the defendant has a reasonable excuse.

Note A defendant bears an evidential burden in relation to the matter mentioned in this subregulation — see section 13.3 of the Criminal Code.

(4) An offence under subregulation (2) is an offence of strict liability.

Note For strict liability, see section 6.1 of the Criminal Code.

54 Copy of records etc to be kept

(1) A person who makes a record under regulation 49, 50 or 51 must keep the record for 2 years after it is made.

(2) A person to whom a declaration is given under subparagraph 48 (1) (b) must keep the declaration for 2 years after it is given.

(3) A person must not fail to comply with subregulation (1) or (2).

Penalty: 10 penalty units.

(4) It is a defence to a prosecution under subregulation (1) or (2) if the defendant has a reasonable excuse.

Note A defendant bears an evidential burden in relation to the matter mentioned in this subregulation — see section 13.3 of the Criminal Code.
(5) An offence under subregulation (3) is an offence of strict liability.

*Note*  For strict liability, see section 6.1 of the Criminal Code.
Part 5 Analysis

55 Analysis of chemical products — tests

(1) Section 7 of the Act (which deals with the power to make orders) applies to prescribing tests for the analysis of samples of substances or mixtures of substances for the purposes of the Code.

(2) For the purposes of Part 5 of the Code, a sample of a substance or mixture of substances must be analysed by means of any of the following tests that apply to the substance or mixture:

(a) a test prescribed in an order made under section 7 of the Act;

(b) if the substance or mixture is a chemical product in respect of which a test is accepted by the APVMA for the purposes of registration of that chemical product — that test;

(c) a test specified in:

(i) the CIPAC Handbook and Addenda published by the Collaborative International Pesticides Analytical Council Limited; or

(ii) the AOAC Manual and Addenda published by the Association of Official Analytical Chemists;

(iii) the British Pharmacopoeia; or

(iv) the British Pharmacopoeia (Veterinary); or

(v) the European Pharmacopoeia; or

(vi) the US Pharmacopoeia;

(d) any other test approved by the APVMA as equivalent to a test specified in paragraph (a), (b) or (c).
56 Analysis at an accredited laboratory

For the purposes of paragraph 99 (4) (c) of the Code (which deals with requirements for analysis), a prescribed laboratory, in relation to the analysis of a substance or mixture of substances, is a laboratory accredited by NATA, or approved by the APVMA, to carry out an analysis of that kind.
Regulation 57

Part 6 Permits

57 Additional requirement for the issue of a permit

For the purposes of paragraph 112 (2) (h) of the Code (which deals with the grant and refusal of permit applications), in the case of an application for a permit in respect of the use of:

(a) a chemical product that is not a registered chemical product; or

(b) an active constituent for a proposed or existing chemical product that is not an approved active constituent; or

(c) a registered chemical product or approved active constituent for a proposed or existing chemical product, otherwise than in accordance with any conditions on the approved label for containers for that product;

the use of the product as proposed in the application must be:

(d) a minor use; or

(e) an emergency use; or

(f) for the purpose of research.
Part 7 Manufacture of chemical products

58 Coming into force of section 121 of the Code
For the purposes of subsection 120 (3) of the Code, the date on which section 121 of the Code (which deals with offences relating to manufacture and licences) comes into force is the date of commencement of the Code.

59 Manufacture of chemical products — exempt products
(1) For the purposes of paragraph 121 (4) (a) of the Code (which deals with exempt products and persons in relation to manufacture), the following are exempt products:
(a) any agricultural chemical product;
(b) an ingredient used in the manufacture of a chemical product if the ingredient:
   (i) does not have a therapeutic or biological effect on a plant or animal; or
   (ii) is a herb, or an oil extracted from a herb, the sole use of which is as a starting material for use in the manufacture of a chemical product;
(c) any product prepared in a research facility or pilot plant solely for experimental use;
(d) any veterinary homeopathic preparation that:
   (i) is more dilute than a one thousandfold dilution of a mother tincture; and
   (ii) is not required to be sterile;
(e) any skin cleanser or shampoo;
(f) any coat conditioner intended for external use only;
(g) any equine hoof protectant;
(h) any sheep branding substance;
(i) a substance of any of the following kinds that is intended to be added to stockfood:
Regulation 59A

(i) organic acids;
(ii) antioxidants;
(iii) pellet-binding products;
(iv) mould inhibitors;
(v) preservatives;
(vi) feed handling improvers;
(vii) colouring agents;
(viii) anticaking agents;
(ix) deodorising agents;
(x) flavours;
(xi) flavour enhancers;
(xii) sweeteners;
(xiii) aromatic substances;
(xiv) appetising substances.

(2) In paragraph (1) (d):

mother tincture means a liquid prepared by the process of solution, extraction or trituration.

veterinary homeopathic preparation means a preparation:

(a) formulated for use on the principle that it is capable of producing in a healthy animal symptoms similar to those which it is administered to alleviate; and

(b) prepared according to the practices of homeopathic pharmacy using the method of:

(i) serial dilution and succussion of a mother tincture in water, ethanol, aqueous ethanol or glycerol; or

(ii) serial trituration in lactose.

59A Manufacture of chemical products — exempt persons — single step

For the purposes of paragraph 121 (4) (a) of the Code, a person who performs only a single step in the manufacture of a product is an exempt person in relation to the manufacture if:

(a) the step consists only of:

(i) packaging or labelling, or both packaging and labelling, the product; or
(ii) analysing or testing the product; and

(b) either:

(i) the licence that authorises the manufacture of the product (being a licence held by another person) permits the first-mentioned person to perform the step for the product; or

(ii) the step consists only of applying a label that contains only a name and address, or the registration number of the product, or both, to a package, or packages, of the product.

59B Manufacture of chemical products — exempt persons — chemical product that ceases to be exempt

For the purposes of paragraph 121 (4) (a) of the Code, if a product ceases to be an exempt product under this Part, each person that:

(a) performs a step in the manufacture of that product; and

(b) is not the holder of a licence authorising the performance of that step in relation to the product; and

(c) applied, before the product ceased to be an exempt product, for a licence authorising the performance of that step in relation to the product;

is an exempt person in relation to that product during the period beginning when the product ceases to be exempt and ending when the APVMA gives notice of its decision on the application.

59C Manufacture of chemical products — exempt persons — legal personal representative etc of licence holder

(1) The legal personal representative of a licence holder who dies is an exempt person in relation to the manufacture of a product the production of which is authorised by the licence, subject to the following conditions:
Regulation 59D

(a) that he or she gives the APVMA notice, in writing, of the grant of probate or administration not later than 3 months after it occurs;
(b) that he or she complies with the terms of the licence as if he or she were the holder of the licence;
(c) that he or she complies with the Code and these Regulations as if he or she were the holder of the licence.

(2) The trustee in bankruptcy of a licence holder is an exempt person in relation to the manufacture of a product the production of which is authorised by the licence, subject to the following conditions:
(a) that he or she gives the APVMA notice, in writing, of the bankruptcy not later than 3 months after it occurs;
(b) that he or she complies with the terms of the licence as if he or she were the holder of the licence;
(c) that he or she complies with the Code and these Regulations as if he or she were the holder of the licence.

(3) An exemption under this regulation has no effect if the licence issued to the deceased person or the bankrupt (as the case may be) is not in force.

(4) If the APVMA reasonably requires the legal personal representative or trustee in bankruptcy to provide further information, or documents, relating to a grant of probate or letters of administration, or a trusteeship (as the case requires), and that request is not complied with within the time allowed by the APVMA, the exemption ceases to have effect at the end of that time.

(5) The time allowed to comply with a request under subregulation (4) must not be shorter than 1 month from the date of the request.

59D Manufacture of chemical products — exempt persons — person that acquires business including transfer of licence

(1) A person who is the transferee of a business:
(a) involving the manufacture of chemical products; and
(b) in relation to which a licence has been issued;

is an exempt person in relation to the manufacture of a product
the production of which is authorised by the licence, subject to
the following conditions:

(c) that the person notifies the APVMA, in writing, of the
transfer not later than 6 weeks after it is agreed;

(d) that the person complies with the terms of the licence as if
he or she were the holder of the licence;

(e) that the person applies for a licence in relation to the
business, in accordance with section 122 of the Code,
within 3 months after acquiring the business.

(2) An exemption under subregulation (1):

(a) ceases to have effect if the person’s application under
paragraph (1) (e) is refused by the APVMA; and

(b) has no effect if the licence referred to in paragraph (1) (b)
is not in force.

60 Licence condition — holder to give information about
manufacture

For the purposes of paragraph 126 (4) (b) of the Code (which
deals with additional conditions of a licence), it is a condition
of each licence that the holder of the licence must give the
APVMA on or before each anniversary of the day on which the
licence comes into force:

(a) the name, qualifications and details of the relevant
experience of any person nominated by the holder of the
licence as the person having control of:

(i) the production of the chemical products
manufactured by or on behalf of the holder of the
licence; and

(ii) the quality control measures that are, or are to be,
employed in the manufacture of the chemical
products; and

(b) if the APVMA so requests — details of chemical products
manufactured by or on behalf of the holder of the licence
during the previous 12 months.
61 Licence conditions — general

(1) For the purposes of paragraph 126 (4) (b) of the Code (which deals with conditions in licences), the following subregulations set out conditions to which each licence to manufacture chemical products is subject.

(2) A holder of a licence must display publicly, at the premises to which the licence relates, a copy of the licence and of any notice issued by the APVMA imposing, varying or removing the conditions applicable to the licence.

(3) A holder of a licence must make records showing:
   (a) the materials used in the manufacture of the chemical products, the supplier and quantities of the materials used and details of the tests performed on those materials; and
   (b) the procedures and controls employed in the manufacture of the chemical products, including the results of tests carried out during the processing of the chemical products; and
   (c) details of the tests performed on the chemical products and the results of those tests; and
   (d) the stability studies (if any) that validate the recommended shelf life and appropriate storage conditions of the chemical products.

(4) If the chemical products are produced in identifiable batches, the holder of the licence must assign a batch number to each batch of the finished products.

(5) A holder of a licence must keep at the premises to which the licence relates:
   (a) the records specified in subregulation (3); and
   (b) if it is not unreasonable in the circumstances — a sample from each batch of the finished products;

for at least 12 months after the expiry date of the products to which they relate or, if there is no expiry date, for at least 6 years after the date on which the manufacture of the products was completed.
(6) The holder of the licence must ensure that a person nominated by the holder as having control of the production of the chemical products or of the quality control measures that are to be employed in the manufacture of the products maintains that control.

(7) If a licence allows a person other than the licence holder (in this subregulation called the contractor) to perform a step of a kind set out in paragraph 59A (a) in the manufacture of a chemical product, the licence holder:
   (a) must supervise the performance of that step; and
   (b) must ensure that the respective responsibilities of the contractor and the licence holder in relation to the step are recorded in writing; and
   (c) must ensure that the contractor maintains any records that, under the licence condition imposed by subregulation (3), the licence holder would be required to maintain if the licence holder performed the step; and
   (d) must ensure that:
      (i) the premises at which the contractor performs the step; and
      (ii) the records referred to in paragraphs (b) and (c);
       are made accessible to a person appointed by the APVMA to inspect the operations of the licence holder.

(8) A holder of a licence must keep a record of complaints and product failures, as specified by Australian/New Zealand Standard AS/NZ/ISO 9002: 1994, Quality systems — Model for quality assurance in production, installation and servicing, as in effect at the commencement of this subregulation.

(9) If the holder of a licence:
   (a) changes his, her or its name; or
   (b) being a corporation that has amalgamated with another corporation, carries on business under a name that is different from the name of the holder stated on the licence;
   the holder must give notice in writing to the APVMA of the new name, and the circumstance giving rise to it, within 3 months after the occurrence of the circumstance.
(10) If a body corporate that is the holder of a licence becomes an externally-administered body corporate, within the meaning of the Corporations Law, the person responsible for its administration must notify the APVMA, in writing, that the body corporate has become an externally-administered body corporate within 3 months after that occurrence.

62 Licence condition — naming persons in control of production etc

For the purposes of paragraph 126 (4) (b) of the Code (which deals with conditions in licences), if:

(a) an applicant for a licence to manufacture chemical products nominates a person as the person having control of the production of chemical products or of the quality control measures to be employed in the manufacture of the chemical products; and

(b) the licence is granted; and

(c) the applicant wishes to replace the nominated person with another person;

it is a condition of the licence that the licence holder must inform the APVMA as soon as practicable of the name, qualifications and experience of that other person.
Part 8 Enforcement

63 Method of securing samples
An inspector who takes a sample of any substance or mixture of substances for the purposes of section 131 or 132 of the Code (which deal with powers of search and seizure) must ensure that:
(a) the sample is contained and sealed in an appropriate vessel or package; and
(b) the vessel or package is so marked as to clearly identify the sample; and
(c) the vessel or package cannot be opened, or the identification of the sample removed, without breaking the seal; and
(d) the sample is stored and transported in such a way that the composition of the sample is not altered.

64 Form of search warrant
For the purposes of subsection 133 (2) of the Code (which deals with the form of a search warrant), the form of warrant in Schedule 5 is prescribed.
Part 9  Miscellaneous

65  Prescribed authorities that may require further information

For the purposes of subsection 159 (1) of the Code (which deals with notices to give further information), each of the following authorities is prescribed:

(a) the Department of Health and Ageing of the Commonwealth;
(b) the Department of the Environment and Heritage of the Commonwealth;
(c) the National Occupational Health and Safety Commission established by the National Occupational Health and Safety Commission Act 1985;
(d) an authority in this jurisdiction having any function or power in relation to a matter referred to in paragraph 159 (a), (b), (c) or (d) of the Code.

66  Disclosure of confidential commercial information about toxicity etc

(1) For the purposes of subparagraphs 162 (3) (a) (iii) and 162 (3) (b) (iii) of the Code, this regulation prescribes the conditions under which confidential commercial information of a kind described in those subparagraphs may be disclosed by the authorised person about a chemical product or any of its constituents.

(2) Information about a protected chemical product that is compensatable protected registration information (the requesting person) on request if the requesting person signs and gives to the APVMA, before the information is disclosed, a declaration stating that the information will not be used in connection with an application for registration, in Australia or elsewhere, of another chemical product, except with the consent of the interested person in relation to the protected chemical product.
(3) Information about a chemical product that is not compensatable protected registration information, may be disclosed to a person on request by making it available to that person, for the purpose of reading only, at the premises of the APVMA or, if the APVMA thinks it appropriate, at other premises.

(4) Despite subregulations (2) and (3), information about a constituent of a chemical product other than an active constituent may be disclosed to a medical practitioner, in connection with his or her professional duties.

(5) In this regulation, *compensatable protected registration information* means protected registration information in respect of which compensation for provision of the information would be payable under Part 3 of the Code.

### 67 Disclosure of confidential commercial information about chemical products not yet registered etc

For the purposes of subparagraph 162 (3) (c) (iii) of the Code a prescribed person is:

(a) in the case of a chemical product in respect of which an application for registration has been made — a person who is expressly authorised to obtain the information by the applicant for registration; or

(b) in the case of an active constituent in respect of which an application for approval has been made — a person who is expressly authorised to obtain the information by the applicant for approval.

### 68 Disclosure of confidential commercial information to international organisations

For the purposes of subparagraph 162 (3) (d) (ii) of the Code, the following organisations are prescribed:

(a) the World Health Organization;

(b) the Food and Agriculture Organization of the United Nations;

(c) the International Labour Organization;

(d) the United Nations Environment Programme;
Regulation 69

(e) the United Nations International Programme on Chemical Safety;
(f) the Organization for Economic Co-operation and Development;
(g) any international organisation established jointly by 2 or more of the international organisations mentioned in paragraphs (a), (b), (c), (d), (e) and (f);
(h) any international organisation that is an agency or committee of an international organisation mentioned in paragraph (a), (b), (c), (d), (e), (f), or (g).

69 Disclosure of confidential commercial information — records

(1) The APVMA must make a record, on each occasion on which confidential commercial information is disclosed, of:
(a) the name and address of the person to whom the information is disclosed; and
(b) the nature of the information disclosed; and
(c) the date on which the information was disclosed.

(2) A record made under subregulation (1) must be kept for a period of 10 years.

(3) A person must not disclose any information contained in a record made under subregulation (1) to a person who is not a member of the staff of the APVMA.

Penalty: 10 penalty units.

(3A) It is a defence to a prosecution under subregulation (3) if the defendant:
(a) has a reasonable excuse; or
(b) has the permission in writing of the Minister or a person authorised under subregulation (4).

Note A defendant bears an evidential burden in relation to the matters mentioned in this subregulation — see section 13.3 of the Criminal Code.

(3B) An offence under subregulation (3) is an offence of strict liability.

Note For strict liability, see section 6.1 of the Criminal Code.
(4) The Minister may, in writing, authorise a person for the purposes of subregulation (3).

(5) In this regulation the Minister means the Minister for Primary Industries and Energy.

70 Fees for applications

(1) For the purposes of section 164 of the Code, this regulation provides for the fees payable in respect of applications under the Code.

Note Regulations 70A, 71, 71A, 72 and 72A make further provision regarding fees payable in respect of applications under the Code.

(2) The fee payable in respect of an application of a kind specified in Column 2 of an item in Part 2 of Schedule 6 is the fee (if any) specified for the item in Column 4 of that Schedule.

(3) A reference in Column 4 of an item in Part 2 of Schedule 6 to a modular assessment fee, is a reference to the modular assessment fee in respect of the application to which that item refers, worked out in accordance with regulation 71.

(4) The fee that is required to be paid at the time of making an application of a kind specified in an item in Part 2 of Schedule 6 is:

(a) if a modular assessment fee is payable for the application — $460; or

(b) if a fee is specified in Column 4 of the item — the fee specified in that column.

Note Paragraph 11 (1) (d) of the Code states that an application must be accompanied by:

(i) if only part of the prescribed fee is required to be paid at the time of making the application — the amount required to be paid; or

(ii) otherwise — the whole of the prescribed fee (if any).
(5) For the purposes of subsection 11A (4) of the Code, the component of the fee in respect of the preliminary assessment of an application made under section 10 of the Code (that is, the component of the fee paid under subregulation (4) in respect of the application that will not be repayable if the APVMA rejects an application on the ground that the application has not been properly made) is:

(a) in the case of an item in Part 2 of Schedule 6 for which a modular assessment fee is payable — $460; and

(b) in the case of an item in Part 2 of Schedule 6 for which the fee specified in Column 4 is nil or less than $460 — that fee specified in that column; and

(c) in the case of an item in Part 2 of Schedule 6 for which the fee specified in Column 4 is $460 or more — $460.

(6) No fee is payable in respect of an application for a permit:

(a) if:

(i) the applicant is:

(A) the Commonwealth, a State or Territory; or

(B) an authority or agency of the Commonwealth, a State or a Territory; or

(C) an officer or employee of the Commonwealth, a State or a Territory, or of an authority or agency of the Commonwealth, a State or a Territory; and

(ii) the permit is in support of the Commonwealth’s, State’s or Territory’s core activities; and

(iii) the permit is for a use that does not have a commercial benefit; or

(b) in respect of an emergency use of a chemical product.

70A Fees in respect of existing use active constituents

(1) Despite regulation 70, no fee is payable under that regulation in respect of an application for approval of an active constituent for a chemical product if:

(a) the active constituent is an existing use active constituent within the meaning of subregulation 40A (3); and
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(b) immediately before the commencement of the Code:
   (i) a clearance for registration that the APVMA granted under section 15 of the repealed Act in respect of the chemical product was in force; or
   (ii) an application under section 12 of the repealed Act for a clearance for registration of the chemical product had been made and had not been refused or withdrawn; and

(c) full technical details of the active constituent had been given, before the commencement of the Code, to a relevant body; and

(d) the application for approval is made within 6 months after the commencement of the Code.

(2) In paragraph (1) (c):

   full technical details, in relation to an active constituent, includes, but is not limited to, the following:
   (a) details of the chemistry of the active constituent;
   (b) details of the manufacture of the active constituent;
   (c) the site at which the active constituent is manufactured;
   (d) a declaration of composition of the active constituent;
   (e) a batch analysis of the active constituent.

   relevant body means any of the following:
   (a) the body known as the Technical Committee on Agricultural Chemicals;
   (b) the body known as the Technical Committee on Veterinary Drugs;
   (c) the Australian Agricultural and Veterinary Chemicals Council established under the repealed Act;
   (d) the APVMA.

71 Modular assessment fee

(1) Schedule 7 sets out the assessment modules that may be necessary to determine an application for which a modular assessment fee is payable.
(2) An assessment module may have different levels or types of assessment.

(3) The fee payable for a module, level or type of assessment is set out in Column 4 of Schedule 7.

(4) The *modular assessment fee* for an application is the sum of the fees payable for:

   (a) the screening assessment module in item 1 in Schedule 7; and

   (b) the other modules, levels and types of assessment that the APVMA considers necessary for the application to undergo; and

   (c) the type of finalisation assessment module in items 11.1 to 11.4 in Schedule 7 that the application must undergo.

*Note 1* The APVMA intends to make, under subsection 164 (1A) of the Code, a legislative instrument, *Agricultural and Veterinary Chemicals Code Instrument No. 2 (Modular Assessment Fees) 2005*, setting out criteria for working out which fees apply under these Regulations in a particular case.

*Note 2* Under subregulation 70 (5), the APVMA will retain the $460 that, under subregulation 70 (4), accompanied an application for which a modular assessment fee is payable if the APVMA rejects the application on the ground that the application had not been properly made.

(5) For the purposes of subsection 164 (2) of the Code, any balance of the modular assessment fee is due and payable on the date specified by the APVMA in a notice under paragraph 78 (3) (b) or subregulation 78A (2).

### 71A Annual fees for continued registration of chemical product

(1) For paragraph 49 (1) (d) of the Code, the fee payable for an application for the renewal of the registration of a chemical product in respect of the financial year commencing on 1 July 2005 or any subsequent financial year is $390.

(2) For paragraph 56ZM (1) (d) of the Code, the fee payable for an application for the renewal of the listed registration of a chemical product in respect of the financial year commencing on 1 July 2005 or any subsequent financial year is $390.
72  Remission of fees for applications

(1) For the purposes of paragraph 164 (8) (b) of the Code, a circumstance in which the APVMA may remit the whole or part of a fee paid:

(a) in respect of an application under the Code, other than an application:
   (i) for the renewal of the registration of a chemical product; or
   (ii) for a permit; or

(b) for a module of assessment;

is that:

(c) in the case of an application — the application is not determined within the period specified or worked out in respect of that application under regulation 76; or

(d) in the case of a module of assessment specified in Schedule 7 — the module is not completed within the time specified for the module in that Schedule.

(2) For the purposes of paragraph 164 (8) (b) of the Code, the APVMA may waive or remit, up to $100, the whole or part of a fee payable or paid under the Code.

72A  Fee for issue of licence

(1) For the purposes of section 164 of the Code, the fee payable for the issue of a licence by the APVMA is $6,000, payable by equal annual instalments as set out in this regulation.

(2) Subject to subregulations (5) and (6), the amount of the annual instalment of the fee payable for the issue of a licence is:

(a) if only 1 product is produced under the authority of the licence at the premises specified in the licence:
   (i) if that product is a Category 1 product — $1,500; or
   (ii) if that product is a Category 2 or 3 product — $1,000; or
   (iii) if that product is a Category 4 product — $500; or
Regulation 72A

(b) if more than 1 product is produced under the licence at the premises specified in the licence, and both or all of those products are of the same category — the amount specified in paragraph (a) in relation to a single product of that category; or

(c) if more than 1 product is produced under the licence at the premises, and not all of those products are of the same category — the highest amount specified in paragraph (a) in relation to any of those products; or

(d) if the licence authorises only the performing of a single step in manufacture (including packaging, labelling, analysis or testing) at the premises, and the step is performed by a person other than a person to whom regulation 59A applies or to whom paragraph (e) refers — $500; or

(e) if the licence authorises only the testing, analysis or sterilisation of a veterinary chemical product, and the holder of the licence is accredited by the National Association of Testing Authorities, Australia for the purposes of the testing, analysis or sterilisation of veterinary chemicals — $300; or

(f) if the holder of the licence also holds a licence issued under the Therapeutic Goods Act 1989 authorising the production of therapeutic goods, within the meaning of that Act, at those premises — $300; or

(g) if the holder of the licence is authorised, by an authority specified in subregulation (4), to manufacture, at those premises, chemicals for therapeutic use in relation to human beings, or chemicals for agricultural or veterinary use — $300.

(3) In subregulation (2):

**Category 1 product** means a veterinary chemical product that is:

(a) registered as being, represented to be, or required to be sterile; or

(b) an immunobiological product.

**Category 2 product** means a veterinary chemical product that is not a Category 1, 3 or 4 product.
Category 3 product means a veterinary chemical product that is an ectoparasiticide.

Category 4 product means a veterinary chemical product that is:
(a) a premix; or
(b) a stockfood supplement.

Note Not all stockfood supplements or premixes are veterinary chemical products for the purposes of the Act. See the definition of veterinary chemical product in section 5 of the Code, and regulation 8.

(4) For the purposes of paragraph (2) (g), each of the following bodies is a specified authority:
(a) the Medicines Control Agency of the Department of Health of the United Kingdom;
(b) the Veterinary Medicine Directorate of the United Kingdom;
(c) the Animal and Plant Health Inspection Service of the Department of Agriculture of the United States of America;
(d) the Centre for Veterinary Medicine of the Food and Drug Administration of the United States of America.

(5) If a licence is granted subject to a condition to the effect that:
(a) the licensee must undergo an audit of its manufacturing processes; and
(b) the audit must demonstrate that the conduct of those manufacturing processes is satisfactory;
until the condition is satisfied, the amount of the annual instalment of the fee for the issue of the licence is $600.

(6) Despite subregulations (2) and (5), the amount of the instalment of the fee due in the following year for the issue of a licence is one-half of the amount worked out in accordance with subregulations (2) and (5) if the holder of the licence provides evidence, to the satisfaction of the APVMA, that:
(a) for the year that began on 1 January 1997 and any succeeding calendar year up to and including 2003 — the total notional wholesale value of all the veterinary chemical products manufactured in a calendar year at the premises specified in the licence is less than $50 000; and
(b) for the six-month period commencing on 1 January 2004 — the total notional wholesale value of all the veterinary chemical products manufactured in that six-month period at the premises specified in the licence is less than $25 000; and

(c) for the financial year commencing on 1 July 2004 and subsequent financial years — the total notional wholesale value of all the veterinary chemical products manufactured in the financial year at the premises specified in the licence is less than $50 000.

(7) In subregulation (6):

(a) notional wholesale value has the same meaning as in the Agricultural and Veterinary Chemicals (Collection of Levy) Act 1994; and

(b) the notional wholesale value of a batch of a veterinary chemical product is the notional wholesale value at the time of completion of manufacture of the batch; and

(c) a reference to ‘veterinary chemical products manufactured’ does not include veterinary chemical products that are exempt products for the purposes of section 121 of the Code.

Note 1 Section 3 of the Agricultural and Veterinary Chemicals (Collection of Levy) Act 1994 has the following definition:

notional wholesale value, in relation to a chemical product at a particular time, means the amount that the APVMA determines would have been received:

(a) if the product is an Australian product—by the manufacturer; or

(b) if the product is an imported product—by the importer;

in respect of the product if, at that time, the product had been sold by the manufacturer or importer, as the case may be, by wholesale to a person with whom the manufacturer or importer was dealing at arm’s length.

Note 2 For exempt products for the purposes of section 121 of the Code, see regulation 59.

(8) An instalment of the fee for issue of a licence is due for payment on the day the licence is granted, and a further instalment is due for payment on each anniversary of that day.
(9) If an instalment of the fee for issue of a licence is not paid before the end of 28 days after the day it is due for payment, all other unpaid instalments for the issue of the licence become due for payment.

(10) Despite subregulation (1), if a licence is cancelled, the APVMA must waive any part of the prescribed fee that has not become due for payment at the time of cancellation.

### 73 Fees for copies and extracts

(1) Subject to subregulation (3), the fee payable:

(a) under subsection 17 (5) of the Code — for a copy of, or extract from, a part of the Record of Approved Active Constituents in respect of an active constituent; or

(b) under subsection 18 (5) of the Code — for a copy of, or extract from, a part of the Register of Agricultural and Veterinary Chemical Products in respect of a chemical product; or

(d) under subsection 97 (4) of the Code — for a copy of a certificate in respect of an analysis; or

(e) under subsection 113 (6) of the Code — for a copy of a permit; or

(f) for the disclosure, under section 162 of the Code, of confidential commercial information:

   (i) of a kind described in subparagraphs 162 (3) (a) (iii) or 162 (3) (b) (iii) of the Code, other than to a medical practitioner referred to in subregulation 66 (4); or

   (ii) to a person referred to in subparagraph 162 (3) (c) (ii);

is the fee worked out in accordance with subregulation (2).

(2) For the purposes of subregulation (1), the fee is the sum of the following:

(a) $90; and

(b) $90 for each additional hour or part of an hour, after the first hour, of work done by the APVMA to make the copy or extract available; and
Regulation 74

(c) 20 cents for each photocopied page in excess of the first 100 pages; and
(d) $4.40 for each page of a copy, other than a photocopy, of a document; and
(e) $4.40 for each page of a transcript of:
   (i) a sound recording; or
   (ii) a document in shorthand.

(3) No fee is payable:
   (a) for a copy or extract referred to in paragraph (1) (a) or (b) — by the person who applied for registration or approval of the constituent, product or label; or
   (b) for a copy referred to in paragraph (1) (e) — by the person who applied for the permit; or
   (c) in respect of any matter referred to in subregulation (1) — by an authority in this jurisdiction having any function or power in relation to a matter referred to in paragraph 159 (a), (b), (c) or (d) of the Code.

74 Payment of fees
A fee payable under these Regulations is payable to the APVMA.

75 Notification that application has been received
Within 10 days of receiving an application under the Code, the APVMA must notify the applicant that the application has been received.

76 Period within which APVMA is to determine application
(1) For the purposes of section 165 (1) of the Code, the APVMA must determine an application of a kind specified in Column 2 of an item in Part 2 of Schedule 6 within the period (if any) specified for the item in Column 3 of that Schedule.
(2) A reference in Column 3 of an item in Part 2 of Schedule 6 to a modular assessment period, is a reference to the modular assessment period in respect of the application to which that item refers, worked out in accordance with regulation 77.

(4) Despite subregulation (1), if:
   (a) the APVMA receives an application for a permit in respect of a chemical product; and
   (b) the application is in respect of an emergency use of the chemical product;
the APVMA must determine the application as soon as is practicable in the circumstances of the case.

Note 1 Subsection 165 (2) of the Code provides that in working out a period for the purposes of an application, no regard is to be had to certain periods that would otherwise be part of that period, including any period during which a requirement made by the APVMA has not been complied with.

Note 2 For the period within which an application for the renewal of the registration of a chemical product must be granted, see subsection 49 (4) of the Code.

77 Modular assessment period

(1) In addition to setting out the fees for modules, levels and types of assessment, Schedule 7 sets out in Column 3 of the Schedule the period within which some of those modules, levels and types must be completed.

(2) The modular assessment period referred to in Column 3 of an item in Part 2 of Schedule 6 (that is, the period within which an assessment of an application must be completed) is the sum of:
   (a) the longest of the periods for such other modules or levels of assessment in other items in Schedule 7 that the APVMA considers necessary for the application to undergo; and
   (b) the period for the type of finalisation assessment module in items 11.1 to 11.4 in Schedule 7 that the application must undergo.
78 Commencement of period for determining applications made under section 10 of the Code

(1) In the case of an application of a kind specified in item 1, 3, 4, 5, 6, 7, 8, 15, 16 or 17 in Part 2 of Schedule 6, the period specified in Column 3 of the item commences at the first moment of the day after the later of:

(a) the day on which the APVMA gives notice under subsection 11A (2) of the Code that the application has passed preliminary assessment; and

(b) the day on which the correct fee specified in respect of the application is paid.

(2) In the case of an application of a kind specified in item 2, 10 or 24 in Part 2 of Schedule 6, the modular assessment period commences immediately after the day on which the balance of the modular assessment fee is paid.

Note Notice of passing preliminary assessment for, or rejection of, applications made under section 10 of the Code are given under subsections 11A (2) and (5) of the Code, respectively.

(3) If the APVMA gives notice under subsection 11A (2) of the Code in relation to an application, the APVMA must also notify the applicant in writing:

(a) that if, under section 159 of the Code, the APVMA requires a person to give further information about the application, consideration of the application may be suspended, or the application may be treated as withdrawn, if the person fails to comply with the requirement; and

(b) if the application is of a kind specified in item 2, 10 or 24 in Part 2 of Schedule 6:

(i) of the modules that the application must undergo; and

(ii) of the balance of the modular assessment fee payable; and

(iii) that the balance is due and payable on the date specified in the notice.

Note The balance payable in relation to an application for which a modular assessment fee is payable is the difference between the modular assessment fee and the $460 that accompanied the application.
78A Commencement of period for determining other applications

(1) In the case of an application of a kind specified in item 9, 11, 12, 13, 14, 18, 19, 20, 21, 23 or 25 in Part 2 of Schedule 6, the period specified in Column 3 of the item commences at the first moment of the day after the later of:

(a) the day the APVMA gives notice under subregulation (2) that the APVMA will proceed with the technical evaluation and assessment of the application; or

(b) the day on which the correct specified fee (if any) in respect of the application is paid.

(2) The APVMA must, within 1 month after receiving an application referred to in subregulation (1), notify the applicant in writing:

(a) whether the APVMA will proceed with the technical evaluation and assessment of the application; and

(b) that if, under section 159 of the Code, the APVMA requires a person to give further information about the application, consideration of the application may be suspended, or the application may be treated as withdrawn, if the person fails to comply with the requirement; and

(c) if the APVMA will proceed with technical evaluation and assessment and a modular assessment fee is payable for the application:

(i) of the modules that the application must undergo; and

(ii) of the balance of the modular assessment fee payable; and

(iii) that the balance is due and payable on the date specified in the notice.

Note 1 The balance payable in relation to an application for which a modular assessment fee is payable is the difference between the modular assessment fee and the $460 that accompanied the application.
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Note 2 For an application of a kind specified in item 22 in Part 2 of Schedule 6 (permit if the proposed use a chemical product or active constituent is determined by the APVMA to be an emergency use), subregulation 76 (4) states that the APVMA must determine the application as soon as is practicable in the circumstances of the case.

79 Logo of the APVMA

For the definition of protected symbol in subsection 170A (5) of the Code, the logo of the APVMA is set out in Schedule 8 of these Regulations.
### Schedule 1  Date-controlled agricultural chemical products

(paragraph 4 (b))

| 1 | An agricultural chemical product containing organisms (including, in particular, nematodes, bacteria, viruses, fungi, algae or protozoa) |
| 2 | An agricultural chemical product containing bacillus thuringiensis |
| 3 | An agricultural chemical product containing mancozeb |
| 4 | An agricultural chemical product containing zineb |
| 5 | An agricultural chemical product containing diazinon |
| 6 | An agricultural chemical product containing dimethoate |
## Schedule 2 Protected registration information — allocated points

(Regulation 6)

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100 Agricultural and Veterinary Chemicals Code Regulations 1995

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<td>30</td>
</tr>
<tr>
<td>Column 1 Item</td>
<td>Column 2 Study</td>
<td>Column 3 Species</td>
<td>Column 4 Points</td>
</tr>
<tr>
<td>--------------</td>
<td>----------------</td>
<td>------------------</td>
<td>----------------</td>
</tr>
<tr>
<td>RESIDUES</td>
<td>Residue Trials</td>
<td></td>
<td>50 (per trial or test)</td>
</tr>
<tr>
<td>56.</td>
<td>Other</td>
<td></td>
<td>30</td>
</tr>
</tbody>
</table>

Agricultural and Veterinary Chemicals Code Regulations
1995

Federal Register of Legislative Instruments F2009C00122
## Schedule 3

### Substances or mixtures declared not to be agricultural chemical products

(subregulation 7 (2))

<table>
<thead>
<tr>
<th>Column 1</th>
<th>Column 2: Class of substance or mixture of substances</th>
</tr>
</thead>
</table>
| 1.       | Any mould inhibitor for use in the manufacture of paper, glue, plywood, carpets, or any surface coating (including paint), if:  
|          | (a) the mould inhibitor is incorporated into the product during manufacture as part of the manufacturing process; and  
|          | (b) the manufactured product is not claimed to have any effect as a pesticide |
| 2.       | Any fungicide, bactericide or deodorant for use in footwear and clothing |
| 3.       | Any soil ameliorant, conditioner or fertiliser if the product is not claimed to have any effect as a regulator of plant growth |
| 4.       | Any invertebrate pest management lure based on food and not containing any active constituent, and any vertebrate pest management lure |
| 5.       | Any disinfectant, mould inhibitor, air freshener or sanitiser sold by retailers, or presented or promoted primarily through retailers, to consumers for domestic use, except any sanitiser for use in swimming pools or spa water |
| 6.       | Cyanuric acid for use in swimming pools as a chlorine stabiliser |
| 7.       | Any cut flower preservative |
| 8.       | Any hay inoculant, silage inoculant or legume inoculant, if the product is based on bacteria or enzymes, or both |
| 9.       | Any predatory insect, predatory mite or macroscopic parasite |
| 10.      | The nematode *Deladenus siricidicola* for the control of *Sirex* species wood wasps in pine plantations |
| 11.      | Any industrial biocide used in the manufacture of paper pulp |
| 12.      | Any head lice or body lice treatment for human beings |
### Schedule 3A

**Prescribed uses (Code, s 34F (5))**

*(regulation 22A)*

*Note*  The text of Parts 1 and 2 of this Schedule is derived from that of the *Codex Alimentarius*. The ‘Codex number’ column and the ‘Major uses’ column are included because they are of assistance to users of the Codex. The food crops listed in the ‘Major uses’ column of Part 1 of this Schedule are also used for the purposes of the definition of *major food crop* in Schedule 6.

#### Part 1  Food crops and food crop groups

<table>
<thead>
<tr>
<th>CODEX no.</th>
<th>Crop/situation group</th>
<th>Major uses</th>
<th>Non-major uses</th>
</tr>
</thead>
<tbody>
<tr>
<td>001</td>
<td>Citrus fruits</td>
<td>Orange, mandarin (tangerine)</td>
<td>Grapefruit, lemon, lime, shaddock (pomelo)</td>
</tr>
<tr>
<td>002</td>
<td>Pome fruits</td>
<td>Apple, pear</td>
<td>Crab-apple, loquat (Japanese medlar), medlar, nashi pear, quince</td>
</tr>
<tr>
<td>003</td>
<td>Stone fruits</td>
<td>Apricot, cherry, nectarine, plum, peach</td>
<td>Sloe</td>
</tr>
<tr>
<td>004</td>
<td>Berries and other small fruits</td>
<td>Grape, strawberry</td>
<td>Blueberry, bearberry, bilberry, blackberry, boysenberry, cloudberry, cowberry, cranberry, blackcurrant, red currant, white currant, dewberry (olallie berry), elderberry, gooseberry, huckleberry, juneberry, loganberry, mulberry, rose hip</td>
</tr>
<tr>
<td>CODEX no.</td>
<td>Crop/situation group</td>
<td>Major uses</td>
<td>Non-major uses</td>
</tr>
<tr>
<td>-----------</td>
<td>----------------------</td>
<td>------------</td>
<td>----------------</td>
</tr>
<tr>
<td>005</td>
<td>Assorted tropical and sub-tropical fruits — edible peel</td>
<td>None specified</td>
<td>Ambarella, arbutus berry, Barbados cherry, bilimbi, carambola, carana, carob, cashew apple, black Chinese olive, white Chinese olive, coco plum, date, desert date, fig, grumichama, hog plum, jaboticaba, Chinese jujube, Indian jujube, kumquat, Natal plum, olive, Otaheite gooseberry, Japanese persimmon, pomerac, rose apple, sea grape, Surinam cherry, tree tomato</td>
</tr>
<tr>
<td>006</td>
<td>Assorted tropical and sub-tropical fruits — inedible peel</td>
<td>Avocado, banana, mango, pineapple</td>
<td>Akee apple, breadfruit, canistel, cherimoya, custard apple, doum palm (dum palm), durian, elephant apple, feijoa, guava, ilama, jackfruit, jambolan, Java apple, kiwifruit, longan, litchi, mammey apple, mangosteen, marmaladebox, yellow mombin, naranjilla, papaya, passionfruit, American persimmon, Japanese persimmon, plantain, pomegranate, prickly pear, pulasan, rambutan, sapodilla, black sapote, green sapote, mammey sapote, white sapote, sentul, soursop, Spanish lime, star apple, sugar apple, tamarind, tonka bean</td>
</tr>
<tr>
<td>009</td>
<td>Bulb vegetables</td>
<td>Onion</td>
<td>Fennel bulb, garlic, great-headed garlic, kurrat, leek, Chinese onion, Welsh onion, shallot, spring onion, silverskin onion, tree onion</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>CODEX no.</th>
<th>Crop/situation group</th>
<th>Major uses</th>
<th>Non-major uses</th>
</tr>
</thead>
<tbody>
<tr>
<td>010</td>
<td>Brassica (cole or cabbage) vegetables, head cabbages, flowerhead cabbages</td>
<td>Cabbage (head), broccoli, cauliflower</td>
<td>Chinese broccoli, Brussels sprout, cabbage (savoy), kohlrabi</td>
</tr>
<tr>
<td>011</td>
<td>Fruiting vegetables — cucurbits</td>
<td>Pumpkin, melon (except watermelon)</td>
<td>Apple and pear balsam, bottle gourd, chayote, cucumber, West Indian gherkin, gherkin, angled loofah, smooth loofah, snake gourd, summer squash, watermelon, zucchini</td>
</tr>
<tr>
<td>012</td>
<td>Fruiting vegetables other than cucurbits</td>
<td>Mushrooms, pepper (sweet capsicum), tomato</td>
<td>Egg plant, edible fungi, ground cherry, okra, pepino, pepper (chilli), roselle, sweet corn</td>
</tr>
<tr>
<td>CODEX no.</td>
<td>Crop/situation group</td>
<td>Major uses</td>
<td>Non-major uses</td>
</tr>
<tr>
<td>-----------</td>
<td>----------------------</td>
<td>------------</td>
<td>---------------</td>
</tr>
<tr>
<td>013</td>
<td>Leafy vegetables (including brassica leafy vegetables)</td>
<td>Lettuce</td>
<td>Amaranth, balsam pear leaves, betel leaves, box thorn, box thorn (gow gee, matrimony vine), cassava leaves, chard (silver beet, spinach beet, Swiss chard), chervil, chicory leaves (red-leaved chicory, sugar loaf), Chinese cabbage (pak-tsaai, pak-tsai, pak-soi), choisum (tsai shim, tsoi sum), corn salad (lamb’s lettuce), cos lettuce, garden cress, dandelion, dock, endive, goosefoot, grape leaves, Indian mustard, Japanese greens (various species), kale (collards, curly kale, Scotch kale, thousand-headed kale), kangkung (water spinach), komatsuma (mustard spinach), mallow, marsh marigold, mustard greens, New Zealand spinach, nightshade, black orach, pak-choi or paksoi (celery mustard), papaya leaves, pepper leaves, plantain leaves, pokeweed (poe-berry leaves), purslane, winter radish leaves, rape greens, roselle leaves (Jamaican sorrel), rucola (rocket salad, roquette), rutabaga greens, salsify leaves, sea kale, sena leaves, sowthistle, spinach, Indian spinach (vine spinach), sweet potato leaves, tannia leaves (yautia leaves), taro leaves, turnip greens (namenia, tendergreen), watercress</td>
</tr>
<tr>
<td>CODEX no.</td>
<td>Crop/situation group</td>
<td>Major uses</td>
<td>Non-major uses</td>
</tr>
<tr>
<td>-----------</td>
<td>----------------------</td>
<td>------------</td>
<td>----------------</td>
</tr>
<tr>
<td>014, 015</td>
<td>Legume vegetables, pulses</td>
<td>Beans (common bean, dwarf bean, field bean, flageolet, French bean, haricot bean, kidney bean, lima bean, mat bean, moth bean, navy bean, runner bean, snap bean, tepary bean, peas (edible-podded pea, garden pea, mangetout pea, podded pea, sugar pea, wrinkled pea), chick-pea (garbanzos, gram), field pea, lupin, mung bean (green gram))</td>
<td>Adzuki bean, bambara groundnut, black gram (urd bean), broad bean (fava bean, horse bean, pigeon bean), cluster bean (guar), cowpea (black-eyed pea, catjang cowpea), Goa bean (asparagus pea, four-angled bean, Manila bean, winged bean), horse gram, hyacinth bean (bonavist bean, lablab), jack bean, Kersting’s groundnut (geocarpa groundnut, geocarpa bean), lentil, lima bean (butter bean, sieva bean), mung bean, navy bean, pigeon pea (Angola pea, cajan pea, red gram, rice bean), scarlet runner bean, soya bean (soybean), sword bean, winged pea, yard-long bean (asparagus bean)</td>
</tr>
</tbody>
</table>
### Part 1 Food crops and food crop groups

<table>
<thead>
<tr>
<th>CODEX no.</th>
<th>Crop/situation group</th>
<th>Major uses</th>
<th>Non-major uses</th>
</tr>
</thead>
<tbody>
<tr>
<td>016</td>
<td>Root and tuber vegetables</td>
<td>Carrot, potato</td>
<td>Alocasia, arracacha, arrowhead, arrowroot, beetroot (red beet), edible burdock (greater burdock), edible canna (achira, gruya, Queensland arrowroot), cassava (bitter or sweet — tapioca, manioc), celeriac, chayote root (christophine), turnip-rooted chervil, chicory root, chufa, greater galangal, lesser galangal, Goa bean root, horseradish, Japanese artichoke, Jerusalem artichoke, leren, oca, turnip-rooted parsley, parsnip, black radish, Japanese radish, Chinese radish, daikon, rampion roots, salsify (oyster plant), Spanish salsify, scorzonera (black salsify), skirrit (skirret), sugar beet, swede (rutabaga), sweet potato, tannia (tanier, cocoyam, yautia), taro (dasheen, eddoe, cocoyam), tiger nut, topee tambu, turnip, ullucu, yams, yam bean (jicama, potato yam)</td>
</tr>
<tr>
<td>017</td>
<td>Stalk and stem vegetables</td>
<td>Asparagus</td>
<td>Globe artichoke, bamboo shoots, cardoon, celery, celtuce, palm hearts, rhubarb, witloof chicory sprouts</td>
</tr>
<tr>
<td>CODEX no.</td>
<td>Crop/situation group</td>
<td>Major uses</td>
<td>Non-major uses</td>
</tr>
<tr>
<td>-----------</td>
<td>----------------------</td>
<td>------------</td>
<td>----------------</td>
</tr>
<tr>
<td>03</td>
<td>Grasses</td>
<td></td>
<td></td>
</tr>
<tr>
<td>020</td>
<td>Cereal grains</td>
<td>Barley, maize (corn), oats, rice, sorghum (chicken corn, dari seed, durra, feterita, guinea corn, Kaffir corn, kaoliang, milo, shallu, sorgo), triticale, wheat (including durum wheat, emmer, spelt)</td>
<td>Buckwheat, cañihua, hungry rice (acha, fonio, fundi), job’s tears (adlay), millet, popcorn, quinoa, rye, teff (tef), teosinte, wild rice</td>
</tr>
<tr>
<td>021</td>
<td>Grasses, for sugar or syrup production</td>
<td>Sugar cane</td>
<td>Sorgo (sweet sorghum)</td>
</tr>
<tr>
<td>04</td>
<td>Nuts and seeds</td>
<td></td>
<td></td>
</tr>
<tr>
<td>022</td>
<td>Tree nuts</td>
<td>Almonds, macadamia nuts (brush nut, Queensland nut)</td>
<td>Beech nuts, Brazil nut, butter nut, cashew nut, chestnuts (chinquapin), coconut, hazelnuts (filberts), hickory nuts, Japanese horse-chestnut, pachira nut, paradise nut, pecan, pine nuts (pignolia, pignoli, pinocchi, piñon nut), pili nuts (Java almonds), pistachios, sapucaia nut, tropical almond, walnuts</td>
</tr>
<tr>
<td>023</td>
<td>Oilseed</td>
<td>Cotton seed, rape seed (canola, colza), sunflower</td>
<td>Mustard seeds, ben moringa seed (drumstick tree seed, horseradish tree seed), kapok, linola, linseed (flax-seed), Niger seed, palm nut, peanut (groundnut), poppy seed, safflower seed, sesame seed, shea nuts</td>
</tr>
<tr>
<td>024</td>
<td>Seed for beverages and sweets</td>
<td>None specified</td>
<td>Cacao beans, coffee beans, cola nuts (kola)</td>
</tr>
</tbody>
</table>
### CodeX no.Crop/situation group Major uses Non-major uses

<table>
<thead>
<tr>
<th>CodeX no.</th>
<th>Crop/situation group</th>
<th>Major uses</th>
<th>Non-major uses</th>
</tr>
</thead>
<tbody>
<tr>
<td>05</td>
<td>Herbs and spices</td>
<td>None specified</td>
<td>Angelica (including garden angelica), balm leaves, basil, bay leaves, borage, great burnet, salad burnet, burning bush (Cretan dittany), catmint (catnip), celery leaves, chives (including Chinese), curry leaves, dill, fennel, horehound, hyssop, lavender, lovage, marigold flowers, marjoram (oregano — sweet and wild), pennyroyal mint, peppermint, spearmint, nasturtium, parsley, rosemary, rue, sage (clary and related salvia species), sassafras leaves, summer savory, winter savory, sorrel, sweet cicely (myrrh), tansy (costmary and related species), tarragon (estragon), thyme, common winter cress, American winter cress, wintergreen leaves, woodruff, wormwoods (mugwort, southernwood)</td>
</tr>
<tr>
<td>027</td>
<td>Herbs</td>
<td>None specified</td>
<td>Angelica, aniseed, calamus, caper, caraway, cardamom, cassia, celery seed, cinnamon bark, cloves, coriander, cumin, dill, elecampane, fennel seed, fenugreek, galangal rhizomes, ginger root, grains of paradise, juniper, liquorice, lovage, mace, nasturtium, nutmeg, black pepper, white pepper, long pepper, pimento, turmeric, vanilla</td>
</tr>
</tbody>
</table>

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# Part 2  Animal foods and animal food groups

<table>
<thead>
<tr>
<th>CODEX no.</th>
<th>Crop/situation group</th>
<th>Major uses</th>
<th>Non-major uses</th>
</tr>
</thead>
<tbody>
<tr>
<td>06</td>
<td><strong>Mammalian products</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>030, 031, 032, 033</td>
<td>Meat, mammalian fats, edible offal</td>
<td>Cattle, sheep, pigs</td>
<td>Goats (including feral goats), llamas, alpacas, deer, camels, buffalos, horses, kangaroo, deer, rabbits</td>
</tr>
<tr>
<td>07</td>
<td><strong>Poultry products</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>036, 037, 038, 039</td>
<td>Poultry meat, poultry fats, poultry edible offal, eggs</td>
<td>Chickens</td>
<td>Turkeys, ostriches, emus, squab pigeons, game birds, ducks, geese</td>
</tr>
<tr>
<td>08</td>
<td><strong>Aquatic animal products</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>040, 041, 042, 043, 044, 045</td>
<td>Freshwater fish, diadromous fish, marine fish, fish roe, marine mammals, crustaceans</td>
<td>All aquatic animals used for food production</td>
<td></td>
</tr>
<tr>
<td>09</td>
<td><strong>Amphibians and reptiles</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>048</td>
<td>Amphibians and reptiles</td>
<td>All amphibians and reptiles used for food production</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td><strong>Invertebrate animals</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>049</td>
<td>Invertebrate animals</td>
<td>All invertebrate animals used for food production</td>
<td></td>
</tr>
<tr>
<td>11</td>
<td><strong>Animal feed crops</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>050, 051, 052</td>
<td>Animal feed crops</td>
<td>Legume animal feeds, grass and grain animal feeds, miscellaneous fodder and forage</td>
<td></td>
</tr>
</tbody>
</table>
### Part 3  Non-food crops and situation groups

<table>
<thead>
<tr>
<th>CODEX no.</th>
<th>Crop/situation group</th>
<th>Major uses</th>
<th>Non-major uses</th>
</tr>
</thead>
<tbody>
<tr>
<td>n/a</td>
<td>Pesticidal and medicinal oil crops</td>
<td>None specified</td>
<td>All pesticidal and medicinal oil crops</td>
</tr>
<tr>
<td>n/a</td>
<td>Ornamentals</td>
<td>Ornamentals (when applied for as a group)</td>
<td>Individual ornamental species</td>
</tr>
<tr>
<td>CODEX no.</td>
<td>Crop/situation group</td>
<td>Major uses</td>
<td>Non-major uses</td>
</tr>
<tr>
<td>-----------</td>
<td>----------------------</td>
<td>------------</td>
<td>----------------</td>
</tr>
</tbody>
</table>
| n/a       | Other situations     | **Agricultural non-crop areas**  
(including land associated with farmland but not used for regular cultivation and/or grazing);  
**commercial forests** (including plantations grown specifically for timber production);  
**fallow land**;  
**commercial and industrial areas**  
(including factories, factory land, industrial sites, parking plots, fuel tank farms, outside chemical storages);  
**domestic and public service areas**  
(including houses, residential subdivisions, schools, hospitals, restaurants, hotels, motels, cafés, rubbish tips and playground and recreational areas such as golf courses, municipal parks and gardens, etc.);  
**non-crop areas**  
(including areas of lands not being used or intended to be used for cropping or grazing — these areas include industrial sites, timber yards, areas around farm buildings, along fences and roadsides, rights-of-way, storage areas, wastelands, vacant lots, cemeteries, etc);  
**bushland and native forests**  
(including natural forest areas used for recreational or scenic purposes, national parks, etc);  
**turf areas**  
(including commercial turf farms, sports ovals, bowling greens, general lawn areas, etc);  
**aquatic areas**  
(including irrigation channels, streams, lakes, dams and drainage ditches) |
Schedule 3B  Listing Schedule
(regulation 23A)

Part 1  Preliminary

1  Particulars of listable chemical products

Each chemical product, or class of chemical product, listed in this Schedule is described in a separate item in the table in Part 2 as follows:

(a) column 2 describes the product;
(b) column 3 describes the product use.

2  Active constituents in listable chemical products

(1) A substance mentioned in column 2 of an item in the table in Part 2 as an active constituent of a chemical product or class of chemical product, means the substance with that name that complies with the particulars specified for that substance in an item in a Subdivision of Part 3 of this Schedule.

(2) Each substance dealt with in a Subdivision of Part 3 is described in a separate item as follows:

(a) the first row gives the common name of the substance;
(b) the second row lists any synonyms for the substance;
(c) the third row gives the Australian approved name, if any, for the substance;
(d) the fourth row gives the chemical name or names of the substance;
(e) the fifth row gives the chemical abstract service number for the substance;
(f) the sixth row identifies the relevant monograph or compendial standard, if any, with which the substance is required to comply.
## Part 2  Listable chemical products

<table>
<thead>
<tr>
<th>Item</th>
<th>Chemical product or class of chemical product</th>
<th>Chemical product or class of chemical product use</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>An agricultural chemical product or class of chemical products that: (a) destroys bacteria, viruses and protozoa; and (b) contains only 1 of the following as an active constituent: (i) calcium hypochlorite; (ii) lithium hypochlorite; (iii) sodium dichloroisocyanurate; (iv) sodium hypochlorite; (v) trichloroisocyanuric acid; and (c) does not contain stabilisers, enhancers or flocculants</td>
<td>Used in home swimming pools and spas</td>
</tr>
<tr>
<td>2</td>
<td>A veterinary chemical product or class of chemical products that: (a) provides an exogenous source of biologically active ingredients to help improve the health of joints in dogs or horses; and (b) contains any 1 or more of the following as an active constituent: (i) chondroitin; (ii) glucosamine</td>
<td>Administered orally to dogs and horses (in the form of oral powder, chewable or non-chewable tablets, capsules containing powder or dry medicated food)</td>
</tr>
</tbody>
</table>
Part 3  Active constituents in listable chemical products

Division 3.1  Agricultural chemical products

Subdivision 3.1.1  Home swimming pool and spa products

1  Calcium hypochlorite

<table>
<thead>
<tr>
<th>Common name</th>
<th>Calcium hypochlorite</th>
</tr>
</thead>
<tbody>
<tr>
<td>Synonyms</td>
<td>Bleaching powder</td>
</tr>
<tr>
<td></td>
<td>Calcium oxychloride</td>
</tr>
<tr>
<td></td>
<td>Chloride of lime</td>
</tr>
<tr>
<td></td>
<td>Chlorinated lime</td>
</tr>
<tr>
<td></td>
<td>Hypochlorous acid – calcium salt</td>
</tr>
<tr>
<td>Australian approved name</td>
<td>None</td>
</tr>
<tr>
<td>Chemical name</td>
<td>Calcium hypochlorite</td>
</tr>
<tr>
<td>Chemical abstract service (CAS) number</td>
<td>7778-53-3</td>
</tr>
<tr>
<td>Monograph or compendial standard with which active constituent is required to comply</td>
<td>None</td>
</tr>
</tbody>
</table>

2  Lithium hypochlorite

<table>
<thead>
<tr>
<th>Common name</th>
<th>Lithium hypochlorite</th>
</tr>
</thead>
<tbody>
<tr>
<td>Synonym</td>
<td>Hypochlorous acid – lithium salt</td>
</tr>
<tr>
<td>Australian approved name</td>
<td>None</td>
</tr>
<tr>
<td>Chemical name</td>
<td>Lithium hypochlorite</td>
</tr>
</tbody>
</table>
3 Sodium dichloroisocyanurate

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical abstract service (CAS) number</td>
<td>13840-33-0</td>
</tr>
<tr>
<td>Monograph or compendial standard with which active constituent is required to comply</td>
<td>None</td>
</tr>
<tr>
<td>Common name</td>
<td>Sodium dichloroisocyanurate</td>
</tr>
<tr>
<td>Synonyms</td>
<td>Dichloroisocyanuric acid sodium salt</td>
</tr>
<tr>
<td></td>
<td>Sodium 1,3-dichloroisocyanurate</td>
</tr>
<tr>
<td>Australian approved name</td>
<td>None</td>
</tr>
<tr>
<td>Chemical name</td>
<td>1,3-dichloro-1,3,5-triazine-2,4,6-(1H,3H,5H)-trione, sodium salt</td>
</tr>
<tr>
<td>Chemical abstract service (CAS) number</td>
<td>2893-78-9</td>
</tr>
<tr>
<td>Monograph or compendial standard with which active constituent is required to comply</td>
<td>None</td>
</tr>
</tbody>
</table>

4 Sodium hypochlorite

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical abstract service (CAS) number</td>
<td>13840-33-0</td>
</tr>
<tr>
<td>Monograph or compendial standard with which active constituent is required to comply</td>
<td>None</td>
</tr>
<tr>
<td>Common name</td>
<td>Sodium hypochlorite</td>
</tr>
<tr>
<td>Synonyms</td>
<td>Hypochlorous acid – sodium salt</td>
</tr>
<tr>
<td></td>
<td>Sodium oxychloride</td>
</tr>
<tr>
<td>Australian approved name</td>
<td>Sodium hypochlorite</td>
</tr>
<tr>
<td>Chemical name</td>
<td>Sodium hypochlorite</td>
</tr>
<tr>
<td>Chemical abstract service (CAS) number</td>
<td>7681-52-9</td>
</tr>
<tr>
<td>Monograph or compendial standard with which active constituent is required to comply</td>
<td>None</td>
</tr>
</tbody>
</table>
5 Trichloroisocyanuric acid

Common name
Trichloroisocyanuric acid

Synonyms
1,3,5–trichloroisocyanuric acid, trichloro-s-triazinetrione symclosene

Australian approved name
None

Chemical name
1,3,5-trichloro-1,3,5-triazine-2,4,6-(1H,3H, 5H)-trione

Chemical abstract service (CAS) number
87-90-1

Monograph or compendial standard with which active constituent is required to comply
None

Division 3.2 Veterinary chemical products

Subdivision 3.2.1 Joint health products for dogs and horses

1 Chondroitin

Common name
Chondroitin

Synonyms
Calcium chondroitin sulfate
Chondroitin sulfate
Chondroitin sulfate sodium
Chondroitin polysulfate
Chondroitin sulphuric acid
Potassium chondroitin sulfate
Sodium chondroitin sulfate

Australian approved name
Chondroitin sulfate
Chemical names
Chondroitin sulfate sodium — [4-](β-D-glucopyranosyluronic acid)-(1→3)-[2-(acetylamino)-2-deoxy-β-D-galactopyranosyl-4-sulfate]
Chondroitin sulfate sodium as sodium salt — [4-](β-D-glucopyranosyluronic acid)-(1→3)-[2-(acetylamino)-2-deoxy-β-D-galactopyranosyl-6-sulfate]

Chemical abstract service (CAS) numbers
9007-28-7   (Chondroitin)
9082-07-9   (Chondroitin sulfate sodium)

Monograph or compendial standard with which active constituent is required to comply
British Pharmacopoeia (BP); or
European Pharmacopoeia (EP); or
United States Pharmacopoeia (USP) for chondroitin sulfate or its salts

2 Glucosamine

Common name
Glucosamine

Synonym
None

Australian approved name
Glucosamine hydrochloride
Glucosamine sulfate

Chemical names
2-amino-2-deoxy-D-glucose hydrochloride
2-amino-2-deoxy-β-D-glucopyranose hydrochloride
Bis(2-amino-2-deoxy-D-glucose) sulfate

Chemical abstract service (CAS) numbers
66-84-2   (Glucosamine hydrochloride)
29031-19-4   (Glucosamine sulfate)

Monograph or compendial standard with which active constituent is required to comply
United States Pharmacopoeia (USP) for glucosamine hydrochloride or glucosamine sulfate
Schedule 3C  Reserved Schedule
(regulation 23G)

Part 1  Preliminary

1  Definitions

In this Schedule:

disinfectant means a substance:

(a) that is recommended by its manufacturer for application to
an inanimate object to kill micro-organisms generally; and

(b) that is not represented by the manufacturer to be effective
for any of the following:
   (i) killing specific or named micro-organisms;
   (ii) use as a sterilant, dairy cleanser, or pool and spa
sanitiser; and

(c) that is not represented by the manufacturer to be effective
for internal use or application on food; and

(d) that is not promoted primarily through retailers to
consumers for domestic use.

sterilant means a chemical agent that kills microbes with the
result that the sterility assurance level of a microbial survivor is
less than 10^-6.

2  Particulars of reserved chemical products

The particulars of a chemical product or class of chemical
product listed in this Schedule are specified in an item in the
table in Part 2 as follows:

(a) column 2 sets out:
   (i) the product use; and
   (ii) the concentration level, if any, of the active
constituent in the product;

(b) column 3 sets out the active constituent or constituents of
the product.
3 Active constituents in reserved chemical products

(1) A substance mentioned in column 3 of Part 2 as an active constituent of a chemical product or class of chemical product, means the substance with that name that complies with the particulars specified for that substance in an item in a Subdivision of Part 3 of this Schedule.

(2) Each substance mentioned in a Subdivision of Part 3 is described in a separate item as follows:
   (a) the first row gives the common name of the substance;
   (b) the second row lists any synonyms for the substance;
   (c) the third row gives the Australian approved name, if any, for the substance;
   (d) the fourth row gives its chemical name;
   (e) the fifth row gives the chemical abstract service number for the substance;
   (f) the sixth row identifies the relevant monograph or compendial standard, if any, with which the substance is required to comply.

Part 2 Reserved chemical products

<table>
<thead>
<tr>
<th>Item</th>
<th>Chemical product or class of chemical product</th>
<th>Active constituent(s) of chemical product</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>An agricultural chemical product used as a disinfectant if:</td>
<td>Benzalkonium chloride</td>
</tr>
<tr>
<td></td>
<td>(a) the product contains the active constituent specified in column 3; and</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(b) the active constituent specified in column 3 does not make up more than 10% of the class of product</td>
<td></td>
</tr>
<tr>
<td>Item</td>
<td>Chemical product or class of chemical product</td>
<td>Active constituent(s) of chemical product or class of chemical product</td>
</tr>
<tr>
<td>------</td>
<td>---------------------------------------------</td>
<td>--------------------------------------------------</td>
</tr>
</tbody>
</table>
| 2    | An agricultural chemical product used as a disinfectant if:  
(a) the product contains the active constituent specified in column 3; and  
(b) the active constituent specified in column 3 does not make up more than 5% of the class of product | Glutaraldehyde |
| 3    | An agricultural chemical product used as a disinfectant if:  
(a) the product contains the active constituent specified in column 3; and  
(b) the active constituent specified in column 3 does not make up more than 6% of the class of product | Hydrogen peroxide |
| 4    | An agricultural chemical product used as a disinfectant if:  
(a) the product contains the active constituent specified in column 3; and  
(b) the active constituent specified in column 3 does not make up more than 3% of the class of product | O-benzyl-p-chlorophenol |
<p>| 5    | An agricultural chemical product used as a disinfectant if the product contains the active constituent specified in column 3 | Ortho-phenylphenol |</p>
<table>
<thead>
<tr>
<th>Item</th>
<th>Chemical product or class of chemical product</th>
<th>Active constituent(s) of chemical product or class of chemical product</th>
</tr>
</thead>
</table>
| 6    | An agricultural chemical product used as a disinfectant if:  
   (a) the product contains the active constituent specified in column 3; and  
   (b) the active constituent specified in column 3 does not make up more than 10% of the class of product | Peroxyacetic acid |
| 7    | An agricultural chemical product used as a disinfectant if:  
   (a) the product contains the active constituent specified in column 3; and  
   (b) the active constituent specified in column 3 does not make up more than 35% of the class of product | Phosphoric acid |
| 8    | An agricultural chemical product used as a disinfectant if:  
   (a) the product contains the active constituent specified in column 3; and  
   (b) the active constituent specified in column 3 does not make up more than 5% of the class of product | Sodium hydroxide |
| 9    | An agricultural chemical product used as a disinfectant if:  
   (a) the product contains the active constituent specified in column 3 for this item is contained; and  
   (b) the active constituent specified in column 3 does not make up more than 20% of the class of product | Sodium hypochlorite |
Item | Chemical product or class of chemical product | Active constituent(s) of chemical product or class of chemical product
--- | --- | ---
10 | An agricultural chemical product used as a disinfectant if: (a) the product contains the active constituent specified in column 3; and (b) the active constituent specified in column 3 does not make up more than 10% of the class of product | Sulfamic acid
11 | An agricultural chemical product used as a disinfectant if: (a) the product contains the active constituent specified in column 3 for this item is contained; and (b) the active constituent specified in column 3 does not make up more than 0.5% of the product | Sulfuric acid

Part 3  Active constituents in reserved chemical products

Division 3.1  Agricultural chemical products

Subdivision 3.1.1  Disinfectants

1  Benzalkonium chloride

<table>
<thead>
<tr>
<th>Common name</th>
<th>Benzalkonium chloride</th>
</tr>
</thead>
</table>
| Synonyms    | Alkyl-benzyl-dimethylammonium chloride  
              Alkylbenzyldimethyl chloride |
| Australian approved name | Benzalkonium chloride |
| Chemical name | Benzalkonium chloride |
### Glutaraldehyde

| **Chemical abstract service (CAS) number** | 8001-54-5 |
| **Monograph or compendial standard with which active constituent is required to comply** | British Pharmacopoeia (BP); or European Pharmacopoeia (EP) |

#### 2 Glutaraldehyde

**Common name**
Glutaraldehyde

**Synonyms**
- Glutaraldehyde
- 1,3-diformylpropane
- 1,5-pentanedicarboxaldehyde
- 1,5-pentanedione

**Australian approved name**
Glutaraldehyde

**Chemical name**
Glutaraldehyde

| **Chemical abstract service (CAS) number** | 111-30-9 |
| **Monograph or compendial standard with which active constituent is required to comply** | British Pharmacopoeia (BP) |

### Hydrogen peroxide

| **Common name** | Hydrogen peroxide |
| **Synonym** | Hydrogen dioxide |
| **Australian approved name** | Hydrogen peroxide |
| **Chemical name(s)** | Hydrogen peroxide |
| **Chemical abstract service (CAS) number** | 7722-84-1 |
| **Monograph or compendial standard with which active constituent is required to comply** | British Pharmacopoeia (BP); or European Pharmacopoeia (EP) |
## 4 O-benzyl-p-chlorophenol

<table>
<thead>
<tr>
<th>Common name</th>
<th>O-benzyl-p-chlorophenol</th>
</tr>
</thead>
<tbody>
<tr>
<td>Synonyms</td>
<td>4-chloro-2-(phenylmethyl)phenol</td>
</tr>
<tr>
<td></td>
<td>4-chloro-alpha-phenyl-ortho-cresol</td>
</tr>
<tr>
<td></td>
<td>5-chloro-2-hydroxydiphenylmethane</td>
</tr>
<tr>
<td></td>
<td>Benzylchlorophenol</td>
</tr>
<tr>
<td></td>
<td>Benzyl-p-chlorophenol</td>
</tr>
<tr>
<td></td>
<td>Chlorophenol</td>
</tr>
<tr>
<td>Australian approved name</td>
<td>None</td>
</tr>
<tr>
<td>Chemical name</td>
<td>O-benzyl-p-chlorophenol</td>
</tr>
<tr>
<td>Chemical abstract service (CAS) number</td>
<td>120-32-1</td>
</tr>
<tr>
<td>Monograph or compendial standard with which active constituent is required to comply</td>
<td>None</td>
</tr>
</tbody>
</table>

## 5 Ortho-phenylphenol

<table>
<thead>
<tr>
<th>Common name</th>
<th>Ortho-phenylphenol</th>
</tr>
</thead>
<tbody>
<tr>
<td>Synonyms</td>
<td>(1,1'-biphenyl)-2-ol</td>
</tr>
<tr>
<td></td>
<td>1,1'-biphenyl-2-ol</td>
</tr>
<tr>
<td></td>
<td>2-biphenylol</td>
</tr>
<tr>
<td></td>
<td>2-phenylphenol</td>
</tr>
<tr>
<td></td>
<td>Hydroxy-2-phenylbenzene</td>
</tr>
<tr>
<td>Australian approved name</td>
<td>Ortho-phenylphenol</td>
</tr>
<tr>
<td>Chemical name</td>
<td>1,1'-biphenyl-2-ol</td>
</tr>
<tr>
<td>Chemical abstract service (CAS) number</td>
<td>90-43-7</td>
</tr>
<tr>
<td>Monograph or compendial standard with which active constituent is required to comply</td>
<td>None</td>
</tr>
</tbody>
</table>
## 6 Peroxyacetic acid

<table>
<thead>
<tr>
<th>Property</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Common name</td>
<td>Peroxyacetic acid</td>
</tr>
<tr>
<td>Synonyms</td>
<td>Acetic peroxide, Acetyl hydroperoxide, Peracetic acid</td>
</tr>
<tr>
<td>Australian approved name</td>
<td>Peracetic acid</td>
</tr>
<tr>
<td>Chemical name</td>
<td>Peroxyacetic acid</td>
</tr>
<tr>
<td>Chemical abstract service (CAS) number</td>
<td>79-21-0</td>
</tr>
<tr>
<td>Monograph or compendial standard with which active constituent is required to comply</td>
<td>None</td>
</tr>
</tbody>
</table>

## 7 Phosphoric acid

<table>
<thead>
<tr>
<th>Property</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Common name</td>
<td>Phosphoric acid</td>
</tr>
<tr>
<td>Synonym</td>
<td>Orthophosphoric acid</td>
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<tr>
<td>Australian approved name</td>
<td>None</td>
</tr>
<tr>
<td>Chemical name</td>
<td>Phosphoric acid</td>
</tr>
<tr>
<td>Chemical abstract service (CAS) number</td>
<td>7664-38-2</td>
</tr>
<tr>
<td>Monograph or compendial standard with which active constituent is required to comply</td>
<td>British Pharmacopoeia (BP); or European Pharmacopoeia (EP)</td>
</tr>
</tbody>
</table>

## 8 Sodium hydroxide

<table>
<thead>
<tr>
<th>Property</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Common name</td>
<td>Sodium hydroxide</td>
</tr>
<tr>
<td>Synonym</td>
<td>Caustic soda</td>
</tr>
<tr>
<td>Australian approved name</td>
<td>Sodium hydroxide</td>
</tr>
<tr>
<td>Chemical name</td>
<td>Sodium hydroxide</td>
</tr>
</tbody>
</table>
9 Sodium hypochlorite

Common name
Sodium hypochlorite

Synonyms
Hypochlorous acid-sodium salt
Sodium oxychloride

Australian approved name
Sodium hypochlorite

Chemical name(s)
Sodium hypochlorite

Chemical abstract service (CAS) number
1310-73-2

Monograph or compendial standard with which active constituent is required to comply
British Pharmacopoeia (BP); or European Pharmacopoeia (EP)

10 Sulfamic acid

Common name
Sulfamic acid

Synonyms
Amidosulfonic acid
Amidosulfuric acid
Aminosulfonic acid
Sulfamidic acid
Sulphamic acid

Australian approved name
Sulfamic acid

Chemical name
Sulfamic acid

Chemical abstract service (CAS) number
7681-52-9

Monograph or compendial standard with which active constituent is required to comply
None
### 11 Sulfuric acid

<table>
<thead>
<tr>
<th><strong>Common name</strong></th>
<th>Sulfuric acid</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Synonyms</strong></td>
<td>Hydrogen sulfate</td>
</tr>
<tr>
<td></td>
<td>Sulphuric acid</td>
</tr>
<tr>
<td><strong>Australian approved name</strong></td>
<td>Sulfuric acid</td>
</tr>
<tr>
<td><strong>Chemical name</strong></td>
<td>Sulfuric acid</td>
</tr>
<tr>
<td><strong>Chemical abstract service (CAS) number</strong></td>
<td>7664-93-9</td>
</tr>
<tr>
<td><strong>Monograph or compendial standard with which active constituent is required to comply</strong></td>
<td>British Pharmacopoeia (BP); or European Pharmacopoeia (EP)</td>
</tr>
</tbody>
</table>

#### Division 3.2 Veterinary chemical products

*Note*  This Division is reserved for future use.
Schedule 4 Restricted chemical products
(regulation 45)

1 A chemical product containing ethylene dibromide (also known as EDB)
2 A chemical product containing chlordane
3 A chemical product containing heptachlor
4 A chemical product containing sodium monofluoroacetate (also known as 1080)
5 A chemical product containing acrolein
6 A chemical product that is a pre-construction termiticide product containing bifenthrin
7 A chemical product that is a pre-construction termiticide product containing chlorpyrifos
8 A chemical product containing endosulfan
9 A chemical product containing pindone that is a concentrate and for which the relevant label instructions require further mixing with carriers before it is ready to use as a bait
10 A chemical product containing mevinphos
11 A chemical product containing rabbit haemorrhagic disease virus (RHDV) (also known as rabbit calicivirus) that is in injectable form and requires mixing with carriers such as oats or carrot before it is ready to use as a bait
AGVET CODE OF [NAME OF JURISDICTION]

SEARCH WARRANT UNDER SUBSECTION 133 (2)

TO (name and address of inspector), an inspector within the meaning of section 3 of the Agvet Code of [name of jurisdiction] (‘the Code’):

1. This warrant is issued on the basis that:
   (a) I am satisfied, by information on oath, that there are reasonable grounds for suspecting that there is, or may be within the next 72 hours, at the premises mentioned below, a particular thing that may be evidence of the commission of an offence against the Code; and
   (b) I have been given, either orally or by affidavit, the further information (if any) that I required about the grounds on which the issue of this warrant is being sought.

2. The nature of the offence in relation to which this warrant is issued is (state the nature of the suspected offence).

3. The purpose for which this warrant is issued is set out in clause 4.

4. This warrant authorises you, with any help, and using any force, that is necessary and reasonable, * at any time of the day or night / * during the following hours of the day or night (specify the hours):
   (a) to enter the premises at (address); and
   (b) exercise the powers referred to in paragraphs 132 (1) (c), (d) and (e) of the Code in respect of the particular thing, namely (specify the particular thing).

   Note Paragraphs 132 (1) (c), (d) and (e) of the Code empower an inspector to:
   (c) search the premises for the thing; and
(d) if the thing is found, take photographs (including video recordings) of the premises or thing, take samples of the thing, seize the thing or undertake more than one of those activities; and

(e) give any directions for, or with respect to, the detention of a thing that has been seized under paragraph (d).

THIS WARRANT CEASES TO HAVE EFFECT ON (date not later than 7 days after the day of issue of the warrant).

Issued by me (full name and designation of magistrate).

On (date) .

(signature of magistrate)

* Omit whichever is inapplicable.
Schedule 6  Applications — fees and assessment periods
(regulations 70, 76, 77, 78 and 78A)

Part 1  Preliminary

1.1  Definitions

In this Schedule:

closely similar, used of 2 chemical products, has the meaning given in section 1.2.

major change, in relation to a registered chemical product or approved label, means a change to a registered chemical product or its approved label that is expected to require data for technical assessment of one or more of the following:

(a) efficacy;
(b) potential risks to the safety of humans, the environment or the host crop or animal;
(c) potential risks to Australian trade.

major food crop means a food crop listed in Column 3 (‘Major uses’) of Part 1 of Schedule 3A.

maximum residue limit means the maximum concentration of a residue, resulting from the officially authorised safe use of an agricultural or veterinary chemical, that is recommended to be legally permitted or recognised as acceptable in or on a food, agricultural commodity, or animal feed.

minor change means a change that is not a major change.

protected information has the meaning given in section 1.5.

similar, used of 2 chemical products, has the meaning given in section 1.3.

the same, used of 2 chemical products, has the meaning given in section 1.4.
1.2 When chemical products are closely similar

(1) Subject to subsection (2), an agricultural chemical product (the proposed chemical product) and a reference chemical product are closely similar if:

(a) the active constituents in the proposed chemical product are the same as the approved active constituents in the reference chemical product; and

(b) the concentration of the active constituents referred to in paragraph (a) are the same; and

(c) either:
   (i) the other ingredients in the formulations of the proposed and reference chemical products are the same; or
   (ii) if the other ingredients in the formulations of the proposed and reference chemical products are different, those other ingredients perform similar functions (for example, as emulsifiers, surfactants, dyes or solvents); and

(d) the formulation type of the proposed and reference chemical products are the same; and

(e) the label of the proposed chemical product refers to the same crops, situations and pests as the approved label of the reference chemical product (that is, the proposed chemical product must have no uses additional to those of the reference chemical product); and

(f) the label of the proposed chemical product includes similar instructions on how to use the product, and precautionary or safety instructions, as the approved label of the reference chemical product; and

(g) either:
   (i) the claims on the labels of the proposed and reference chemical products are the same; or
   (ii) if the claims are different, the claims on the label of the proposed chemical product are fewer or reduced compared to the claims on the approved label of the reference chemical product.
(2) However, the proposed agricultural chemical product and the reference chemical product are taken not to be closely similar if information about the reference chemical product is protected information.

(3) Subject to subsection (4), a veterinary chemical product (the **proposed chemical product**) and a reference chemical product are closely similar if:

(a) the active constituents in the proposed chemical product are the same as the approved active constituents in the reference chemical product; and

(b) the concentration of the active constituents referred to in paragraph (a) are the same; and

(c) either:

   (i) the non-active constituents in the formulations of the proposed and reference chemical products are the same, or are equivalent substances, at the same or equivalent concentrations; or

   (ii) if the non-active constituents in the formulations of the proposed and reference chemical products are neither the same nor equivalent, the differences in the formulations are minor and are not expected to have adverse implications on product quality or biological activity in terms of efficacy, safety or residues; and

(d) either:

   (i) the proposed and reference chemical products specifications (including release and expiry limits and test methods) and physico-chemical properties (including pH, particle size, crystal form and, where applicable, dissolution profile, payout rate and payout period) are the same or equivalent; or

   (ii) if the specifications and physico-chemical properties of the proposed and reference chemical products are neither the same nor equivalent, the differences in the specifications and properties are minor and are not expected to have adverse implications for product quality or biological activity in terms of efficacy, safety or residues; and
Note for paragraphs (c) and (d)  Efficacy, safety and residues data are not required to demonstrate similarity of the proposed chemical product to the reference chemical product.

(e) the dose form and formulation type of the proposed and reference chemical products are the same; and

(f) the use patterns (including target animal species, dose rates, routes of administration and withholding periods) and instructions on the labels of the proposed and reference chemical products are the same; and

(g) either:
   (i) the claims on the labels of the proposed and reference chemical products are the same; or
   (ii) if the claims are different, the claims on the label of the proposed chemical product are fewer or reduced compared to the claims on the approved label of the reference chemical product.

(4) However, the proposed veterinary chemical product and the reference chemical product are taken not to be closely similar if information about the reference chemical product is protected information.

1.3 When chemical products are similar

(1) Subject to subsection (2), an agricultural chemical product (the proposed agricultural chemical product) and a reference chemical product are similar if the conditions in paragraphs 1.2 (1) (a), (d), (e), (f) and (g) are complied with in relation to the products.

(2) However, the proposed agricultural chemical product and the reference chemical product are taken not to be similar if information about the reference chemical product is protected information.

(3) Subject to subsection (4), a veterinary chemical product (the proposed veterinary chemical product) and a reference chemical product are similar if:
   (a) the conditions in paragraphs 1.2 (3) (a), (b), (e), (f) and (g) are complied with in relation to the products; and
(b) the non-active constituents in the proposed and reference chemical products have similar properties and are in similar proportions; and
(c) efficacy, safety or residues data is required to demonstrate similarity of the proposed chemical product to the reference chemical product.

(4) However, the proposed veterinary chemical product and the reference chemical product are taken not to be similar if information about the reference chemical product is protected information.

1.4 When chemical products are the same

(1) Subject to subsection (2), a proposed chemical product and a reference chemical product are the same if they are the same in all respects except their names, their distinguishing numbers, and the name and business address of the applicant.

(2) However, a proposed chemical product and a reference chemical product are taken not to be the same if information about the reference chemical product is protected information.

1.5 Meaning of protected information

For this Schedule, information is protected information if:
(a) it is information about an approved active constituent, a registered chemical product or an approved label for containers for a chemical product; and
(b) any of the following provisions limits its use by the APVMA:
   (i) Division 4A of Part 2 of the Code;
   (ii) Part 3 of the Code;
1.6 Effect of Part 2 where information is protected information

(1) If information about an active constituent is protected information, the fee payable for an application that would otherwise rely on or utilise that information is to be determined as if the active constituent were not approved.

(2) If information about a registered chemical product is protected information, the fee payable for an application that would otherwise rely on or utilise that information is to be determined as if the chemical product were not registered.

(3) If information about an approved label for containers for a chemical product is protected information, the fee payable for an application that would otherwise rely on or utilise that information is to be determined as if the label were not approved.

1.7 Fee when application for registration preceded by application for permit

If:

(a) an application for the registration of a chemical product is preceded by an application for a permit in relation to the product; and

(b) the assessment of the permit is relevant to, and included as, part of the assessment of the product;

despite anything else in Part 2 or in Schedule 7, the fee for the application for the registration of the product is to be worked out using the modular assessment fee only for any additional assessments that are actually undertaken by the APVMA at the time of the assessment.
## Part 2  
### Table of fees and assessment periods

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<thead>
<tr>
<th>Column 1</th>
<th>Column 2 Description of application</th>
<th>Column 3 Assessment period</th>
<th>Column 4 Fee ($)</th>
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<tbody>
<tr>
<td><strong>Applications for approval of active constituent contained in a chemical product, registration of the chemical product and approval of the product label</strong></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>1</td>
<td>Application for approval of an active constituent contained in a chemical product, registration of the associated chemical product and approval of the product label requiring a full assessment of the active constituent and chemical product</td>
<td>15 months</td>
<td>48 860</td>
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<tr>
<td>2</td>
<td>Application for approval of an active constituent contained in a chemical product, registration of the associated chemical product and approval of the product label requiring less than full assessment of the active constituent and chemical product</td>
<td>The modular assessment period</td>
<td>The modular assessment fee</td>
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<tr>
<td><strong>Applications for registration of a chemical product containing an approved active constituent and approval of the product label</strong></td>
<td></td>
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</tbody>
</table>
| 3 | Application for registration of a chemical product containing an approved active constituent, and approval of the product label, if:  
   (a) there is no registered chemical product containing the active constituent; and  
   (b) a full assessment of the chemical product is required | 15 months | 31 750 |
### Schedule 6

**Applications — fees and assessment periods**

#### Part 2

**Table of fees and assessment periods**

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<tr>
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<th>Column 4 Fee ($)</th>
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<tbody>
<tr>
<td>4</td>
<td>Application for registration of a chemical product containing an approved active constituent, and approval of the product label, if: (a) there is a registered chemical product containing the active constituent; and (b) the chemical product is to be used on a major food crop; and (c) there are no relevant maximum residue limits; and (d) poison schedule classification is required</td>
<td>15 months</td>
<td>21 210</td>
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<tr>
<td>5</td>
<td>Application for registration of a chemical product containing an approved active constituent, and approval of the product label, if: (a) the chemical product is similar to a registered chemical product; and (b) chemistry and manufacture, efficacy or target species safety data is the only data required to demonstrate the similarity of the chemical product to the registered chemical product</td>
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<td>Assessment period</td>
<td>Fee ($)</td>
</tr>
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<tr>
<td>6</td>
<td>Application for registration of a chemical product containing an approved active constituent, and approval of the product label, if: (a) the chemical product is closely similar to a registered chemical product; and (b) efficacy and safety data are not required to demonstrate the similarity of the chemical product to the registered chemical product; and (c) chemistry and manufacture data are required</td>
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<td>7</td>
<td>Application for registration of a chemical product containing an approved active constituent, and approval of the product label, if: (a) the chemical product is closely similar to a registered chemical product; and (b) efficacy and safety data are not required to demonstrate the similarity of the chemical product to the registered chemical product; and (c) chemistry and manufacture data are not required</td>
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<td>600</td>
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<td>8</td>
<td>Application for registration of a chemical product containing an approved active constituent, and approval of the product label, if: (a) the chemical product is the same as a registered chemical product; and (b) the chemical product is to be registered with a different name</td>
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<td>540</td>
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<td>Column 2 Description of application</td>
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<td>9</td>
<td>Application for a listed registration of a chemical product containing an approved active constituent and approval of a product label for which an established standard has been approved in accordance with section 56D of the Code</td>
<td>3 months</td>
<td>495</td>
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<tr>
<td>10</td>
<td>Application for registration of a chemical product containing an approved active constituent (or an active constituent for which the APVMA has received an application for approval) and approval of the product label for all situations other than those described in items 3 to 9</td>
<td>The modular assessment period</td>
<td>The modular assessment fee</td>
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<td>Applications to vary a registration or label approval</td>
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<tr>
<td>11</td>
<td>Application to vary particulars or conditions of registration or label approval where the variation is to extend the use of the chemical product to a new major food crop</td>
<td>8 months</td>
<td>14 260</td>
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<tr>
<td>12</td>
<td>Application to vary particulars or conditions of registration or label approval if: (a) the variation is to allow a minor change; and (b) no data of a technical nature is required</td>
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<td>560</td>
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<td>Description of application</td>
<td>Assessment period</td>
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<tr>
<td>13</td>
<td>Application to vary particulars or conditions of registration or listed registration or label approval if: (a) the variation is to allow a minor change; and (b) no data of a technical nature is required; and (c) the variation is a change required by the APVMA</td>
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<td>Application to vary particulars or conditions of registration or listed registration or label approval if the application is not of a kind described in any of items 11 to 13</td>
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<td>The modular assessment fee</td>
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<td>15</td>
<td>Application for approval of an active constituent requiring a full assessment</td>
<td>12 months</td>
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<td>16</td>
<td>Application for approval of an active constituent requiring less than full assessment but requiring a toxicological assessment</td>
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<td>17</td>
<td>Application for approval of an active constituent requiring less than full assessment but not requiring a toxicological assessment</td>
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<td>18</td>
<td>Application to vary particulars or conditions of an approved active constituent</td>
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### Application for a permit

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<th>Column 4 Fee ($)</th>
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<tr>
<td>19</td>
<td>Application for a permit to possess or supply, other than for use in Australia, an active constituent that is not an approved active constituent or a chemical product that is not a registered chemical product</td>
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<td>Application for a permit where a previous assessment remains valid and no data of a technical nature is required</td>
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<td>21</td>
<td>Application for a permit where the proposed use is a minor use</td>
<td>The modular assessment period</td>
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</tr>
<tr>
<td>22</td>
<td>Application for a permit in respect of a chemical product or an active constituent if the proposed use of the chemical product or active constituent is determined by the APVMA to be an emergency use</td>
<td>Not applicable — (see subregulation 76 (4))</td>
<td>nil — (see paragraph 70 (6) (b))</td>
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<td>23</td>
<td>Application for a permit in respect of a chemical product or an active constituent if the application is not of a kind described in any of items 19 to 21</td>
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### Other applications

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<td>24</td>
<td>Application made under section 10 of the Code (other than those of the kinds described in any of items 1, 2, 3, 4, 5, 6, 7, 8, 10, 15, 16 or 17) requiring assessment of a technical nature</td>
<td>The modular assessment period</td>
<td>The modular assessment fee</td>
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<tr>
<td>Item</td>
<td>Column 2 Description of application</td>
<td>Column 3 Assessment period</td>
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<td>25</td>
<td>Any other application: (a) that is not made under section 10 of the Code; and (b) that is not of a kind listed in an item of this Schedule; requiring assessment of a technical nature</td>
<td>The modular assessment period</td>
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**Schedule 7**  
Table of fees and periods for completion of modules, levels and types of assessments  
(regulations 71 and 77)

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<td>Chemistry</td>
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<td>2.1</td>
<td>Chemistry — level 1</td>
<td>12 months</td>
<td>2 960</td>
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<td>Chemistry — level 2</td>
<td>8 months</td>
<td>2 025</td>
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<td>2.3</td>
<td>Chemistry — level 3</td>
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<td>3</td>
<td><strong>Toxicology</strong> (not requiring poison schedule classification)</td>
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<td>3.1</td>
<td>Toxicology — level 1</td>
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<td>Toxicology — level 3</td>
<td>4 months</td>
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<td>4</td>
<td><strong>Toxicology</strong> (requiring poison schedule classification)</td>
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<td>5</td>
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<td>5.3</td>
<td>Residues — level 3 (permit only)</td>
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<td>Residues — level 4 (registration only)</td>
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<td>5.5</td>
<td>Residues — level 5 (permit only)</td>
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<td>Column 1 Item</td>
<td>Column 2 Module, level or type</td>
<td>Column 3 Period for completion</td>
<td>Column 4 Fee ($)</td>
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<td>Environment — level 2</td>
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<td>Efficacy and safety — level 3</td>
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<td>Non-food trade</td>
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<td>Special data — level 3</td>
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<td>Finalisation — type 3 (permit only)</td>
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Agricultural and Veterinary Chemicals Code Regulations
1995

Federal Register of Legislative Instruments F2009C00122
Schedule 8  Logo of the Australian Pesticides and Veterinary Medicines Authority (APVMA)  
(regulation 79)
Notes to the Agricultural and Veterinary Chemicals Code Regulations 1995

Note 1
The Agricultural and Veterinary Chemicals Code Regulations 1995 (in force under the Agricultural and Veterinary Chemicals Code Act 1994) as shown in this compilation comprise Statutory Rules 1995 No. 27 amended as indicated in the Tables below.

For all relevant information pertaining to application, saving or transitional provisions see Table A.

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